FY 2017 Inspectional Observation Summaries

Number of 483s Issued from the System*

Inspections ending between 10/1/2016 and 9/30/2017

Center Name	483s Issued
Biologics	115
Bioresearch Monitoring	243
Devices	1030
Drugs	694
Foods	2662
Human Tissue for Transplantation	61
Parts 1240 and 1250	75
Radiological Health	31
Veterinary Medicine	244
Sum Product Area 483s from System*	**5155**
Actual Total in System 483s**	**5045**

*This table does not represent the complete set of 483's issued during the fiscal year as some 483's were manually prepared and not available in this format. The sum of 483's for all Product Areas will be greater than the actual Total 483's issued during the fiscal year since a 483 may include citations related to multiple product areas, and counted more than once, under each relevant product center.

** This is the Actual Total number of 483's issued from this system, and that are represented in this spreadsheet.

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Biologics

Bioresearch Monitoring

Devices

Drugs

Foods

Cite Id	Reference Number	Short Description	Long Description	Frequ
1560	21 CFR 110.35(c)	Lack of effective pest exclusion	Effective measures are not being taken to [exclude pests from the processing areas] [protect against the contamination of food on the premises by pests]. Specifically, ***	330
1306	21 CFR 110.20(b)(7)	Screening	Failure to provide adequate screening or other protection against pests. Specifically, ***	211

Cite Id	Reference Number	Short Description	Long Description	Frequ
1524	21 CFR 123.11(b)	Sanitation monitoring	You are not monitoring the sanitation conditions and practices with sufficient frequency to assure conformance with Current Good Manufacturing Practices including [safety of water that comes into contact with food or food contact surfaces, including water used to manufacture ice] [condition and cleanliness of food contact surfaces] [prevention of cross-contamination from insanitary objects] [maintenance of hand washing, hand sanitizing, and toilet facilities] [protection of food, food packaging material, and food contact surfaces from adulteration] [proper labeling, storage and use of toxic chemicals] [control of employee health conditions] [exclusion of pests]. Specifically, ***	203

Cite Id	Reference Number	Short Description	Long Description	Frequ
1422	21 CFR 110.20(b)(4)	Floors, walls and ceilings	The plant is not constructed in such a manner as to allow [floors] [walls] [ceilings] to be [adequately cleaned and kept clean] [kept in good repair]. Specifically, ***	192
1552	21 CFR 110.35(a)	Buildings/sanitary	Failure to maintain buildings, fixtures, or other physical facilities in a sanitary condition. Specifically, ***	176
905	21 CFR 123.6(b)	HACCP plan implementation	You did not implement the [monitoring] [recordkeeping] [verification] procedures listed in your HACCP plan. Specifically, ***	162
1554	21 CFR 110.35(a)	Cleaning and sanitizing operations	Failure to conduct cleaning and sanitizing operations for utensils and equipment in a manner that protects against contamination of [food] [food-contact surfaces] [food-packaging materials]. Specifically, ***	157

Cite Id	Reference Number	Short Description	Long Description	Frequ
1695	21 CFR 110.80(b)(2)	Manufacturing conditions	Failure to [manufacture] [package] [store] foods under conditions and controls necessary to minimize [the potential for growth of microorganisms] [contamination]. Specifically, ***	156
1689	21 CFR 110.80	Reasonable precautions	All reasonable precautions are not taken to ensure that production procedures do not contribute contamination from any source. Specifically, ***	146
1287	21 CFR 110.20(a)(1)	Harborage areas	Failure to [properly store equipment] [remove litter and waste] [cut weeds or grass] that may constitute an attractant, breeding place, or harborage area for pests, within the immediate vicinity of the plant buildings or structures. Specifically, ***	137

Cite Id	Reference Number	Short Description	Long Description	Frequ
990	21 CFR 110.10(b)(3)	Not washed/sanitized when appropriate	Employees did not [wash] [sanitize] hands thoroughly in an adequate hand-washing facility [before starting work] [after each absence from the work station] [at any time their hands may have become soiled or contaminated]. Specifically, ***	130
1701	21 CFR 110.80(b)(7)	Equipment, containers, utensils	Failure to [construct] [handle] [maintain] equipment, containers and utensils used to [convey] [hold] [store] food in a manner that protects against contamination. Specifically, ***	127
1405	21 CFR 110.10(b)(6)	Failure to wear	Failure to wear [hair nets] [head bands] [caps] [beard covers] [hair restraints] where appropriate. Specifically, ***	124
1553	21 CFR 110.35(a)	Buildings/good repair	Failure to maintain [buildings] [fixtures] [physical facilities] in repair sufficient to prevent food from becoming adulterated. Specifically, ***	118

Cite Id	Reference Number	Short Description	Long Description	Frequ
1562	21 CFR 110.35(d)	Failure to clean - general	Failure to clean [food-contact surfaces] [utensils] as frequently as necessary to protect against contamination of food. Specifically, ***	118
960	21 CFR 123.6(c)(2)	Critical control points	Your HACCP plan does not list one or more critical control points that are necessary for each of the identified food safety hazards. Specifically, ***	117
18254	21 CFR 1.502(a)	Develop FSVP	You did not develop an FSVP. Specifically, ***	108
961	21 CFR 123.6(c)(3)	Critical limits	Your HACCP plan [does not list a critical limit that ensures control of one or more hazards] [lists a critical limit that does not ensure control of one or more hazards]. Specifically,	106

Cite Id	Reference Number	Short Description	Long Description	Frequ
945	21 CFR 123.12(a)(2)	Importer verification	You do not have or have not implemented [written verification procedures] [product specifications] [an affirmative step] for ensuring that [fish] [fishery products] you import are processed in compliance with the Seafood HACCP regulation. Specifically, ***	104
1427	21 CFR 110.20(b)(5)	Safety lighting and glass	Failure to provide safety-type [light bulbs] [lighting fixtures] [skylights] [glass] suspended over exposed food. Specifically, ***	102
959	21 CFR 123.6(c)(1)	Food safety hazards	Your HACCP plan does not list the food safety hazards that are reasonably likely to occur. Specifically, ***	99
1292	21 CFR 110.20(b)(1)	Sufficient space	Failure to provide sufficient space for [placement of equipment] [storage of materials] as necessary for the maintenance of sanitary operations and the production of safe food. Specifically, ***	93

Cite Id	Reference Number	Short Description	Long Description	Frequ
1125	21 CFR 110.40(a)	Materials and workmanship	The [design] [materials] [workmanship] of [equipment] [utensils] does not allow proper [cleaning] [maintenance]. Specifically, ***	92
6004	21 CFR 123.6(c)(4)	Monitoring - adequacy	Your HACCP plan lists monitoring [procedures] [frequencies] that do not ensure compliance with the critical limit. Specifically***	92
15839	21 CFR 111.70(e)	Specifications - identity, purity, strength, composition	You did not establish product specifications for the [identity] [purity] [strength] [composition] of the finished dietary supplement. Specifically, ***	92
2386	21 CFR 110.80(a)(1)	Storage	Failure to store raw materials in a manner that [protects against contamination] [minimizes deterioration]. Specifically, ***	88

Cite Id	Reference Number	Short Description	Long Description	Frequ
2392	21 CFR 110.80(b)(1)	Maintenance of equip., utensils, and finished food packaging	Failure to maintain [equipment] [utensils] [finished food containers] in an acceptable condition through appropriate cleaning and sanitizing. Specifically, ***	87
1581	21 CFR 110.37(e)	Running water at suitable temperature	Hand-washing facilities lack running water of a suitable temperature. Specifically, ***	86
1424	21 CFR 110.20(b)(4)	Drip and condensate	The plant is not constructed in such a manner as to prevent [drip] [condensate] from contaminating [food] [food-contact surfaces] [food-packaging materials]. Specifically, ***	84
1597	21 CFR 110.37(b)(3)	As source of contamination	Plumbing constitutes a source of contamination to [food] [water supplies] [equipment] [utensils]. Specifically, ***	84

Cite Id	Reference Number	Short Description	Long Description	Frequ
904	21 CFR 123.6(b)	No HACCP plan	You do not have a written HACCP plan that outlines controls for a food safety hazard that is reasonably likely to occur. Specifically, ***	82
963	21 CFR 123.6(c)(5)	Corrective action plan	Your HACCP plan includes a corrective action plan that is not in accordance with 21 CFR 123.7(b) to ensure [affected product is not entered into commerce] [the cause of the deviation was corrected]. Specifically***	81
1005	21 CFR 110.10(b)(7)	Storage of personal items	Personal [clothing] [belongings] were stored in an area where [food is exposed] [equipment or utensils are washed]. Specifically, ***	76

Cite Id	Reference Number	Short Description	Long Description	Frequ
1556	21 CFR 110.35(b)(2)	Storage requirements	Failure to properly [identify] [hold] [store] toxic [cleaning compounds] [sanitizing agents] [pesticide chemicals] in a manner that protects against contamination of [food] [food-contact surfaces] [food-packaging materials]. Specifically, ***	76
1066	21 CFR 110.40(b)	Seams on food contact surfaces	Failure to have smoothly bonded or well maintained seams on food contact surfaces, to minimize accumulation of [food particles] [dirt] [organic matter] and the opportunity for growth of microorganisms. Specifically, ***	75
908	21 CFR 123.6(d)	Signed and dated	Your HACCP plan was not signed and dated [upon initial acceptance] [upon modification] [at least annually]. Specifically, ***	74
15927	21 CFR 111.103	Written procedures - quality control operations	You did not [establish] [follow] written procedures for quality control operations. Specifically, ***	73

Cite Id	Reference Number	Short Description	Long Description	Frequ
1007	21 CFR 110.10(b)(9)	Precautions against contamination--micro, foreign substances	Failure to take necessary precautions to protect against contamination of [food] [food contact surfaces] [food packaging systems] with [microorganisms] [foreign substances]. Specifically, ***	66
6005	21 CFR 123.6(c)(6)	Verification procedures - adequacy	Your HACCP plan lists verification [procedures] [frequencies] that have not been developed in accordance with 21 CFR 123.8(a) to ensure that your HACCP plan is adequate to control food safety hazards, and is being effectively implemented. Specifically, ***	63

Cite Id	Reference Number	Short Description	Long Description	Frequ
6008	21 CFR 123.8(a)(3)	Verification - record review - frequency	You did not review [some of] your [critical control point monitoring] [corrective action] [calibration] [in-process testing] [end-product testing] records [within one week] [within a reasonable time] after the records were made. Specifically, ***	63
15797	21 CFR 111.553	Written procedures - product complaint	You did not [establish] [follow] written procedures for the requirements to review and investigate a product complaint. Specifically, ***	63
15869	21 CFR 111.75(c)	Specifications met - verify; finished batch	You did not verify that your finished batch of dietary supplement meets product specifications for [identity] [purity] [strength] [composition] [limits on contamination that may adulterate or that may lead to adulteration of the dietary supplement]. Specifically, ***	61

Cite Id	Reference Number	Short Description	Long Description	Frequ
4470	21 CFR 108.25(c)(2)	Process filing	Failure to provide the FDA, before packing any new product, information on the scheduled processes for each acidified food in each container size. Specifically, ***	60
3658	21 CFR 110.37(e)(2)	Hand cleaning and sanitizing preparations	Lack of effective hand [cleaning] [sanitizing] preparations. Specifically, ***	59
1006	21 CFR 110.10(b)(8)	Personal food/drink/tobacco	Employees were observed to be [eating food] [chewing gum] [drinking beverages] [using tobacco] in areas where [food is exposed] [equipment or utensils are washed]. Specifically, ***	58
1406	21 CFR 110.10(b)(6)	Effective use of hair restraint	Failure to wear [hair nets] [head bands] [caps] [beard covers] [appropriate hair restraints] in an effective manner. Specifically, ***	58
3643	21 CFR 110.10(b)(5)	Glove condition	Gloves used in food handling are not maintained in an intact, clean, and sanitary condition. Specifically, ***	58

Cite Id	Reference Number	Short Description	Long Description	Frequ
1525	21 CFR 123.11(c)	Sanitation Records	You are not maintaining sanitation control records that document [monitoring] [corrections of sanitation deficiencies] for [safety of water that comes into contact with food or food contact surfaces, including water used to manufacture ice] [condition and cleanliness of food contact surfaces] [prevention of cross-contamination from insanitary objects] [maintenance of hand washing, hand sanitizing, and toilet facilities] [protection of food, food packaging material, and food contact surfaces from adulteration] [proper labeling, storage and use of toxic chemicals] [control of employee health conditions] [exclusion of pests]. Specifically, ***	57

Cite Id	Reference Number	Short Description	Long Description	Frequ
1702	21 CFR 110.80(b)(8)	Metal / extraneous materials	Failure to take effective measures to protect against the inclusion of [metal] [extraneous material] in food. Specifically, ***	56
3652	21 CFR 110.37(e)(1)	Suitable locations	Failure to provide [hand washing] [hand sanitizing] facilities at each location in the plant where needed. Specifically, ***	56
1402	21 CFR 110.10(b)(4)	Unsecured jewelry	Employees failed to remove unsecured jewelry or other objects which might fall into [food] [equipment] [containers]. Specifically, ***	55
18149	21 CFR 117.40	Equipment and Utensils - Design and Maintenance	Your equipment and utensils were not designed and constructed to be adequately cleaned or maintained to protect against [allergen cross-contact] [contamination]. Specifically, ***	54

Cite Id	Reference Number	Short Description	Long Description	Frequ
18161	21 CFR 117.80(c)	Manufacturing, Processing, Packing, Holding - Controls	You did not conduct operations under conditions and controls necessary to minimize the potential for [growth of microorganisms] [allergen cross-contact] [contamination of food] [deterioration of food]. Specifically, ***	53
15762	21 CFR 111.205(a)	Master manufacturing record - each batch	You did not [prepare] [follow] a written master manufacturing record for each batch size of a dietary supplement that you manufactured. Specifically, ***	50
15861	21 CFR 111.75(a)(2)(ii)(A)	Component - qualify supplier	You did not qualify a supplier of a component by establishing the reliability of the supplier's certificate of analysis through confirmation of the results of their tests or examinations. Specifically, ***	50

Cite Id	Reference Number	Short Description	Long Description	Frequ
1615	21 CFR 110.93	Storage/transportation of finished goods (contamination)	Failure to [store] [transport] finished food under conditions that would protect against [physical] [chemical] [microbial] contamination. Specifically, ***	49
1698	21 CFR 110.80(b)(5)	Work-in-progress	Failure to handle work-in-progress in a manner that protects against contamination. Specifically, ***	48
18141	21 CFR 117.35(a)	Sanitary Operations - Plant Maintenance	You did not [maintain your plant in a clean and sanitary condition] [keep your plant in repair]. Specifically, ***	48
985	21 CFR 110.10(b)(1)	Suitable outer garments	Suitable outer garments are not worn that protect against contamination of [food] [food contact surfaces] [food packaging materials]. Specifically, ***	47

Cite Id	Reference Number	Short Description	Long Description	Frequ
1173	21 CFR 110.40(f)	Q.C. instrument accuracy, maintenance	Instruments used for [measuring] [regulating] [recording] conditions that control or prevent the growth of undesirable microorganisms are not [accurate] [adequately maintained]. Specifically,***	47
15532	21 CFR 111.255(b)	Batch record - complete	Your batch production record did not include complete information relating to the production and control of each batch. Specifically, ***	47
15641	21 CFR 111.453	Written procedures - holding	You did not [establish] [follow written] procedures for holding and distributing operations. Specifically, ***	46
18138	21 CFR 117.10	Personnel	You did not take a reasonable measure and precaution related to personnel practices. Specifically, ***	46
3659	21 CFR 110.37(e)(3)	Hand drying	Lack of a sanitary towel service or suitable hand drying devices. Specifically, ***	45

Cite Id	Reference Number	Short Description	Long Description	Frequ
3661	21 CFR 110.37(e)(5)	Signs	Lack of posted, readily understandable signs directing employees to wash and sanitize hands as appropriate. Specifically, ***	45
15858	21 CFR 111.75(a)(1)(i)	Component - verify identity, dietary ingredient	You did not conduct at least one appropriate test or examination to verify the identity of a dietary ingredient, prior to its use. Specifically, ***	45
15830	21 CFR 111.70(b)(2)	Specifications-component purity, strength, composition	You did not establish component specifications for [purity] [strength] [composition]. Specifically, ***	44
6021	21 CFR 123.10	HACCP training or qualification	No one associated with your firm has completed the required HACCP training or is HACCP qualified through job experience. Specifically, ***	43

Cite Id	Reference Number	Short Description	Long Description	Frequ
1429	21 CFR 110.20(b)(6)	Fans/air blowing equipment	Failure to [locate] [operate] fans and other air-blowing equipment in a manner that minimizes the potential for contaminating [food] [food-contact surfaces] [food-packaging materials]. Specifically, ***	41

Cite Id	Reference Number	Short Description	Long Description	Frequ
9931	21 CFR 120.6(b)	Sanitation monitoring	You are not monitoring the sanitation conditions and practices with sufficient frequency to assure conformance with current good manufacturing practice including [safety of water that comes into contact with food or food contact surfaces, including water used to manufacture ice] [condition and cleanliness of food contact surfaces] [prevention of cross-contamination from insanitary objects] [maintenance of hand washing, hand sanitizing, and toilet facilities] [protection of food, food packaging material, and food contact surfaces from adulteration] [proper labeling, storage and use of toxic chemicals] [control of employee health conditions] [exclusion of pests]. Specifically, ***	41

Cite Id	Reference Number	Short Description	Long Description	Frequ
6018	21 CFR 123.7(a)	Corrective action per predetermined plan	You did not take corrective action that ensured [affected product was not entered into commerce] [the cause of the deviation was corrected]. Specifically,***	40
16042	21 CFR 111.503	Written procedures - returned dietary supplement	You did not [establish] [follow] written procedures for when a returned dietary supplement is received. Specifically, ***	40
3071	21 CFR 114.80(a)(1)	Scheduled process	Acidified food is not manufactured in accordance with the scheduled process. Specifically, ***	39
6020	21 CFR 123.9(a)	Records - content	Your records do not include the [name and location of the processor or importer] [date and time of the activity the record reflects] [signature or initials of the person performing the operation] [identity of the product and the production code, if any]. Specifically, ***	39

Cite Id	Reference Number	Short Description	Long Description	Frequ
15825	21 CFR 111.65	Quality control - quality, dietary supplement	You did not implement quality control operations to ensure the quality of the dietary supplement. Specifically, ***	38
15897	21 CFR 111.83(a)	Reserve sample - collect, hold	You did not collect and hold reserve samples of packaged and labeled dietary supplements that you distributed. Specifically, ***	38
3086	21 CFR 114.100(b)	Maintenance of processing and production records	Failure to maintain [processing] [production] records showing adherence to the scheduled processes, including records of [pH measurement] [critical factors] intended to ensure a safe product. Specifically, ***	36
15659	21 CFR 111.475(b)(1)	Written procedures - holding; distributing	You did not make and keep written procedures for holding and distributing operations. Specifically, ***	36
933	21 CFR 123.8(a)(2)(ii)	Calibration - adequacy	Your process monitoring equipment is not calibrated to ensure that it reads accurately. Specifically, ***	34

Cite Id	Reference Number	Short Description	Long Description	Frequ
3078	21 CFR 114.80(b)	Code - required elements	Each container is not marked with an identifying code specifying the [establishment where the product was packed] [product contained therein] [year] [date] [packing period]. Specifically, ***	34
1126	21 CFR 110.40(a)	Precluding contaminants	The [design] [construction] [use] of equipment and utensils fails to preclude the adulteration of food with [lubricants] [fuel] [metal fragments] [contaminated water] [contaminants]. Specifically, ***	33
15829	21 CFR 111.70(b)(1)	Specifications - component identity	You did not establish an identity specification for each component. Specifically, ***	33
18140	21 CFR 117.20(b)	Plant Construction and Design	Your plant was not [constructed] [designed] to facilitate maintenance and sanitary operations. Specifically, ***	32

Cite Id	Reference Number	Short Description	Long Description	Frequ
1565	21 CFR 110.35(d)(3)	Non-food-contact surfaces (S)	Failure to clean non-food-contact surfaces of equipment as frequently as necessary to protect against contamination. Specifically, ***	31
1571	21 CFR 110.35(d)(5)	Shown to be effective	The [facility] [procedure] [machine] used for [cleaning] [sanitizing] of [equipment] [utensils] has not been shown to provide adequate [cleaning] [sanitizing treatment]. Specifically, ***	31
1763	21 CFR 110.35(b)(1)	Safe and adequate for use	Use of cleaning compounds and sanitizing agents which are not [free from undesirable microorganisms] [safe and adequate under the conditions of use]. Specifically, ***	31

Cite Id	Reference Number	Short Description	Long Description	Frequ
1293	21 CFR 110.20(b)(2)	Contamination with microorganisms, chemicals, filth, etc.	Proper precautions to protect [food] [food-contact surfaces] [food-packaging materials] from contamination with [microorganisms] [chemicals] [filth] [extraneous material] cannot be taken because of deficiencies in plant [size] [construction] [design]. Specifically, ***	30
6001	21 CFR 123.11(b)	Sanitation monitoring documentation	Your sanitation control records do not accurately document the conditions or practices observed at your firm. Specifically***	29
18148	21 CFR 117.37	Sanitary Facilities and Control	Your plant did not have adequate sanitary facilities and accommodations. Specifically, ***	29

Cite Id	Reference Number	Short Description	Long Description	Frequ
3080	21 CFR 114.83	Scheduled process establishment	A scheduled process was not established by a qualified person who has expert knowledge acquired through appropriate training and experience in acidification and processing of acidified foods. Specifically, ***	28
15531	21 CFR 111.255(a)	Batch record - every batch	You did not prepare a batch production record every time you manufactured a batch of dietary supplement. Specifically, ***	28
15809	21 CFR 111.570(b)(1)	Written procedures - product complaint; review, investigate	You did not make and keep written procedures to fulfill the requirements that apply to the review and investigation of a product complaint. Specifically, ***	28
1067	21 CFR 110.40(c)	Non food-contact equipment in processing area	Non food-contact equipment in [manufacturing] [food handling] areas is not constructed so that it can be kept in a clean condition. Specifically, ***	27

Cite Id	Reference Number	Short Description	Long Description	Frequ
1570	21 CFR 110.35(d)(5)	Safe and adequate for use	Sanitizing agents are [inadequate] [unsafe] under conditions of use. Specifically, ***	27
1599	21 CFR 110.37(b)(5)	Backflow prevention	Lack of backflow protection from piping systems that discharge [waste water] [sewage]. Specifically, ***	27
901	21 CFR 123.6(a)	Hazard analysis	You did not conduct, or have conducted for you, a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur for each kind of fish and fishery product you process. Specifically, ***	26
1426	21 CFR 110.20(b)(5)	Adequate lighting	Failure to provide adequate lighting in [hand-washing areas] [dressing and locker rooms] [toilet rooms] [areas where food is examined, stored, or processed] [areas where equipment and utensils are cleaned]. Specifically, ***	26

Cite Id	Reference Number	Short Description	Long Description	Frequ
4464	21 CFR 108.25(c)(1)	Registration	Failure to register with the FDA information including the name, principal place of business and the location of the processing establishment within 10 days after engaging in the manufacture, processing and packaging of acidified foods. Specifically, ***	26
18142	21 CFR 117.35(a)	Sanitary Operations - Plant Sanitation	You did not clean and sanitize your utensils or equipment in a manner that protects against [allergen cross-contact] [contamination]. Specifically, ***	26
1596	21 CFR 110.37(b)(2)	Convey sewage	Plumbing is not [of adequate size and design] [adequately installed and maintained] to properly convey sewage and liquid disposable waste from the plant. Specifically, ***	25
3656	21 CFR 110.37(d)(3)	Self-closing doors	Toilet facilities lack self-closing doors. Specifically, ***	25

Cite Id	Reference Number	Short Description	Long Description	Frequ
18145	21 CFR 117.35(c)	Pest Control	You did not [exclude pests from your food plant] [use pesticides under precautions and restrictions] to protect against contamination of food. Specifically, ***	25
1184	21 CFR 110.35(e)	Storage of cleaned portable equipment (S)	Failure to store cleaned and sanitized portable equipment in a [location] [manner] which protects food-contact surfaces from contamination. Specifically, ***	24
1709	21 CFR 110.80(b)(13)	Filling, assembling, packing controls	Failure to perform [filling] [assembling] [packaging] in a manner that protects food from becoming contaminated. Specifically, ***	24
3654	21 CFR 110.37(d)(1)	Maintained	Failure to maintain toilet facilities in a sanitary condition. Specifically, ***	24

Cite Id	Reference Number	Short Description	Long Description	Frequ
4479	21 CFR 108.25(e)	Recall procedures	Failure to prepare and maintain in files current procedures for [recalling products that may be injurious to health] [identifying, collecting, warehousing and controlling products] [determining the effectiveness of recalls] [notifying FDA] [implementing recall programs]. Specifically, ***	24
15763	21 CFR 111.205(a)	Master manufacturing record - unique formulation	You did not [prepare] [follow] a written master manufacturing record for each unique formulation of a dietary supplement that you manufactured. Specifically, ***	24
16057	21 CFR 111.535(b)(1)	Records - returned dietary supplement: written procedures	You did not make and keep records of written procedures for fulfilling requirements for returned dietary supplements. Specifically, ***	23

Cite Id	Reference Number	Short Description	Long Description	Frequ
1403	21 CFR 110.10(b)(4)	Hand jewelry - remove/cover	Failure to [remove] [adequately cover] hand jewelry which cannot be adequately sanitized during periods where food is being manipulated by hand. Specifically, ***	22
6015	21 CFR 123.6(c)(6)	Verification procedures - none/frequency	Your HACCP plan does not list verification [procedures] [frequencies] that have been developed to ensure that the HACCP plan is adequate to control food safety hazards, and is being effectively implemented. Specifically, ***	22
906	21 CFR 123.6(b)	HACCP plan location	Your HACCP plan is not specific to [the location where the fish are processed] [the kind of fish or fishery product processed]. Specifically, ***	21

Cite Id	Reference Number	Short Description	Long Description	Frequ
1561	21 CFR 110.35(c)	Insecticides/rodenticides	Use of [insecticides] [rodenticides] without observing necessary precautions and restrictions to protect against contamination of [food] [food-contact surfaces] [food-packaging materials]. Specifically, ***	21
1598	21 CFR 110.37(b)(4)	Drainage	Plumbing is not [of adequate size and design] [adequately installed and maintained] to provide adequate floor drainage. Specifically, ***	21
3647	21 CFR 110.10(c)	Training of handlers and supervisors	Appropriate training in food handling techniques and food protection principles has not been provided to [food handlers] [supervisors]. Specifically, ***	21
6010	21 CFR 123.8(a)(3)(i)	Monitoring record review adequacy	Your review of critical control point monitoring records does not [ensure that the records are complete] [verify that they document values that are within critical limits]. Specifically, ***	21

Cite Id	Reference Number	Short Description	Long Description	Frequ
1578	21 CFR 110.37(f)	Odor, attractant for pests, harborage	The [conveyance] [storage] [disposal] of [rubbish] [offal] does not minimize the [development of odor] [potential for waste becoming an attractant and harborage or breeding place for pests]. Specifically, ***	20
1130	21 CFR 110.40(a)	Food-contact - withstand food & cleaning cmpds.	Food contact surfaces are not designed to [withstand the environment of their intended use] [withstand the action of food] [withstand cleaning compounds and sanitizing agents]. Specifically, ***	19
1696	21 CFR 110.80(b)(3)	Holding foods - refrigerate/freeze/heat	Failure to hold foods which can support the rapid growth of undesirable microorganisms at a temperature that prevents the food from becoming adulterated. Specifically, ***	19

Cite Id	Reference Number	Short Description	Long Description	Frequ
3073	21 CFR 114.80(a)(2)	pH testing	Failure to exercise sufficient control including [frequent testing] [recording of results] so that the finished equilibrium pH values are not higher than 4.6. Specifically, ***	19
3085	21 CFR 114.100(a)	Raw materials, packaging, finished product	Records are not maintained of the examination of [raw materials] [packaging materials] [finished products] [supplier's guarantees or certificates] to verify compliance with FDA regulations and guidelines or action levels. Specifically, ***	19
3877	21 CFR 113.60(c)	Coding - required elements	The identification code for hermetically sealed containers did not identify in code the [establishment where packed] [product in the container] [year packed] [day packed] [period during which packed]. Specifically, ***	19

Cite Id	Reference Number	Short Description	Long Description	Frequ
6007	21 CFR 123.9(a)	Records entries - timing	Processing or other information was not [always] entered on your records at the time it was observed. Specifically, ***	19
6019	21 CFR 123.8(a)(2)	Ongoing verification - complaints, calibration records	Your verification procedures do not include, at a minimum, ongoing verification activities including [review of consumer complaints] [calibration of process monitoring instruments] [review of monitoring, corrective action, and calibration records]. Specifically, ***	19
12742	21 CFR 120.8(a)	HACCP plan not implemented	You did not [fully] implement the [monitoring] [validation] [verification] [recordkeeping] procedures listed in your HACCP plan. Specifically, ***	19
15838	21 CFR 111.70(d)	Specifications - labels, packaging	You did not establish [label] [packaging] specifications. Specifically, ***	19

Cite Id	Reference Number	Short Description	Long Description	Frequ
18165	21 CFR 117.93	Storage and Transportation	You did not store or transport food, including ingredients, under conditions that protect against [allergen cross-contact] [contamination] [deterioration] [adulteration]. Specifically, ***	19
918	21 CFR 123.8(a)	Verification - reviewers qualifications	The [reassessment of your HACCP plan] [monitoring, corrective action, or verification record review] was not done by an individual who had successfully completed training in the application of HACCP principles to fish and fishery product processing, or was otherwise qualified through job experience to perform these functions. Specifically, ***	18

Cite Id	Reference Number	Short Description	Long Description	Frequ
3062	21 CFR 114.10	Personnel	Operators of processing and packaging systems are not under the operating supervision of a person who has attended and satisfactorily completed a school approved by the Commissioner. Specifically, ***	18
3067	21 CFR 114.80(a)	Quality control procedures	Appropriate quality control procedures are not employed to ensure that finished foods do not present a health hazard. Specifically, "***	18
15819	21 CFR 111.55	Production, process controls - implement	You did not implement a system of production and process controls that covers all stages of manufacturing, packaging, labeling, and holding of dietary supplements to ensure the quality of the dietary supplement. Specifically, ***	18

Cite Id	Reference Number	Short Description	Long Description	Frequ
18146	21 CFR 117.35(d)	Sanitation of food contact surfaces - frequency	You did not clean and sanitize your utensils or equipment as frequently as necessary to protect against [allergen cross-contact] [contamination of food]. Specifically, ***	18
2361	21 CFR 110.80	Testing	Failure to perform [chemical] [microbial] [extraneous material] testing where necessary to identify [sanitation failures] [possible food contamination]. Specifically, ***	17
15831	21 CFR 111.70(b)(3)	Specifications - contamination limits	You did not establish limits for contamination that may adulterate or may lead to adulteration of the finished dietary supplement. Specifically, ***	17

Cite Id	Reference Number	Short Description	Long Description	Frequ
913	21 CFR 123.8(a)(1)	Reassessment of HACCP plan	Your verification procedures do not include, at a minimum, reassessment of the HACCP plan [at least annually] [whenever modifications to the process are made]. Specifically, ***	16
2393	21 CFR 110.80(b)(1)	Teardown equipment/thorough cleaning	Failure to take apart equipment as necessary to ensure thorough cleaning. Specifically, ***	16
4475	21 CFR 108.25(c)(3)(i)	Process adherence	Failure to process each food in conformity with at least the scheduled process filed with FDA. Specifically, ***	16
15828	21 CFR 111.70(a)	Specifications - manufacturing process	You did not establish a specification for a point, step, or stage in the manufacturing process where control is necessary to ensure [the quality of the dietary supplement] [that the dietary supplement is packaged and labeled as specified in the master manufacturing record]. Specifically, ***	16

Cite Id	Reference Number	Short Description	Long Description	Frequ
4511	21 CFR 108.25(f)	Approved school	Failure to have personnel involved in [acidification] [pH control] [heat treatment] [critical factors] under the operating supervision of a person who has attended and satisfactorily completed a school approved by the Commissioner. Specifically, ***	15
6006	21 CFR 123.6(c)(7)	Records values/observations	Your monitoring records do not contain the actual values and observations obtained during monitoring. Specifically, ***	15
18153	21 CFR 117.80(a)	Plant Operations - precautions	You did not [conduct operations in accordance with adequate sanitation principles] [have plant sanitation under the supervision of a competent individual] [take adequate precautions to ensure that production procedures did not contribute to allergen cross-contact and to contamination]. Specifically, ***	15

Cite Id	Reference Number	Short Description	Long Description	Frequ
986	21 CFR 110.10(b)(2)	Personal cleanliness	Employees in contact with [food] [food-contact surfaces] [food-packaging materials] were not maintaining adequate personal cleanliness. Specifically, ***	14
1128	21 CFR 110.40(a)	Installation and maintenance of equipment (S)	Failure to [install] [maintain] equipment so as to facilitate cleaning of [the equipment] [all adjacent spaces]. Specifically, ***	14
1132	21 CFR 110.40(a)	Food-contact - unlawful indirect additives	Failure to maintain food contact surfaces to protect food from contamination by any source, including unlawful indirect food additives. Specifically, ***	14

Cite Id	Reference Number	Short Description	Long Description	Frequ
1172	21 CFR 110.40(e)	Lack of thermometer	Lack of an accurate indicating thermometer, temperature measuring device, or temperature recording device in each freezer and cold storage compartment used to store food capable of supporting the growth of microorganisms. Specifically, ***	14
2388	21 CFR 110.80(a)(5)	Holding in bulk or suitable containers	Failure to hold [raw materials] [rework materials] [ingredients] in bulk or in suitable containers so as to protect against contamination. Specifically, ***	14

Cite Id	Reference Number	Short Description	Long Description	Frequ
9955	21 CFR 120.11(a)(1)	Verification activities - minimum	Your verification activities do not include, at a minimum, [review of consumer complaints to determine whether they relate to the performance of the HACCP plan] [calibration of process monitoring instruments] [end-product or in-product testing] [review of critical control point monitoring, corrective action, and calibration records] to ensure that your HACCP system is being properly implemented. Specifically, ***	14
15453	21 CFR 111.16	Written procedures - cleaning	You did not [establish] [follow] written procedures for cleaning the physical plant. Specifically, ***	14
931	21 CFR 123.8(d)	Verification - recordkeeping	You do not maintain records of [calibration of process-monitoring instruments] [periodic end-product or in-process testing]. Specifically, ***	13

Cite Id	Reference Number	Short Description	Long Description	Frequ
932	21 CFR 123.7(d)	Corrective action documentation	You do not have records that document corrective actions that were taken. Specifically, ***	13
1129	21 CFR 110.40(a)	Food-contact - corrosion resistant	Lack of corrosion-resistant food contact surfaces. Specifically, ***	13
1289	21 CFR 110.20(a)(3)	Drainage	Lack of adequate drainage of areas which may contribute to contamination of food by [seepage] [foot-borne filth] [providing a breeding place for pests]. Specifically, ***	13
4515	21 CFR 108.35(c)(2)	Process filing	Failure to provide FDA, before packing any new product, information as to the scheduled process for each low-acid canned food in each container. Specifically, ***	13
6016	21 CFR 123.6(c)(7)	Records system	Your HACCP plan does not provide for a recordkeeping system that documents the monitoring of the critical control points. Specifically, ***	13

Cite Id	Reference Number	Short Description	Long Description	Frequ
18262	21 CFR 1.504(a)	Hazard analysis written	You did not have a written hazard analysis to identify and evaluate known or reasonably foreseeable hazards [to determine whether there are any hazards requiring a control]. Specifically, ***	13
2384	21 CFR 110.80(a)(7)	Receipt/storage - liquid and dry raw materials	Failure to receive and store [liquid] [dry] raw materials in bulk form in a manner which protects against contamination. Specifically, ***	12
3712	21 CFR 110.93	Storage/transportation of finished goods (deterioration)	Failure to [store] [transport] finished food under conditions that would protect against deterioration of the food and its container. Specifically, ***	12

Cite Id	Reference Number	Short Description	Long Description	Frequ
9930	21 CFR 120.6(c)	SSOP records	You do not [always] maintain sanitation standard operating procedure records that document [the monitoring of conditions and practices during processing] [corrections to conditions and practices that were not met]. Specifically, ***	12
12746	21 CFR 120.8(b)(2)	HACCP plan - critical control points not listed	Your HACCP plan does not list the critical control points for each of the identified food hazards. Specifically, ***	12
12747	21 CFR 120.8(b)(3)	HACCP plan - critical limits not listed or not adequate	Your HACCP plan [does not list one or more of the critical limits that must be met at each critical control point] [lists a critical limit that does not prevent, eliminate, or reduce to an acceptable level the occurrence of an identified food hazard]. Specifically, ***	12

Cite Id	Reference Number	Short Description	Long Description	Frequ
15494	21 CFR 111.25(c)	Procedures - equipment - cleaning, sanitizing	You did not [establish] [follow] written procedures for maintaining, cleaning, and sanitizing, equipment, utensils, and any other contact surfaces that are used to manufacture, package, label, or hold components or dietary supplements. Specifically, ***	12
15790	21 CFR 111.403	Written procedures - labeling operations	You did not [establish] [follow] written procedures for labeling operations. Specifically, ***	12
15840	21 CFR 111.70(e)	Specifications - contamination limits	You did not establish product specifications for limits on contamination that may adulterate, or that may lead to adulteration of, the finished dietary supplement. Specifically, ***	12
16013	21 CFR 111.140(b)(1)	Records - quality control operations; responsibilities	You did not make and keep written procedures for the responsibilities of the quality control operations. Specifically, ***	12

Cite Id	Reference Number	Short Description	Long Description	Frequ
18147	21 CFR 117.35(e)	Sanitation of non-food contact surfaces - frequency	You did not clean your non-food contact surface in a manner and as frequently as necessary to protect against [allergen cross-contact] [contamination]. Specifically, ***	12
1090	21 CFR 110.40(d)	Holding, conveying, mfg systems - design & construction	Lack of appropriate [design] [construction] to enable [holding] [conveying] [manufacturing] systems to be maintained in an appropriate sanitary condition. Specifically, ***	11
1566	21 CFR 110.35(d)(4)	Single-service articles	Failure to [store] [handle] [dispense] [use] [dispose of] single-service articles in a manner that protects against the contamination of food and food-contact surfaces. Specifically, ***	11
2385	21 CFR 110.80(a)(1)	Inspection, segregation, handling of raw materials	Failure to [inspect] [segregate] [handle] raw materials to ascertain that they are clean and suitable for processing into food. Specifically, ***	11

Cite Id	Reference Number	Short Description	Long Description	Frequ
3090	21 CFR 114.100(d)	Product distribution	Records identifying initial distribution of finished product are not maintained. Specifically, ***	11
3657	21 CFR 110.37(d)(4)	Doors opening into processing areas	Toilet doors open into areas where food is exposed to airborne contamination, and there are no alternative means taken to prevent such contamination. Specifically, ***	11
4519	21 CFR 108.35(c)(3)(i)	Process adherence	Failure to process each low-acid canned food in conformity with at least the scheduled process. Specifically, ***	11
6002	21 CFR 123.11(b)	Sanitation corrections	You did not correct sanitation deficiencies in a timely manner. Specifically,***	11
9941	21 CFR 120.8(a)	No HACCP plan	You do not have a written HACCP plan that outlines controls for one or more food safety hazards that are reasonably likely to occur. Specifically, ***	11

Cite Id	Reference Number	Short Description	Long Description	Frequ
15410	21 CFR 111.14(b)(2)	Personnel - records - training	You did not make and keep documentation of training. Specifically, ***	11
15702	21 CFR 111.320(b)	Examination, testing; scientifically valid	You did not identify and use an appropriate scientifically valid method for each established specification for which testing or examination is required to determine whether the specification was met. Specifically, ***	11
16089	FDCA 417(d)(1)(A)	Reportable food report - submission	You did not submit a reportable food report to FDA within 24 hours after you determined that a food was a reportable food. Specifically, ***	11
16118	21 CFR 118.4	Written SE plan not implemented/followed	Your written SE prevention plan is not [fully] implemented and followed. Specifically,***	11

Cite Id	Reference Number	Short Description	Long Description	Frequ
19058	21 CFR 117.135(c)(3)	Sanitation Controls Procedures	Your sanitation controls procedures did not ensure [cleanliness of food-contact surfaces] [prevention of allergen cross-contact] [prevention of cross-contamination]. Specifically, ***	11
2394	21 CFR 110.80(b)(6)	Contamination by raw materials, refuse, other ingredients	Failure to take effective measures to protect finished food from contamination by [raw materials] [refuse] [other ingredients] . Specifically, ***	10
3088	21 CFR 114.100(b)	Processing and production - required information	The [processing] [production] records do not contain sufficient additional information such as [product code] [date] [container size] [product] to permit a public health hazard evaluation of the processes applied to each [lot] [batch] [portion] of production. Specifically, ***	10
3653	21 CFR 110.37(d)	Readily accessible	Failure to provide employees with [readily accessible] [adequate] toilet facilities. Specifically, ***	10

Cite Id	Reference Number	Short Description	Long Description	Frequ
6022	21 CFR 123.12(c)	Lack of records	You do not have records to document the performance and results of the affirmative steps taken to demonstrate that [fish] [fishery products] imported into the United States were processed in accordance with the seafood HACCP regulation. Specifically, ***	10
9954	21 CFR 120.11(a)(1)(iv)	Verification - CCP, CA record review	You did not review [all of] your [critical control point monitoring] [corrective action] records within one week (7 days) of the day the records are made. Specifically, ***	10
12745	21 CFR 120.8(b)(1)	HACCP plan - food hazards not listed	Your HACCP plan does not list all food hazards that are reasonably likely to occur. Specifically, ***	10

Cite Id	Reference Number	Short Description	Long Description	Frequ
15747	21 CFR 111.210(g)	Packaging description, representative label	Your master manufacturing record did not include [a description of the packaging] [a representative label, or a cross-reference to the physical location of the actual or representative label]. Specifically,	10
15871	21 CFR 111.75(c)(2)	Specifications met - test, examinations; compliance	You did not conduct appropriate tests or examinations to determine compliance with the specifications established for [identity] [purity] [strength] [composition] [limits on contamination that may adulterate or that may lead to adulteration of the dietary supplement]. Specifically, ***	10
15885	21 CFR 111.77(a)	Specifications not met - reject, quality control	Your quality control personnel did not reject a [component] [dietary supplement] [package] [label] for which a specification was not met. Specifically, ***	10

Cite Id	Reference Number	Short Description	Long Description	Frequ
15932	21 CFR 111.105(a)	Processes, specifications, written procedures	Your quality control personnel did not approve or reject [processes] [specifications] [written procedures] [controls] [tests] [examinations] [deviations or modifications] that may affect the identity, purity, strength, or composition of a dietary supplement. Specifically, ***	10
19030	21 CFR 117.130(a)(1)	Hazard Analysis - Identification of Hazard	Your hazard analysis did not identify a known or reasonably foreseeable hazard that required a preventive control. Specifically, ***	10
1568	21 CFR 110.35(d)(2)	Before use and after interruption	Failure to clean and sanitize food-contact surfaces in wet-processing [before use] [after any interruption during which they may have been contaminated], to preclude contamination with microorganisms. Specifically, ***	9

Cite Id	Reference Number	Short Description	Long Description	Frequ
1766	21 CFR 110.35(b)(1)	Unacceptable toxic compounds	Storage or use of toxic materials which are not required to maintain clean and sanitary conditions, are unnecessary for use in laboratory testing procedures, are unnecessary for plant and equipment maintenance, and are unnecessary for use in plant operations. Specifically, ***	9
3093	21 CFR 114.89	Process deviation evaluation - record	Failure to record the [procedures used in the evaluation of process deviations] [results of process deviation evaluations]. Specifically, ***	9
3650	21 CFR 110.35(d)(1)	Wet cleaning	Failure to sanitize and thoroughly dry, prior to use, food-contact surfaces which have been wet cleaned. Specifically, ***	9

Cite Id	Reference Number	Short Description	Long Description	Frequ
9958	21 CFR 120.12(c)	Records - signed/dated	Your [written hazard analysis] [written HACCP plan], required by the juice HACCP regulation, [was] [were] not signed and dated [upon initial acceptance] [upon modification] [upon verification] [upon validation] [by the most responsible individual onsite at the processing facility or by a higher level official]. Specifically, ***	9
12743	21 CFR 120.8(b)(4)	HACCP plan - monitoring procedures not adequate	Your HACCP plan lists monitoring [procedures] [frequencies of performing procedures] that do not ensure compliance with the critical limits. Specifically, ***	9

Cite Id	Reference Number	Short Description	Long Description	Frequ
12755	21 CFR 120.11(a)(1)(iv)	Records - not signed and dated by qualified individual	Your review of [critical control point monitoring records] [corrective action records] [calibration records] [periodic end-product or in-process testing records] are not [performed] [signed] [dated] by an individual who is trained in the application of HACCP principles to juice processing or otherwise qualified through job experience. Specifically, ***	9
15425	21 CFR 111.15(i)	Hand-washing facilities	Your hand-washing facilities [are not adequate] [are not convenient] [do not furnish running water at a suitable temperature]. Specifically, ***	9
15434	21 CFR 111.15(d)(2)	Pest control measures	You did not take effective measures [to exclude pests from the physical plant] [to protect against contamination of components, dietary supplements, and contact surfaces on the premises by pests]. Specifically, ***	9

Cite Id	Reference Number	Short Description	Long Description	Frequ
15454	21 CFR 111.16	Written procedures - pest control	You did not [establish] [follow] written procedures for pest control. Specifically, ***	9
15642	21 CFR 111.455(a)	Hold - temperature, humidity, light	You did not hold [components] [dietary supplements] under appropriate conditions of temperature, humidity, or light so that their identity, purity, strength, and composition are not affected. Specifically, ***	9
15737	21 CFR 111.210(h)(5)	Corrective action plans	The written instructions in your master manufacturing record did not include instructions for corrective action plans to use when specifications are not met. Specifically, ***	9
15744	21 CFR 111.210(h)(2)	Master manufacturing record - sampling, tests, examinations	The written instructions in your master manufacturing record did not include [procedures for sampling] [a cross-reference to procedures for tests or examinations]. Specifically, ***	9

Cite Id	Reference Number	Short Description	Long Description	Frequ
15761	21 CFR 111.205(b)(1)	Master manufacturing record - specifications; quality	Your master manufacturing record did not identify specifications for the points, steps, or stages in the manufacturing process where control is necessary to ensure the quality of the dietary supplement. Specifically, ***	9
15862	21 CFR 111.75(a)(2)	Appropriate tests, examinations; certificate of analysis	You did not conduct appropriate tests or examinations or rely on a certificate of analysis to determine whether components met established specifications. Specifically, ***	9
15930	21 CFR 111.105	Ensure quality; package, labeled, master record	Your quality control personnel did not ensure that your [manufacturing] [packaging] [labeling] [holding] operations ensure the quality of the dietary supplement. Specifically, ***	9

Cite Id	Reference Number	Short Description	Long Description	Frequ
18139	21 CFR 117.20(a)	Grounds	You did not keep the grounds around your plant in a condition that would protect against the contamination of food. Specifically, ***	9
18143	21 CFR 117.35(b)(1)	Cleaning and sanitizing substances- safe and adequate	You did not ensure that your cleaning compounds and sanitizing agents are safe and adequate under the conditions of use. Specifically, ***	9
1196	21 CFR 110.10(a)	Employees with illness, lesions, contamination source	Employees who appear to have an [illness] [open lesion] [abnormal source of microbial contamination] are not excluded from operations where there is a reasonable possibility of [food] [food contact surfaces] [food packaging materials] becoming contaminated. Specifically, ***	8
1425	21 CFR 110.20(b)(4)	Spacing of equipment	Aisles or working spaces between equipment and walls are [obstructed] [of inadequate width]. Specifically, ***	8

Cite Id	Reference Number	Short Description	Long Description	Frequ
1577	21 CFR 110.37(f)	Contamination of food, contact surfaces, water supplies, etc	The [conveyance] [storage] [disposal] of [rubbish] [offal] does not protect against contamination of [food] [food-contact surfaces] [water supplies] [ground surfaces]. Specifically, ***	8
1601	21 CFR 110.37(a)	Safe and adequate sanitary quality	Failure to use water which is [safe] [of adequate sanitary quality] in food and on food-contact surfaces. Specifically, ***	8
3075	21 CFR 114.80(a)(4)	Container testing	Failure to [test] [examine] containers often enough to ensure that containers suitably protect the food from leakage and contamination. Specifically, ***	8

Cite Id	Reference Number	Short Description	Long Description	Frequ
9939	21 CFR 120.7(c)	All hazards not considered	In evaluating what food hazards are reasonably likely to occur, [you] [the person who performed the evaluation for you] did not consider [microbiological contamination] [parasites] [chemical contamination] [unlawful pesticide residues] [decomposition] [natural toxins] [use of unapproved color or food additives] [presence of undeclared ingredients that may be allergens] [physical hazards]. Specifically, ***	8
12748	21 CFR 120.8(b)(5)	HACCP plan - corrective action plan not included	Your HACCP plan includes a corrective action plan that is not in accordance with 21 CFR 120.10(a) to ensure [affected product is not entered into commerce] [the cause of the deviation was corrected]. Specifically,***	8

Cite Id	Reference Number	Short Description	Long Description	Frequ
15481	21 CFR 111.23(b)	Records - cleaning, pest control	You did not make and keep records of the written procedures for [cleaning the physical plant] [pest control]. Specifically, ***	8
15492	21 CFR 111.25(a)	Procedures - calibrating instruments	You did not [establish] [follow] written procedures for calibrating instruments and controls that you use in manufacturing or testing a component or dietary supplement. Specifically, ***	8
15496	21 CFR 111.27(b)	Instruments - calibration	You did not calibrate instruments or controls used in manufacturing or testing a component or dietary supplement [before the first use] [at the frequency specified in writing by the manufacturer or at routine intervals or as necessary] to ensure the accuracy and precision of the instruments or controls. Specifically, ***	8

Cite Id	Reference Number	Short Description	Long Description	Frequ
15543	21 CFR 111.260(c)	Batch record - date, time; maintenance	Your batch production records did not include the date and time of the maintenance, cleaning, and sanitizing of the equipment and processing lines used in producing the batch, or a cross-reference to records, such as individual equipment logs, where this information is retained. Specifically, ***	8
15546	21 CFR 111.260(f)	Batch record - yield	Your batch production records did not include [a statement of the actual yield] [a statement of the percentage of theoretical yield] at appropriate phases of processing. Specifically, ***	8
15645	21 CFR 111.455(c)	Hold - mix-up, contamination, deterioration	You held [components] [dietary supplements] [packaging] [labels] under conditions that lead to mix-up, contamination, or deterioration. Specifically, ***	8

Cite Id	Reference Number	Short Description	Long Description	Frequ
15660	21 CFR 111.475(b)(2)	Records - product distribution	You did not make and keep records of product distribution. Specifically, ***	8
15863	21 CFR 111.75(a)(2)(ii)(B)	Component - certificate of analysis	The certificate of analysis for a component does not include [a description of the test or examination method(s) used] [limits of the test or examination] [actual results of the tests or examinations]. Specifically, ***	8
15963	21 CFR 111.113(b)(2)	Quality control - reject; specification not met	Your quality control personnel did not reject a [component] [dietary supplement] [package] [label] when an established specification was not met. Specifically, ***	8

Cite Id	Reference Number	Short Description	Long Description	Frequ
16014	21 CFR 111.140(b)(1)	QC ops; written procedures; material review, disposition	You did not make and keep [written procedures for the responsibilities of the quality control operations for conducting a material review and making a disposition decision] [written procedures for approving or rejecting any reprocessing]. Specifically, ***	8
16120	21 CFR 118.4	Written SE plan lacks required elements	Your written SE prevention plan lacks appropriate SE prevention measures. Specifically,***	8
16135	21 CFR 118.4(b)(4)	Stray animals	Stray animals are not prevented from entering poultry houses. Specifically,***	8
18293	21 CFR 1.506(b)	Supplier verification - establish written procedures	You did not establish [adequate] written procedures for ensuring that appropriate foreign supplier verification activities are conducted with respect to a food you import. Specifically, ***	8

Cite Id	Reference Number	Short Description	Long Description	Frequ
19059	21 CFR 117.145(a)	Sanitation Controls Monitoring Proced: Establish Implement	You did not [establish] [implement] adequate written procedures for monitoring sanitation controls. Specifically, ***	8
950	21 CFR 123.12(d)	Determination of compliance	You have not provided evidence that the [fish] [fishery products] you import have been processed under conditions that comply with the Seafood HACCP regulation. Specifically, ***	7
1316	21 CFR 113.87(c)	Initial temperature of container contents	The initial temperature of the contents of the containers to be processed was not [determined] [recorded] with sufficient frequency to ensure the temperature of the product was no lower than the minimum initial temperature specified in the scheduled process. Specifically, ***	7

Cite Id	Reference Number	Short Description	Long Description	Frequ
1330	21 CFR 113.100(a)	Process records - forms missing information	Processing and production information forms did not include [the product] [the code number] [the date] [the retort or processing system number] [the size of container] [the approximate number of containers per coding interval] [the initial temperature] [the actual processing time] [the temperature-indicating device readings] [temperature-recording device readings] [appropriate processing data]. Specifically, ***	7
1472	21 CFR 113.83	Critical factors not stated	A critical factor that may affect the scheduled process was not specified in the scheduled process. Specifically, ***	7

Cite Id	Reference Number	Short Description	Long Description	Frequ
1602	21 CFR 110.37(a)	Suitable temp. and pressure	Failure to provide running water [at a suitable temperature] [under suitable pressure] for [processing of food] [cleaning of equipment, utensils and food-packaging materials] [employee sanitary facilities]. Specifically, ***	7
1711	21 CFR 110.80(b)(15)	Proper pH controls	Failure to adequately [monitor pH] [maintain a pH of 4.6 or below] for foods that rely principally on the control of pH to prevent the growth of undesirable microorganisms. Specifically, ***	7
2101	21 CFR 113.40(a)(13)	Measured, recorded	A critical factor specified in the scheduled process was not [measured] [recorded] on the processing record [at intervals of sufficient frequency to ensure that the factor was within the limits specified in the scheduled process]. Specifically, ***	7

Cite Id	Reference Number	Short Description	Long Description	Frequ
2396	21 CFR 110.80(b)(6)	Conveyor transportation	Failure to take effective measures to protect food transported by conveyor from contamination. Specifically, ***	7
3645	21 CFR 110.10(d)	Supervision	Responsibility for assuring compliance with current good manufacturing practices relating to personnel has not been assigned to competent supervisory personnel. Specifically, ***	7
3655	21 CFR 110.37(d)(2)	Good repair	Failure to keep toilet facilities in good repair. Specifically, ***	7
3662	21 CFR 110.37(e)(6)	Refuse receptacles	Refuse receptacles for hand washing facilities are not [constructed] [maintained] to protect against contamination of food. Specifically, ***	7
4181	21 CFR 113.89	Process deviation identification	Failure to identify, from processor check or otherwise, deviations from the scheduled process or critical factors which are out of control. Specifically, ***	7

Cite Id	Reference Number	Short Description	Long Description	Frequ
6014	21 CFR 123.6(c)(2)	Monitoring - none	Your HACCP plan does not list the [procedures for monitoring] [frequency of monitoring] at each critical control point to ensure compliance with the critical limit. Specifically,	7
12734	21 CFR 120.12(a)	Records required - not maintained	You do not maintain [complete] records documenting [the implementation of your sanitation standard operating procedure] [your written HACCP plan] [your written hazard analysis] [monitoring of critical control points and their critical limits] [corrective actions taken in response to a deviation] [the verification of your HACCP system] [the validation of your HACCP plan] [the validation of your hazard analysis]. Specifically, ***	7

Cite Id	Reference Number	Short Description	Long Description	Frequ
12749	21 CFR 120.8(b)(6)	HACCP plan - verify procedures / frequency - none listed	Your HACCP plan does not list the verification [procedures] [frequencies] that have been developed to ensure that the HACCP plan is being implemented. Specifically, ***	7
15401	21 CFR 111.12(b)	Personnel - quality control operations	You have not identified personnel to be responsible for your quality control operations. Specifically, ***	7
15404	21 CFR 111.12(c)	Personnel - education, training, experience	Personnel engaged in [manufacturing] [packaging] [labeling] [holding] dietary supplements do not have the education, training, or experience to perform the person's assigned functions. Specifically, ***	7
15652	21 CFR 111.465(b)	Retain reserve samples - 1 year, 2 years	You did not retain reserve samples for the required time. Specifically, ***	7

Cite Id	Reference Number	Short Description	Long Description	Frequ
15748	21 CFR 111.210(f)	Master manufacturing record theoretical and expected yield	Your master manufacturing record did not include a statement of [the theoretical yield for each point, step, or stage of the manufacturing process to ensure quality control] [the expected yield of the finished dietary supplement] [the maximum and minimum percentages of theoretical yield beyond which a deviation investigation of a batch is necessary and material review is conducted and disposition decision is made]. Specifically, ***	7
15853	21 CFR 111.73	Specifications met - identity, purity, strength, composition	You did not determine whether you met established product specifications for [identity] [purity] [strength] [composition of the finished batch of the dietary supplement]. Specifically, ***	7

Cite Id	Reference Number	Short Description	Long Description	Frequ
15872	21 CFR 111.75(c)(3)	Specifications met identity,purity, strength, comp,; basis	You did not provide adequate documentation of your basis for determining that compliance with the specification[s] you selected for identity, purity, strength, and composition will ensure that the finished batch of dietary supplement meets the specification[s]. Specifically, ***	7
15933	21 CFR 111.105(b)	Quality control - supplier qualification	Your quality control personnel did not review and approve the documentation setting forth the basis for qualification of suppliers. Specifically, ***	7
16040	21 CFR 111.610(a)	Records - available; FDA	You did not have required records, or copies of such records, readily available during the retention period for inspection and copying by FDA when requested. Specifically, ***	7

Cite Id	Reference Number	Short Description	Long Description	Frequ
16494	FDCA 601(c)	Insanitary conditions; contaminated with filth	Your cosmetic was prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth. Specifically, ***	7
18144	21 CFR 117.35(b)(2)	Toxic Chemicals - identified, held, stored	You did not [identify] [hold] [store] a toxic chemical in a manner that protects against contamination. Specifically, ***	7
18151	21 CFR 117.40(f)	Instruments and Controls	Your instruments and controls were not [accurate] [precise] [adequately maintained] [adequate in number]. Specifically, ***	7
18163	21 CFR 117.80(c)(8)	Process Control - Foreign Objects	You did not take an adequate measure to protect against inclusion of metal or extraneous material in food. Specifically, ***	7
18283	21 CFR 1.505(b)	Supplier approval - document	You did not document your approval of your foreign supplier. Specifically, ***	7

Cite Id	Reference Number	Short Description	Long Description	Frequ
19066	21 CFR 117.165(b)	Sanitation Controls Verif Procedures: Establish Implement	You did not [establish] [implement] adequate written sanitation controls verification procedures for [product testing] [environmental monitoring]. Specifically, ***	7
1642	21 CFR 113.100(b)	Review not signed/dated	A [processing] [production] record was not [signed or initialed] [dated] by the reviewer. Specifically, ***	6
3082	21 CFR 114.89	Process deviation	Failure to fully reprocess, thermally process as a low-acid food under 21 CFR 113, or set aside for further evaluation as to any potential public health significance, a portion of food which [deviated from a scheduled process] [had an equilibrium pH of the finished product higher than 4.6]. Specifically, ***	6
3644	21 CFR 110.10(b)(5)	Impermeable (S)	Gloves used for food handling are not impermeable. Specifically, ***	6

Cite Id	Reference Number	Short Description	Long Description	Frequ
3874	21 CFR 113.60(b)	Cooling water - not chlorinated, sanitized	Container cooling water was not chlorinated or otherwise sanitized [for cooling canals] [for recirculated water supplies]. Specifically, ***	6
4514	21 CFR 108.35(c)(1)	Registration	Failure to register with the FDA information including the name, principal place of business and the location of the processing establishment within 10 days after engaging in the manufacture, processing and packaging of low-acid canned foods. Specifically, ***	6
4523	21 CFR 108.35(f)	Recall procedures	Failure to prepare and maintain in files current procedures for [recalling products which may be injurious to health] [identifying, collecting, warehousing and controlling products] [determining effectiveness of recalls] [notifying FDA] [implementing recall programs]. Specifically, ***	6

Cite Id	Reference Number	Short Description	Long Description	Frequ
4524	21 CFR 108.35(g)	Approved school	Failure to have personnel involved in [retorts] [thermal processing systems] [aseptic processing and packaging systems] [thermal processing systems] [container closure inspections] under the operating supervision of a person who has attended and satisfactorily completed a school approved by the Commissioner. Specifically, ***	6
9932	21 CFR 120.6(a)	Sanitation SSOP - none or not implemented	You do not [always] have or have not implemented a sanitation standard operating procedure that addresses sanitation conditions and practices before, during and after processing. Specifically, ***	6

Cite Id	Reference Number	Short Description	Long Description	Frequ
9935	21 CFR 120.7(a)	No hazard analysis	You did not develop, or have developed for you, a written hazard analysis to determine whether there are food hazards that are reasonably likely to occur for [each type of] juice you produce. Specifically, *** . Specifically, ***	6
9947	21 CFR 120.11(b)	HACCP plan - not validated	You did not validate that your HACCP plan is adequate to control food hazards [at least once within 12 months after implementation] [at least annually] [when a change in the process occurred that could have affected the hazard analysis or altered the HACCP plan in any way]. Specifically, ***	6

Cite Id	Reference Number	Short Description	Long Description	Frequ
9961	21 CFR 120.24(a)	Process controls - HACCP plan - 5 log reduction	Your HACCP plan does not include control measures that will consistently produce a 5 log reduction in the most resistant microorganism of public health significance that is likely to occur in the juice, for a period at least as long as the shelf life of the product. Specifically, ***	6
9986	21 CFR 120.24(c)	Process controls - not exempt, single facility	You do not conduct the 5-log reduction process and perform final packaging of your juice within a single production facility operating under current good manufacturing practices. Specifically, ***	6
15480	21 CFR 111.20(h)	Physical plant - screening against pests	Your physical plant did not use adequate screening or other protection against pests. Specifically, ***	6

Cite Id	Reference Number	Short Description	Long Description	Frequ
15498	21 CFR 111.27(d)	Equipment - maintain, clean, sanitize	You did not [maintain] [clean] [sanitize] equipment and utensils used to manufacture, package, label, or hold components or dietary supplements. Specifically, ***	6
15526	21 CFR 111.30(c)	Equipment - automated - calibrate, inspect	You did not routinely [calibrate] [inspect] [check] the automated, mechanical, or electronic equipment to ensure proper performance. Specifically, ***	6
15732	21 CFR 111.365(a)	Conditions, controls -protect; microorganisms, contamination	You did not perform manufacturing operations under conditions and controls that protect against [the potential for growth of microorganisms] [the potential for contamination]. Specifically, ***	6
15736	21 CFR 111.353	Manufacturing operations - written procedures	You did not [establish] [follow] written procedures for manufacturing operations. Specifically, ***	6

Cite Id	Reference Number	Short Description	Long Description	Frequ
15841	21 CFR 111.70(f)	Specifications - product received for packaging, labeling	You did not establish specifications to [sufficiently] assure that the product you received for packaging or labeling as a dietary supplement is adequately identified and is consistent with your purchase order. Specifically,	6
15893	21 CFR 111.80(c)	Specifications - representative samples; finished batch	You did not collect representative samples [of a subset] of finished batches of dietary supplements that you manufacture [before releasing for distribution] to verify that the finished batch of dietary supplement meets established product specifications. Specifically, ***	6
15920	21 CFR 111.95(b)(1)	Records - established specifications	You did not make and keep records of established specifications. Specifically, ***	6
15978	21 CFR 111.123(a)(2)	Quality control operations - batch production records	Your quality control operations did not include reviewing and approving all batch production-related records. Specifically, ***	6

Cite Id	Reference Number	Short Description	Long Description	Frequ
16058	21 CFR 111.535(b)(2)	Records - ret'nd dietary supplement: material review, dispos	You did not make and keep records of a material review and disposition decision on a returned dietary supplement. Specifically, ***	6
18398	21 CFR 117.4	Training of employees and records	You did not [train employees in the principles of food hygiene and food safety] [have records documenting training of qualified individuals]. Specifically, ***	6
929	21 CFR 123.8(b)	Verification - corrective action	You did not take immediate corrective action to ensure that [no affected product entered into commerce] [the cause of the deviation was corrected] [the HACCP plan was reassessed] when your verification procedure revealed the need to take a corrective action. Specifically, ***	5

Cite Id	Reference Number	Short Description	Long Description	Frequ
1428	21 CFR 110.20(b)(6)	Adequate ventilation	Failure to provide [adequate ventilation] [control equipment] to minimize odors and vapors in areas where they may contaminate food. Specifically, ***	5
1697	21 CFR 110.80(b)(4)	Preventive control measures	Failure to use adequate [sterilization] [irradiation] [pasteurization] [freezing] [refrigeration] [pH control] [water activity control] to destroy or prevent the growth of undesirable microorganisms in food. Specifically, ***	5
3660	21 CFR 110.37(e)(4)	Devices and fixtures	Devices and fixtures are not designed and constructed to protect against recontamination of clean, sanitized hands. Specifically, ***	5
4296	21 CFR 110.80(a)(5)	Temperature and humidity	Failure to hold [raw materials] [rework materials] [ingredients] at proper temperature and humidity to prevent the food from becoming adulterated. Specifically, ***	5

Cite Id	Reference Number	Short Description	Long Description	Frequ
4476	21 CFR 108.25(c)(3)(ii)	Process information availability	Failure to provide the FDA, after written request, any process and procedure information deemed necessary to determine the adequacy of the process. Specifically, ***	5
9928	21 CFR 120.12(b)	Records - general - include name, date, time	Your required records do not [always] include [the name of the processor] [the name of the importer] [the location of the processor] [the location of the importer] [the date and time of the activity] [the signature or initials of the person performing the operation or creating the record] [the identity of the product] [the production code]. Specifically, ***	5

Cite Id	Reference Number	Short Description	Long Description	Frequ
12750	21 CFR 120.8(b)(6)	HACCP plan - valid procedures / frequency - none listed	Your HACCP plan does not list the validation [procedures] [frequencies] that have been developed to ensure that the HACCP plan is adequate to control food hazards that are reasonably likely to occur. Specifically, ***	5
15391	21 CFR 111.10(b)(3)	Hand washing	Your personnel did not thoroughly [wash] [wash and sanitize] their hands in an adequate hand-washing facility [before starting work] [at any time when the hands may have become soiled or contaminated]. Specifically, ***	5
15402	21 CFR 111.12	Personnel - quality control personnel - qualified	The personnel you identified to perform quality control operations [are not qualified to do so] [do not have the education, training or experience to perform the assigned functions]. Specifically, ***	5

Cite Id	Reference Number	Short Description	Long Description	Frequ
15499	21 CFR 111.27(a)	Equipment - design - suitable	You did not use equipment or utensils of appropriate design, construction, and workmanship to enable them to be [suitable for its intended use] [adequately cleaned] [properly maintained]. Specifically, ***	5
15534	21 CFR 111.255(c)	Batch record - each step	You did not perform each step in the production of a batch, according to the master production record. Specifically, ***	5
15544	21 CFR 111.260(d)	Batch record - component; unique identifier	Your batch production records did not include the unique identifier that you assigned to [a component] [a product that you received from a supplier for packaging or labeling as a dietary supplement] [the packaging used] [the label used]. Specifically, ***	5

Cite Id	Reference Number	Short Description	Long Description	Frequ
15545	21 CFR 111.260(e)	Batch record - component; identity, weight	Your batch production records did not include the [identity] [weight or measure] of each component used. Specifically, ***	5
15578	21 CFR 111.155(c)	Components - quarantine	You did not quarantine components before you used them in the manufacture of a dietary supplement. Specifically, ***	5
15745	21 CFR 111.210(h)(1)	Instructions; specifications; packaged, labeled	The written instructions in your master manufacturing record did not include specifications for each point, step, or stage in the manufacturing process where control is necessary to ensure that the dietary supplement is packaged and labeled as specified in the master manufacturing record. Specifically, ***	5

Cite Id	Reference Number	Short Description	Long Description	Frequ
15746	21 CFR 111.210(h)(1)	Instructions; specifications; quality	The written instructions in your master manufacturing record did not include specifications for each point, step, or stage in the manufacturing process where control is necessary to ensure the quality of the dietary supplement. Specifically, ***	5
15786	21 CFR 111.410(b)	Labels - issuance, use	You did not control the [issuance] [use] of labels, Specifically, ***	5
15817	21 CFR 111.570(b)(2)(ii)(F)	Record - product complaint; findings	The written record of a product complaint did not include the [findings of the investigation] [follow-up action taken]. Specifically, ***	5
15843	21 CFR 111.70(g)	Specifications - finished packaging, labeling	You did not establish specifications [for the packaging and labeling of the finished dietary supplement] [to ensure that you used the specified packaging] [to ensure that you applied the specified label]. Specifically, ***	5

Cite Id	Reference Number	Short Description	Long Description	Frequ
15921	21 CFR 111.95(b)(2)	Documentation - supplier qualification	You did not make and keep documentation of your qualification of a supplier. Specifically, ***	5
15954	21 CFR 111.113(a)(2)	QC master manufacturing record; material review, disposition	Your quality control personnel did not conduct a material review and make a disposition decision when a batch deviated from the master manufacturing record. Specifically, ***	5
16043	21 CFR 111.503	Written procedures - returned dietary supplement; destroyed	You did not [establish] [follow] written procedures for when a returned dietary supplement must be destroyed, or otherwise suitably disposed. Specifically, ***	5
16047	21 CFR 111.510	Returned dietary supplement - material review, disposition	You did not identify and quarantine returned dietary supplements until quality control personnel conducted a material review and made a disposition decision. Specifically, ***	5

Cite Id	Reference Number	Short Description	Long Description	Frequ
18154	21 CFR 117.80(a)(2)	Appropriate quality control operations	You did not have appropriate quality control operations to ensure that [food is suitable for human consumption] [food packaging materials are safe and suitable]. Specifically, ***	5
18263	21 CFR 1.504(b)(1)	Hazard analysis biological, chemical, physical	Your hazard analysis did not include a known or reasonably foreseeable [biological] [chemical] [physical] hazard that requires a control. Specifically, ***	5
19033	21 CFR 117.135(a)(1)	Preventive Controls - Identify	You did not identify a preventive control for a hazard when one was needed. Specifically, ***	5
19036	21 CFR 117.145(a)	Process Controls Monitoring Procedures: Establish Implement	You did not [establish] [implement] adequate written procedures for monitoring process controls. Specifically, ***	5

Cite Id	Reference Number	Short Description	Long Description	Frequ
19062	21 CFR 117.150(a)(1)	Sanitation Controls Corrective Action Proced: Estab Implemnt	You did not [establish] [implement] adequate written corrective action procedures for sanitation controls. Specifically, ***	5
938	21 CFR 123.9(c)	Official review	You did not make available for official review and copying at reasonable times [all records] [all plans and procedures] required by the regulations. Specifically, ***	4
1176	21 CFR 110.40(f)	Insufficient number of Q.C. instruments	An inadequate number of instruments used for [measuring] [regulating] [recording] conditions that control or prevent the growth of undesirable microorganisms. Specifically,***	4
1294	21 CFR 110.20(b)(3)	Outdoor fermentation	Proper precautions to protect food in outdoor bulk fermentation vessels cannot be taken because of deficiencies in plant [construction] [design]. Specifically, ***	4

Cite Id	Reference Number	Short Description	Long Description	Frequ
1471	21 CFR 113.83	Scheduled processes not established	Scheduled processes for low-acid foods have not been established by qualified persons having expert knowledge of thermal processing. Specifically, ***	4
1529	21 CFR 113.89	Process deviation log/file	Process deviations were not recorded in a separate file or log that details both the deviations and the actions taken. Specifically, ***	4
1640	21 CFR 113.100(b)	Record form not signed	A [processing] [production] record form was not signed or initialed by a processing system operator or other designated person. Specifically, ***	4
2387	21 CFR 110.80(a)(1)	Washing and cleaning	Failure to adequately [wash] [clean] raw materials as necessary to remove soil or other contamination. Specifically, ***	4

Cite Id	Reference Number	Short Description	Long Description	Frequ
2901	21 CFR 113.40(i)	Critical factor - scheduled process	A critical factor was not [measured] [recorded] at intervals of sufficient frequency to ensure that the critical factor was within the limits specified in the scheduled process. Specifically, ***	4
3089	21 CFR 114.100(c)	Process deviations-identification and records	Departures from a scheduled process having a possible bearing on public health or the safety of a food are not [noted] [identified] [recorded] [made the subject of a separate file (or log identifying the appropriate data) delineating them]. Specifically, ***	4
4512	21 CFR 108.25(g)	Record retention	Failure to prepare, review and retain at [the processing plant] [a reasonably accessible location] for three years all records [of processing] [of deviations in processing] [specified in 21 CFR 114]. Specifically, ***	4

Cite Id	Reference Number	Short Description	Long Description	Frequ
9919	21 CFR 120.10(a)	Corrective action - predetermined plan inadequate	You did not take corrective action that ensured [affected product was not entered into commerce] [the cause of the deviation was corrected]. Specifically, ***	4
9981	21 CFR 120.12(b)(4)	Records - actual values	Your records do not [always] contain the actual values and observations obtained during monitoring. Specifically, ***	4
12720	21 CFR 1.225	Not registered	Your food facility is not registered as required. Specifically, ***	4
12744	21 CFR 120.8(b)(4)	HACCP plan - monitoring procedures - none listed	Your HACCP plan does not list the [procedures for monitoring] [frequency of monitoring] at each critical control point to ensure compliance with the critical limits. Specifically, ***	4
15302	21 CFR 120.11(a)(2)	Calibration, testing - no records	You do not maintain records of [calibration of process-monitoring instruments] [periodic end-product or in-process testing]. Specifically, ***	4

Cite Id	Reference Number	Short Description	Long Description	Frequ
15381	21 CFR 111.8	Written procedures - hygienic practices	You did not [establish] [follow] written procedures for hygienic practices. Specifically, ***	4
15403	21 CFR 111.12(b)	Personnel - quality control operations; responsibilities	The personnel you identified to perform quality control operations do not have distinct and separate responsibilities related to performing such operations from those responsibilities that the personnel otherwise have when not performing such operations. Specifically, ***	4
15442	21 CFR 111.15(b)(1)	Physical plant - clean and sanitary	You did not maintain your physical plant in a clean and sanitary condition. Specifically, ***	4
15458	21 CFR 111.20(d)(1)(i)	Floors, walls, ceilings	Your [floors] [walls] [ceilings] were not designed and constructed so they can be adequately cleaned and kept clean and in good repair. Specifically, ***	4

Cite Id	Reference Number	Short Description	Long Description	Frequ
15491	21 CFR 111.25	Equipment - procedures	You did not [establish] [follow] written procedures for fulfilling the requirements for equipment and utensils. Specifically, ***	4
15533	21 CFR 111.255(c)	Batch record - follow master	Your batch production record did not accurately follow the appropriate master manufacturing record. Specifically, ***	4
15547	21 CFR 111.260(g)	Batch record - results; monitoring	Your batch production records did not include the actual results obtained during a monitoring operation. Specifically, ***	4
15559	21 CFR 111.260(k)(1)	Batch record - identifier; labels	Your batch production records did not include [the unique identifier assigned to labels used] [the quantity of the labels used] [reconciliation of discrepancies between issuance and use of labels]. Specifically, ***	4

Cite Id	Reference Number	Short Description	Long Description	Frequ
15566	21 CFR 111.260(l)(3)	Batch record - approved, released, rejected; batch	Your batch production records did not include documentation that quality control personnel approved and released, or rejected, a batch for distribution. Specifically, ***	4
15573	21 CFR 111.153	Written procedures - product received; packaging, labeling	You did not [establish] [follow] written procedures for the requirements for product received for packaging or labeling as a dietary supplement. Specifically, ***	4
15605	21 CFR 111.165(c)	Product received - quarantine	You did not quarantine received product. Specifically, ***	4

Cite Id	Reference Number	Short Description	Long Description	Frequ
15610	21 CFR 111.165(d)(1)	Product received - identify	You did not identify each unique lot within each unique shipment of received product in a manner that allows you to trace the lot to [the supplier] [the date received] [the name of the received product] [the status of the received product] [the product that you packaged or labeled and distributed as a dietary supplement]. Specifically, ***	4
15623	21 CFR 111.180(b)(2)	Records - receiving; components, packaging, labels, products	You did not make and keep receiving records for [components] [packaging] [labels] [products you received for packaging or labeling as a dietary supplement]. Specifically, ***	4
15662	21 CFR 111.303	Written procedures - laboratory operations	You did not [establish] [follow] written procedures for laboratory operations. Specifically, ***	4

Cite Id	Reference Number	Short Description	Long Description	Frequ
15734	21 CFR 111.360	Manufacturing operations - sanitation	You did not conduct manufacturing operations in accordance with adequate sanitation principles. Specifically, ***	4
15755	21 CFR 111.205(c)	Master manufacturing record: readily available	You did not have records or copies of records required for your master manufacturing records readily available during the required retention period for inspection and copying by FDA when requested. Specifically, ***	4
15760	21 CFR 111.205(b)(1)	Master manufacturing record-specifications; packaged, label	Your master manufacturing record did not identify specifications for the points, steps, or stages in the manufacturing process where control is necessary to ensure that the dietary supplement is packaged and labeled as specified in the master manufacturing record. Specifically, ***	4

Cite Id	Reference Number	Short Description	Long Description	Frequ
15783	21 CFR 111.410(d)	Manufacturing history	You were not able to determine the complete manufacturing history and control of a packaged and labeled dietary supplement through distribution. Specifically, ***	4
15791	21 CFR 111.403	Written procedures -packaging operations	You did not [establish] [follow] written procedures for packaging operations. Specifically, ***	4
15800	21 CFR 111.560(a)(2)	Product complaint - quality control investigate	A qualified person did not investigate a product complaint that involved a possible failure of a dietary supplement to meet a specification, or other requirement. Specifically, ***	4
15860	21 CFR 111.75(a)(2)	Component - confirm identity; specifications met	You did not confirm the identity of components. Specifically, ***	4
15939	21 CFR 111.105(g)	Quality control - reserve samples	Your quality control personnel did not ensure that required reserve samples were collected and held. Specifically, ***	4

Cite Id	Reference Number	Short Description	Long Description	Frequ
15975	21 CFR 111.120(e)	Quality control operations - quarantine	Your quality control operations did not include approving, and releasing from quarantine, all [components] [packaging] [labels] before they were used. Specifically, ***	4
16070	21 CFR 111.35(b)(2)	Document-equipment date of use, maintain, clean, sanitize	You did not make and keep documentation of [the date of the use] [maintenance] [cleaning] [sanitizing] of the equipment. Specifically, ***	4
16139	21 CFR 118.4(c)(1)	Satisfactory rodent control methods	When your monitoring indicated unacceptable rodent activity within a poultry house, appropriate methods were not used to achieve satisfactory rodent control. Specifically,***	4
16152	21 CFR 118.5(a)	Testing when laying hens 40 to 45 weeks	Environmental testing for SE, using approved methods, was not done in a poultry house when any group of laying hens constituting the flock was 40 to 45 weeks of age. Specifically,***	4

Cite Id	Reference Number	Short Description	Long Description	Frequ
18160	21 CFR 117.80(b)(8)	Raw Materials - Allergen Identification	You did not [identify] [hold] raw materials and other ingredients that are food allergens, and rework that contains food allergens, in a manner that protects against allergen cross-contact. Specifically, ***	4
18272	21 CFR 1.504(d)	Document review entity's hazard analysis	You did not document [your review and assessment of a hazard analysis conducted by another entity] [that a hazard analysis conducted by another entity was conducted by a qualified individual]. Specifically, ***	4
18281	21 CFR 1.505(a)(2)	Evaluation - performance, risk	You did not document the evaluation you conducted to determine [a foreign supplier's performance] [the risk posed by a food]. Specifically, ***	4

Cite Id	Reference Number	Short Description	Long Description	Frequ
972	21 CFR 123.8(a)(1)	Modification HACCP plan	You did not immediately modify your HACCP plan after a reassessment revealed the plan to no longer be adequate. Specifically, ***	3
975	21 CFR 123.9(b)(1)	Record retention	Your [monitoring] [corrective action] [verification] records are not maintained at your facility for at least the required time period. Specifically, ***	3
1600	21 CFR 110.37(a)	General inadequacy	Failure to use a water supply that is [sufficient for the operations] [derived from an adequate source]. Specifically, ***	3
1643	21 CFR 113.100(e)	Incomplete information	A record of a container closure examination did not specify [the product code] [the date of container closure inspections] [the time of container closure inspections] [the measurements obtained] [all corrective actions taken]. Specifically, ***	3

Cite Id	Reference Number	Short Description	Long Description	Frequ
1688	21 CFR 110.80	Supervisory competence	The function of supervising overall sanitation of the plant has not been designated to the supervision of one or more competent individuals assigned responsibility for this function. Specifically, ***	3
1710	21 CFR 110.80(b)(14)	Water activity controls	Failure to adequately [process to] [maintain at] a safe moisture level foods that rely on the control of water activity to prevent the growth of undesirable microorganisms. Specifically, ***	3
2391	21 CFR 110.80(a)(6)	Thawed appropriately	Failure to thaw frozen raw materials in a manner that prevents them and other ingredients from becoming adulterated. Specifically, ***	3

Cite Id	Reference Number	Short Description	Long Description	Frequ
2848	21 CFR 113.40(g)(1)(i)(B)(3)	Adjusted to agree with TID	A temperature-recording device was not adjusted with sufficient frequency to ensure agreement as nearly as possible with, but to be in no event higher than, the temperature-indicating device during processing. Specifically, ***	3
3077	21 CFR 114.80(b)	Visible code	Each container is not marked with an identifying code permanently visible to the naked eye. Specifically, ***	3
3083	21 CFR 114.89	Process deviation evaluation	Process deviations are not evaluated by a competent processing authority in accordance with procedures recognized by competent processing authorities as being adequate to detect any potential hazard to public health. Specifically, ***	3

Cite Id	Reference Number	Short Description	Long Description	Frequ
3648	21 CFR 110.20(a)(4)	Neighboring grounds	Failure to take adequate care to exclude contamination of food from adverse conditions on bordering grounds not under your control. Specifically, ***	3
3663	21 CFR 110.40(e)	Lack of automatic control / alarm (S)	Lack of [an automatic control for regulating temperature] [an automatic temperature alarm system] for each freezer and cold storage compartment used to store food capable of supporting the growth of microorganisms. Specifically, ***	3
3710	21 CFR 110.80(b)(16)	Ice manufacturing	Ice in contact with food has been made from water which is [unsafe] [of inadequate sanitary quality]. Specifically, ***	3

Cite Id	Reference Number	Short Description	Long Description	Frequ
3859	21 CFR 113.60(a)	Frequency: visual closure examinations, record	A qualified container closure inspection person did not record the observations made of [the top seam of a can randomly selected from each seaming head] [the container closures] at intervals of sufficient frequency to ensure proper closure. Specifically, ***	3
4295	21 CFR 110.40(a)	Food contact - non-toxic materials	Food-contact surfaces are not made of non-toxic materials. Specifically, ***	3
4421	21 CFR 110.20(a)	Maintenance of grounds	Maintenance of the grounds is inadequate to protect against contamination of food. Specifically, ***	3
4528	21 CFR 108.35(c)(2)(ii)	Process change recording	For an intentional change in a previously filed scheduled process, substantiation was not [promptly recorded] [verified in writing by the authority] [placed in your files for review by FDA]. Specifically, ***	3

Cite Id	Reference Number	Short Description	Long Description	Frequ
6009	21 CFR 123.8(a)(3)(iii)	Verification - record review - calibration	You did not review [some of] your calibration records within a reasonable time after the records were made. Specifically, ***	3
9926	21 CFR 120.14(a)	Importer - written procedures	You do not have written procedures that describe [product specifications] [affirmative steps] to ensure that juice you receive for import into the United States was processed in accordance with the juice HACCP regulation. Specifically, ***	3
12751	21 CFR 120.8(b)(7)	HACCP plan - recordkeeping system	Your HACCP plan does not provide for a recordkeeping system that documents the monitoring of critical control points. Specifically, ***	3
15396	21 CFR 111.10(b)(6)	Hair restraints	Your personnel did not wear [effective] hair restraints [in an effective manner]. Specifically, ***	3

Cite Id	Reference Number	Short Description	Long Description	Frequ
15445	21 CFR 111.15(c)(1)	Sanitizing agents	You did not use sanitizing agents that [are free from microorganisms of public health significance] [are safe and adequate under the conditions of use]. Specifically, ***	3
15511	21 CFR 111.27(d)	Equipment - maintain - general	You did not [maintain] [clean] [sanitize] equipment, utensils, and contact surfaces used to manufacture, package, label, or hold components or dietary supplements. Specifically, ***	3
15538	21 CFR 111.255(d)	Batch record - readily available	You did not have batch production records or copies of batch production records readily available during the required retention period for inspection and copying by FDA when requested. Specifically, ***	3

Cite Id	Reference Number	Short Description	Long Description	Frequ
15551	21 CFR 111.260(j)(1)	Batch record - date, each step	Your batch production records did not include the date on which each step of the master manufacturing record was performed. Specifically, ***	3
15554	21 CFR 111.260(j) (2)(ii)	Batch record - initials; verifying weight	Your batch production records did not include the initials of the person responsible for verifying the weight or measure of each component used in the batch. Specifically, ***	3
15558	21 CFR 111.260(k)(1)	Batch record - identifier; packaging	Your batch production records did not include [the unique identifier assigned to packaging used] [the quantity of the packaging used]. Specifically, ***	3
15563	21 CFR 111.260(l)(1)(i)	Batch record - quality control review; monitoring	Your batch production records did not include documentation that quality control personnel reviewed required monitoring operations. Specifically, ***	3

Cite Id	Reference Number	Short Description	Long Description	Frequ
15583	21 CFR 111.155(d)(1)	Components - identify lot received	You did not identify each unique lot within each unique shipment of components that you received in a manner that allows you to trace the lot to [the supplier] [the date received] [the name of the component] [the status of the component] [the dietary supplement that you manufactured and distributed]. Specifically, ***	3
15584	21 CFR 111.155(d)(1)	Components - identify lot produced	You did not identify each lot of components that you produced in a manner that allows you to trace the lot to [the supplier] [the date received] [the name of the component] [the status of the component] [the dietary supplement that you manufactured and distributed]. Specifically, ***	3

Cite Id	Reference Number	Short Description	Long Description	Frequ
15600	21 CFR 111.160(d)(2)	Packaging, labels - unique identifier, disposition	You did not use a unique identifier whenever you recorded the disposition of each unique lot within each unique shipment of [packaging] [labels]. Specifically, ***	3
15619	21 CFR 111.180(b)(1)	Written procedures - packaging, labeling received	You did not make and keep written procedures for fulfilling the requirements that apply to packaging and labeling received. Specifically, ***	3
15620	21 CFR 111.180(b)(1)	Written procedures - product received	You did not make and keep written procedures for fulfilling the requirements that apply to product received for packaging or labeling as a dietary supplement and for distribution rather than for return to the supplier. Specifically,	3
15671	21 CFR 111.315	Laboratory control processes - requirements	You did not [establish] [follow] laboratory control processes. Specifically, ***	3

Cite Id	Reference Number	Short Description	Long Description	Frequ
15723	21 CFR 111.365(i)	Metal, foreign material	You did not use effective measures to protect against the inclusion of metal or other foreign material in [components] [dietary supplements]. Specifically, ***	3
15728	21 CFR 111.365(d)	Chemical,microbiological,other test-contaminated components	You did not perform chemical, microbiological, or other testing, as necessary to prevent the use of contaminated components. Specifically, ***	3
15739	21 CFR 111.210(h)(3)(ii)(B)	Components; add, verify	The specific actions in your written instructions in your master manufacturing record for a manual operation did not include one person to add and another person to verify the addition of the components. Specifically, ***	3

Cite Id	Reference Number	Short Description	Long Description	Frequ
15743	21 CFR 111.210(h)(3)	Master manufacturing record - specific actions; quality	The written instructions in your master manufacturing record did not include specific actions necessary to perform and verify points, steps, or stages in the manufacturing process where control is necessary to ensure the quality of the dietary supplement. Specifically, ***	3
15752	21 CFR 111.210(c)	Master manufacturing record - components; weight, measure	Your master manufacturing record did not include an accurate weight or measure of each component to be used. Specifically, ***	3
15753	21 CFR 111.210(b)	Master manufacturing record - list components	Your master manufacturing record did not include a complete list of components to be used. Specifically, ***	3

Cite Id	Reference Number	Short Description	Long Description	Frequ
15754	21 CFR 111.210(a)	Master manufacturing record - dietary ingredients	Your master manufacturing record did not include the [name] [strength] [concentration] [weight] [measure] of each dietary ingredient for each batch size. Specifically, ***	3
15759	21 CFR 111.205(b)(2)	Master manufacturing record - controls, procedures	Your master manufacturing record did not establish [controls] [procedures] to ensure that each batch met specifications. Specifically, ***	3
15796	21 CFR 111.430(b)	Records - packaging, labeling operations	You did not make and keep records of the written procedures for [packaging] [labeling] operations. Specifically, ***	3
15832	21 CFR 111.70(c)(1)	In-process identity, purity, strength, composition	You did not establish in-process specifications for a point, step, or stage in the master manufacturing record where control is necessary to help ensure that specifications are met for [identity] [purity] [strength] [composition]. Specifically, ***	3

Cite Id	Reference Number	Short Description	Long Description	Frequ
15864	21 CFR 111.75(a)(2)(ii)(C)	Documentation - qualify supplier	You did not maintain documentation of how you qualified the supplier of a component. Specifically, ***	3
15875	21 CFR 111.75(d)(1)	Documentation specifications met; exempted, periodic testing	You did not document why an exempted product specification is met without verification by periodically testing the finished batch. Specifically, ***	3
15882	21 CFR 111.75(h)(2)	Tests, examinations - scientifically valid	You did not ensure that the tests or examinations that you used to determine whether the specifications are met are appropriate, scientifically valid methods. Specifically, ***	3
15928	21 CFR 111.103	Written procedure quality control operations material review	You did not [establish] [follow] written procedures for quality control operations for conducting a material review and making a disposition decision. Specifically, ***	3

Cite Id	Reference Number	Short Description	Long Description	Frequ
15944	21 CFR 111.105(i)	QC - required operations master manufacturing/batch records	Your quality control personnel did not perform required operations for the [master manufacturing record] [batch record] [manufacturing operations]. Specifically, ***	3
15983	21 CFR 111.123(a)(7)	Quality control operations - finished batch, specifications	Your quality control operations did not include determining whether each finished batch conforms to established product specifications. Specifically, ***	3
15995	21 CFR 111.127(d)	QC operations - packaged, labeled; specifications	Your quality control operations did not include determining whether the finished [packaged] [labeled] dietary supplement conforms to established specifications. Specifically, ***	3

Cite Id	Reference Number	Short Description	Long Description	Frequ
16008	21 CFR 111.135	Quality control operations - product complaints; investigate	Your quality control operations for product complaints did not include [reviewing and approving decisions about whether to investigate a product complaint] [reviewing and approving the findings and follow-up action of any investigation performed]. Specifically, ***	3
16074	21 CFR 111.35(b)(4)	Records - equipment; calibrations, inspections, checks	You did not make and keep written records of calibrations, inspections, or checks of automated, mechanical, or electronic equipment. Specifically, ***	3
16122	21 CFR 118.4(a)(2)(i)	Pullet environment testing	Your pullet environment is not tested for SE when pullets are 14 to 16 weeks of age. Specifically,***	3
16138	21 CFR 118.4(c)(1)	Monitoring for rodents	The presence of rodents is not monitored by appropriate monitoring methods. Specifically,***	3

Cite Id	Reference Number	Short Description	Long Description	Frequ
16149	21 CFR 118.4(e)	Egg transport temperature/time	Eggs were not [held] [transported] at or below 45 deg. F beginning 36 hours after time of lay. Specifically,***	3
18295	21 CFR 1.506(d)(1)(i)	Verification activity assurance	You did not [determine] [document] which verification activity or activities were needed to provide adequate assurances that a food you obtain from a foreign supplier is produced in compliance with processes and procedures that provide the required level of public health protection. Specifically, ***	3
18559	21 CFR 1.512(b) (1)(i)(A)	Definition very small importer	You chose to comply with the requirements for a very small importer, but you did not document that you meet the definition of a very small importer [before initially] [annually each year after] importing food as a very small importer. Specifically, ***	3
18562	21 CFR 1.512(b)(2)	Develop FSVP	You did not develop an FSVP. Specifically, ***	3

Cite Id	Reference Number	Short Description	Long Description	Frequ
19042	21 CFR 117.150(d)	Process Controls Corrective Action Records	You did not have process controls corrective action records. Specifically, ***	3
19048	21 CFR 117.135(c)(2)	Allergen Controls Procedures	Your allergen controls procedures did not include appropriate controls for [protection of food from allergen cross-contact] [labeling]. Specifically, ***	3
19049	21 CFR 117.145(a)	Allergen Controls Monitoring Proced: Establish Implement	You did not [establish] [implement] adequate written procedures for monitoring allergen controls. Specifically, ***	3
1188	21 CFR 110.37(c)	Sewage disposal	Failure to dispose of sewage into an adequate sewerage system or by other adequate means. Specifically, ***	2
1245	21 CFR 113.81(a)	Raw ingredients	There was no means to assure that raw materials and ingredients susceptible to microbiological contamination were suitable for use in processing low-acid food. Specifically, ***	2

Cite Id	Reference Number	Short Description	Long Description	Frequ
1290	21 CFR 110.20(a)(4)	Waste disposal	Failure to properly maintain operating systems for waste treatment and disposal so that they do not constitute a source of contamination in areas where food is exposed. Specifically, ***	2
1487	21 CFR 113.87(b)	Visual indicators not used	Each retort [basket] [truck] [car] [crate] that contained retorted food product was not plainly and conspicuously marked with a heat-sensitive indicator or by other effective means to visually indicate the retorted units. Specifically, ***	2
1533	21 CFR 113.100(b)	Recording device records - dated; retort number	Temperature-recording device records were not identified by [date] [retort number] [data necessary to correlate the temperature-recording device with the record of lots processed]. Specifically, ***	2

Cite Id	Reference Number	Short Description	Long Description	Frequ
1641	21 CFR 113.100(b)	Review not timely	A [processing] [production] record was not reviewed [within 1 working day after the actual process] [before shipment or release for distribution] to determine completeness of the record and to ensure that the product received the scheduled process. Specifically, ***	2
2149	21 CFR 113.40(b)(1)(v)	TID not reference instrument	The reference instrument for indicating the processing temperature was not a temperature-indicating device. Specifically, ***	2
2166	21 CFR 113.40(b)(7)	Flexible containers	Dividers, racks, trays, or other means of positioning of flexible containers were not [designed] [employed] to ensure even circulation of the heating medium around all containers in the retort. Specifically, ***	2

Cite Id	Reference Number	Short Description	Long Description	Frequ
2274	21 CFR 129.80(g)(1)	Bacteriological test - bottled water	You did not take and analyze samples of bottled drinking water for bacteriological testing at least once a week [for each type of bottled drinking water produced during a day's production run]. Specifically, ***	2
2362	21 CFR 110.80	Reject and rework	Food which has become contaminated to the extent of being adulterated within the meaning of the Act is not rejected or if permissible, treated or processed to eliminate the contamination.. Specifically, ***	2
2886	21 CFR 113.40(i)	Thermal process crit factors-measurement adequate & accurate	The [time] [temperature] of processing [was] [were] not measured with an instrument having the accuracy and dependability adequate to ensure that the requirements of the scheduled process were met. Specifically, ***	2

Cite Id	Reference Number	Short Description	Long Description	Frequ
2887	21 CFR 113.40(j)	Processing: conform to other systems	A system for processing a low-acid food in hermetically sealed containers did not conform to the requirements for [manufacturing] [processing] [packing] low-acid foods. Specifically, ***	2
3068	21 CFR 114.80(a)(1)	pH control	Acidified foods are not manufactured, processed and packaged to [achieve within the time designated in the scheduled process] [maintain] a pH value of 4.6 or lower in all finished foods. Specifically, ***	2
3072	21 CFR 114.80(a)(1)	Thermal processing	Acidified foods are not thermally processed to an extent that is sufficient to destroy the vegetative cells of microorganisms of public health significance and those of nonhealth significance capable of growing in the food. Specifically, ***	2

Cite Id	Reference Number	Short Description	Long Description	Frequ
3074	21 CFR 114.80(a)(2)	Using pH meter	Failure to [use a potentiometer to measure pH] [relate in-process measurements by titration or colorimetry to the finished equilibrium pH] when the finished equilibrium pH is above 4.0. Specifically, ***	2
3651	21 CFR 110.37(b)(5)	Cross contamination	Systems that discharge waste water or sewage are cross-connected to systems that carry water for food or food manufacturing. Specifically, ***	2
3708	21 CFR 110.80(a)(1)	Water quality -- wash, rinse, convey food	Water [used] [re-used] to [wash] [rinse] [convey] food is not [safe] [of adequate sanitary quality]. Specifically, ***	2
3876	21 CFR 113.60(c)	Coding - no mark, permanently visible	Hermetically sealed containers of low-acid processed food were not marked with an identifying code [that was permanently visible to the naked eye]. Specifically, ***	2

Cite Id	Reference Number	Short Description	Long Description	Frequ
4069	21 CFR 113.40(b)(14)	Heat distribution data, other retort installation	No evidence in the form of heat distribution data or other suitable information was on file to demonstrate that heat distribution was adequate for the [retort installation] [operating procedures]. Specifically, ***	2
4179	21 CFR 113.83	Records of process establishment	Complete records [covering all aspects of the establishment of the scheduled process] [for incubation tests associated with establishing the scheduled process] were not [prepared] [permanently retained] by the person or organization making the determination. Specifically, ***	2
4419	21 CFR 110.10(c)	Level of competency (S)	Personnel responsible for identifying [sanitation failures] [food contamination] lack a background of education and experience to provide a needed level of competency. Specifically, ***	2

Cite Id	Reference Number	Short Description	Long Description	Frequ
4527	21 CFR 108.25(g)	Record retention and copying	Failure to permit [inspection] [copying] of records [of processing] [of deviations in processing] [specified in 21 CFR 114], upon written demand by FDA, to verify pH and the adequacy of processing. Specifically, ***	2
4529	21 CFR 108.35(c)(2)(ii)	Process change reporting to CFSAN	For an intentional change in a previously filed scheduled process, failure to submit to CFSAN, within 30 days after first use, [a complete description of the modifications made and utilized] [a copy of the file record showing prior substantiation by a qualified scientific authority as to the safety of the changed process]. Specifically, ***	2

Cite Id	Reference Number	Short Description	Long Description	Frequ
6012	21 CFR 123.8(a)(3)(iii)	Calibration record review adequacy	Your review of [calibration] [in-process testing] [end-product testing] records does not ensure [that the records are complete] [that the activities occurred in accordance with your written procedures] [occurred within a reasonable time after the records were made]. Specifically, ***	2

Cite Id	Reference Number	Short Description	Long Description	Frequ
6017	21 CFR 123.7(c)	Corrective action per regulation	You did not take corrective action that ensured [the affected product was segregated] [a review of the affected product was done to determine its acceptability] [affected product was not entered into commerce] [the cause of the deviation was corrected] [the HACCP plan was reassessed in a timely manner to determine if modifications were needed to reduce the risk of reoccurrence of the deviation and modified as necessary]. Specifically, ***	2

Cite Id	Reference Number	Short Description	Long Description	Frequ
9921	21 CFR 120.10(b)	Corrective action - no predetermined plan	Your HACCP plan does not include a corrective action plan. There was a deviation from a critical limit and you did not take corrective action that ensured [affected product was segregated and held] [a review of the affected product by someone who is adequately trained or experienced was done to determine its acceptability] [product that was injurious to health or otherwise adulterated was not entered into commerce] [the cause of the deviation was corrected] [the HACCP plan was verified by someone meeting the training requirements of the regulation to determine if modifications were needed to reduce the risk of recurrence of the deviation and to modify the HACCP plan as necessary]. Specifically, ***	2

Cite Id	Reference Number	Short Description	Long Description	Frequ
9936	21 CFR 120.7(a)	Hazard analysis - written - elements	Your written hazard analysis does not consist of [an identification of food hazards] [an evaluation of each food hazard identified to determine if it must be addressed in the HACCP plan] [an identification of the control measures that can be applied] [a review of your current process to determine whether modifications are necessary] [an identification of critical control points]. Specifically, ***	2
9946	21 CFR 120.11(b)	Validation - reviewer's qualifications	Your [validation of the HACCP plan] [validation of the hazard analysis] was not done by an individual who had successfully completed training in the application of HACCP principles to juice processing or otherwise qualified through job experience to perform these function. Specifically, ***	2

Cite Id	Reference Number	Short Description	Long Description	Frequ
9962	21 CFR 120.24(b)	Process controls - direct treatment - not exempt	Your treatments intended to achieve a 5-log reduction in the most resistant microorganism of public health significance are not applied directly to the juice, and the exemption for surface treatment of fruit does not apply. Specifically, ***	2
15351	FDCA 761(b)(1)	No AE report made (dietary supplement)	No report was made of a serious adverse event associated with a dietary supplement marketed in the United States. Specifically, ***	2
15380	21 CFR 111.8	Written procedures - sick or infected personnel	You did not [establish] [follow] written procedures for preventing microbial contamination from sick or infected personnel. Specifically, ***	2
15382	21 CFR 111.8	Written procedures - personnel qualifications	You did not [establish] [follow] written procedures for determining personnel qualification requirements. Specifically, ***	2

Cite Id	Reference Number	Short Description	Long Description	Frequ
15398	21 CFR 111.10(b)(8)	Food, gum, beverages, tobacco	Your personnel [ate food] [chewed gum] [drank beverages] [used tobacco products] in areas where components, dietary supplements, or contact surfaces are exposed or where contact surfaces are washed. Specifically, ***	2
15400	21 CFR 111.12(a)	Personnel - qualified - general	Your personnel are not qualified to [manufacture] [package] [label] [hold] dietary supplements. Specifically, ***	2
15409	21 CFR 111.14(b)(1)	Personnel - records - written procedures	You did not make and keep written procedures for [preventing microbial contamination from sick or infected personnel] [hygienic practices] [determining personnel qualification requirements]. Specifically, ***	2
15436	21 CFR 111.15(a)	Grounds - condition	You did not keep the grounds of your physical plant in a condition that protects against contamination. Specifically, ***	2

Cite Id	Reference Number	Short Description	Long Description	Frequ
15437	21 CFR 111.15(a)(1)	Grounds - equipment, litter, weeds	You did not [properly store equipment] [remove litter and waste] [cut weeds or grass] within the immediate vicinity of the physical plant. Specifically, ***	2
15444	21 CFR 111.15(c)(1)	Cleaning compounds	You did not use cleaning compounds that [are free from microorganisms of public health significance] [are safe and adequate under the conditions of use]. Specifically, ***	2
15456	21 CFR 111.20(b)	Physical plant - space; equipment, materials	Your physical plant did not have adequate space for the orderly placement of equipment and holding of materials as necessary [for maintenance, cleaning, and sanitizing operations] [to prevent contamination and mix-ups of components and dietary supplements]. Specifically, ***	2

Cite Id	Reference Number	Short Description	Long Description	Frequ
15459	21 CFR 111.20(d)	Physical plant - design and construction	Your physical plant was not [designed] [constructed] in a manner that prevents contamination of components, dietary supplements, or contact surfaces. Specifically, ***	2
15462	21 CFR 111.20(d) (1)(iv)	Physical plant - temperature, humidity controls	Your physical plant did not have equipment that controls temperature and humidity when it is necessary to ensure the quality of the dietary supplement. Specifically, ***	2
15493	21 CFR 111.25(b)	Procedures - calibrating automated, mechanical equip	You did not [establish] [follow] written procedures for calibrating, inspecting, and checking automated, mechanical, and electronic equipment. Specifically, ***	2

Cite Id	Reference Number	Short Description	Long Description	Frequ
15507	21 CFR 111.27(a)(5)(i)	Refrigerator, freezer - temperature recording device	Your freezer, refrigerator, or other cold storage compartment that you use to hold components or dietary supplements does not have an indicating thermometer, temperature-measuring device, or temperature-recording device that indicates and records, or allows for recording by hand, the accurate temperature within the compartment. Specifically, ***	2
15518	21 CFR 111.27(d)(4)	Contact surfaces - not in direct contact - cleaning	You did not clean surfaces that do not come into direct contact with components or dietary supplements as frequently as necessary to protect against contaminating components or dietary supplements. Specifically, ***	2

Cite Id	Reference Number	Short Description	Long Description	Frequ
15521	21 CFR 111.27(d)(6)	Cleaning compounds - adequate, safe	Cleaning compounds or sanitizing agents were not [adequate for their intended use] [safe under their conditions of use]. Specifically, ***	2
15542	21 CFR 111.260(b)	Batch record - date, time; maintenance	Your batch production records did not include the identity of equipment and processing lines used in producing the batch. Specifically, ***	2
15552	21 CFR 111.260(j)(2)	Batch record - initials; each step	Your batch production records did not include initials of the persons performing each step. Specifically, ***	2
15560	21 CFR 111.260(k)(2)	Batch record - label	Your batch production records did not include an actual or representative label, or a cross-reference to the physical location of the actual or representative label specified in the master manufacturing record. Specifically, ***	2

Cite Id	Reference Number	Short Description	Long Description	Frequ
15572	21 CFR 111.153	Written procedures - labels	You did not [establish] [follow] written procedures for the requirements for labels received. Specifically, ***	2
15597	21 CFR 111.160(c)(3)	Labels - quality control; approve, release	Your quality control personnel did not approve labels for use in the manufacture of a dietary supplement and release them from quarantine. Specifically, ***	2
15598	21 CFR 111.160(d)(1)	Packaging - identify	You did not identify each unique lot within each unique shipment of packaging in a manner that allows you to trace the lot to [the supplier] [the date received] [the name of the packaging] [the status of the packaging] [the dietary supplement that you distributed]. Specifically, ***	2

Cite Id	Reference Number	Short Description	Long Description	Frequ
15604	21 CFR 111.165(b)	Product received - visually examine invoice, guarantee, cert	You did not visually examine the supplier's invoice, guarantee, or certification in a shipment of received product to ensure that the received product was consistent with your purchase order. Specifically, ***	2
15607	21 CFR 111.165(c)(2)	Product received - quality control; documentation; specs	Your quality control personnel did not review and approve documentation to determine whether quarantined received product meets established specifications. Specifically, ***	2
15614	21 CFR 111.170	Quarantine component, package, labels, rejected product	You did not clearly identify, hold, and control under a quarantine system for appropriate disposition [a component] [packaging] [labels] [product] that you received for packaging or labeling as a dietary supplement that was rejected and unsuitable for use in manufacturing, packaging, or labeling operations. Specifically, ***	2

Cite Id	Reference Number	Short Description	Long Description	Frequ
15650	21 CFR 111.465(a)	Hold - reserve samples; contamination, deterioration	You did not hold reserve samples of dietary supplements in a manner that protects against contamination or deterioration. Specifically, ***	2
15665	21 CFR 111.303	Written procedures - tests, examinations; specifications met	You did not [establish] [follow] written procedures for the tests and examinations conducted to determine whether specifications are met. Specifically, ***	2
15681	21 CFR 111.315(d)	Standard reference materials; criteria for selecting	You did not [establish] [follow] laboratory control processes for use of criteria for selecting standard reference materials used in performing tests and examinations. Specifically, ***	2
15698	21 CFR 111.320(a)	Examination, testing; appropriate	You did not verify that the laboratory examination and testing methodologies are appropriate for their intended use. Specifically, ***	2

Cite Id	Reference Number	Short Description	Long Description	Frequ
15715	21 CFR 111.375(b)	Records - manufacturing operations; written procedures	You did not make and keep records of the written procedures for manufacturing operations. Specifically, ***	2
15733	21 CFR 111.365	Manufacturing operations - prevent contamination	You did not take necessary precautions during the manufacture of a dietary supplement to prevent contamination of [components] [dietary supplements]. Specifically, ***	2
15740	21 CFR 111.210(h)(3)(ii)(A)	Instructions; components; weight, measure	The specific actions in your written instructions in your master manufacturing record for a manual operation did not include one person weighing or measuring and another person verifying the weight or measure of components. Specifically, ***	2

Cite Id	Reference Number	Short Description	Long Description	Frequ
15741	21 CFR 111.210(h)(3)(i)	Components, verify weight, measure	The written instructions in your master manufacturing record did not include instructions to verify the weight or measure and addition of components. Specifically, ***	2
15749	21 CFR 111.210(e)	Master manufacturing record - intentional overage	Your master manufacturing record did not include a statement of intentional overage amount of a dietary ingredient. Specifically, ***	2
15765	21 CFR 111.430(a)	Packaging, labeling operations:originals, copies, electronic	You did not keep the records required for your packaging and labeling operations as original records, true copies, or as electronic records. Specifically, ***	2
15774	21 CFR 111.415(f)(1)	Batch-lot,control number packaged, labeled dietary supplemen	You did not assign a batch, lot, or control number to each lot of packaged and labeled dietary supplement from a finished batch of dietary supplement. Specifically, ***	2

Cite Id	Reference Number	Short Description	Long Description	Frequ
15799	21 CFR 111.560(a)(1)	Product complaint - quality control review	A qualified person did not review a product complaint to determine whether the product complaint involves a possible failure of a dietary supplement to meet specifications or any other requirements. Specifically, ***	2
15801	21 CFR 111.560(b)	Quality control, review, approve; investigate, follow-up	Your quality control personnel did not [review and approve decisions about whether to investigate a product complaint] [review and approve the findings and follow-up action of an investigation]. Specifically, ***	2
15810	21 CFR 111.570(b)(2)	Record - product complaint; good manufacturing practice	You did not make and keep a written record of every product complaint that was related to good manufacturing practice. Specifically, ***	2

Cite Id	Reference Number	Short Description	Long Description	Frequ
15821	21 CFR 111.60(a)	Production, in- process control system - design, quality	Your production and in-process control system is not designed to ensure that the dietary supplement is manufactured, packaged, labeled, and held in a manner that will ensure the quality of the dietary supplement. Specifically, ***	2
15834	21 CFR 111.70(c)(2)	Specifications identity, purity strength, composition	You did not provide adequate documentation of your basis for why meeting the in-process specifications, in combination with meeting component specifications, will help ensure that the specifications are met for [the identity] [purity] [strength] [composition]. Specifically, ***	2

Cite Id	Reference Number	Short Description	Long Description	Frequ
15842	21 CFR 111.70(f)	Specifications - product received for packaging, labeling	You did not establish specifications to [sufficiently] assure that the product you received for packaging or labeling as a dietary supplement is adequately identified and is consistent with your purchase order. Specifically, ***	2
15845	21 CFR 111.73	Specifications met - quality	You did not determine whether you met specifications established to ensure the quality of the dietary supplement. Specifically, ***	2
15867	21 CFR 111.75(b)(1)	Specifications met, in-process - quality finished batch	You did not monitor the in-process points, steps, or stages, where control is necessary to ensure that the quality of the finished batch of dietary supplement, to determine whether the in-process specifications are met. Specifically, ***	2

Cite Id	Reference Number	Short Description	Long Description	Frequ
15868	21 CFR 111.75(b)(2)	Specifications met - deviation, unanticipated occurrence	You did not monitor the in-process points, steps, or stages to detect any deviation or unanticipated occurrence that may result in a failure to meet specifications. Specifically, ***	2
15870	21 CFR 111.75(c)(1)	Specifications met - verify; production, process control	You did not select one or more established specifications for [identity] [purity] [strength] [composition] [limits on contamination that may adulterate or that may lead to adulteration of the dietary supplement] that, if tested or examined on the finished batches of the dietary supplement, would verify that the production and process control system is producing a dietary supplement that meets all product specifications. Specifically, ***	2

Cite Id	Reference Number	Short Description	Long Description	Frequ
15878	21 CFR 111.75(e)	Product - visually examine, identified	You did not [visually examine a product that you received for packaging or labeling] [have documentation that the product you received for packaging or labeling is adequately identified and is consistent with your purchase order]. Specifically, ***	2
15883	21 CFR 111.75(i)	Corrective action plan	You did not establish a corrective action plan to use when an established specification is not met. Specifically, ***	2
15898	21 CFR 111.83(b)(1)	Reserve sample -container-closure system	Your reserve sample of a dietary supplement was not held using the same container-closure system in which the packaged and labeled dietary supplement was distributed. Specifically, ***	2
15903	21 CFR 111.87	Material review, disposition - quality control	Your quality control personnel did not [conduct required material reviews] [make required disposition decisions]. Specifically,	2

Cite Id	Reference Number	Short Description	Long Description	Frequ
15935	21 CFR 111.105(d)	Quality control - basis; tests, examinations	Your quality control personnel did not review and approve the documentation setting forth the basis for why the results of appropriate tests or examinations for each product specification will ensure that the finished batch of the dietary supplement meets product specifications. Specifically, ***	2
15952	21 CFR 111.113	Quality control operations - material review, disposition	You do not have quality control operations for a material review and disposition decision. Specifically, ***	2
15953	21 CFR 111.113(a)(1)	QC production, process control; material review, disposition	Your quality control personnel did not conduct a material review and make a disposition decision for a specification established for the production and process control system that was not met. Specifically, ***	2

Cite Id	Reference Number	Short Description	Long Description	Frequ
15955	21 CFR 111.113(a)(3)	Quality control - adulteration; material review, disposition	Your quality control personnel did not conduct a material review and make a disposition decision for an unanticipated occurrence during the manufacturing operations that adulterated or may lead to adulteration of the [component] [dietary supplement] [packaging]. Specifically, ***	2
15964	21 CFR 111.113(c)	Document - material review, disposition	The person who conducted a material review and made the disposition decision did not document the material review and the disposition decision [at the time of performance]. Specifically, ***	2
15976	21 CFR 111.123	Quality control operations - master, batch, manufacturing	You do not have quality control operations required for the [master manufacturing record] [batch production record] [manufacturing operations]. Specifically, ***	2

Cite Id	Reference Number	Short Description	Long Description	Frequ
16017	21 CFR 111.140(b)(3)	Records - material review, disposition	You did not make and keep documentation of your material review and disposition decision. Specifically, ***	2
16037	21 CFR 111.605	Records - keep: 1 year, 2 years	You did not keep required written records for 1 year past the shelf life date or for 2 years beyond the date of distribution of the last batch of dietary supplements associated with the records. Specifically, ***	2
16065	21 CFR 111.35(b)(1)	Written procedures - equipment, utensils; make, keep	You did not make and keep written procedures for fulfilling the requirements for equipment and utensils. Specifically, ***	2
16068	21 CFR 111.35(b)(1)(iii)	Equipment, utensils; maintaining, cleaning, sanitizing	You did not make and keep written procedures for [maintaining] [cleaning] [sanitizing] equipment and utensils that are used to manufacture, package, label, or hold components or dietary supplements. Specifically, ***	2

Cite Id	Reference Number	Short Description	Long Description	Frequ
16071	21 CFR 111.35(b)(3)	Documentation - instruments, controls; calibrations	You did not make and keep documentation of calibrations for instruments or controls that you use in manufacturing or testing a component or dietary supplement. Specifically, ***	2
16132	21 CFR 118.4(b)(1)	Limiting visitors	Visitors are not limited [on the farm] [in the poultry houses]. Specifically,***	2
16134	21 CFR 118.4(b)(3)	Cross contamination from people	You do not maintain practices that will protect against cross contamination when people move between poultry houses. Specifically,***	2
16140	21 CFR 118.4(c)(2)	Monitoring for flies	The presence of flies is not monitored by appropriate monitoring methods. Specifically,***	2

Cite Id	Reference Number	Short Description	Long Description	Frequ
16156	21 CFR 118.5(b)	Environmental testing after induced molting period	Environmental testing of SE in a poultry house was not performed at 4 to 6 weeks after the end of the molting process which followed your inducing of a molt in a flock or a group in the flock. Specifically,***	2
16190	21 CFR 118.10(a)(1)	Written SE prevention plan	You do not have a written SE prevention plan. Specifically,***	2
16192	21 CFR 118.10(a)(3)(1)	Biosecurity measures documentation	You did not maintain records documenting compliance with biosecurity measures. Specifically,***	2
16193	21 CFR 118.10(a)(3)(ii)	Rodent and pest control documentation	You did not maintain records documenting compliance with rodent and other pest control measures. Specifically,***	2
16203	21 CFR 118.10(b)(1)	Name and location	All required records do not include [your name] [the location of your farm]. Specifically,***	2

Cite Id	Reference Number	Short Description	Long Description	Frequ
16288	21 CFR 113.100(b)	Review of processing and production records	A [processing] [production] record was not reviewed by a representative of plant management [qualified by suitable training or experience] to determine [completeness of the record] [whether the product received the scheduled process]. Specifically, ***	2
16510	FDCA 402(a)(4)	On farm processing of shell eggs	You have prepared, packed or held shell eggs under insanitary conditions whereby [they may have become contaminated with filth] [they may have been rendered injurious to health]. Specifically, ***	2
18150	21 CFR 117.40(e)	Temperature Devices	Your cold storage unit used to store and hold food did not have a temperature device [installed] [installed to show temperature accurately]. Specifically, ***	2

Cite Id	Reference Number	Short Description	Long Description	Frequ
18156	21 CFR 117.80(b)(1)	Raw Material Control - Cleaning - Water Quality	You did not inspect, segregate or otherwise handle raw materials and other ingredients to ensure they were clean and suitable for processing. Specifically, ***	2
18290	21 CFR 1.506(a)(1)	Procedures - establish, approve supplier	You did not establish written procedures to ensure that you import foods only from foreign suppliers you have approved based on an evaluation of the foreign supplier's performance and the risk posed by the food. Specifically, ***	2
18397	21 CFR 117.4	Management responsibilities - qualified individuals	You did not ensure that all individuals are qualified to perform their duties. Specifically, ***	2
18399	21 CFR 117.305	Training Records - general requirements	Your training records did not meet general record requirements. Specifically, ***	2
18401	21 CFR 117.320	Record Availability	You did not [promptly] provide records for [review] [copying]. Specifically, ***	2

Cite Id	Reference Number	Short Description	Long Description	Frequ
18682	21 CFR 106.20(i)	Toilet, hand washing facilities - readily accessible	You did not provide employees with readily accessible [toilet facilities] [hand washing facilities]. Specifically, ***	2
19027	21 CFR 117.126(a)(1)	Food Safety Plan	You [did not have] [did not implement] a written food safety plan. Specifically, ***	2
19029	21 CFR 117.310	Food Safety Plan - Signing	Your food safety plan was not signed and dated [upon initial completion] [when modified]. Specifically, ***	2
19039	21 CFR 117.150(a)(1)	Process Controls Corrective Action Proced: Estab Implement	You did not [establish] [implement] adequate written corrective action procedures for process controls. Specifically, ***	2
19043	21 CFR 117.165(a)(4)	Process Controls Record Review	Your process controls records [were not reviewed by a preventive controls qualified individual or such review was not overseen by a preventive controls qualified individual] [were not reviewed within specified timeframes]. Specifically, ***	2

Cite Id	Reference Number	Short Description	Long Description	Frequ
19056	21 CFR 117.165(b)	Allergen Controls Verif Procedures: Establish Implement	You did not [establish] [implement] adequate written allergen controls verification procedures. Specifically, ***	2
19064	21 CFR 117.150(d)	Sanitation Controls Corrective Action Records	You did not have sanitation controls corrective action records. Specifically, ***	2
939	21 CFR 123.9(f)	Computerized records	Your computerized records do not provide that appropriate controls are implemented to ensure the integrity of the electronic data and signatures. Specifically, ***	1
977	21 CFR 123.9(b)(3)	Records stored at another location	You did not immediately return your records for official review upon demand. Specifically, ***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
1040	21 CFR 113.10	Operators	Operators of [processing systems] [retorts] [aseptic processing systems] [product formulating systems] are not under the operating supervision of a person that has attended and satisfactorily completed, a school approved by the Commissioner. Specifically, ***	1
1060	21 CFR 123.11(a)	SSOP(S)	You [do not have] [have not implemented] a written sanitation standard operating procedure (SSOP). Specifically, ***	1
1255	21 CFR 129.20(a)	Bottling room separation, plant operations	The bottling room was not separated from other plant operations by [tight walls] [ceilings] [self-closing doors] to protect against contamination. Specifically, ***	1
1277	21 CFR 129.20(d)	Wash, sanitize - enclosed room	You did not [wash] [sanitize] containers for bottled drinking water in an enclosed room. Specifically, ***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
1300	21 CFR 113.81(c)	Fill	The filling of containers is not controlled to ensure that the filling requirements specified in the scheduled process are met. Specifically, ***	1
1302	21 CFR 113.81(e)	pH	The equilibrium pH of the finished product is not controlled so as to meet the pH requirements in the scheduled process. Specifically, ***	1
1324	21 CFR 113.100(f)	Distribution record	Records were not maintained to identify the initial distribution of finished product. Specifically, ***	1
1329	21 CFR 113.100(a)	Process records - not done; not timely	Processing and production information was not recorded [at the time it was observed] [by the retort or processing system operator or other designated person]. Specifically, ***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
1334	21 CFR 113.100(a)(4)	Aseptic processing - records	For an aseptic processing and packaging system, records were not maintained for [product temperature in the holding tube outlet] [differential pressure] [product flow rate] [sterilization media flow rate] [sterilization media temperature] [retention time of containers] [retention time of closures] [sterilization cycle times] [sterilization cycle temperatures]. Specifically, ***	1
1417	21 CFR 129.37(c)	Single-service container, cap, seal-exam, sanitize, handle	Your single-service containers, caps, or seals were not [examined] [washed, rinsed, and sanitized when necessary] [handled in a sanitary manner] prior to use. Specifically, ***	1
1453	21 CFR 129.40(a)(1)	Suitability - equipment, utensils	Plant equipment or utensils were not suitable for their intended use. Specifically, ***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
1473	21 CFR 113.83	Scheduled process - scientific methods not used	Acceptable scientific methods for establishing heat sterilization processes were not used in establishing a scheduled process. Specifically, ***	1
1484	21 CFR 113.87(a)	Vent not posted	Retort venting procedures for each product and container size were not [posted in a conspicuous place near the processing equipment] [readily available to the retort or processing system operator] [readily available to FDA investigators]. Specifically, ***	1
1488	21 CFR 113.87(b)	Post processing - visual check of indicator not done	A visual check of the heat-sensitive indicator was not performed to ensure that containers had been retorted . Specifically, ***	1
1499	21 CFR 113.89	No corrective action taken	No corrective action was taken, e.g. fully reprocessing or setting the lot aside for evaluation, when a deviation from the scheduled process was found. Specifically, ***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
1500	21 CFR 113.89	Evaluation by process authority	Failure to have a deviation from the scheduled process evaluated for public health significance by a competent processing authority. Specifically, ***	1
1531	21 CFR 113.100(a)(6)	Water activity - critical factor	For a food preservation method for which another critical factor was used in conjunction with thermal processing, records were not maintained for [the product formulation] [the scheduled processes used] [a critical factor]. Specifically, ***	1
1563	21 CFR 110.35(d)(1)	Low-moisture food requirements	Food contact surfaces used for [manufacturing] [holding] low-moisture food were [wet] [insanitary] at time of use. Specifically, ***	1
1569	21 CFR 110.35(d)(2)	Continuous operations	Failure to clean and sanitize utensils and food-contact surfaces of equipment in continuous wet-processing operations as necessary. Specifically, ***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
1595	21 CFR 110.37(b)(1)	Sufficient quantities of water	Plumbing is not [of adequate size and design] [adequately installed and maintained] to carry sufficient quantities of water to required locations throughout the plant. Specifically, ***	1
1639	21 CFR 113.100(b)	Entry not timely	An entry on a [processing record] [production record] was not made at the time the specific retort or processing system condition or operation occurred. Specifically, ***	1
1645	21 CFR 113.100(e)	Insufficient frequency of management review	Records of container closure examinations were not reviewed by management with sufficient frequency to ensure that the containers were hermetically sealed. Specifically, ***	1
1649	21 CFR 113.40(a)(1)(iv)	MIG - range	The temperature range of a mercury-in-glass thermometer exceeded 17 ?F per inch (4 ?C per centimeter) of graduated scale. Specifically, ***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
1651	21 CFR 113.40(a)(1)	TID accuracy test frequency	A temperature-indicating device was not tested for accuracy [upon installation] [at least once a year] [as frequently as necessary to ensure accuracy during processing]. Specifically, ***	1
1665	21 CFR 110.80(a)(2)	Pasteurization or other adequate treatment	[Raw materials] [Ingredients] which contain levels of microorganisms that may produce food poisoning or other disease are not pasteurized or otherwise adequately treated. Specifically, ***	1
1669	21 CFR 110.80(a)(3)	Aflatoxin and other natural toxins	There is no assurance that [raw materials] [ingredients] which are susceptible to contamination with aflatoxin or other natural toxins comply with current FDA standards before being incorporated into food. Specifically, ***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
1708	21 CFR 110.80(b)(12)	Batters, breading, gravies, sauces, etc.	Failure to treat and maintain [batters] [breading] [sauces] [gravies] [dressings and similar preparations] in a manner that protects against [contamination] [growth of microorganisms]. Specifically, ***	1
1716	21 CFR 113.40(a)(11)	Water valves, leakage	A retort that used water for cooling was not equipped with a suitable valve to prevent leakage of water into the retort during processing. Specifically, ***	1
1732	21 CFR 113.40(a)(2)(i)	Range, chart graduations	Graduations on a temperature-recording device chart exceeded 2 ?F (1?C) within a range of 10 ?F (5 ?C) of the process temperature. Specifically, ***	1
1734	21 CFR 113.40(a)(2)(iii)	Adjusted to agree with TID	A temperature-recording device was not adjusted with sufficient frequency to ensure agreement as nearly as possible with, but not higher than, the temperature-indicating device during processing. Specifically, ***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
1752	21 CFR 113.40(a)(8)	Location - from ends	Bleeders for a horizontal still retort were not located within approximately 1 foot (30.5 centimeters) of the outermost locations of containers at each end along the top of the retort and there was no evidence in the form of heat distribution data that adequate removal of air and circulation of steam within the retort was accomplished. Specifically, ***	1
1757	21 CFR 113.40(a)(8)	Observable	A bleeder was not arranged so that the operator could observe that it was functioning properly. Specifically, ***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
1761	21 CFR 129.80(a)	Records - equipment inspection	You did not maintain records at the plant pertaining to physical inspection of equipment used for treatment of product water, including the [type and date of physical inspections of equipment] [conditions found] [performance and effectiveness of equipment]. Specifically, ***	1
1806	21 CFR 129.80(b)(1)	Mechanical washers - records	You did not keep records of [inspections and conditions found] [physical maintenance] [performance] for mechanical washers. Specifically, ***	1
1812	21 CFR 129.80(c)	Sample, test - cleaning, sanitizing solutions	You did not [sample] [test] cleaning and sanitizing solutions [as often as necessary] to assure adequate performance. Specifically, ***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
1865	21 CFR 113.40(a)(12)	Timing before vent, before temperature reached	Timing of a process began [before the retort was properly vented] [before the processing temperature was reached]. Specifically, ***	1
2142	21 CFR 113.40(b)(1)	No accurate TID	Each retort did not have at least one temperature-indicating device that accurately indicated the temperature during processing. Specifically, ***	1
2153	21 CFR 113.40(b)(2)(iii)	Adjusted to agree with TID	A temperature-recording device was not adjusted with sufficient frequency to ensure agreement as nearly as possible with, but not higher than, the temperature-indicating device during processing. Specifically, ***	1
2154	21 CFR 113.40(b)(2)(iii)	Unauthorized adjustment	A means of preventing unauthorized adjustment to the temperature-recording device was not provided. Specifically, ***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
2169	21 CFR 113.40(b)(10)	Operator check, record, frequency	The operator did not [check] [record] the water level in the retort [at intervals sufficient to ensure its adequacy]. Specifically, ***	1
2206	21 CFR 113.40(b)(15)	Measured, recorded	A critical factor specified in the scheduled process was not [measured] [recorded] on the processing record [at intervals of sufficient frequency to ensure that the factor was within the limits specified in the scheduled process]. Specifically, ***	1
2275	21 CFR 129.80(g)(2)	Chemical, physical, radiological tests - bottled water	You did not take and analyze samples of bottled drinking water for [chemical] [physical] [radiological] testing at least annually [for each type of bottled drinking water produced during a day's production run]. Specifically, ***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
2301	21 CFR 129.80(f)	Bacteriological swab, rinse count - containers, closures (S)	You did not take a bacteriological swab or rinse count at least every three months from at least four containers and closures selected just prior to filling and sealing. Specifically, ***	1
2369	21 CFR 129.80(a)	Treatment product water - equipment, substances	You treated product water [in and by equipment] [with substances] that may have adulterated the bottled product. Specifically, ***	1
2389	21 CFR 110.80(a)(5)	Identify rework	Failure to identify material scheduled for rework as such. Specifically, ***	1
2390	21 CFR 110.80(a)(6)	Kept frozen prior to use	Failure to keep frozen raw materials frozen prior to use. Specifically, ***	1
2427	21 CFR 110.80(b)(9)	Proper disposal of adulterated product	Failure to dispose of adulterated [food] [raw materials] in a manner which protects against the contamination of other food. Specifically, ***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
2428	21 CFR 110.80(b)(9)	Proper reconditioning	Failure to use a proven effective method of reconditioning adulterated food. Specifically, ***	1
2503	21 CFR 113.40(e)(2)(iii)	Unauthorized adjustment	A means of preventing unauthorized adjustment to the temperature-recording device was not provided. Specifically, ***	1
2843	21 CFR 113.40(g)(1)(i)(A)(5)	TID not reference instrument	The reference instrument for indicating the processing temperature was not a temperature-indicating device. Specifically, ***	1
2852	21 CFR 113.40(g)(1)(i)(C)	Range	Graduations on the temperature recorder-controller chart exceeded 2 degrees F within a range of 10 degrees F of the product sterilization temperature. Specifically, ***	1
2860	21 CFR 113.40(g)(1)(i)(F)	Unauthorized flow adjustments	A means of preventing unauthorized adjustments to the flow control device was not provided. Specifically, ***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
2896	21 CFR 113.40(g)(2)(ii)(B)	Packaging deviation - segregate product	Product that was packaged under conditions below those specified in the scheduled process was not segregated from product that received the scheduled process. Specifically, ***	1
2898	21 CFR 113.40(g)(2)(ii)(C)	Operating conditions observed, recorded - frequency	Observation and measurement of an operating condition was not [made] [recorded] at intervals of sufficient frequency to ensure that commercial sterility of the food product was being achieved. Specifically, ***	1
3079	21 CFR 114.80(b)	Code - packing period	The packing period is not changed often enough to enable ready identification of lots during sale and distribution Specifically, ***	1
3091	21 CFR 114.100(e)	Retention	Required records are not maintained at the processing plant or other reasonably accessible location for a period of three years from the date of manufacture. Specifically, ***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
3649	21 CFR 110.35(d)(1)	Dry and sanitary	Failure to keep food-contact surfaces used in the [manufacture] [holding] of low-moisture food in a dry, sanitary condition at the time of use. Specifically, ***	1
3773	21 CFR 113.40(a)(7)	Number and size of steam spreader perforations (S)	In a still steam retort, the total cross-sectional area of steam spreader perforations was [less than 1 1/2] [greater than 2] times the cross-sectional area of the smallest restriction in the steam inlet line. Specifically, ***	1
3864	21 CFR 113.60(a)(1)	Recording of teardown examinations	Teardown examinations for double-seam cans were not performed on enough containers from each seaming station to ensure maintenance of seam integrity. Specifically, ***	1
3865	21 CFR 113.60(a)(1)	Teardown examinations - record of corrective action	Corrective action taken for closure defects revealed during can seam teardown examinations was not recorded. Specifically, ***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
3866	21 CFR 113.60(a)(1)(i)(a)	Required can seam measurements (micrometer)	Measurements were not [taken] [recorded] for the can seam [cover hook] [body hook] [width (length, height)] [tightness] [thickness]. Specifically, ***	1
3871	21 CFR 113.60(a)(2)	Record of cold water vacuum check	The results of glass container capper cold water vacuum tests were not recorded. Specifically, ***	1
3887	21 CFR 113.89	Methods of process deviation evaluation	Failure to use procedures recognized by competent processing authorities as being adequate to detect any potential hazard to public health in the evaluation of a deviation from the scheduled process. Specifically, ***	1
3892	21 CFR 113.60(a)	Regular observations for gross closure defects	Regular observations for gross container closure defects were not made during production runs. Specifically, ***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
4067	21 CFR 113.40(a)(12)(iii)	Venting, other installations	You did not have evidence in the form of heat distribution data that adequate venting of air is accomplished for a retort installation that deviates from established air venting requirements for still retorts. Specifically, ***	1
4465	21 CFR 114.100(c)	Process deviations - action to rectify	Failure to record the action taken to rectify a departure from a scheduled process. Specifically, ***	1
4517	21 CFR 108.35(c)(2)(ii)	Process change substantiation	Failure to obtain substantiation by a qualified scientific authority as to the adequacy of any intentional change in a previously filed scheduled process, where the change is basic to the adequacy of that scheduled process. Specifically, ***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
4518	21 CFR 108.35(c)(2)(ii)	Process change - increase	Failure to file with FDA changes in previously filed scheduled processes, where processing parameters were higher or longer, when the processes became regularly scheduled. Specifically, ***	1
4521	21 CFR 108.35(d)	Notify FDA - spoilage	Failure to notify FDA about [spoilage] [process deviations] of potential public health significance when all or part of a lot was distributed. Specifically, ***	1
6011	21 CFR 123.8(a)(3)(ii)	Corrective action record review adequacy	Your review of corrective action records does not [ensure that the records are complete] [verify that the appropriate corrective actions have been taken]. Specifically, ***	1
9929	21 CFR 120.12(b)(4)	Records - information not entered when observed	Processing and other information is not [always] entered on your records at the time it is observed. Specifically, ***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
9933	21 CFR 120.6(b)	GMP correction - timely	You do not [always] correct deficiencies from good manufacturing practice in a timely manner. Specifically, ***	1
9943	21 CFR 120.8(a)	HACCP plan - location and type of juice	Your HACCP plan is not specific to [each location where juice is processed] [each type of juice processed]. Specifically, ***	1
9949	21 CFR 120.11(b)	HACCP plan not modified	You did not immediately modify your HACCP plan after a validation revealed that the plan was no longer adequate. Specifically, ***	1
9953	21 CFR 120.11(a)(1)(iv)(A)	CCP record review adequacy	Your review of critical control point monitoring records does not [ensure that the records are complete] [verify that they document values that are within critical limits]. Specifically, ***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
9963	21 CFR 120.24(c)	Process controls - exempt process, single facility	You do not process and perform final product packaging in a single facility operating under current good manufacturing practices. Specifically, ***	1
12701	21 CFR 129.35(a)(4)(iii)	Testing for disinfectants & DBPs	Your [product] [operations] source water from a non-public source has been treated with a chlorine-based disinfectant or ozone, but has not been tested for residual disinfectants and disinfection by-products that are likely to result from such treatment. Specifically, ***	1
12703	21 CFR 129.80(a)	Product water samples after processing	You did not take product water samples after processing and prior to bottling. Specifically, ***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
12754	21 CFR 120.11(a)(1)(iv)(C)	Calibration, testing - record review adequacy	Your review of [calibration of process monitoring instruments] [periodic end-product testing] [periodic in-process testing] records does not ensure that [the records are complete] [the activities occurred in accordance with your written procedures]. Specifically, ***	1
15001	21 CFR 113.60(a)(1)	Closure examinations - corrective actions taken and recorded	Corrective action was not taken for closure defects revealed by teardown examinations of double-seam cans. Specifically, ***	1
15304	21 CFR 120.12(g)	Records - computerized	Your computerized records do not provide that appropriate controls are implemented to ensure the integrity of the electronic data and signatures. Specifically, ***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
15305	21 CFR 120.14(a)(2)	Importer - implementation of affirmative steps	You have not implemented affirmative steps to ensure juice you receive for import into the United States was processed in accordance with the juice HACCP regulation. Specifically, ***	1
15358	FDCA 761(c)(1)	Timing of AE report submission (dietary supplement)	An adverse event report for a dietary supplement was not submitted to the Secretary of HHS within 15 business days of receipt of the report,. Specifically, ***	1
15388	21 CFR 111.10(b)	Personnel - hygienic practices	Your personnel did not use hygienic practices to the extent necessary to protect against contamination of components, dietary supplements, or contact surfaces. Specifically, ***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
15392	21 CFR 111.10(b)(4)	Jewelry and objects - remove	Your personnel did not remove unsecured [jewelry] [objects] that might fall into components, dietary supplements, equipment, or packaging. Specifically, ***	1
15395	21 CFR 111.10(b)(5)	Gloves	Your personnel used gloves that were not [intact] [clean] [in a sanitary condition] [made of impermeable material]. Specifically, ***	1
15397	21 CFR 111.10(b)(7)	Personal belongings	Your personnel stored clothing or other personal belongings in areas where [components, dietary supplements, or contact surfaces are exposed] [contact surfaces are washed]. Specifically, ***	1
15411	21 CFR 111.14(b)(2)	Personnel - records - training date, type, persons	Your training documentation did not include the [date of the training] [type of training] [persons trained]. Specifically, ***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
15427	21 CFR 111.15(h)	Bathrooms - adequate, accessible	You did not provide your employees with [adequate] [readily accessible] bathrooms. Specifically, ***	1
15428	21 CFR 111.15(h)	Bathrooms - clean	Your bathrooms [were not clean] [were a potential source of contamination to components, dietary supplements, or contact surfaces]. Specifically, ***	1
15429	21 CFR 111.15(k)	Sanitation supervisors - assigned	You did not assign one or more employees to supervise overall sanitation. Specifically, ***	1
15438	21 CFR 111.15(a)(2)	Roads, yards, parking lot	You did not maintain [roads] [yards] [parking lots] so that they do not constitute a source of contamination in areas where components, dietary supplements, or contact surfaces are exposed. Specifically, ***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
15449	21 CFR 111.15(f)(2)	Plumbing - sewage, liquid waste	The plumbing in your physical plant was not adequate to properly convey sewage and liquid disposable waste from your physical plant. Specifically, ***	1
15450	21 CFR 111.15(f)(3)	Plumbing - source of contamination	The plumbing in your physical plant was not adequate to avoid being a source of contamination to components, dietary supplements, water supplies, or any contact surface or creating an unsanitary condition. Specifically, ***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
15452	21 CFR 111.15(f)(5)	Plumbing - backflow, cross connection	The plumbing in your physical plant allows [backflow from] [cross connection between] piping systems that discharge waste water or sewage and piping systems that carry water used for manufacturing dietary supplements, for cleaning contact surfaces, or for use in bathrooms or hand-washing facilities. Specifically, ***	1
15461	21 CFR 111.20(d)(1)(iii)	Physical plant - ventilation, environmental control	Your physical plant did not have [adequate ventilation] [environmental control equipment] to minimize odors and vapors in areas where they may contaminate components, dietary supplements, or contact surfaces. Specifically, ***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
15466	21 CFR 111.20(c)	Physical plant - prevent mix-ups, contamination	Your physical plant did not permit the use of proper precautions to reduce the potential for mix-ups or contamination of components, dietary supplements, or contact surfaces, with microorganisms, chemicals, filth, or other extraneous material. Specifically, ***	1
15469	21 CFR 111.20(c)(3)	Physical plant - separate areas for products	You [did not have] [did not use] separate or defined areas of adequate size or other control systems to prevent contamination or mix-ups of components or dietary supplement by separating the [manufacturing] [packaging] [labeling] [holding] of different product types. Specifically, ***	1
15475	21 CFR 111.20(e)(1)	Adequate light - processing, holding	Your physical plant did not provide adequate light in areas where components or dietary supplements are [examined] [processed] [held]. Specifically, ***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
15478	21 CFR 111.20(f)	Physical plant - bulbs, fixtures, skylights	You did not use safety-type [light bulbs] [fixtures] [skylights] [glass] over exposed components or dietary supplements. Specifically, ***	1
15505	21 CFR 111.27(a)(3)(v)	Equipment - protect from contamination	Your equipment or utensils are not maintained to protect components and dietary supplements from being contaminated. Specifically, ***	1
15506	21 CFR 111.27(a)(4)	Equipment - bonded seams	You used equipment or utensils that do not have seams that are smoothly bonded or maintained to minimize accumulation of extraneous materials or contaminants. Specifically, ***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
15508	21 CFR 111.27(a)(5)(ii)	Refrigerator, freezer - alarm	Your freezer, refrigerator, or other cold storage compartments that you use to hold components or dietary supplements does not have either an automated device for regulating temperature or an automated alarm system to indicate a significant temperature change. Specifically, ***	1
15513	21 CFR 111.27(d)(2)	Contact surfaces - low moisture products	You did not ensure that contact surfaces used for manufacturing or holding low-moisture components or dietary supplements were [dry] [sanitary]. Specifically, ***	1
15522	21 CFR 111.27(d)(7)	Portable equipment - store	You did not store cleaned and sanitized portable equipment used to manufacture, package, label, or hold components or dietary supplements [in a manner] [in a location] that protects it from contamination. Specifically, ***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
15523	21 CFR 111.27(d)(7)	Utensils - store	You did not store cleaned and sanitized utensils that are used to manufacture, package, label, or hold components or dietary supplements [in a manner] [in a location] that protects them from contamination. Specifically, ***	1
15525	21 CFR 111.30(b)	Equipment - automated - suitability	You did not determine the suitability of the automated, mechanical, or electronic equipment by ensuring that the equipment is capable of operating satisfactorily within the operating limits required by the process. Specifically, ***	1
15548	21 CFR 111.260(h)	Batch record - results; testing, examination; batch	Your batch production records did not include the results of testing or examination performed during batch production, or a cross-reference to such results. Specifically, ***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
15549	21 CFR 111.260(i)	Batch record - specifications	Your batch production records did not include documentation that the finished dietary supplement meets established specifications. Specifically, ***	1
15553	21 CFR 111.260(j)(2)(i)	Batch record - initials; weighing	Your batch production records did not include the initials of the person responsible for weighing or measuring each component used in the batch. Specifically, ***	1
15555	21 CFR 111.260(j) (2)(iii)	Batch record - initials; component	Your batch production records did not include the initials of the person responsible for adding a component to the batch. Specifically, ***	1
15556	21 CFR 111.260(j) (2)(iv)	Batch record - initials; verifying component	Your batch production records did not include initials of the person responsible for verifying the addition of components to the batch. Specifically, ***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
15557	21 CFR 111.260(k)	Batch record - packaging, labeling	Your batch production records did not include documentation, at the time of performance, of [packaging] [labeling] operations. Specifically, ***	1
15567	21 CFR 111.260(l)(4)	Batch record - approved, released, rejected	Your batch production records did not include documentation that quality control personnel approved and released, or rejected, the packaged and labeled dietary supplement. Specifically, ***	1
15568	21 CFR 111.260(m)	Batch record - performance	Your batch production records did not include documentation [at the time of performance] of a required material review and disposition decision. Specifically, ***	1
15570	21 CFR 111.153	Written procedures - components	You did not [establish] [follow] written procedures for the requirements for components of dietary supplements. Specifically, ***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
15577	21 CFR 111.155(b)	Visually examine - supplier's invoice	You did not visually examine the supplier's invoice, guarantee, or certification in [a shipment] [shipments] you received to ensure the components are consistent with your purchase order. Specifically, ***	1
15579	21 CFR 111.155(c)(1)	Components - representative samples	You did not collect representative samples of components while the components were quarantined. Specifically, ***	1
15582	21 CFR 111.155(e)	Components - contamination, deterioration, mix-ups	You did not hold components under conditions that will [protect against contamination] [protect against deterioration] [avoid mix-ups]. Specifically, ***	1
15585	21 CFR 111.155(d)(2)	Components - unique identifier	You did not use a unique identifier whenever you recorded the disposition of [each unique lot within each unique shipment of components that you received] [each lot of components that you produced]. Specifically, ***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
15589	21 CFR 111.160(c)	Packaging, labels - quarantine	You did not quarantine [packaging] [labels] before you used them in the manufacture of a dietary supplement. Specifically, ***	1
15599	21 CFR 111.160(d)(1)	Labels - identify	You did not identify each unique lot within each unique shipment of labels in a manner that allows you to trace the lot to [the supplier] [the date received] [the name of the labels] [the status of the labels] [the dietary supplement that you distributed]. Specifically, ***	1
15613	21 CFR 111.165(e)	Product received - mix-ups	You did not hold received product under conditions that will avoid mix-ups. Specifically, ***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
15617	21 CFR 111.180(a)	Records - comp, package, labels, product received: Available	You did not have records or copies of records required for [components] [packaging] [labels] [product received for packaging or labeling] readily available during the required retention period for inspection and copying by FDA when requested. Specifically, ***	1
15618	21 CFR 111.180(b)(1)	Written procedures - components	You did not make and keep written procedures for fulfilling the requirements that apply to components of dietary supplements. Specifically, ***	1
15625	21 CFR 111.180(b)(3)	Documentation - components	You did not make and keep documentation that the requirements that apply to production and process control for components of dietary supplements were met. Specifically, ***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
15626	21 CFR 111.180(b)(3)	Documentation - packaging	You did not make and keep documentation that the requirements that apply to production and process control for packaging received were met. Specifically, ***	1
15633	21 CFR 111.180(b)(3)(ii)(C)	Documentation - required operation; results	Your documentation of a required operation did not include the results of [tests or examinations conducted on components, packaging, or labels] [visual examination of product that you received for packaging or labeling as a dietary supplement]. Specifically, ***	1
15646	21 CFR 111.460(a)	Hold, identify - in-process material	You did not identify and hold in-process material under conditions that protect against mix-up, contamination, or deterioration. Specifically, ***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
15649	21 CFR 111.465(a)(1)	Hold - reserve samples; ordinary storage	You did not hold reserve samples [under conditions consistent with product labels] [under ordinary storage conditions]. Specifically, ***	1
15658	21 CFR 111.475(a)	Records - holding, distribution: readily available	You did not have records or copies of records required for your holding and distributing operations readily available during the required retention period for inspection and copying by FDA when requested. Specifically, ***	1
15675	21 CFR 111.315(b)	Sampling plans; establish, follow	You did not [establish] [follow] sampling plans for obtaining representative samples. Specifically, ***	1
15680	21 CFR 111.315(d)	Standard reference materials; criteria for selecting, QC	Your laboratory control processes for use of criteria for selecting standard reference materials used in performing tests and examinations were not reviewed and approved by quality control personnel. Specifically, ***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
15689	21 CFR 111.315(b)(3)	Sampling plans; finished batches	You did not [establish] [follow] sampling plans for obtaining representative samples of finished batches of dietary supplements. Specifically, ***	1
15696	21 CFR 111.315(e)	Examination, testing; established criteria	You did not [establish] [follow] laboratory control processes for use of test methods and examinations in accordance with established criteria. Specifically, ***	1
15709	21 CFR 111.325(b)(2)	Laboratory methodology followed	You did not make and keep documentation that established laboratory methodology was followed. Specifically, ***	1
15720	21 CFR 111.370	Rejected dietary supplements - identify, hold, control	You did not clearly [identify] [hold] [control] under a quarantine system for appropriate disposition a dietary supplement that was rejected and unsuitable for use in manufacturing, packaging, or labeling operations. Specifically,	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
15742	21 CFR 111.210(h)(3)	Specific actions; packaged, labeled	The written instructions in your master manufacturing record did not include specific actions to perform and verify points, steps, or stages in the manufacturing process where control is necessary to ensure that the dietary supplement is packaged and labeled as specified in the master manufacturing record. Specifically, ***	1
15769	21 CFR 111.420(b)	Repackaged, relabeled - specifications	You did not examine a representative sample of each batch of [repackaged] [relabeled] dietary supplement to determine whether the established specifications were met. Specifically, ***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
15771	21 CFR 111.415(h)	Obsolete labels, packaging - dispose	You did not suitably dispose of labels and packaging for dietary supplements that are obsolete or incorrect to ensure that they are not used in any future packaging and label operations. Specifically, ***	1
15772	21 CFR 111.415(g)	Representative sample - packaged, labeled dietary supplement	You did not examine a representative sample of each batch of packaged and labeled dietary supplement to determine whether the dietary supplement meets established specifications. Specifically, ***	1
15776	21 CFR 111.415(d)	Packaging, labeling - physical separation	You did not establish physical or spatial separation of [packaging] [label] operations from operations on other components and dietary supplements to prevent mix-ups. Specifically, ***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
15777	21 CFR 111.415(c)	Filling, assembling, packaging, labeling - sanitary handling	You did not use sanitary handling procedures during [filling] [assembling] [packaging] [labeling] operations. Specifically, ***	1
15778	21 CFR 111.415(b)	Dietary supplement - protect, contamination	You did not protect manufactured dietary supplements from contamination during [filling] [assembling] [packaging] [labeling] operations. Specifically, ***	1
15779	21 CFR 111.415(a)	Clean, sanitize - filling, packaging equipment	You did not clean and sanitize [filling and packaging equipment] [utensils] [dietary supplement packaging], as appropriate. Specifically, ***	1
15781	21 CFR 111.415	Fill, assemble, package, label - quality	You did not [fill] [assemble] [package] [label] [perform operations related to packaging and labeling] in a way that ensured the quality of the dietary supplement. Specifically, ***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
15802	21 CFR 111.560(c)	Product complaint - review, investigation	Your review and investigation of a product complaint did not extend to all relevant batches and records. Specifically, ***	1
15803	21 CFR 111.560(c)	Product complaint -investigate, findings, follow-up	Your [review about whether to investigate a product complaint] [findings and follow-up action of an investigation performed] did not extend to all relevant batches and records. Specifically, ***	1
15808	21 CFR 111.570(a)	Records - product complaints: readily available	You did not have records or copies of records required for product complaints readily available during the required retention period for inspection and copying by FDA when requested. Specifically, ***	1
15811	21 CFR 111.570(b)(2)(i)	Record - person document; time of performance	The person who performed a requirement relating to product complaints did not document, at the time of performance, that the requirement was performed. Specifically, ***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
15813	21 CFR 111.570(b)(2)(ii)(B)	Record - product complaint; batch, lot, control number	The written record of a product complaint did not include the batch, lot, or control number of the dietary supplement. Specifically, ***	1
15814	21 CFR 111.570(b)(2)(ii)(C)	Record - product complaint; date received, complainant	The written record of a product complaint did not include [the date the complaint was received] [the name, address, or telephone number of the complainant]. Specifically, ***	1
15850	21 CFR 111.73	Specifications met in-process purity, strength, composition	You did not determine whether you met in-process specifications to ensure the [purity] [strength] [composition] of the dietary supplements. Specifically, ***	1
15854	21 CFR 111.73	Specifications met - contamination limits	You did not determine whether you met established limits on contamination that may adulterate, or that may lead to adulteration of, the finished batch of the dietary supplement. Specifically, ***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
15855	21 CFR 111.73	Specifications met - received product identified	You did not determine whether you met established specifications to provide sufficient assurance that product you receive from a supplier is adequately identified and is consistent with your purchase order. Specifically, ***	1
15865	21 CFR 111.75(a)(2)(ii)(D)	Re-confirm certificate of analysis	You did not periodically re-confirm the supplier's certificate of analysis for a component. Specifically, ***	1
15866	21 CFR 111.75(a)(2)(ii)(E)	Documentation - quality control, review, approve supplier	Your quality control personnel did not review and approve the documentation setting forth the basis for [qualification] [re-qualification] of a supplier of a component. Specifically, ***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
15874	21 CFR 111.75(c)(4)	Documentation - specifications met; basis, quality control	Your quality control personnel did not review and approve your documentation of the basis for determining compliance with [an] established specification[s] for [identity] [purity] [strength] [composition] [limits on contamination that may adulterate or that may lead to adulteration of the dietary supplement]. Specifically, ***	1
15886	21 CFR 111.77(b)	Specifications not met - identity; component, reject	Your quality control personnel did not reject a component that did not meet an identity specification. Specifically, ***	1
15887	21 CFR 111.77(c)	Specifications not met - received product identified	Your quality control personnel did not reject a product that was not [adequately identified] [consistent with your purchase order]. Specifically, ***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
15891	21 CFR 111.80(a)	Components packaging, labels received	You did not collect representative samples of each unique lot of [components] [packaging] [labels] that you received from a supplier to determine whether the [components] [packaging] [labels] meet[s] established specifications. Specifically, ***	1
15894	21 CFR 111.80(d)	Specifications - representative samples; unique lot	You did not collect representative samples of [each unique shipment] [each unique lot within each unique shipment] product that you received for packaging or labeling as a dietary supplement to determine whether the received product meets established specifications. Specifically, ***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
15895	21 CFR 111.80(e)	Specifications - representative samples; packaged, labeled	You did not collect representative samples of each lot of [packaged] [labeled] dietary supplements to determine whether the [packaging] [labeling] of the finished dietary supplements meets established specifications. Specifically, ***	1
15900	21 CFR 111.83(b)(2)	Reserve sample - batch, lot, control number	Your reserve sample of dietary supplement was not identified with the batch, lot, or control number. Specifically, ***	1
15901	21 CFR 111.83(b)(3)	Reserve sample - retained	You did not retain reserve samples for the required time. Specifically, ***	1
15902	21 CFR 111.83(b)(4)	Reserve sample - twice the quantity	Your reserve sample did not consist of at least twice the quantity necessary for all tests or examinations to determine whether or not the dietary supplement meets product specifications. Specifically, ***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
15908	21 CFR 111.90(b)(1)	Reprocessed, dietary supplement - no material review	You reprocessed a dietary supplement for which quality control personnel did not [conduct a material review] [make a disposition decision to approve the reprocessing]. Specifically, ***	1
15922	21 CFR 111.95(b)(3)	Documentation - ensure specifications met	You did not make and keep documentation for why meeting in-process specifications, in combination with meeting component specifications, helps ensure that the dietary supplement meets the specifications for [identity] [purity] [strength] [composition] [limits on contamination that may adulterate or may lead to adulteration of the finished batch of the dietary supplement]. Specifically, ***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
15923	21 CFR 111.95(b)(4)	Documentation - specifications met; test, examinations	You did not make and keep documentation for why the results of tests or examinations you selected for the product specifications ensure that the dietary supplement meets all product specifications. Specifically, ***	1
15934	21 CFR 111.105(c)	Basis; in-process, component, specifications	Your quality control personnel did not review and approve the documentation setting forth the basis for why meeting in-process specifications, in combination with meeting component specifications, will help ensure that the identity, purity, strength, and composition of the dietary supplement are met. Specifically, ***	1
15940	21 CFR 111.105(h)	Quality control - production, process control	Your quality control personnel did not determine that specifications established for the production and process control system were met. Specifically, ***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
15941	21 CFR 111.105(i)	QC required operations production and process control	Your quality control personnel did not perform required operations for the production and process control system. Specifically, ***	1
15945	21 CFR 111.105(i)	QC - required operations packaging/labeling operations	Your quality control personnel did not perform required operations for [packaging] [labeling] operations. Specifically, ***	1
15947	21 CFR 111.105(i)	Quality control - required operations product complaints	Your quality control personnel did not perform required operations for product complaints. Specifically, ***	1
15951	21 CFR 111.110(c)	Quality control operations - tests, examinations; results	Your quality control operations did not include reviewing and approving the results of required [tests] [examinations]. Specifically, ***	1
15958	21 CFR 111.113(a)(5)	QC returned dietary supplement; material review, disposition	Your quality control personnel did not conduct a material review and make a disposition decision when a dietary supplement was returned. Specifically, ***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
15972	21 CFR 111.120(b)	QC operations -specifications; components, packaging, labels	Your quality control operations did not include determining whether [components] [packaging] [labels] conform to established specifications. Specifically, ***	1
15973	21 CFR 111.120(c)	QC operations - material review, disposition decision	Your quality control operations did not include conducting a required material review and making a required disposition decision for [components] [packaging] [labels] prior to [their] use. Specifically, ***	1
15977	21 CFR 111.123(a)(1)	QC operations - master manufacturing record, modifications	Your quality control operations did not include reviewing and approving [master manufacturing records] [modifications to the master manufacturing records]. Specifically, ***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
15980	21 CFR 111.123(a)(4)	QC operations - material review, disposition decision	Your quality control operations for [the master manufacturing record] [the batch production record] [manufacturing operations] did not include conducting a required material review and making a required disposition decision. Specifically, ***	1
15982	21 CFR 111.123(a)(6)	Quality control operations - in-process specifications	Your quality control operations did not include determining whether established in-process specifications were met. Specifically, ***	1
15984	21 CFR 111.123(a)(8)	Quality control - finished batch, distribution	Your quality control operations did not include approving and releasing, or rejecting, each finished batch for distribution. Specifically, ***	1
15985	21 CFR 111.123(b)(1)	Quality control - components, identity specifications	Your quality control personnel approved and released for distribution a batch of dietary supplement for which one or more components did not meet identity specifications. Specifically, ***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
15986	21 CFR 111.123(b)(2)	Quality control - batch, product specifications	Your quality control personnel approved and released for distribution a batch of dietary supplement that did not meet established product specifications. Specifically, ***	1
15989	21 CFR 111.127	Quality control operations - packaging, labeling	You do not have quality control operations for [packaging] [labeling]. Specifically, ***	1
15994	21 CFR 111.127(c)	Quality control operations - packaging, labeling; records	Your quality control operations did not include reviewing and approving all records for [packaging] [label] operations. Specifically, ***	1
16000	21 CFR 111.130	Quality control operations - returned dietary supplement	You do not have quality control operations for returned dietary supplements. Specifically, ***	1
16007	21 CFR 111.135	Quality control operations - product complaints	You do not have quality control operations for product complaints. Specifically, ***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
16012	21 CFR 111.140(a)	Records - quality control operations: readily available	You did not have records or copies of records required for your quality control operations readily available during the required retention period for inspection and copying by FDA when requested. Specifically, ***	1
16021	21 CFR 111.140(b)(3)(iii)	Records material review, disposition, follow-up; evaluation	Your documentation of your material review and disposition decision and follow-up did not include an evaluation of whether or not the deviation or unanticipated occurrence has resulted in or could lead to a failure to ensure the quality of the dietary supplement or a failure to package and label the dietary supplement as specified in the master manufacturing record. Specifically, ***	1
16039	21 CFR 111.605(c)	Records - electronic	Your electronic records do not comply with the electronic records requirements. Specifically, ***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
16048	21 CFR 111.515	Returned dietary supplement - destroyed	You did not destroy, or otherwise suitably dispose of, a returned dietary supplement not approved for salvaging and redistribution or not approved for reprocessing. Specifically, ***	1
16052	21 CFR 111.530	Returned dietary supplement - investigation	You did not conduct an investigation of your manufacturing processes, and of each other batch implicated when a dietary supplement was returned, to determine compliance with specifications. Specifically, ***	1
16054	21 CFR 111.535(a)	Records-Rtn'd dietary supplement: originals, copies, elec	You did not keep the records required for returned dietary supplements as original records, true copies, or as electronic records. Specifically, ***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
16056	21 CFR 111.535(a)	Records - returned dietary supplement: readily available	You did not have records or copies of records required for returned dietary supplements readily available during the required retention period for inspection and copying by FDA when requested. Specifically, ***	1
16060	21 CFR 111.535(b)(4)	Returned dietary supplement: reevaluation, determination	You did not make and keep records [of documentation of the reevaluation by quality control personnel of a dietary supplement that was reprocessed] [of the determination by quality control personnel of whether the reprocessed dietary supplement met established product specifications]. Specifically, ***	1
16066	21 CFR 111.35(b)(1)(i)	Written procedures - instruments, controls; calibrating	You did not make and keep written procedures for calibrating instruments or controls that you use in [manufacturing] [testing] a component or dietary supplement. Specifically, ***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
16072	21 CFR 111.35(b)(3)	Instruments, controls; calibrate date, reference std, method	Your calibration documentation did not [identify the instrument or control calibrated] [provide the date of calibration] [identify the reference standard used] [include the certification of accuracy of the known reference standard] [include a history of recertification of accuracy of a known reference standard] [identify the calibration method used] [include appropriate limits for accuracy and precision] [provide the calibration reading or readings found] [identify the recalibration method used] [identify the reading or readings of recalibration found if the accuracy or precision limits were not met] [include the initials of the person who performed the calibration or recalibration]. Specifically, ***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
16083	21 CFR 111.35(b)(6)	Documentation - equipment functions; intended use	You did not make and keep documentation of the controls you use to ensure that equipment functions according to its intended use. Specifically, ***	1
16087	21 CFR 111.123(b)(4)	QC supplier product released assurance not provided package	Your quality control personnel approved and released for distribution product received from a supplier for [packaging] as a dietary supplement for which sufficient assurance was not provided [to adequately identify the product] [to determine that the product was consistent with your purchase order]. Specifically, ***	1
16091	FDCA 417(d)(1)(B)	RFR - investigate cause	You did not investigate the cause of the adulteration of a reportable food within 24 hours after you determined that the food was a reportable food. Specifically, ***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
16117	21 CFR 118.4	No written SE prevention plan	Your firm does not have a written SE prevention plan that is specific to [each farm] [the farm] where you produce eggs. Specifically,***	1
16131	21 CFR 118.4(b)	Transfer or introduction of SE	You have not taken [adequate] steps to assure that there is no introduction or transfer of SE into or among poultry houses. Specifically,***	1
16133	21 CFR 118.4(b)(2)	Cross contamination from equipment	You do not maintain practices that will protect against cross contamination when equipment is moved among poultry houses. Specifically,***	1
16141	21 CFR 118.4(c)(2)	Satisfactory fly control methods	When your monitoring indicated unacceptable fly activity within a poultry house, appropriate methods were not used to achieve satisfactory fly control. Specifically,***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
16142	21 CFR 118.4(c)(3)	Removal of pest harborages	Potential harborages for pests in and outside your poultry house have not been eliminated by [removing debris within a poultry house] [removing debris and vegetation outside the poultry house]. Specifically,***	1
16150	21 CFR 118.4(e)	Eggs to be processed as table eggs	Eggs intended to be processed as table eggs [were not held and transported as required at or below 45 deg. F] [were held at room temperature for more than 36 hours just prior to processing]. Specifically,***	1
16172	21 CFR 118.7(a)	Plan appropriate to layout	The poultry house environmental sampling plan was not appropriate to the poultry house layout. Specifically,***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
16183	21 CFR 118.9	Supervisor(s) training/job experience	Supervisory personnel responsible for ensuring compliance with the SE prevention plan(s) [have not successfully completed training on SE prevention measures for egg production that is equivalent to that received under a standardized curriculum recognized by FDA] [lack qualification through appropriate job experience to administer the SE prevention measures]. Specifically,***	1
16189	21 CFR 118.10(c)	Records retention time	All records are not retained for 1 year after the flock to which they pertain has been taken permanently out of production. Specifically,***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
16191	21 CFR 118.10(a)(2)	Pullets records documentation	You do not maintain documentation [that pullets were "SE monitored" or were raised under "SE monitored" conditions] [that adequate environmental testing records for pullets were kept as required by CFR regulations]. Specifically,***	1
16194	21 CFR 118.10(a)(3)(iii)	Depopulation cleaning and disinfection procedures	You did not maintain records documenting compliance with cleaning and disinfection procedures performed at depopulation. Specifically,***	1
16196	21 CFR 118.10(a)(3)(v)	Sampling procedures documentation	You did not maintain records documenting compliance with environmental and egg sampling procedures. Specifically,***	1
16204	21 CFR 118.10(b)(2)	Date and time of activity	All your required records do not include the [date] [time] of the activity that the records reflect. Specifically,***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
16205	21 CFR 118.10(b)(3)	Signatures or initials on operational records	All required records do not have the signature or initials of the person performing the operation or creating the record. Specifically,***	1
16209	21 CFR 118.11(a)	Registration within 30 days	Your firm did not register your farm(s) with the FDA [within 30 days of becoming an egg producer] [by the applicable effective date of the regulation (21 CFR Part 118)]. Specifically,***	1
16218	21 CFR 118.11(b)(2)(vi)	Updating previously submitted info	Registration information you submitted to FDA by mail or fax [was incorrect at the time of submission and was not immediately updated] [changed after submission and was not updated within 60 calendar days of the change(s)]. Specifically,***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
16286	21 CFR 113.87(c)	Temperature-indicating device accuracy - initial temperature	The temperature-indicating device used to determine the initial temperature of the product was not tested for accuracy [against a reference device for which the accuracy is traceable to a National Institute of Standards and Technology (NIST), or other national metrology institute standard reference device, by appropriate standard procedures] [with sufficient frequency to ensure that initial temperature measurements are accurate]. Specifically, ***	1
16296	21 CFR 113.100(c)(6)	TID: accuracy record - date, results	A record of the accuracy of a temperature-indicating device did not include the date on or before which the next accuracy test must be performed. Specifically, ***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
16304	21 CFR 113.100(d)(6)	Reference Device: accuracy record - next test date	The record of the accuracy of a reference device did not include the date on or before which the next accuracy test must be performed. Specifically, ***	1
16307	21 CFR 113.40(a)(8)	Still steam retorts: Bleeder not wide open during process	A bleeder was not wide open during the entire process [including the come-up time]. Specifically, ***	1
16313	21 CFR 113.40(a)(1)	RD accuracy test frequency	A reference device was not tested for accuracy once a year or more frequently when necessary to ensure accuracy. Specifically, ***	1
16352	21 CFR 113.40(b)(2)(iv)	Still water retorts:Recorder-controller sensor:heating media	The temperature recorder-controller sensor was not located where the recorded temperature was an accurate measurement of the scheduled process temperature [and was not affected by the heating media]. Specifically, ***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
16459	21 CFR 113.40(g)(1)(i)(B)	Aseptic processing: recorder, permanent record	A temperature-recording device did not have a mechanism for recording temperatures to a permanent record. Specifically, ***	1
16476	21 CFR 113.40(g)(1)(ii)(E)	Aseptic processing: product flow rate, records, frequency	The product flow rate was not [observed] [recorded] at intervals of sufficient frequency to ensure that these values were as specified in the scheduled process. Specifically, ***	1
16489	21 CFR 113.40(j)	Other systems: Methods, controls - scheduled process	The methods and controls used for the [manufacture] [processing] [packing] of a low-acid food [was not] [were not] as established in the scheduled process. Specifically, ***	1
16497	FDCA 601(e)	Unsafe color additive	Your cosmetic is, bears, or contains an unsafe color additive. Specifically, ***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
16511	21 CFR 129.35(a)(3)(i)	Sample frequency - operations water	You did not take and analyze samples of operations water [as often as necessary] [at least once every year for chemical contamination] [at least once every four years for radiological contaminants]. Specifically, ***	1
18155	21 CFR 117.80(a)(5)	Use of testing procedures	You did not use testing procedures to identify [sanitation failures] [possible allergen cross-contact] [food contamination]. Specifically, ***	1
18157	21 CFR 117.80(b)(2)	Raw Materials Control - Treatment for Microorganisms	You did not ensure that raw materials and other ingredients were not adulterated by pathogenic microorganisms. Specifically, ***	1
18158	21 CFR 117.80(b)(5)	Identification Of Rework	You did not identify materials scheduled for rework. Specifically, ***	1
18162	21 CFR 117.80(c)	Process Control Measures	You did not take an adequate measure to destroy or prevent the growth of undesirable microorganisms in your food. Specifically, ***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
18164	21 CFR 117.80(c)(9)	Adulterated Food Disposition	You did not properly [dispose of] [recondition] adulterated food. Specifically, ***	1
18166	21 CFR 117.95(a)	Human Food By-Products	You did not hold a human food by-product intended for distribution as animal food under conditions that will protect against contamination. Specifically, ***	1
18167	21 CFR 117.95(a)(3)	Human Food By-Product: Identifying as Animal food	You did not accurately identify a human food by-product held for use as animal food. Specifically, ***	1
18256	21 CFR 1.502(b)(1)	LACF compliance	For a low-acid canned food, with respect to microbiological hazards that your supplier must control according to the low-acid food regulations, you did not verify and document that the food was produced according to the low-acid canned foods regulations. Specifically, ***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
18257	21 CFR 1.502(b)(1)	LACF nonmicrobiological hazard	For a low-acid canned food, your FSVP did not address all matters that are not controlled by the low-acid canned foods regulations. Specifically, ***	1
18259	21 CFR 1.503(a)	Qualified individual develop FSVP	A qualified individual did not develop your FSVP. Specifically, ***	1
18267	21 CFR 1.504(c)(1)	Evaluation absence of control	Your hazard analysis did not include an evaluation of an identified hazard to assess the probability that the hazard will occur in the absence of a control. Specifically, ***	1
18271	21 CFR 1.504(d)	Review entity's hazard analysis	You did not [review] [assess] the hazard analysis conducted by another entity. Specifically, ***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
18288	21 CFR 1.505(d)	Evaluation, reevaluation - another entity	You did not document your review and assessment of [an evaluation] [a reevaluation] of a foreign supplier's performance and the risk posed by a food that was performed by another entity. Specifically, ***	1
18291	21 CFR 1.506(a)(1)	Procedures - establish unapproved supplier	You did not establish written procedures for using an unapproved foreign supplier on a temporary basis. Specifically, ***	1
18292	21 CFR 1.506(a)(2)	Supplier approval - another entity	You did not document your review and assessment of another entity's documentation of procedures and activities established to ensure that you import food only from foreign suppliers approved based on an evaluation of the risk posed by a food and foreign supplier's performance. Specifically, ***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
18296	21 CFR 1.506(d)(1)(i)	Verification activity frequency	You did not [determine] [document] the frequency of the verification activities that were needed to provide adequate assurances that a food you obtain from a foreign supplier is produced in compliance with processes and procedures that provide the required level of public health protection. Specifically, ***	1
18299	21 CFR 1.506(d)(1)(ii)	Verification activity - appropriate	You did not conduct an appropriate supplier verification activity. Specifically, ***	1
18303	21 CFR 1.506(e)(1)	Verification activity before import, periodically	You did not conduct and document or obtain documentation of one or more supplier verification activities [before importing the food into the United States] [periodically after importing the food into the United States]. Specifically, ***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
18331	21 CFR 1.510(a)(2)	Record - sign, date	You did not [sign] [date] an FSVP record [upon initial completion] [upon modification]. Specifically, ***	1
18366	21 CFR 1.511(c)(1)	No CGMPs - supplier approval, performance, risk	You did not document the evaluation you conducted to determine [a foreign supplier's performance] [the risk posed by a food]. Specifically, ***	1
18388	21 CFR 1.511(c)(2)(i)	No CGMPs - approval procedures	You did not establish written procedures to ensure that you import foods only from foreign suppliers you have approved based on an evaluation of the foreign supplier's performance and the risk posed by the food. Specifically, ***	1
18392	21 CFR 1.511(c)(3)	No CGMPs - verification activities, procedures	You did not [establish] [follow] written procedures [adequate] for ensuring that appropriate foreign supplier verification activities were conducted for a food you import. Specifically, ***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
18400	21 CFR 117.315	Record Retention	You did not retain records as required. Specifically, ***	1
18541	21 CFR 1.507(a)(2)(i)	Disclosure - customer subject cGMP	For a food for which you relied on your customer to significantly minimize or prevent an identified hazard, you did not disclose in documents accompanying the food that the food is "not processed to control {identified hazard}". Specifically, ***	1
18572	21 CFR 1.512(b)(3)(i)	Very small importer assurances, supplier	As a very small importer, you did not obtain written assurance, [before importing a food] [every 2 years after initially importing a food], that your foreign supplier produced the food in compliance with process and procedures that provide the required level of public health protection. Specifically, ***	1
18641	21 CFR 118.10(a)(4)	SE prevention plan corrective actions	You did not maintain a record of the corrective actions taken under your SE prevention plan. Specifically, ***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
18683	21 CFR 106.20(i)	Toilet, hand washing facilities - water, soap, dryers	A toilet facility or hand washing facility did not include [hot and cold water] [soap or detergent] [single-service towels or air dryers]. Specifically, ***	1
18690	21 CFR 106.30(b)	Equipment, utensil - design: cleanable, intended use	You did not ensure that an equipment or utensil was designed [to be easily cleanable] [to withstand the environment of the intended use]. Specifically, ***	1
18876	21 CFR 106.100(f)(4)	Record - date, time	A record of cleaning, sanitizing, or maintenance did not show the [date] [time] of such cleaning, sanitizing, or maintenance. Specifically, ***	1
19035	21 CFR 117.135(c)(1)	Process Controls Procedures - Adequate	Your process controls procedures did not include appropriate [parameters] [maximum/minimum values]. Specifically, ***	1
19038	21 CFR 117.145(c)(1)	Process Controls Monitoring Records	You did not have process controls monitoring records. Specifically, ***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
19040	21 CFR 117.150(a)(2)	Process Controls Corrective Action Procedures - Content	Your corrective action procedures for process controls were not adequate. Specifically, ***	1
19041	21 CFR 117.150(b)(2)	Corrective Action for Unanticipated Food Safety Problems	You did not take an appropriate corrective action in response to an unanticipated food safety problem. Specifically, ***	1
19044	21 CFR 117.165(b)	Process Controls Verif Procedures: Establish Implement	You did not [establish] [implement] adequate written process controls verification procedures. Specifically, ***	1
19046	21 CFR 117.160(b)	Process Controls Validation Requirements	Your process controls validation [was not performed by or overseen by a preventive controls qualified individual] [was not performed when necessary] [was not based on scientific evidence]. Specifically, ***	1
19060	21 CFR 117.145(b)	Sanitation Controls - Monitoring Frequency	Your sanitation controls monitoring frequency was not adequate. Specifically, ***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
19063	21 CFR 117.150(a)(2)	Sanitation Controls Corrective Action Procedures - Content	Your corrective action procedures for sanitation controls were not adequate. Specifically, ***	1
19084	21 CFR 117.305	Preventive controls records - general requirements	Your preventive controls records did not meet general records requirements. Specifically, ***	1
21037	21 CFR 112.30(b)	Training records	You did not establish and keep records that document personnel training, including [the date of training] [training topics] [persons trained]. Specifically, ***	1
21098	21 CFR 112.123(a)	Equip & tools - cleanability	You did not use equipment and tools that are of adequate design, construction, and workmanship to enable them to be adequately cleaned and maintained. Specifically, ***	1

Cite Id	Reference Number	Short Description	Long Description	Frequ
21110	21 CFR 112.127(a)(1)	Domestic animals excluded from buildings	You did not exclude domesticated animals from fully-enclosed buildings where covered produce, food contact surfaces, or food-packing material is exposed. Specifically, ***	1
21113	21 CFR 112.128(b)	Pest exclusion from fully-enclosed buildings	You did not take adequate measures to exclude pests from your fully-enclosed buildings. Specifically, ***	1
21134	21 CFR 112.140(b)	Records - equipment cleaning and sanitizing	You did not establish and keep documentation of the date and method of cleaning and sanitizing of equipment. Specifically, ***	1
21276	21 CFR 117.405(a)(1)	Supply-Chain Program Establish and Implement	You did not [establish] [implement] a written supply-chain program. Specifically, ***	1

Human tissue for transplantation

Parts 1240 and 1250

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