Table D-2. Weighted Responses for Section 2: Good Manufacturing Practices (GMPs) (continued)

	Very Small (n = 110)				Small (n = 114)				Large (n = 14)				Overall (n = 238)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
2.3* [If 2.1 is No] If *not* following published GMPs, how does this plant verify the identity, purity, and composition of dietary supplement products and ingredients?																
1. Sanitation standard operating procedures (SSOPs)	8	22.56	—	—[a]	6	14.18	—	—[a]	—[b]	—	—	—	14	19.09	—	—[a]
2. Other quality assurance (QA) program	11	20.18	—	—[a]	9	33.99	—	—[a]	—[b]	—	—	—	20	25.29	—	—[a]
3. Certificate of Analysis	27	64.55	—	—[a]	19	85.73	—	—[a]	—[b]	—	—	—	46	72.02	—	—[a]
4. Certificate of Identity	10	11.96	—	—[a]	6	23.66	—	—[a]	—[b]	—	—	—	16	16.34	—	—[a]
5. Other	17	45.57	—	—[a]	7	24.70	—	—[a]	—[b]	—	—	—	24	37.05	—	—[a]
Not applicable	6	13.50	—	—[a]	0	—	—	—[a]	—[b]	—	—	—	7	9.22	—	—[a]
No answer	1	1.27	—	—[a]	0	—	—	—[a]	—[b]	—	—	—	1	0.77	—	—[a]
2.4 [If 2.1 is No] Why does this plant *not* follow published GMPs?	(verbatims provided in Table D-11)															
2.5 Does this plant have standard operating procedures (SOPs)?																
1. Yes	79	65.17	50.98	77.10	104	91.11	81.08	96.08	12	88.98	63.97	97.35	195	79.73	71.54	86.02
2. No (Skip to Section 3)	19	22.27	12.35	36.82	5	5.20	1.52	16.28	0	0.00	0.00	0.00	24	12.34	7.29	20.14
Not applicable	5	2.87	1.16	6.91	0	0.00	0.00	0.00	1	6.54	0.90	34.91	6	1.59	0.71	3.52
Don't know	1	0.52	0.07	3.66	0	0.00	0.00	0.00	0	0.00	0.00	0.00	1	0.23	0.03	1.60
No answer	6	9.18	3.17	23.79	5	3.69	1.40	9.37	1	4.49	0.61	26.47	12	6.11	2.84	12.65

(continued)

Table D-2. Weighted Responses for Section 2: Good Manufacturing Practices (GMPs) (continued)

	Very Small (n = 110)				Small (n = 114)				Large (n = 14)				Overall (n = 238)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
2.6 [If 2.5 is Yes] Is there written documentation of the SOPs?																
1. Yes	62	81.57	67.04	90.59	86	81.33	68.89	89.55	11	91.43	57.02	98.85	159	82.01	73.47	88.24
2. No	10	7.86	4.15	14.38	9	12.16	5.42	25.08	0	0.00	0.00	0.00	19	9.92	5.34	17.69
Don't know	1	0.83	0.11	5.82	0	0.00	0.00	0.00	0	0.00	0.00	0.00	1	0.30	0.04	2.10
No answer	6	9.75	3.05	27.02	9	6.51	3.09	13.19	1	8.57	1.15	42.98	16	7.78	4.05	14.42

[a]Confidence interval could not be estimated because there was only one observation (respondent) in a stratum for that question.

[b]Could not estimate because there were no respondents for that question.

*Total may sum to greater than 100% because respondents could select more than one answer.

Table D-3. Weighted Responses for Section 3: Personnel

	Very Small (n = 110)				Small (n = 114)				Large (n = 14)				Overall (n = 238)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
3.0 Do personnel at this plant or site handle raw materials, in-process materials, or finished products, including distribution of finished products?																
1. Yes	96	83.19	68.87	91.72	109	96.94	92.05	98.86	13	95.51	73.53	99.39	218	90.90	83.90	95.03
2. No (Skip to Section 4)	14	16.81	8.28	31.13	5	3.06	1.14	7.95	1	4.49	0.61	26.47	20	9.10	4.97	16.10
3.1 Are there written procedures for personnel on *disease control*?																
1. Yes	47	55.74	41.51	69.09	74	71.17	58.99	80.90	13	100.00	100.00	100.00	134	66.62	57.96	74.29
2. No	47	43.01	29.81	57.29	35	28.83	19.10	41.01	0	0.00	0.00	0.00	82	32.88	25.24	41.55
Not applicable	2	1.25	0.31	4.92	0	0.00	0.00	0.00	0	0.00	0.00	0.00	2	0.50	0.12	1.96
3.2 Are there written procedures for personnel on maintaining *personal cleanliness*?																
1. Yes	67	69.80	55.01	81.38	95	84.99	72.39	92.44	13	100.00	100.00	100.00	175	79.78	71.44	86.16
2. No	27	28.95	17.55	43.82	14	15.01	7.56	27.61	0	0.00	0.00	0.00	41	19.73	13.39	28.08
Not applicable	2	1.25	0.31	4.92	0	0.00	0.00	0.00	0	0.00	0.00	0.00	2	0.50	0.12	1.96
3.3 Are there written procedures ensuring that all personnel employed in the manufacturing process have the proper *education, training, or experience* needed to perform the assigned functions?																
1. Yes	53	53.95	39.41	67.84	82	70.98	58.20	81.12	12	93.15	63.84	99.06	147	65.43	56.37	73.49
2. No	38	39.21	26.19	53.96	27	29.02	18.88	41.80	0	0.00	0.00	0.00	65	31.47	23.63	40.53
Not applicable	4	2.66	0.94	7.31	0	0.00	0.00	0.00	1	6.85	0.94	36.16	5	1.43	0.58	3.49
No answer	1	4.19	0.58	24.84	0	0.00	0.00	0.00	0	0.00	0.00	0.00	1	1.67	0.23	11.18

(continued)

Table D-3. Weighted Responses for Section 3: Personnel (continued)

	Very Small (n = 110)				Small (n = 114)				Large (n = 14)				Overall (n = 238)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
3.4 Does plant management verify and keep records that the procedures for personnel on disease control, personal cleanliness, and training are being followed?																
1. Yes	45	47.68	33.87	61.85	75	69.31	56.93	79.42	12	93.15	63.84	99.06	132	62.02	53.13	70.18
2. No (Skip to question 3.6)	46	42.04	28.97	56.34	34	30.69	20.58	43.07	0	0.00	0.00	0.00	80	33.51	25.71	42.33
Not applicable	2	1.25	0.31	4.92	0	0.00	0.00	0.00	1	6.85	0.94	36.16	3	0.87	0.27	2.77
No answer	3	9.03	2.56	27.28	0	0.00	0.00	0.00	0	0.00	0.00	0.00	3	3.59	1.00	12.08
3.5 [If 3.4 is Yes] Are records made of any corrective actions taken if procedures are *not* followed?																
1. Yes, for some procedures	24	58.21	36.93	76.82	38	47.77	33.56	62.35	5	43.29	18.65	71.77	67	50.59	39.34	61.78
2. Yes, for all procedures	12	21.94	10.22	40.97	22	33.07	20.33	48.88	7	56.71	28.23	81.35	41	31.63	21.99	43.15
3. No	6	15.11	4.51	40.13	9	13.94	6.68	26.80	0	0.00	0.00	0.00	15	13.14	6.83	23.79
No answer	3	4.74	1.39	14.98	6	5.22	2.19	11.95	0	0.00	0.00	0.00	9	4.64	2.32	9.07
3.6 Are records maintained of personnel education, training, or experience?																
1. Yes	54	54.22	39.63	68.12	84	73.66	61.31	83.15	12	93.15	63.84	99.06	150	67.00	57.99	74.92
2. No (Skip to Section 4)	40	44.51	30.71	59.20	25	26.34	16.85	38.69	0	0.00	0.00	0.00	65	32.11	24.23	41.17
Not applicable	2	1.28	0.31	5.09	0	0.00	0.00	0.00	1	6.85	0.94	36.16	3	0.88	0.27	2.81

(continued)

Table D-3. Weighted Responses for Section 3: Personnel (continued)

	Very Small (n = 110)				Small (n = 114)				Large (n = 14)				Overall (n = 238)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
3.7 [If 3.6 is Yes] How long are records of personnel education, training, or experience maintained?																
1. Term of employment	36	71.57	—	—[a]	47	55.69	—	—[a]	4	34.26	—	—[a]	87	59.16	—	—[a]
2. ___ Year(s) after expiration date	2	2.30	—	—[a]	7	9.75	—	—[a]	1	8.57	—	—[a]	10	7.26	—	—[a]
3. ___ Year(s) from date of manufacture	3	3.67	—	—[a]	5	7.90	—	—[a]	0	0.00	—	—[a]	8	5.94	—	—[a]
4. Other	12	21.31	—	—[a]	20	22.90	—	—[a]	6	52.10	—	—[a]	38	24.63	—	—[a]
Don't know	0	0.00	—	—[a]	0	0.00	—	—[a]	1	5.07	—	—[a]	1	0.39	—	—[a]
No answer	1	1.15	—	—[a]	5	3.76	—	—[a]	0	0.00	—	—[a]	6	2.63	—	—[a]
Mean years after expiration date	2	2.50	—	—[a]	7	2.14	—	—[a]	1	6.00	—	—[a]	10	2.53	—	—[a]
Mean years from date of manufacture	3	2.67	—	—[a]	5	3.74	—	—[a]	—[b]	—	—	—	8	3.52	—	—[a]

[a]Confidence interval could not be estimated because there was only one observation (respondent) in a stratum for that question.

[b]Could not estimate because there were no respondents for that question.

Table D-4. Weighted Responses for Section 4: Buildings and Facilities

	Very Small (n = 110)				Small (n = 114)				Large (n = 14)				Overall (n = 238)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
4.0 Are raw materials, in-process materials, or finished products handled or stored at this plant or site?																
1. Yes	101	92.04	80.78	96.95	111	98.10	93.12	99.49	13	95.51	73.53	99.39	225	95.33	90.21	97.84
2. No (Skip to Section 5)	9	7.96	3.05	19.22	3	1.90	0.51	6.88	1	4.49	0.61	26.47	13	4.67	2.16	9.79
4.1 What percentage of plants are owned vs. leased?[b] *(Include warehouse facilities located at this plant.)*																
a. Owned	39	36.10	24.01	50.27	68	59.80	47.47	71.00	11	85.17	55.41	96.37	118	51.19	42.43	59.88
b. Leased	62	63.90	49.73	75.99	43	40.20	29.00	52.53	2	14.83	3.63	44.59	107	48.81	40.12	57.57
Owned Facilities																
4.2 Are there written procedures on *maintenance of the grounds* about the plant?																
1. Yes	9	24.33	9.49	49.63	38	60.35	45.34	73.64	10	90.63	53.87	98.77	57	52.35	40.65	63.79
2. No	27	70.92	46.84	87.10	29	37.70	24.69	52.77	1	9.37	1.23	46.13	57	45.05	33.75	56.88
Not applicable	1	1.63	0.22	11.29	0	0.00	0.00	0.00	0	0.00	0.00	0.00	1	0.48	0.07	3.43
Don't know	1	1.56	0.21	10.80	0	0.00	0.00	0.00	0	0.00	0.00	0.00	1	0.46	0.06	3.29
No answer	1	1.56	0.21	10.80	1	1.94	0.26	12.98	0	0.00	0.00	0.00	2	1.66	0.35	7.42

(continued)

Table D-4. Weighted Responses for Section 4: Buildings and Facilities (continued)

	Very Small (n = 110)				Small (n = 114)				Large (n = 14)				Overall (n = 238)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
4.3 Are there written procedures on *general maintenance and sanitation of the buildings, fixtures, and other physical facilities* of the plant?																
1. Yes	20	61.22	41.95	77.52	54	79.35	63.66	89.39	10	94.46	68.48	99.26	84	75.31	64.74	83.51
2. No	17	35.59	19.93	55.08	14	20.65	10.61	36.34	1	5.54	0.74	31.52	32	23.75	15.60	34.42
Not applicable	2	3.19	0.75	12.64	0	0.00	0.00	0.00	0	0.00	0.00	0.00	2	0.94	0.23	3.78
4.4 Are there written procedures on the storage and use of *cleaning and sanitizing materials*?																
1. Yes	16	52.82	31.31	73.33	47	69.33	52.88	81.99	11	100.00	100.00	100.00	74	67.13	55.17	77.22
2. No	21	43.99	24.16	65.94	21	30.67	18.01	47.12	0	0.00	0.00	0.00	42	31.93	21.88	43.98
Not applicable	2	3.19	0.75	12.64	0	0.00	0.00	0.00	0	0.00	0.00	0.00	2	0.94	0.23	3.78
4.5 Are there written procedures on *pest control*?																
1. Yes	20	59.40	37.16	78.36	52	77.27	61.84	87.69	10	94.46	68.48	99.26	82	73.48	62.04	82.45
2. No	17	37.41	19.14	60.15	16	22.73	12.31	38.16	1	5.54	0.74	31.52	34	25.57	16.67	37.11
Not applicable	1	1.56	0.21	10.80	0	0.00	0.00	0.00	0	0.00	0.00	0.00	1	0.46	0.06	3.29
No answer	1	1.63	0.22	11.29	0	0.00	0.00	0.00	0	0.00	0.00	0.00	1	0.48	0.07	3.43
4.6 Does plant management verify and keep records that procedures for buildings and facilities maintenance are being followed?																
1. Yes	15	52.51	33.50	70.82	50	78.44	63.61	88.34	9	81.26	47.18	95.47	74	71.02	61.23	79.18
2. No (Skip to Section 5)	23	45.86	27.89	64.97	18	21.56	11.66	36.39	2	18.74	4.53	52.82	43	28.50	20.34	38.36
No answer	1	1.63	0.22	11.29	0	0.00	0.00	0.00	0	0.00	0.00	0.00	1	0.48	0.07	3.43

(continued)

Table D-4. Weighted Responses for Section 4: Buildings and Facilities (continued)

	Very Small (n = 110)				Small (n = 114)				Large (n = 14)				Overall (n = 238)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
4.7 [If 4.6 is Yes] Are records made of any corrective actions taken if procedures are *not* followed?																
1. Yes, for some procedures	7	24.73	11.32	45.81	26	53.26	36.07	69.71	2	23.68	5.18	63.81	35	44.06	29.77	59.40
2. Yes, for all procedures	4	29.24	6.60	70.72	15	31.37	17.34	49.90	7	76.32	36.19	94.82	26	35.41	22.58	50.74
3. No	1	2.97	0.37	20.11	6	10.84	4.52	23.80	0	0.00	0.00	0.00	7	8.03	3.59	16.98
No answer	3	43.06	13.56	78.48	3	4.53	1.24	15.18	0	0.00	0.00	0.00	6	12.51	4.56	29.95
Leased Facilities																
4.8 What is the *remaining* term of the lease?																
Years (mean response)	55	3.04	—	—[a]	41	4.63	—	—[a]	1	0.00	—	—[a]	97	3.77	—	—[a]
Open lease (%)	5	4.59	1.91	10.60	1	1.23	0.16	8.56	0	0.00	0.00	0.00	6	3.05	1.44	6.34
4.9 For leased facilities, who is primarily responsible for *maintaining the grounds* about the plant?																
1. Plant management (lessee)	21	31.99	17.69	50.72	26	57.57	37.64	75.30	1	53.82	6.58	95.07	48	43.46	31.15	56.64
2. Facility owner (lessor) (Skip to question 4.11)	40	62.08	42.91	78.10	16	39.54	22.33	59.81	1	46.18	4.93	93.42	57	52.03	38.75	65.02
No answer	1	5.93	0.78	33.54	1	2.89	0.38	18.82	0	0.00	0.00	0.00	2	4.51	0.94	19.09
4.10 [If 4.9 is 1 (lessee)] For leased facilities, are there written procedures on *maintenance of the grounds* about the plant?																
1. Yes	4	31.20	7.78	70.93	13	32.16	16.50	53.21	0	0.00	0.00	0.00	17	31.13	15.72	52.29
2 No	15	63.16	26.49	89.08	11	55.67	29.57	78.98	1	100.00	100.00	100.00	27	59.58	37.22	78.56
No answer (Skip to question 4.12)	2	5.64	1.24	22.18	2	12.17	1.89	49.91	0	0.00	0.00	0.00	4	9.29	2.23	31.49

(continued)

Table D-4. Weighted Responses for Section 4: Buildings and Facilities (continued)

	Very Small (n = 110)				Small (n = 114)				Large (n = 14)				Overall (n = 238)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
4.11 [If 4.9 is 2 (lessor)] Does plant management verify and keep records that the facility owner is properly *maintaining the grounds*?																
1. Yes	6	15.80	5.67	36.94	5	36.58	11.49	71.93	1	100.00	100.00	100.00	12	23.86	11.42	43.25
2. No	23	42.88	23.83	64.31	7	49.00	18.65	80.11	0	0.00	0.00	0.00	30	44.30	27.51	62.50
Don't know	1	1.48	0.19	10.54	0	0.00	0.00	0.00	0	0.00	0.00	0.00	1	0.97	0.13	6.96
No answer	10	39.83	20.44	63.04	4	14.42	3.82	41.65	0	0.00	0.00	0.00	14	30.86	15.63	51.82
4.12 For leased facilities, who is primarily responsible for *general maintenance and sanitation of the buildings, fixtures, and other physical facilities* of the plant?																
1. Plant management (lessee)	44	63.35	43.38	79.60	39	95.63	88.47	98.42	1	53.82	6.58	95.07	84	77.23	63.39	86.92
2. Facility owner (lessor) (Skip to question 4.15)	17	30.72	16.10	50.61	4	4.37	1.58	11.53	1	46.18	4.93	93.42	22	19.51	10.85	32.56
No answer	1	5.93	0.78	33.54	0	0.00	0.00	0.00	0	0.00	0.00	0.00	1	3.26	0.43	20.75
4.13 [If 4.12 is 1 (lessee)] For leased facilities, are there written procedures on *general maintenance and sanitation of the buildings, fixtures, and other physical facilities* of the plant?																
1. Yes	21	39.51	21.46	60.97	25	61.57	40.29	79.19	1	100.00	100.00	100.00	47	52.06	37.84	65.96
2. No	19	54.13	33.43	73.49	12	36.71	19.39	58.32	0	0.00	0.00	0.00	31	44.15	30.76	58.45
No answer	4	6.36	2.21	16.94	2	1.71	0.43	6.55	0	0.00	0.00	0.00	6	3.79	1.62	8.61

(continued)

Table D-4. Weighted Responses for Section 4: Buildings and Facilities (continued)

	Very Small (n = 110)				Small (n = 114)				Large (n = 14)				Overall (n = 238)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
4.14 [If 4.12 is 1 (lessee)] For leased facilities, are there written procedures on the storage and use of *cleaning and sanitizing materials*?																
1. Yes	18	33.35	16.81	55.34	26	59.94	38.32	78.28	1	100.00	100.00	100.00	45	48.41	34.39	62.68
2. No	22	61.02	39.75	78.79	11	38.34	20.27	60.34	0	0.00	0.00	0.00	33	48.13	34.18	62.37
No answer	4	5.63	2.04	14.62	2	1.71	0.43	6.55	0	0.00	0.00	0.00	6	3.46	1.56	7.52
(Skip to question 4.17)																
4.15 [If 4.12 is 2 (lessor)] Does plant management verify and keep records that the facility owner is properly *maintaining the buildings, fixtures, and other physical facilities* of the plant?																
1. Yes	5	48.44	—	—[a]	0	0.00	—	—[a]	1	100.00	—	—[a]	6	45.67	—	—[a]
2. No	9	26.39	—	—[a]	4	100.00	—	—[a]	0	0.00	—	—[a]	13	32.57	—	—[a]
Don't know	0	0.00	—	—[a]	0	0.00	—	—[a]	0	0.00	—	—[a]	0	0.00	—	—[a]
No answer	3	25.17	—	—[a]	0	0.00	—	—[a]	0	0.00	—	—[a]	3	21.76	—	—[a]
4.16 [If 4.12 is 2 (lessor)] Does plant management verify and keep records that the *cleaning and sanitizing materials* used by the facility owner are being properly stored and used?																
1. Yes	6	51.31	—	—[a]	0	0.00	—	—[a]	1	100.00	—	—[a]	7	48.15	—	—[a]
2. No	8	23.52	—	—[a]	4	100.00	—	—[a]	0	0.00	—	—[a]	12	30.09	—	—[a]
Don't know	0	0.00	—	—[a]	0	0.00	—	—[a]	0	0.00	—	—[a]	0	0.00	—	—[a]
No answer	3	25.17	—	—[a]	0	0.00	—	—[a]	0	0.00	—	—[a]	3	21.76	—	—[a]

(continued)

Table D-4. Weighted Responses for Section 4: Buildings and Facilities (continued)

	Very Small (n = 110)				Small (n = 114)				Large (n = 14)				Overall (n = 238)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
4.17 For leased facilities, who is primarily responsible for *pest control*?																
1. Plant management (lessee)	43	63.42	43.62	79.53	38	88.14	65.12	96.73	1	53.82	6.58	95.07	82	74.02	60.19	84.29
2. Facility owner (lessor) (Skip to question 4.19)	17	29.77	15.47	49.56	5	11.86	3.27	34.88	1	46.18	4.93	93.42	23	22.25	12.77	35.87
Not applicable	1	0.88	0.12	6.25	0	0.00	0.00	0.00	0	0.00	0.00	0.00	1	0.48	0.07	3.45
No answer	1	5.93	0.78	33.54	0	0.00	0.00	0.00	0	0.00	0.00	0.00	1	3.26	0.43	20.75
4.18 [If 4.17 is 1 (lessee)] For leased facilities, are there written procedures on *pest control*?																
1. Yes	14	32.43	15.72	55.26	31	89.35	76.29	95.63	1	100.00	100.00	100.00	46	62.69	47.96	75.40
2. No	26	63.70	41.49	81.28	6	9.72	3.75	22.95	0	0.00	0.00	0.00	32	35.01	22.52	49.95
No answer	3	3.87	1.16	12.12	1	0.93	0.12	6.66	0	0.00	0.00	0.00	4	2.30	0.84	6.13
(Skip to question 4.20)																
4.19 [If 4.17 is 2 (lessor)] Does plant management verify and keep records that the facility owner is taking proper *pest control* measures?																
1. Yes	4	42.29	—	—[a]	1	6.91	—	—[a]	1	100.00	—	—[a]	6	36.00	—	—[a]
2. No	9	44.18	—	—[a]	4	93.09	—	—[a]	0	0.00	—	—[a]	13	54.05	—	—[a]
Don't know	1	2.96	—	—[a]	0	0.00	—	—[a]	0	0.00	—	—[a]	1	2.18	—	—[a]
No answer	3	10.57	—	—[a]	0	0.00	—	—[a]	0	0.00	—	—[a]	3	7.77	—	—[a]

(continued)

Table D-4. Weighted Responses for Section 4: Buildings and Facilities (continued)

	Very Small (n = 110)				Small (n = 114)				Large (n = 14)				Overall (n = 238)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
4.20 Does plant management verify and keep records that procedures for buildings and facilities maintenance are being followed?																
1. Yes	24	40.26	24.33	58.55	30	61.62	42.38	77.81	2	100.00	100.00	100.00	56	50.50	39.61	61.35
2. No (Skip to Section 5)	34	46.08	28.93	64.21	12	30.89	15.54	52.07	0	0.00	0.00	0.00	46	38.74	27.06	51.88
Not applicable	1	0.88	0.12	6.25	0	0.00	0.00	0.00	0	0.00	0.00	0.00	1	0.48	0.07	3.45
Don't know	1	0.92	0.12	6.49	0	0.00	0.00	0.00	0	0.00	0.00	0.00	1	0.51	0.07	3.61
No answer	2	11.85	3.04	36.55	1	7.49	1.04	38.42	0	0.00	0.00	0.00	3	9.77	3.41	24.94
4.21 [If 4.20 is Yes] Are records made of any corrective actions taken if procedures are *not* followed?																
1. Yes, for some procedures	12	68.41	50.03	82.41	15	37.83	21.07	58.11	2	100.00	100.00	100.00	29	53.19	38.23	67.59
2. Yes, for all procedures	6	17.89	7.30	37.60	6	21.37	7.42	47.97	0	0.00	0.00	0.00	12	19.17	9.29	35 46
3. No	4	9.10	3.28	22.79	7	31.41	13.93	56.44	0	0.00	0.00	0.00	11	20.65	10.15	37.47
No answer	2	4.60	1.07	17.72	2	9.39	2.25	31.82	0	0.00	0.00	0.00	4	7.00	2.35	19.05

[a]Confidence interval could not be estimated because there was only one observation (respondent) in a stratum for that question.

[b]If 50% or more of the plant's facilities are *owned*, the respondent completed questions 4.2 through 4.7. If 50% or more of the plant's facilities are *leased*, the respondent completed questions 4.8 through 4.21.

Table D-5. Weighted Responses for Section 5: Equipment

	Very Small (n = 110)				Small (n = 114)				Large (n = 14)				Overall (n = 238)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
5.0 Is equipment at this plant or site used to process raw materials, in-process materials, or finished products?																
1. Yes	92	84.06	71.38	91.77	110	97.61	92.85	99.23	13	95.51	73.53	99.39	215	91.62	85.53	95.28
2. No (Skip to Section 6)	18	15.94	8.23	28.62	4	2.39	0.77	7.15	1	4.49	0.61	26.47	23	8.38	4.72	14.47
5.1 Are there written procedures on the *cleaning, sanitizing, and maintaining of equipment and utensils?*																
1. Yes	57	60.50	45.22	73.98	95	81.04	68.32	89.44	13	100.00	100.00	100.00	165	73.89	64.92	81.23
2. No (Skip to question 5.4)	35	39.50	26.02	54.78	15	18.96	10.56	31.68	0	0.00	0.00	0.00	50	26.11	18.77	35.08
5.2 [If 5.1 is Yes] Does plant management verify and keep records that these procedures are being followed?																
1. Yes	45	73.52	52.51	87.45	83	87.71	75.57	94.28	12	93.15	63.79	99.06	140	83.48	73.77	90.08
2. No (Skip to question 5.4)	11	24.93	11.38	46.19	10	11.30	4.97	23.69	1	6.85	0.94	36.21	22	15.42	8.99	25.17
No answer	1	1.55	0.21	10.63	2	0.99	0.24	4.06	0	0.00	0.00	0.00	3	1.10	0.33	3.59
5.3 [If 5.2 is Yes] Are records made of any corrective actions taken if procedures are *not* followed?																
1. Yes, for some procedures	20	40.12	24.32	58.29	32	34.40	22.60	48.52	4	30.77	11.30	60.78	56	35.75	26.13	46.68
2. Yes, for all procedures	16	39.10	20.86	60.99	37	48.75	34.97	62.72	7	60.67	31.85	83.58	60	46.96	36.19	58.02
3. No	7	10.06	4.62	20.55	13	16.22	8.60	28.48	1	8.57	1.14	43.22	21	13.82	8.37	21.96
No answer	2	10.71	1.86	43.15	1	0.63	0.09	4.46	0	0.00	0.00	0.00	3	3.48	0.71	15.32

(continued)

Table D-5. Weighted Responses for Section 5: Equipment (continued)

	Very Small (n = 110)				Small (n = 114)				Large (n = 14)				Overall (n = 238)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
5.4 Does this plant *validate* that equipment, instruments, and controls are *installed* correctly?																
1. Yes	63	67.71	52.41	79.96	70	56.25	44.36	67.47	11	85.17	55.40	96.37	144	62.40	53.62	70.44
2 No	25	26.29	15.30	41.34	37	40.24	29.29	52.26	1	6.85	0.94	36.16	63	32.85	25.07	41.71
No answer	4	6.00	1.45	21.69	3	3.50	1.13	10.36	1	7.98	1.08	40.85	8	4.74	1.99	10.90
5 5 Does this plant *validate* that equipment, instruments, and controls are *used* correctly?																
1 Yes	68	67.42	51.84	79.90	80	66.19	53.65	76.80	11	85.17	55.40	96.37	159	67.72	59 01	75 35
2. No	22	27.82	16.14	43.56	28	31.48	21.15	44.03	1	6.85	0.94	36.16	51	28 67	21.25	37 45
No answer	2	4.76	0.83	23.09	2	2.34	0.58	8.96	1	7.98	1.08	40.85	5	3.61	1.23	10.11
5.6 Does this plant *validate* the equipment used in quality control? Quality control equipment includes automatic, mechanical, electronic, and computer equipment, including hardware and software.																
1. Yes	55	62.98	47.92	75.88	82	67.11	54.22	77.86	10	77.20	47.55	92.67	147	66.02	56.77	74.18
2. No	28	24.22	14.66	37.29	25	30.10	19.67	43.09	2	14.83	3.63	44.60	55	26.92	19.49	35.92
No answer	9	12.80	5.09	28.65	3	2.79	0.83	8.98	1	7.98	1.08	40.85	13	7.06	3.39	14.15

Table D-6. Weighted Responses for Section 6: Quality Control and Laboratory Operations

	Very Small (n = 110)				Small (n = 114)				Large (n = 14)				Overall (n = 238)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
6.1 Is there a unit or person responsible for quality control?																
1. Yes	85	74.45	60.20	84.87	108	92.39	79.86	97.38	12	91.00	69.49	97.82	205	84.52	76.64	90.08
2. No (Skip to question 6.4)	11	12.12	5.24	25.59	4	6.85	2.11	20.04	1	4.51	0.61	26.58	16	9.02	4.71	16.59
Not applicable (Skip to question 6.4)	10	8.53	3.44	19.61	0	0.00	0.00	0.00	0	0.00	0.00	0.00	10	3.70	1.50	8.87
No answer	4	4.91	1.15	18.66	2	0.76	0.18	3.09	1	4.49	0.61	26.47	7	2.76	0.87	8.40
6.2 [If 6.1 is Yes] Are there written procedures on the responsibilities and procedures required of the quality control unit/person?																
1. Yes	48	64.53	49.77	76.96	91	86.03	75.54	92.47	12	100.00	100.00	100.00	151	78.59	70.70	84.81
2. No	29	29.04	17.62	43.92	14	11.15	5.47	21.40	0	0.00	0.00	0.00	43	17.37	11.65	25.08
No answer	8	6.44	3.10	12.87	3	2.82	0.81	9.37	0	0.00	0.00	0.00	11	4.04	2.11	7.62

(continued)

Table D-6. Weighted Responses for Section 6: Quality Control and Laboratory Operations (continued)

	Very Small (n = 110)				Small (n = 114)				Large (n = 14)				Overall (n = 238)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
6.3* [If 6.1 is Yes] For which of the following does the quality control unit/person have responsibility and authority?																
1. Approval/rejection of cleaning and maintenance procedures	65	77.50	62.87	87.51	73	64.90	52.46	75.60	10	83.25	51.43	95.89	148	70.76	61.79	78.36
2. Approval/rejection of procedures, specifications, controls, tests, and examinations for purity, quality, and composition	68	83.20	69.82	91.39	95	89.28	81.33	94.09	12	100.00	100.00	100.00	175	87.56	81.10	92.03
3. Approval/rejection of raw materials	70	76.70	59.75	87.95	96	84.69	72.64	92.02	11	91.63	57.70	98.87	177	82.02	72.99	88.51
4. Approval/rejection of packaging materials	70	77.25	60.44	88.29	84	71.57	58.90	81.56	11	91.63	57.70	98.87	165	74.88	65.58	82.34
5. Approval/rejection of labeling	70	80.35	64.30	90.27	83	74.32	62.43	83.44	9	74.88	44.00	91.87	162	76.66	67.86	83.63
6. Approval/rejection of finished dietary products	67	83.51	72.48	90.69	95	85.94	74.87	92.62	12	100.00	100.00	100.00	174	85.81	78.62	90.86
7. Other	4	3.21	1.15	8.64	4	2.75	0.92	7.97	2	16.75	4.11	48.57	10	3.72	1.92	7.10
No answer	4	3.18	1.14	8.60	5	5.29	2.10	12.67	0	0.00	0.00	0.00	9	4.18	2.05	8.34

(continued)

Table D-6. Weighted Responses for Section 6: Quality Control and Laboratory Operations (continued)

	Very Small (n = 110)				Small (n = 114)				Large (n = 14)				Overall (n = 238)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
6.4 Does this plant require suppliers to provide a *Certificate of Analysis*?																
1. Yes, from some suppliers	39	29.68	19.28	42.71	29	20.05	12.54	30.49	5	32.10	13.20	59.52	73	24.86	18.49	32.55
2. Yes, from all suppliers	42	45.16	32.17	58.84	76	72.18	60.75	81.31	7	55.79	29.94	78.85	125	59.58	51.21	67.43
3. No, do not require CofA from any suppliers (Skip to question 6.7)	14	10.53	4.93	21.08	3	1.11	0.35	3.45	0	0.00	0.00	0.00	17	5.14	2.60	9.92
4. Do not receive ingredients (Skip to question 6.7)	6	6.40	2.00	18.62	3	4.76	1.24	16.56	1	7.62	1.03	39.47	10	5.63	2.48	12.27
Don't know	2	1.06	0.26	4.23	0	0.00	0.00	0.00	0	0.00	0.00	0.00	2	0.46	0.11	1.84
No answer	7	7.16	2.48	18.96	3	1.90	0.51	6.88	1	4.49	0.61	26.47	11	4.32	1.89	9.58
6.5 [If 6.4 is Yes] Does this plant verify the reliability of the suppliers' *Certificate of Analysis*?																
1. Yes	46	66.65	51.67	78.88	85	80.62	68.80	88.70	10	87.43	60.01	96.99	141	75.62	67.14	82.48
2. No (Skip to question 6.7)	33	32.33	20.25	47.33	20	19.38	11.30	31.20	2	12.57	3.01	39.99	55	23.99	17.16	32.48
No answer	2	1.02	0.26	3.93	0	0.00	0.00	0.00	0	0.00	0.00	0.00	2	0.39	0.10	1.52

(continued)

Table D-6. Weighted Responses for Section 6: Quality Control and Laboratory Operations (continued)

	Very Small (n = 110)				Small (n = 114)				Large (n = 14)				Overall (n = 238)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
6.6* [If 6.5 is Yes] How is reliability of the suppliers' *Certificate of Analysis* verified?																
1 Conduct on-site review of suppliers' operations	20	57.74	38.59	74.81	33	29.92	20.82	40.94	9	90.08	52.32	98.69	62	43.16	32.61	54.37
2. Perform tests in-house to confirm results	12	20.92	9.33	40.50	57	68.63	54.57	79.93	10	100.00	100.00	100.00	79	54.42	43.60	64.83
3. Use off-site laboratory to confirm results	32	74.19	53.37	87.84	63	68.50	53.79	80.25	4	35.91	13.14	67.47	99	68.37	57.29	77.70
4. Require suppliers to conduct tests as part of supply specifications	17	50.37	30.64	69.98	33	42.45	29.60	56.40	4	35.91	13.14	67.47	54	44.72	34.42	55.50
5. Standard reference materials	16	30.43	15.72	50.64	35	39.73	27.17	53.80	3	25.99	7.95	58.80	54	35.70	25.88	46.90
6 Other	3	8.13	1.96	28.12	2	3.72	0.65	18.59	1	9.92	1.31	47.68	6	5.60	2.25	13.27
No answer	2	2.08	0.51	8.08	1	1.53	0.21	10.39	0	0.00	0.00	0.00	3	1.62	0.45	5.63
6.7* Does this plant conduct tests on any *raw materials*?																
1. Yes, in-house	45	31.56	21.50	43.70	78	70.16	58.24	79.85	10	73.32	44.42	90.43	133	53.55	45.26	61.66
2 Yes, off-site	48	45.32	32.51	58.78	68	59.33	47.23	70.40	4	29.40	11.26	57.76	120	51.67	43.08	60.17
3. No (Skip to question 6.14)	23	21.47	12.13	35.13	11	9.53	4.41	19.40	2	15.66	3.50	48.70	36	15.04	9.73	22.52
Not applicable (Skip to question 6.14)	7	6.89	2.32	18.74	0	0.00	0.00	0.00	0	0.00	0.00	0.00	7	2.99	1.01	8.55
No answer	5	5.72	1.59	18.55	4	2.39	0.77	7.15	1	4.49	0.61	26.47	10	3.94	1.62	9.28

(continued)

Table D-6. Weighted Responses for Section 6: Quality Control and Laboratory Operations (continued)

	Very Small (n = 110)				Small (n = 114)				Large (n = 14)				Overall (n = 238)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
6.8 [If 6.7 is Yes] What percentage of raw materials are sampled and tested? *(Provide average for all raw materials.)*																
% of lots (mean response)	71	58.49	44.87	72.11	96	70.64	59.91	81.37	11	93.20	83.87	102.54	178	67.48	59.43	75.53
6.9* [If 6.7 is Yes] Which of the following testing techniques are used to confirm *identity of ingredients* for raw materials?																
1. Physical	61	76.08	57.62	88.16	85	88.94	79.76	94.25	10	90.46	53.91	98.71	156	84.30	75.52	90.34
2. Chemical	35	59.40	44.41	72.82	76	82.51	72.88	89.22	11	100.00	100.00	100.00	122	74.96	67.54	81.17
3. Microbiological	30	53.88	39.01	68.09	53	57.49	44.55	69.48	7	61.83	31.65	85.00	90	56.40	47.06	65.30
4. Visual (macroscopic or microscopic)	54	62.88	45.49	77.48	73	78.26	68.68	85.53	7	61.83	31.65	85.00	134	71.73	62.41	79.50
5. Organoleptic	34	33.66	21.70	48.16	59	61.11	48.15	72.67	5	46.36	20.44	74.41	98	50.24	40.72	59.74
6. No tests are conducted to confirm identity of ingredients	1	5.29	0.72	29.93	1	0.52	0.07	3.71	0	0.00	0.00	0.00	2	2.24	0.39	11.85
7. Other	5	8.71	2.43	26.73	8	4.49	2.04	9.60	0	0.00	0.00	0.00	13	5.80	2.62	12.33
No answer	0	0.00	0.00	0.00	1	0.37	0.05	2.62	0	0.00	0.00	0.00	1	0.21	0.03	1.52

(continued)

Table D-6. Weighted Responses for Section 6: Quality Control and Laboratory Operations (continued)

	Very Small (n = 110)				Small (n = 114)				Large (n = 14)				Overall (n = 238)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
6.10* [If 6.7 is Yes] Which of the following testing techniques are used for detecting *contamination* of raw materials?																
1. Physical	50	65.48	48.49	79.26	68	68.38	56.04	78.58	7	61.83	31.65	85.00	125	66.96	57.52	75.22
2. Chemical	31	54.24	39.31	68.44	51	49.84	37.35	62.36	9	80.91	47.11	95.28	91	53.13	43.81	62.23
3. Microbiological	44	67.04	51.71	79.44	77	74.26	60.62	84.39	7	61.83	31.65	85.00	128	70.94	61.34	78.98
4. Visual (macroscopic or microscopic)	53	63.35	45.94	77.86	76	81.50	72.34	88.13	6	52.28	24.62	78.61	135	73.27	64.00	80.86
5. Organoleptic	32	31.64	20.08	46.02	45	49.68	37.11	62.29	3	27.28	8.85	59.16	80	41.85	32.67	51.64
6. No tests are conducted to detect contamination	1	5.29	0.72	29.93	1	0.55	0.08	3.87	1	9.54	1.29	46.09	3	2.77	0.64	11.23
7. Other	2	1.61	0.39	6.42	4	2.10	0.79	5.43	0	0.00	0.00	0.00	6	1.80	0.82	3.94
No answer	0	0.00	0.00	0.00	2	1.66	0.33	7.92	0	0.00	0.00	0.00	2	0.96	0.19	4.65
6.11 [If 6.7 is Yes] Does this plant conduct chemical tests to determine *potency* of raw materials?																
1. Yes	28	38.38	24.01	55.11	71	75.86	63.93	84.78	10	91.81	58.94	98.87	109	62.96	53.58	71.46
2. No	45	55.54	39.45	70.55	26	22.48	13.84	34.35	1	8.19	1.13	41.06	72	33.85	25.87	42.87
No answer	2	6.08	1.06	28.17	2	1.66	0.33	7.92	0	0.00	0.00	0.00	4	3.19	0.85	11.27

(continued)

Table D-6. Weighted Responses for Section 6: Quality Control and Laboratory Operations (continued)

	Very Small (n = 110)				Small (n = 114)				Large (n = 14)				Overall (n = 238)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
6.12 [If 6.7 is Yes] For the most recent fiscal year, approximately what percentage of raw materials was rejected because of the wrong identity, contamination, or potency?																
% of lots (mean response)	74	2.58	1.02	4.15	95	3.84	2.37	5.32	11	1.78	0.75	2.80	180	3.26	2.24	4.29
6.13 [If 6.12 > 0] What was the reason(s) for the rejection? (mean response in %)																
1. Microbial contamination	41	28.85	13.26	44.43	72	35.41	24.69	46.12	8	7.87	0.59	15.16	121	31.86	23.51	40.20
2. Pesticide, herbicide, fungicide contamination	41	2.77	0.02	5.52	72	1.04	0.00[b]	2.29	8	3.28	0.00[b]	7.37	121	1.66	0.53	2.80
3. Other chemical contamination	41	0.66	0.00[b]	1.57	72	3.75	0.37	7.13	8	25.86	0.00[b]	52.66	121	4.25	1.32	7.18
4. Wrong ingredient	41	23.56	10.28	36.82	72	14.68	8.05	21.31	8	2.10	0.00[b]	4.62	121	16.40	10.55	22.25
5 Subpotency	41	27.47	18.94	36.00	72	21.95	11.45	32.45	8	29.66	9.05	50.26	121	23.98	16.54	31.43
6. Superpotency	41	2.01	0.00[b]	5.30	72	1.37	0.00[b]	2.91	8	2.62	0.04	5.21	121	1.63	0.26	2.99
7. Aflatoxin or other toxin	41	0.34	0.00[b]	1.02	72	1.23	0.00[b]	2.85	8	0.00	0.00	0.00	121	0.90	0.00[b]	1.98
8. Other	41	14.35	4.34	24.35	72	20.57	12.49	28.66	8	28.61	0.00[b]	58.22	121	19.32	13.06	25.58

(continued)

Table D-6. Weighted Responses for Section 6: Quality Control and Laboratory Operations (continued)

	Very Small (n = 110)				Small (n = 114)				Large (n = 14)				Overall (n = 238)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
6 14 Does this plant conduct tests on any *in-process materials and/or finished products?*																
1. Yes	61	55.81	42.08	68.71	91	79.94	68.05	88.17	10	73.32	44.42	90.43	162	69.11	60.65	76.45
2. No (Skip to question 6.21)	37	31.69	20.60	45.34	21	19.30	11.16	31.28	2	15.66	3.50	48.70	60	24.49	17.72	32.81
Not applicable (Skip to question 6.21)	8	7.14	2.51	18.65	0	0.00	0.00	0.00	1	6.54	0.90	34.91	9	3.45	1.32	8.70
No answer	4	5.36	1.38	18.67	2	0.76	0.18	3.09	1	4.49	0.61	26.47	7	2.96	0.99	8.53
6.15 [If 6.14 is Yes] What percentage of in-process materials and/or finished products ... are sampled and tested?																
In-process materials: % of batches (mean response)	60	48.76	31.01	66.51	89	58.20	47.44	68.97	10	91.68	75.98	107.39	159	56.76	47.49	66.02
Finished products: % of batches (mean response)	60	50.19	32.60	67.79	89	72.32	62.79	81.86	10	89.61	69.97	109.24	159	65.46	56.54	74.37

(continued)

Table D-6. Weighted Responses for Section 6: Quality Control and Laboratory Operations (continued)

	Very Small (n = 110)				Small (n = 114)				Large (n = 14)				Overall (n = 238)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
6.16* [If 6.14 is Yes] Which of the following testing techniques are used to confirm *identity of ingredients* for in-process materials and/or finished products?																
1. Physical	48	83.46	69.34	91.85	61	71.56	60.05	80.81	8	79.21	43.95	94.88	117	76.16	68.43	82.49
2. Chemical	21	45.50	28.81	63.27	66	74.47	62.04	83.89	10	100.00	100.00	100.00	97	65.73	56.01	74.29
3. Microbiological	19	36.01	20.40	55.27	35	40.16	28.04	53.62	6	58.42	27.81	83.67	60	39.72	30.13	50.17
4. Visual (macroscopic or microscopic)	38	53.17	35.55	70.04	62	71.16	60.18	80.12	6	58.42	27.81	83.67	106	64.14	53.86	73.27
5. Organoleptic	25	30.61	18.01	46.99	47	57.50	44.99	69.12	4	41.58	16.33	72.19	76	47.18	37.13	57.47
6. No tests are conducted to confirm identity of ingredients	1	0.93	0.13	6.52	3	1.56	0.50	4.73	0	0.00	0.00	0.00	4	1.25	0.47	3.28
7. Other	7	12.63	4.28	31.87	4	3.19	1.07	9.13	1	10.39	1.39	48.80	12	6.90	3.17	14.39
No answer	1	0.93	0.13	6.52	3	3.40	1.00	10.89	0	0.00	0.00	0.00	4	2.35	0.80	6.68

(continued)

Table D-6. Weighted Responses for Section 6: Quality Control and Laboratory Operations (continued)

	Very Small (n = 110)				Small (n = 114)				Large (n = 14)				Overall (n = 238)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
6.17* [If 6.14 is Yes] Which of the following testing techniques are used for detecting *contamination* of in-process materials and/or finished products?																
1. Physical	40	68.61	50.80	82.23	47	49.93	37.09	62.78	7	68.82	35.66	89.78	94	57.54	47.48	67.00
2. Chemical	21	44.06	27.51	62.05	40	38.13	26.57	51.20	8	79.21	43.95	94.88	69	42.50	32.89	52.71
3. Microbiological	33	62.17	45.41	76.46	66	75.07	62.71	84.36	7	68.82	35.66	89.78	106	70.20	60.83	78.13
4. Visual (macroscopic or microscopic)	37	57.42	38.89	74.08	55	64.97	52.42	75.75	6	58.42	27.81	83.67	98	61.96	51.72	71.23
5. Organoleptic	24	29.20	16.89	45.56	36	47.27	35.10	59.79	2	20.79	5.12	56.05	62	39.46	29.89	49.91
6. No tests are conducted to detect contamination	1	0.93	0.13	6.52	5	4.64	1.76	11.69	1	10.39	1.39	48.80	7	3.66	1.64	7.97
7 Other	4	4.00	1.39	10.97	4	4.01	1.37	11.18	1	10.39	1.39	48.80	9	4.36	2.12	8.75
No answer	2	1.90	0.46	7.56	3	3 40	1.00	10.89	0	0.00	0.00	0.00	5	2.69	1.01	6.92
6.18 [If 6.14 is Yes] Does this plant conduct chemical tests to determine *potency* of in-process materials and/or finished products?																
1. Yes	25	49.56	32.38	66.85	70	82.44	73.10	89.03	10	100.00	100.00	100.00	105	71.88	62.85	79.44
2. No	35	49.51	32.33	66.80	18	14.16	8.50	22.64	0	0.00	0.00	0.00	53	25.77	18.52	34.65
No answer	1	0.93	0.13	6.52	3	3.40	1.00	10.89	0	0.00	0.00	0.00	4	2.35	0.80	6.68

(continued)

Table D-6. Weighted Responses for Section 6: Quality Control and Laboratory Operations (continued)

	Very Small (n = 110)				Small (n = 114)				Large (n = 14)				Overall (n = 238)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
6.19 [If 6.14 is Yes] For the most recent fiscal year, approximately what percentage of in-process materials and/or finished products was rejected because of the wrong identity, contamination, or potency?																
In-process materials: % of batches (mean response)	44	2.07[c]	0.00[b]	4.90	71	1.88	0.63	3.14	10	2.82	0.79	4.84	125	2.01	0.82	3.20
Finished products: % of batches (mean response)	49	2.23[c]	0.00[b]	4.94	80	4.85	1.14	8.56	9	3.72	1.35	6.10	138	3.95	1.48	6.42
6.20 [If 6.19 > 0] What was the reason(s) for the rejection?																
In-Process Materials (mean responses in %)																
1. Microbial contamination	20	11.85	0.00[b]	25.73	37	28.65	9.87	47.42	7	5.80	0.44	11.16	64	21.55	9.25	33.86
2. Pesticide, herbicide, fungicide contamination	20	0.00	0.00	0.00	37	0.08	0.00[b]	0.25	7	0.00	0.00	0.00	64	0.05	0.00[b]	0.15
3. Other chemical contamination	20	3.96	0.00[b]	11.88	37	5.22	0.00[b]	11.48	7	9.16	0.00[b]	23.46	64	5.33	0.82	9.85
4. Wrong ingredient	20	18.13	0.80	35.47	37	11.84	1.53	22.15	7	0.91	0.00[b]	2.32	64	12.29	3.46	21.11
5. Subpotency	20	15.69	0.00[b]	31.48	37	14.60	6.23	22.96	7	61.48	32.07	90.88	64	20.21	12.06	28.35
6. Superpotency	20	0.00	0.00	0.00	37	4.31	0.67	7.95	7	1.51	0.00[b]	3.77	64	2.84	0.68	4.99
7 Formulation with missing ingredient	20	6.64	0.00[b]	15.58	37	10.16	2.68	17.63	7	6.19	0.00[b]	17.62	64	8.77	3.71	13.82
8. Aflatoxin or other toxin	20	1.80	0.00[b]	5.50	37	0.00	0.00	0.00	7	0.00	0.00	0.00	64	0.48	0.00[b]	1.45
9. Other	20	41.92	9.87	73.98	37	25.15	12.00	38.30	7	14.95	0.00[b]	40.10	64	28.49	17.44	39.54

(continued)

Table D-6. Weighted Responses for Section 6: Quality Control and Laboratory Operations (continued)

	Very Small (n = 110)				Small (n = 114)				Large (n = 14)				Overall (n = 238)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
6.20 (continued)																
Finished Products (mean responses in %)																
1. Microbial contamination	22	26.32	8.63	44.01	48	16.68	5.33	28.02	8	4.09	0.00[b]	8.31	78	17.83	9.26	26.39
2. Pesticide, herbicide, fungicide contamination	22	0.71	0.00[b]	2.17	48	0.00	0.00	0.00	8	1.97	0.00[b]	5.69	78	0.35	0.00[b]	0.85
3. Other chemical contamination	22	1.42	0.00[b]	3.42	48	2.47	0.00[b]	6.24	8	15.86	0.00[b]	34.21	78	3.46	0.31	6.60
4. Wrong ingredient	22	9.53	0.00[b]	20.21	48	15.11	4.69	25.54	8	1.97	0.00[b]	5.69	78	12.56	5.37	19.75
5. Subpotency	22	17.41	3.88	30.95	48	23.34	11.76	34.91	8	39.76	10.37	69.15	78	23.43	13.51	33.36
6. Superpotency	22	0.00	0.00	0.00	48	5.43	0.57	10.30	8	1.44	0.00[b]	4.17	78	3.76	0.52	7.00
7. Formulation with missing ingredient	22	0.87	0.00[b]	2.60	48	3.08	0.49	5.67	8	1.31	0.00[b]	3.79	78	2.39	0.48	4.30
8. Aflatoxin or other toxin	22	0.00	0.00	0.00	48	0.00	0.00	0.00	8	0.00	0.00	0.00	78	0.00	0.00	0.00
9. Other	22	43.73	20.63	66.83	48	33.89	20.13	47.65	8	33.59	5.43	61.75	78	36.22	24.97	47.48

(continued)

Table D-6. Weighted Responses for Section 6: Quality Control and Laboratory Operations (continued)

	Very Small (n = 110)				Small (n = 114)				Large (n = 14)				Overall (n = 238)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
6.21* Which of the following testing methods are generally used for testing of raw materials, in-process materials, or finished products?																
1. Association of Analytical Chemists (AOAC)	28	25.25	15.29	38.74	67	58.80	46.73	69.90	3	21.78	7.03	50.64	98	42.28	34.07	50.94
2. U.S. Pharmacopeia (USP)	27	33.61	21.61	48.19	76	72.07	61.19	80.86	10	73.32	44.42	90.43	113	55.43	47.34	63.24
3. Food Chemical CODEX (FCC)	11	12.59	5.83	25.12	43	45.60	34.47	57.19	7	49.37	24.71	74.35	61	31.46	23.94	40.09
4. American Chemical Society (ACS)	6	4.02	1.66	9.41	22	20.79	12.66	32.21	0	0.00	0.00	0.00	28	12.41	7.90	18.98
5. In-house methods	49	40.33	28.34	53.60	63	57.37	45.38	68.56	8	58.08	31.45	80.71	120	50.01	41.52	58.49
6. Other	27	20.12	12.13	31.48	24	18.92	11.40	29.74	1	7.62	1 03	39.47	52	18.85	13.35	25.93
7. No testing conducted (Skip to question 6 24)	16	14.72	7.26	27.56	10	8.12	3.44	17.97	2	15.66	3.50	48.70	28	11.38	6.83	18.36
Don't know	0	0.00	0.00	0.00	1	2.44	0.34	15.37	0	0.00	0 00	0.00	1	1.25	0.17	8.41
No answer	8	7.73	2.86	19.22	2	0.76	0.18	3.09	1	4.49	0.61	26.47	11	3.98	1.70	9.08
6.22 [If 6.2 is 1-6] Does your testing policy specify the use of standard reference materials?																
1. Yes	47	48.90	34.59	63.39	78	72.45	59.72	82.35	11	94.68	69.66	99.28	136	63.72	54.43	72.08
2. No (Skip to question 6.24)	34	36.64	23.83	51.67	18	18.01	10.24	29.74	0	0.00	0.00	0.00	52	24.90	17.69	33.85
Don't know	2	1.28	0.31	5.09	0	0.00	0.00	0.00	0	0.00	0.00	0.00	2	0.53	0.13	2.14
No answer	11	13.18	5.71	27.56	8	9.53	4.07	20.76	1	5.32	0.72	30.34	20	10.85	6.07	18.64

(continued)

Table D-6. Weighted Responses for Section 6: Quality Control and Laboratory Operations (continued)

	Very Small (n = 110)				Small (n = 114)				Large (n = 14)				Overall (n = 238)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
6.23* [If 6.22 is Yes] What is the source of the standard reference materials?																
1. Compendial reference standard	18	51.40	32.06	70.32	61	86.26	77.44	91.99	10	90.46	53.65	98.73	89	75.39	66.56	82.50
2. In-house *primary* reference materials	23	39.05	22.30	58.85	40	53.61	39.85	66.84	10	90.46	53.65	98.73	73	51.67	40.53	62.66
3. In-house *working* reference materials	22	30.80	18.86	46.02	39	50.68	36.40	64.84	10	90.46	53.65	98.73	71	47.25	36.57	58.19
4. Other	5	7.69	3.09	17.87	7	7.19	3.13	15.67	0	0.00	0.00	0.00	12	6.82	3.70	12.27
No answer	2	9.60	1.65	40.14	2	2.41	0.52	10.48	0	0.00	0.00	0.00	4	4.54	1.23	15.36
6.24 Does your plant hold representative reserve samples of each batch manufactured?																
1. Yes	73	64.98	50.98	76.80	96	83.67	72.25	90.97	10	72.24	42.95	89.99	179	74.95	66.64	81.75
2. No (Skip to question 6.26)	24	21.73	12.39	35.28	12	12.32	5.90	23.96	2	15.66	3.50	48.70	38	16.58	10.90	24.42
Not applicable (Skip to question 6.26)	8	7.41	2.67	18.95	0	0.00	0.00	0.00	0	0.00	0.00	0.00	8	3.22	1.16	8.61
No answer	5	5.88	1.68	18.58	6	4.01	1.62	9.59	2	12.11	2.81	39.67	13	5.25	2.53	10.55

(continued)

Table D-6. Weighted Responses for Section 6: Quality Control and Laboratory Operations (continued)

	Very Small (n = 110)				Small (n = 114)				Large (n = 14)				Overall (n = 238)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
6.25 [If 6.24 is Yes] How long do you hold representative reserve samples?																
1. ____ year(s) after expiration date	21	26.18	14.54	42.50	39	46.09	33.67	59.02	5	52.75	23.96	79.82	65	38.93	29.68	49.05
2. ____ year(s) from date of manufacture	39	58.78	42.20	73.59	44	40.63	29.35	53.00	4	38.20	14.42	69.40	87	47.34	37.72	57.17
3. Other	11	13.44	5.58	28.98	10	7.81	3.88	15.10	0	0.00	0.00	0.00	21	9.53	5.41	16.27
Don't know	0	0.00	0.00	0.00	0	0.00	0.00	0.00	1	9.05	1.24	44.01	1	0.46	0.06	3.26
No answer	2	1.60	0.39	6.27	3	5.47	1.36	19.49	0	0.00	0.00	0.00	5	3.73	1.13	11.67
Mean years after expiration date	21	2.79	1.58	4.00	39	1.91	1.44	2.38	5	1.00	1.00	1.00	65	2.07	1.56	2.58
Mean years from date of manufacture	39	4.52	3.87	5.17	44	4.11	3.47	4.75	4	4.72	2.72	6.73	87	4.33	3.85	4.81
6.26 Are there written procedures for *laboratory operations*?																
1. Yes	39	30.17	20.15	42.51	74	64.49	52.21	75.11	9	65.70	37.75	85.82	122	49.64	41.72	57.57
2. No (Skip to question 6.31)	20	10.51	6.77	15.95	10	14.69	7.26	27.45	1	4.51	0.61	26.58	31	12.34	7.64	19.31
3. Do not have laboratory operations (Skip to Section 7)	46	53.45	40.63	65.83	25	18.00	10.82	28.44	1	11.15	1.56	49.74	72	33.04	25.45	41.63
Don't know	0	0.00	0.00	0.00	0	0.00	0.00	0.00	1	6.54	0.90	34.91	1	0.34	0.05	2.44
No answer	5	5.88	1.68	18.58	5	2.83	1.04	7.48	2	12.11	2.81	39.67	12	4.64	2.12	9.86

(continued)

Table D-6. Weighted Responses for Section 6: Quality Control and Laboratory Operations (continued)

	Very Small (n = 110)				Small (n = 114)				Large (n = 14)				Overall (n = 238)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
6.27 [If 6.26 is Yes] Does plant management verify and keep records that these procedures are being followed?																
1 Yes	32	85.91	71.54	93.67	68	90.44	79.85	95.76	9	100.00	100.00	100.00	109	89.91	82.59	94.36
2. No (Skip to question 6.29)	7	14.09	6.33	28.46	4	6.02	2.15	15.76	0	0.00	0.00	0.00	11	7.73	4.06	14.24
No answer	0	0.00	0.00	0.00	2	3.54	0.87	13.29	0	0.00	0.00	0.00	2	2.36	0.58	9.04
6 28 [If 6.27 is Yes] Are records made of any corrective actions taken if procedures are *not* followed?																
1. Yes, for some procedures	14	47.63	24.89	71.39	32	42.81	28.87	57.99	2	23.20	5.67	60.31	48	42.51	31.00	54.89
2. Yes, for all procedures	14	44.17	22.11	68.80	30	48.64	34.11	63.41	7	76.80	39.69	94.33	51	49.69	37.74	61.67
3. No	4	8.20	2.85	21.37	6	8.55	3.60	18.97	0	0.00	0.00	0.00	10	7.80	3.94	14.84

(continued)

Table D-6. Weighted Responses for Section 6: Quality Control and Laboratory Operations (continued)

	Very Small (n = 110)				Small (n = 114)				Large (n = 14)				Overall (n = 238)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
6.29* [If 6.26 is Yes] Do your written procedures for laboratory operations include any of the following?																
1. Sample selection, method description, validation of methodology and results, acceptance/rejection criteria, and use of test results	31	86.53	73.78	93.62	68	88.72	72.96	95.82	9	100.00	100.00	100.00	108	88.93	78.66	94.59
2. Methods for determining ingredient identity and for detecting adulteration	25	72.53	55.45	84.85	58	78.80	64.20	88.51	9	100.00	100.00	100.00	92	78.62	68.26	86.28
3. Tests to assess the stability characteristics of products in determining appropriate storage conditions and expiration dating (include testing conducted at corporate headquarters)	19	56.90	38.14	73.88	43	58.58	43.64	72.09	9	100.00	100.00	100.00	71	61.01	49.32	71.56
4. Procedures for handling and filing test records	24	72.61	56.34	84.48	53	73.16	58.63	83.98	9	100.00	100.00	100.00	86	74.88	64.37	83.10
No answer	2	3.44	0.83	13.23	1	1.77	0.24	11.89	0	0.00	0.00	0.00	3	2.09	0.58	7.22

(continued)

Table D-6. Weighted Responses for Section 6: Quality Control and Laboratory Operations (continued)

	Very Small (n = 110)				Small (n = 114)				Large (n = 14)				Overall (n = 238)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
6.30 [If 6.26 is Yes] How long are records for laboratory operations retained?																
1. ___ year(s) after expiration date	9	28.58	11.93	54.18	25	36.69	23.75	51.90	4	46.40	18.30	76.99	38	35.23	24.90	47.15
2. ___ year(s) from date of manufacture	20	52.99	31.53	73.41	31	40.15	27.16	54.68	5	53.60	23.01	81.70	56	44.47	33.56	55.94
3. Other	8	14.99	7.01	29.20	17	21.39	11.69	35.85	0	0.00	0.00	0.00	25	18.21	11.04	28.55
No answer	2	3.44	0.83	13.23	1	1.77	0.24	11.89	0	0.00	0.00	0.00	3	2.09	0.58	7.22
Mean years after expiration date	9	3.51	—	—[a]	25	1.80	—	—[a]	4	3.00	—	—[a]	38	2.28	—	—[a]
Mean years from date of manufacture	20	4.89	3.79	5.99	31	4.67	3.61	5.73	5	6.08	5.27	6.89	56	4.86	4.14	5.57
6.31 [If 6.26 is 1 or 2] Does this plant verify and keep records that laboratory equipment is calibrated correctly?																
1. Yes	36	69.39	55.82	80.27	72	76.73	62.20	86.85	9	93.58	64.78	99.14	117	75.64	65.41	83.60
2. No	20	26.52	16.69	39.40	11	21.83	12.03	36.31	1	6.42	0.86	35.22	32	22.25	14.60	32.39
Don't know	1	1.28	0.17	8.84	0	0.00	0.00	0.00	0	0.00	0.00	0.00	1	0.36	0.05	2.59
No answer	2	2.81	0.73	10.25	1	1.44	0.20	9.77	0	0.00	0.00	0.00	3	1.75	0.50	5.86

[a]Confidence interval could not be estimated because there was only one observation (respondent) in a stratum for that question.

[b]Estimated confidence interval for lower bound was less than zero so we truncated the interval.

[c]One respondent in the very small category entered 100% for question 6.19 for both in-process materials and finished products. The means excluding this response are 0.66 for in-process materials and 0.89 for finished products for very small respondents and 1.55 for in-process materials and 3.54 for finished products for all respondents. This respondent did not answer question 6.20.

[d]Confidence interval could not be estimated because of matrix conformability error.

*Total may sum to greater than 100% because respondents could select more than one answer.

Table D-7. Weighted Responses for Section 7: Production and Process Controls

	Very Small (n = 110)				Small (n = 114)				Large (n = 14)				Overall (n = 238)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
7.1 Are there written procedures for *receipt of dietary supplement ingredients*?																
1. Yes	56	52.68	39.22	65.77	86	81.14	71.24	88.19	10	75.76	48.32	91.26	152	68.49	60.21	75.75
2. No (Skip to question 7.6)	23	21.43	12.10	35.08	13	6.38	3.48	11.40	1	4.51	0.61	26.58	37	12.82	8.17	19.55
3. Do not receive dietary supplement ingredients (Skip to question 7.6)	25	19.24	10.99	31.50	12	10.58	5.13	20.56	2	15.24	3.77	45.23	39	14.59	9.59	21.57
No answer	6	6.65	2.14	18.79	3	1.90	0.51	6.88	1	4.49	0.61	26.47	10	4.10	1.72	9.43
7.2 [If 7.1 is Yes] Does plant management verify and keep records that these procedures are being followed?																
1. Yes	45	77.24	56.71	89.79	75	86.08	73.69	93.17	10	100.00	100.00	100.00	130	83.93	74.03	90.54
2. No (Skip to question 7.4)	11	22.76	10.21	43.29	10	12.52	5.82	24.87	0	0.00	0.00	0.00	21	15.21	8.77	25.08
No answer	0	0.00	0.00	0.00	1	1.41	0.19	9.57	0	0.00	0.00	0.00	1	0.85	0.12	5.94
7.3 [If 7.2 is Yes] Are records made of any corrective actions taken if procedures are *not* followed?																
1 Yes, for some procedures	24	43.29	27.45	60.62	35	45.42	31.72	59.86	2	24.77	6.18	62.21	61	43.34	32.35	55.03
2. Yes, for all procedures	13	38.98	20.98	60.58	27	37.65	24.46	52.96	7	65.17	31.51	88.38	47	39.96	29.14	51.87
3. No	7	9.17	4.18	18.93	13	16.93	9.17	29.15	1	10.06	1.33	48.19	21	14.07	8.62	22.12
No answer	1	8.57	1.17	42.62	0	0.00	0.00	0.00	0	0.00	0.00	0.00	1	2.63	0.35	17.14

(continued)

Table D-7. Weighted Responses for Section 7: Production and Process Controls (continued)

	Very Small (n = 110)				Small (n = 114)				Large (n = 14)				Overall (n = 238)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
7.4* [If 7.1 is Yes] Do your written procedures for receipt of dietary supplement ingredients include any of the following?																
1. Written acceptance criteria for dietary supplement ingredients developed by a competent individual	37	57.67	38.69	74.62	68	79.36	65.76	88.50	10	100.00	100.00	100.00	115	73.31	62.59	81.85
2. Certificate of Analysis specifications	43	86.82	77.78	92.54	80	95.42	88.71	98.22	10	100.00	100.00	100.00	133	92.82	88.60	95.55
3. Representative sample and authenticated plant reference held in an environmentally appropriate repository for each receiving and production lot/batch	23	41.65	24.73	60.79	55	65.97	52.09	77.57	7	65.17	31.61	88.34	85	57.80	47.01	67.89
4. Records linking the Certificate of Analysis to the identity of the unprocessed raw material and to the finished product	42	83.40	71.86	90.81	65	77.75	64.26	87.17	7	69.82	36.59	90.27	114	79.18	70.06	86.07
5. Records to trace and verify compliance with laws on harvest of wildcrafted botanicals	10	10.07	5.37	18.08	9	11.09	4.52	24.74	0	0.00	0.00	0.00	19	10.11	5.35	18.28
6. Audit records concerning the reliability of supplier Certificate of Analysis	12	29.48	14.84	50.06	29	35.83	23.64	50.16	8	75.23	37.92	93.79	49	35.99	26.39	46.86
7. Records for source of animal derived materials or products	6	17.75	6.53	40.00	17	21.75	12.49	35.12	0	0.00	0.00	0.00	23	19.15	11.81	29.53

(continued)

Table D-7. Weighted Responses for Section 7: Production and Process Controls (continued)

	Very Small (n = 110)				Small (n = 114)				Large (n = 14)				Overall (n = 238)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
7.4 [Continued]																
8. Records for fish and fishery demonstrating that FDA fish and fishery products HACCP regulations are followed	1	1.03	0.14	7.18	1	0.57	0.08	4.03	1	8.63	1.18	42.85	3	1.19	0.38	3.66
9. Records for raw materials to assure segregation of raw, in-process, and finished product and protection against adulteration	26	44.76	27.76	63.09	46	55.85	42.16	68.70	7	65.17	31.61	88.34	79	52.68	42.00	63.13
No answer	0	0.00	0.00	0.00	1	1.41	0.19	9.57	0	0.00	0.00	0.00	1	0.85	0.12	5.94
7.5 [If 7.1 is Yes] How long are records on receipt of dietary supplement ingredients retained?																
1. _____ year(s) after expiration date	14	22.86	11.20	41.05	29	33.56	22.00	47.51	3	30.18	9.73	63.41	46	29.79	21.15	40.16
2. _____ year(s) from date of manufacture	28	55.72	37.40	72.60	30	31.15	20.61	44.09	5	45.05	18.62	74.60	63	40.17	30.53	50.62
3. Other	9	9.29	4.61	17.86	26	33.88	22.14	48.01	2	24.77	6.21	62.08	37	25.14	16.97	35.55
Don't know	2	7.60	1.32	33.64	0	0.00	0.00	0.00	0	0.00	0.00	0.00	2	2.54	0.44	13.45
No answer	3	4.53	1.26	14.99	1	1.41	0.19	9.57	0	0.00	0.00	0.00	4	2.37	0.81	6.74
Mean years after expiration date	14	3.17	—	—[a]	29	1.94	—	—[a]	3	3.00	—	—[a]	46	2.31	—	—[a]
Mean years from date of manufacture	28	4.07	—	—[a]	30	4.79	—	—[a]	5	6.50	—	—[a]	63	4.57	—	—[a]

(continued)

Table D-7. Weighted Responses for Section 7: Production and Process Controls (continued)

	Very Small (n = 110)				Small (n = 114)				Large (n = 14)				Overall (n = 238)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
7.6 Are there written procedures for *production processes*?																
1. Yes	65	55.54	41.78	68.50	94	80.39	68.23	88.67	12	91.00	69.49	97.82	171	70.15	61.67	77.44
2. No (Skip to question 7.11)	14	7.27	4.31	12.00	9	8.07	3.37	18.08	1	4.51	0.61	26.58	24	7.53	4.43	12.53
3. No production processes conducted (Skip to Section 8)	24	30.01	18.43	44.87	7	9.15	3.58	21.50	0	0.00	0.00	0.00	31	17.74	11.58	26.19
No answer	7	7.19	2.50	18.98	4	2.39	0.77	7.15	1	4.49	0.61	26.47	12	4.58	2.08	9.78
7.7 [If 7.6 is Yes] Does plant management verify and keep records that these procedures are being followed?																
1. Yes	55	90.49	82.95	94.90	92	98.01	91.27	99.57	12	100.00	100.00	100.00	159	95.56	92.13	97.53
2. No (Skip to question 7.9)	8	7.60	3.76	14.74	2	1.99	0.43	8.73	0	0.00	0.00	0.00	10	3.79	1.96	7.20
No answer	2	1.91	0.46	7.58	0	0.00	0.00	0.00	0	0.00	0.00	0.00	2	0.66	0.16	2.63
7.8 [If 7.7 is Yes] Are records made of any corrective actions taken if procedures are *not* followed?																
1. Yes, for some procedures	23	45.63	27.92	64.52	45	45.63	33.00	58.84	2	20.62	5.13	55.54	70	43.85	33.92	54.29
2. Yes, for all procedures	22	43.20	25.92	62.30	35	40.83	28.79	54.08	9	71.00	38.82	90.43	66	43.75	34.14	53.86
3. No	10	11.17	5.76	20.57	12	13.54	7.12	24.23	1	8.37	1.12	42.46	23	12.40	7.80	19.14

(continued)

Table D-7. Weighted Responses for Section 7: Production and Process Controls (continued)

	Very Small (n = 110)				Small (n = 114)				Large (n = 14)				Overall (n = 238)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
7.9* [If 7.6 is Yes] Do your written procedures for production processes include any of the following?																
1. Master production and control records	44	66.83	48.54	81.15	85	94.54	88.86	97.40	12	100.00	100.00	100.00	141	85.38	77.18	90.98
2. Batch production and control records	59	88.93	69.17	96.64	91	97.99	93.71	99.38	12	100.00	100.00	100.00	162	95.01	87.60	98.09
3. Equipment use and cleaning records, including dates of use and product and lot number of each batch processed	44	72.20	55.90	84.18	80	83.27	70.90	91.05	11	91.63	57.59	98.88	135	80.03	71.14	86.69
4. Records that demonstrate that automatic equipment, including mechanical and electronic equipment (computers), used in the manufacturing process is designed, installed, tested, calibrated, validated, maintained, and checked to ensure that they are capable of and are performing the intended functions	21	32.39	18.20	50.77	50	52.92	39.93	65.53	10	83.25	51.34	95.90	81	47.93	38.14	57.88
5. Records for reprocessing of a product	31	46.35	29.89	63.65	71	78.05	65.91	86.73	10	79.38	44.49	94.87	112	67.24	57.28	75.85
6. Records to assure that correct labels and labeling and safe packaging materials are used	51	81.69	64.86	91.51	73	80.42	68.48	88.59	12	100.00	100.00	100.00	136	82.19	73.50	88.47
7. Records to permit tracking the history of the manufacturing process	54	83.32	65.63	92.89	89	96.82	92.35	98.71	12	100.00	100.00	100.00	155	92.39	85.61	96.12

(continued)

Table D-7. Weighted Responses for Section 7: Production and Process Controls (continued)

	Very Small (n = 110)				Small (n = 114)				Large (n = 14)				Overall (n = 238)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
7.9 [Continued]																
8. Reserve samples of each batch of dietary supplement product are retained and stored under conditions consistent with the product labeling	51	80.88	63.87	91.01	90	96.04	88.88	98.66	12	100.00	100.00	100.00	153	91.10	83.98	95.23
No answer	2	1.91	0.46	7.58	0	0.00	0.00	0.00	0	0.00	0.00	0.00	2	0.66	0.16	2.63
7.10 [If 7.6 is Yes] How long are records on production processes retained?																
1 ____ year(s) after expiration date	14	20.40	9.79	37.69	34	38.29	26.45	51.71	3	25.12	8.11	56.07	51	31.24	22.73	41.24
2. ____ year(s) from date of manufacture	36	63.22	46.78	77.06	42	40.49	29.03	53.10	6	45.88	20.96	73.05	84	48.68	38.90	58.55
3 Other	9	10.21	5.01	19.71	18	21.22	12.08	34.56	2	20.62	5.13	55.51	29	17.39	11.04	26.31
Don't know	0	0.00	0.00	0.00	0	0.00	0.00	0.00	1	8.37	1.12	42.41	1	0.57	0.08	4.03
No answer	6	6.18	2.65	13.71	0	0.00	0.00	0.00	0	0.00	0.00	0.00	6	2.12	0.94	4.71
Mean years after expiration date	14	3.09	—	—[a]	34	2.22	—	—[a]	3	3.00	—	—[a]	51	2.46	—	—[a]
Mean years from date of manufacture	36	4.90	—	—[a]	42	4.48	—	—[a]	6	6.41	—	—[a]	84	4.79	—	—[a]
7.11 [If 7.6 is NOT 3] Does this plant use production and process controls that identify the points, steps, or stages in the manufacturing process to prevent adulteration?																
1 Yes	48	56.99	41.78	70.99	83	77.88	65.77	86.58	10	76.84	50.25	91.60	141	70.09	61.27	77.64
2. No (Skip to Section 8)	23	22.70	13.15	36.30	17	16.62	8.98	28.72	2	11.05	2.66	36.09	42	18.51	12.46	26.61
Don't know	0	0.00	0.00	0.00	0	0.00	0.00	0.00	0	0.00	0.00	0.00	0	0.00	0.00	0.00
No answer	15	20.31	10.04	36.78	7	5.49	2.36	12.25	2	12.11	2.80	39.71	24	11.39	6.63	18.88

(continued)

Table D-7. Weighted Responses for Section 7: Production and Process Controls (continued)

	Very Small (n = 110)				Small (n = 114)				Large (n = 14)				Overall (n = 238)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
7.12* [If 7.11 is Yes] Does this plant's production and process controls have specifications that must be met for identity, purity, quality, strength, and composition of components, ingredients, or dietary supplements and packing and labeling materials?																
1. Yes, for components	31	75.31	61.18	85.51	45	53.94	39.99	67.30	10	100.00	100 00	100.00	86	63.58	52.78	73.18
2. Yes, for ingredients	40	88.65	77.83	94.56	67	83.07	71.54	90.54	8	75.58	38.28	93.92	115	84.22	76.40	89.80
3. Yes, for dietary supplements	35	81.80	69.31	89.94	60	70.85	56.67	81.88	9	90.08	52.31	98.69	104	75.49	65.48	83 33
4. Yes, for packing and labeling materials	36	79.32	64.73	88.90	50	58.49	44.29	71.40	8	80.16	45.20	95.19	94	66.26	55.38	75.66
5. No, none of the above	1	1.98	0.26	13.40	4	5.17	1.33	18.09	0	0.00	0.00	0.00	5	3.85	1.19	11.76
No answer	1	1.30	0.17	9.04	0	0.00	0.00	0.00	0	0.00	0.00	0.00	1	0.39	0.05	2.78

(continued)

Table D-7. Weighted Responses for Section 7: Production and Process Controls (continued)

	Very Small (n = 110)				Small (n = 114)				Large (n = 14)				Overall (n = 238)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
7.13* [If 7.11 is Yes] Does this plant conduct tests to monitor the production and in-process control points, steps, or stages to ensure the identity, purity, quality, strength, and composition of components, ingredients, or dietary supplements?																
1. Yes, for components	17	32.62	17.03	53.31	43	46.00	32.92	59.65	7	65.66	32.00	88.60	67	43.35	33.26	54.03
2. Yes, for ingredients	29	52.62	32.73	71.72	57	65.98	53.28	76.73	6	55.74	25.37	82.35	92	61.25	50.25	71.21
3. Yes, for dietary supplements	27	57.90	37.42	75.99	54	63.30	49.26	75.39	8	75.58	38.28	93.92	89	62.53	51.51	72.40
4. No, none of the above	9	25.87	10.82	50.10	12	15.22	7.90	27.31	1	14.50	2.01	58.36	22	18.37	11.01	29.04
No answer	1	1.30	0.17	9.04	0	0.00	0.00	0.00	0	0.00	0.00	0.00	1	0.39	0.05	2.78

[a]Confidence interval could not be estimated because there was only one observation (respondent) in a stratum for that question.

*Total may sum to greater than 100% because respondents could select more than one answer.

Table D-8. Weighted Responses for Section 8: Warehousing

	Very Small (n = 110)				Small (n = 114)				Large (n = 14)				Overall (n = 238)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
8.0 Does this plant or site have warehouses to store raw materials, in-process materials, or finished products?																
1. Yes	104	93.87	81.59	98.15	113	99.68	97.70	99.96	13	95.51	73.53	99.39	230	96.94	91.52	98.93
2. No (Skip to Section 9)	6	6.13	1.85	18.41	1	0.32	0.04	2.30	1	4.49	0.61	26.47	8	3.06	1.07	8.48
8.1* Does your warehouse have temperature or humidity controls?																
1. Temperature controls	72	74.04	61.19	83.77	72	67.90	56.20	77.72	8	66.39	38.36	86.25	152	70.40	62.28	77.41
2. Humidity controls	13	19.27	9.56	35.03	23	23.54	14.53	35.79	3	27.63	9.17	59.07	39	21.95	15.15	30.71
3. No temperature or humidity controls	32	25.96	16.23	38.81	41	32.10	22.28	43.80	5	33.61	13.75	61.64	78	29.60	22.59	37.72
8.2 Are there written procedures for *storage procedures* to control against physical, chemical, and microbial adulteration as well as deterioration of the product and container?																
1. Yes	47	49.70	36.07	63.37	77	66.71	54.77	76.83	11	87.30	58.83	97.06	135	60.62	51.85	68.74
2. No (Skip to question 8.7)	56	49.75	36.14	63.40	36	33.29	23.17	45.23	2	12.70	2.94	41.17	94	39.15	31.03	47.92
No answer	1	0.55	0.08	3.90	0	0.00	0.00	0.00	0	0.00	0.00	0.00	1	0.23	0.03	1.65

(continued)

Table D-8. Weighted Responses for Section 8: Warehousing (continued)

	Very Small (n = 110)				Small (n = 114)				Large (n = 14)				Overall (n = 238)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
8.3 [If 8.2 is Yes] Does plant management verify and keep records that these procedures are being followed?																
1. Yes	30	68.94	48.05	84.19	67	92.64	85.65	96.37	11	100.00	100.00	100.00	108	85.01	76.03	91.03
2. No (Skip to question 8.5)	17	31.06	15.81	51.95	9	6.87	3.26	13.93	0	0.00	0.00	0.00	26	14.70	8.72	23.72
No answer	0	0.00	0.00	0.00	1	0.49	0.07	3.47	0	0.00	0.00	0.00	1	0.28	0.04	2.02
8.4 [If 8.3 is Yes] Are records made of any corrective actions taken if procedures are *not* followed?																
1. Yes, for some procedures	13	43.26	20.70	69.01	31	38.26	24.58	54.09	1	7.84	1.07	40.08	45	36.99	25.72	49.89
2. Yes, for all procedures	17	56.74	30.99	79.30	27	46.44	31.10	62.48	9	83.02	50.44	95.92	53	52.52	39.73	64.99
3. No	0	0.00	0.00	0.00	7	11.60	4.32	27.62	1	9.14	1.20	45.47	8	8.14	3.24	19.01
No answer	0	0.00	0.00	0.00	2	3.70	0.91	13.86	0	0.00	0.00	0.00	2	2.34	0.58	8.96
8.5* [If 8.2 is Yes] Do your written procedures for warehousing include any of the following?																
1. Procedures and records for forward and backward tracing of product	43	94.97	86.35	98.26	71	92.27	76.92	97.71	10	90.86	54.71	98.79	124	93.10	84.44	97.10
2. Procedures and records for salvaged products that include product examination and reprocessing as appropriate	23	35.47	19.92	54.84	59	78.15	64.16	87.72	10	90.86	54.71	98.79	92	64.37	52.44	74.75
No answer	3	3.34	1.05	10.08	3	2.32	0.67	7.73	0	0.00	0.00	0.00	6	2.50	1.09	5.63

(continued)

Table D-8. Weighted Responses for Section 8: Warehousing (continued)

	Very Small (n = 110)				Small (n = 114)				Large (n = 14)				Overall (n = 238)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
8.6 [If 8.2 is Yes] How long are records on warehousing retained?																
1. _____ year(s) after expiration date	14	29.06	14.09	50.55	27	30.66	19.55	44.58	2	18.28	4.43	51.90	43	29.18	20.28	40.03
2. _____ year(s) from date of manufacture	22	50.13	30.12	70.10	25	29.71	18.42	44.16	7	59.21	28.92	83.82	54	38.95	28.48	50.54
3. Other	7	14.55	4.76	36.71	20	32.29	19.95	47.71	1	13.37	1.84	55.88	28	24.76	15.96	36.32
Don't know	1	1.16	0.16	8.10	0	0.00	0.00	0.00	0	0.00	0.00	0.00	1	0.40	0.06	2.85
No answer	3	5.11	1.42	16.81	5	7.35	2.94	17.18	1	9.14	1.21	45.29	9	6.71	3.42	12.73
Mean years after expiration date	14	1.97	—	—[a]	27	2.29	—	—[a]	2	4.00	—	—[a]	43	2.26	—	—[a]
Mean years from date of manufacture	22	4.71	—	—[a]	25	4.30	—	—[a]	7	4.96	—	—[a]	54	4.56	—	—[a]
8.7 Are there written procedures on proper precautions to *reduce the potential for mix-ups or adulteration or contamination* of ingredients, raw materials, or in-process formulations (e.g., safety controls and operating practices or separation of ingredients)?																
1. Yes	50	40.31	28.51	53.35	86	76.04	64.43	84.75	11	87.30	58.83	97.06	147	61.59	52.92	69.58
2. No (Skip to Section 9)	44	44.34	31.08	58.46	25	21.67	13.36	33.18	2	12.70	2.94	41.17	71	30.75	23.23	39.44
Not applicable	5	6.24	1.78	19.67	0	0.00	0.00	0.00	0	0.00	0.00	0.00	5	2.62	0.75	8.80
Don't know	2	1.13	0.28	4.51	0	0.00	0.00	0.00	0	0.00	0.00	0.00	2	0.48	0.12	1.90
No answer	3	7.98	2.23	24.80	2	2.29	0.57	8.78	0	0.00	0.00	0.00	5	4.56	1.65	12.00

(continued)

Table D-8. Weighted Responses for Section 8: Warehousing (continued)

	Very Small (n = 110)				Small (n = 114)				Large (n = 14)				Overall (n = 238)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
8.8 [If 8.7 is Yes] Does plant management verify and keep records that these procedures are being followed?																
1. Yes	41	87.90	77.28	93.95	77	90.73	82.13	95.42	11	100.00	100.00	100.00	129	90.63	84.93	94.32
2. No (Skip to Section 9)	8	10.67	5.14	20.84	9	9.27	4.58	17.87	0	0.00	0.00	0.00	17	8.97	5.35	14.67
No answer	1	1.43	0.19	9.84	0	0.00	0.00	0.00	0	0.00	0.00	0.00	1	0.39	0.05	2.80
8.9 [If 8.8 is Yes] Are records made of any corrective actions taken if procedures are *not* followed?																
1. Yes, for some procedures	20	45.47	27.75	64.41	40	47.88	33.42	62.70	0	0.00	0.00	0.00	60	43 36	32.35	55.06
2. Yes, for all procedures	14	34.39	17.35	56.68	30	41.99	27.97	57.44	10	90.86	54.71	98.79	54	43.91	32.77	55.70
3. No	6	9.66	4.08	21.21	7	10.13	4.16	22.66	1	9.14	1 21	45.29	14	9.93	5.20	18.13
No answer	1	10.48	1.49	47.48	0	0.00	0.00	0.00	0	0.00	0.00	0.00	1	2.80	0.37	18.09

[a]Confidence interval could not be estimated because there was only one observation (respondent) in a stratum for that question.

*Total may sum to greater than 100% because respondents could select more than one answer.

Table D-9. Weighted Responses for Section 9: Consumer Complaints

	Very Small (n = 110)				Small (n = 114)				Large (n = 14)				Overall (n = 238)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
9.1 Are there written procedures at the plant or corporate level for handling *consumer complaints*?																
1. Yes	52	55.44	42.10	68.03	85	77.68	67.24	85.52	13	95.49	73.42	99.39	150	68.95	60.93	75.98
2. No (Skip to question 9.6)	55	42.96	30.51	56.38	26	19.71	12.35	29.95	1	4.51	0.61	26.58	82	29.01	22.16	36.99
Not applicable (Skip to Section 10)	2	1.06	0.26	4.23	0	0.00	0.00	0.00	0	0.00	0.00	0.00	2	0.46	0.11	1.84
No answer	1	0.54	0.07	3.82	3	2.60	0.75	8.68	0	0.00	0.00	0.00	4	1.57	0.53	4.60
9.2 [If 9.1 is Yes] Does management verify and keep records that these procedures are being followed?																
1. Yes	46	88.95	68.85	96.70	79	93.96	85.99	97.53	13	100.00	100.00	100.00	138	92.65	84.93	96.58
2. No (Skip to question 9.4)	6	11.05	3.30	31.15	6	6.04	2.47	14.01	0	0.00	0.00	0.00	12	7.35	3.42	15.07
9.3 [If 9.2 is Yes] Are records made of any corrective actions taken if procedures are *not* followed?																
1. Yes, for some procedures	14	35.62	18.38	57.60	37	47.00	33.00	61.49	3	24.35	7.49	56.15	54	41.40	30.73	52.96
2. Yes, for all procedures	23	43.95	25.18	64.63	33	41.78	28.17	56.77	9	67.67	37.62	87.90	65	44.54	33.65	55.99
3. No	8	13.36	5.10	30.67	9	11.22	5.09	22.92	1	7.98	1.06	41.19	18	11.68	6.70	19.59
No answer	1	7.07	0.95	37.56	0	0.00	0.00	0.00	0	0.00	0.00	0.00	1	2.37	0.32	15.56

(continued)

Table D-9. Weighted Responses for Section 9: Consumer Complaints (continued)

	Very Small (n = 110)				Small (n = 114)				Large (n = 14)				Overall (n = 238)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
9.4* [If 9.1 is Yes] Do your written procedures for handling consumer complaints include any of the following?																
1. Procedures for handling all written and oral complaints	47	95.18	88.52	98.06	81	96.05	88.64	98.70	13	100.00	100.00	100.00	141	96.04	91.92	98.10
2. Records concerning the handling of complaints including any investigations, investigation findings, and follow-up action taken	39	65.44	44.02	82.01	79	91.81	78.37	97.20	12	95.30	72.43	99.37	130	82.85	71.90	90.12
3. Procedures for requiring reporting of serious adverse events to FDA MEDWATCH	4	4.27	1.49	11 64	13	18.74	9.71	33.09	4	31 92	12 26	61.16	21	14.64	8.61	23.81
Don't know	1	0.94	0.13	6.60	0	0.00	0.00	0.00	0	0.00	0.00	0.00	1	0.33	0.05	2.33
No answer	1	0.94	0.13	6.60	0	0.00	0.00	0.00	0	0 00	0.00	0.00	1	0.33	0.05	2 33
9.5 [If 9.1 is Yes] How long are records on consumer complaints retained at the plant or corporate headquarters?																
1. _____ year(s) after expiration date	11	25.60	11.59	47.44	35	42 54	29.40	56.82	2	15.96	3.90	47.04	48	34.69	24.95	45.91
2. _____ year(s) from date of manufacture	20	43.10	25.18	63.04	25	25.43	15.60	38.61	3	19.78	6.16	48.09	48	31.19	22.10	42.01
3. Other	16	21.27	10.44	38.50	25	32.03	20.35	46.51	6	51.58	25 71	76.63	47	29.69	21.00	40.15
Don't know	3	8.16	1.68	31.63	0	0.00	0.00	0.00	0	0.00	0.00	0.00	3	2.85	0.59	12.71
No answer	2	1.87	0.46	7.33	0	0.00	0.00	0.00	2	12.68	2.91	41.32	4	1.58	0.56	4.33
Mean years after expiration date	11	1.50	1.03	1.97	35	2.22	1.56	2.88	2	5.50	0.00[a]	12.16	48	2.14	1.65	2.64
Mean years from date of manufacture	20	4.47	3.86	5.09	25	4.23	3.54	4.91	3	5.11	2.98	7.25	48	4.39	3.95	4.82

(continued)

Table D-9. Weighted Responses for Section 9: Consumer Complaints (continued)

	Very Small (n = 110)				Small (n = 114)				Large (n = 14)				Overall (n = 238)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
9.6* What are your procedures for handling adverse events associated with consumer complaints?																
1. Incident is reported to FDA	15	19.37	9.90	34.43	17	17.24	9.69	28.79	5	32.10	13.20	59.52	37	18.94	12.70	27.30
2. Product is tested for identity and composition	66	62.40	48.41	74.58	83	73.98	62.49	82.91	8	56.99	30.46	80.04	157	68.08	59.55	75.55
3. Product is reformulated	19	19.23	10.64	32.23	34	34.49	23.93	46.84	5	34.13	14.36	61.56	58	27.88	20.79	36.28
4. Product is recalled	59	60.13	46.51	72.35	75	62.60	50.43	73.36	6	41.75	19.33	68.20	140	60.43	51.80	68.47
5. Other	34	25.62	16.25	37.93	22	22.15	13.42	34.29	4	34.01	13.51	62.97	60	24.27	17.67	32.37
Don't know	2	1.05	0.26	4.14	0	0.00	0.00	0.00	0	0.00	0.00	0.00	2	0.45	0.11	1.79
No answer	3	1.62	0.52	4.95	8	5.25	2.42	11.02	1	4.49	0.61	26.47	12	3.64	1.97	6.63
9.7 Does this plant have a recall procedure in place?																
1. Yes	70	68.43	55.12	79.27	91	80.16	68.75	88.13	11	76.75	45.88	92.78	172	74 91	66.86	81.55
2. No	36	30.48	19.74	43.86	17	15.17	8.14	26.53	1	11.15	1.56	49.75	54	21.57	15.30	29.52
No answer	2	1.10	0.27	4.26	6	4.66	1.92	10.91	2	12.11	2.80	39.67	10	3.51	1.80	6.76

(continued)

Table D-9. Weighted Responses for Section 9: Consumer Complaints (continued)

	Very Small (n = 110)				Small (n = 114)				Large (n = 14)				Overall (n = 238)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
9.8* Who evaluates reports on consumer complaints?																
1. In-house medical personnel	16	11.10	5.98	19.68	11	10.04	4.50	20.92	4	27.35	10.17	55.59	31	11.41	7.22	17.57
2. In-house scientific personnel	23	23.64	14.05	36.96	58	53.31	41.41	64.85	8	53.86	28.01	77.79	89	40.53	32.53	49.06
3. In-house quality control personnel	70	61.61	47.35	74.13	93	82.84	72.68	89.76	13	92.38	60.53	98.97	176	74.18	65.75	81.13
4. In-house regulatory affairs personnel	15	14.02	6.98	26.15	44	39.62	28.72	51.67	6	38.62	17.42	65.23	65	28.51	21.40	36.88
5. Outside contractor	12	12.41	5.46	25.80	13	9.69	4.61	19.23	1	11.15	1.56	49.75	26	10.94	6.44	17.98
6. Other	29	29.28	18.20	43.51	21	15.13	8.79	24.78	1	7.62	1.03	39.47	51	20.84	14.64	28.79
Don't know	1	3.52	0.48	21.57	0	0.00	0.00	0.00	0	0.00	0.00	0.00	1	1.52	0.21	10.26
No answer	1	0.55	0.08	3.86	3	1.92	0.52	6.90	0	0.00	0.00	0.00	4	1.23	0.40	3.69

[a]Estimated confidence interval for lower bound was less than zero so we truncated the interval.

*Total may sum to greater than 100% because respondents could select more than one answer.

Table D-10. Weighted Responses for Section 10: Your Plant

	Very Small (n = 110)				Small (n = 114)				Large (n = 14)				Overall (n = 238)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
10.1 What was the calendar year during which this plant was built? *(If multiple buildings, use date of oldest building.)*																
Year (mean response)	80	1981	1977	1985	102	1979	1975	1982	12	1967	1956	1978	194	1979	1976	1982
10.2 What was the calendar year during which the *dietary supplement operations* began at this plant? (If multiple buildings, use date of earliest operation.)																
Year (mean response)	95	1992	1990	1994	103	1989	1986	1991	13	1971	1958	1983	211	1989	1988	1991
10.3 What is the total square footage of this plant?																
Square feet (mean response)	91	24,675	355	48,994	102	71,355	52,980	89,730	11	595,734	3,771	1,187,696	204	75,733	42,203	109,263
10.4 Are this plant's facilities connected to a city water supply?																
1. Yes (Skip to question 10.6)	86	80.90	68.58	89.16	88	80.90	69.92	88.53	12	87.89	60.33	97.19	186	81.27	73.83	86.97
2. No	17	12.20	6.23	22.52	20	13.18	7.31	22.61	1	7.62	1.03	39.47	38	12.47	8.12	18.67
Don't know	2	4.00	0.70	19.90	0	0.00	0.00	0.00	0	0.00	0.00	0.00	2	1.74	0.30	9.37
No answer	5	2.89	1.16	7.01	6	5.91	1.97	16.41	1	4.49	0.61	26.47	12	4.52	2.05	9.70

(continued)

Table D-10 Weighted Responses for Section 10: Your Plant (continued)

	Very Small (n = 110)				Small (n = 114)				Large (n = 14)				Overall (n = 238)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
10.5 [If 10.4 is No] Is the water supply at this plant potable?																
1. Yes	12	54.43	22.21	83.32	16	88.26	68.34	96.32	1	100.00	100.00	100.00	29	74.25	42.21	91.92
2. No	3	12.75	3.54	36.82	1	2.45	0.29	17.89	0	0.00	0.00	0.00	4	6.76	2.54	16.77
Don't know	0	0.00	0.00	0.00	1	3.33	0.41	22.35	0	0.00	0.00	0.00	1	1.81	0.23	12.85
No answer	2	32.82	7.19	75.49	2	5.95	1.20	24.86	0	0.00	0.00	0.00	4	17.19	3.34	55.52
10.6 Does your company own plants at other locations?																
1. Yes	15	21.49	11.45	36.68	33	24.54	16.47	34.91	10	75.76	48.32	91.26	58	25.91	19.12	34.08
2. No	90	75.89	61.11	86.32	74	66.40	54.60	76.46	3	19.75	6.14	48.10	167	68.08	59.55	75.55
No answer	5	2.62	1.08	6.20	7	9.05	3.65	20.74	1	4.49	0.61	26.47	13	6.02	2.88	12.14
10.7 How many employees are currently employed at this plant?																
1. Full-time (mean response)	102	7.63	6.06	9.20	103	95.51	73.20	117.81	13	1,005.23	300.43	1,710.03	218	105.47	58.66	152.27
2. Part-time (mean response)	56	18.80	0.00[a]	50.45	47	12.83	4.39	21.26	6	53.30	15.74	90.87	109	17.64	1.04	34.23
10.8 How many employees employed at this plant are working in *quality control*?																
1. Full-time (mean response)	79	3.01	0.18	5.85	99	7.24	5.31	9.17	12	88.24	25.65	150.83	190	10.27	5.51	15.03
2. Part-time (mean response)	49	1.65	1.29	2.02	37	3.28	0.52	6.04	5	2.79	0.00[a]	6.71	91	2.49	1.08	3.90

(continued)

Table D-10 Weighted Responses for Section 10: Your Plant (continued)

	Very Small (n = 110)				Small (n = 114)				Large (n = 14)				Overall (n = 238)			
			95% CI				95% CI				95% CI				95% CI	
	n	mean	Low	High	n	mean	Low	High	n	mean	Low	High	n	mean	Low	High
10.9 For the most recent fiscal year, provide the number of batches of *dietary supplement* product by product form. (Mean response in batches)																
a. Powder	87	49.71	20.79	78.63	76	120.54	80.18	160.90	12	85.98	0.00[a]	182.43	175	84.60	59.57	109.62
b. Liquid	87	45.60	25.11	66.09	76	80.30	30.55	130.04	12	5.13	0.00[a]	15.09	175	59.04	33.33	84.75
c. Paste	87	0.04	0.00[a]	0.09	76	14.20	0.00[a]	38.12	12	0.00	0.00	0.00	175	6.56	0.00[a]	17.59
d. Capsule	87	55.57	23.25	87.89	76	138.68	78.39	198.96	12	13.51	0.00[a]	31.19	175	91.20	57.49	124.91
e. Tablet or caplet	87	53.92	5.91	101.93	76	171.63	93.50	249.77	12	170.88	39.25	302.52	175	115.45	70.79	160.10
f. Gelcap	87	0.40	0.00[a]	1.07	76	18.35	3.42	33.27	12	2.23	0.00[a]	6.46	175	8.78	1.88	15.67
g. Other	87	14.07	3.90	24.25	76	10.33	2.01	18.66	12	31.22	0.00[a]	91.00	175	13.42	6.28	20.56
h. Other	87	3.64	0.00[a]	9.12	76	0.04	0.00[a]	0.12	12	0.00	0.00	0.00	175	1.75	0.00[a]	4.35
Total	87	222.95	134.52	311.38	76	554.07	407.25	700.89	12	308.96	181.59	436.33	175	380.80	292.64	468.95

(continued)

Table D-10 Weighted Responses for Section 10: Your Plant (continued)

	Very Small (n = 110)				Small (n = 114)				Large (n = 14)				Overall (n = 238)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
10.10 What were the gross sales revenue for the *dietary supplement operations only* at this plant for the most recent fiscal year?																
1. Less than $500,000	47	34.11	23.66	46.37	21	14.30	8.17	23.84	1	4.51	0.61	26.58	69	22.39	16.66	29.40
2. $500,000 to just under $1 million	20	19.64	10.62	33.44	6	2.68	1.16	6.04	0	0.00	0.00	0.00	26	9.90	5.70	16.66
3. $1 to just under $2.5 million	18	23.97	13.42	39.06	10	13.17	6.18	25.86	1	6.54	0.90	34.91	29	17.51	11.37	26.00
4. $2.5 to just under $5 million	9	7.94	3.39	17.49	7	6.24	2.19	16.51	1	7.62	1.03	39.47	17	7.05	3.70	13.03
5. $5 to just under $10 million	2	0.92	0.22	3.76	24	24.00	14.89	36.31	2	12.11	2.81	39.67	28	13.35	8.33	20.72
6. $10 to just under $20 million	3	1.63	0.51	5.05	14	10.32	5.77	17.80	2	15.24	3.77	45.23	19	6.81	4.22	10.80
7. $20 to just under $50 million	2	4.00	0.70	19.90	12	12.76	6.63	23.14	2	12.35	2.89	40.02	16	8.93	4.94	15.62
8. $50 to just under $100 million	0	0.00	0.00	0.00	2	0.92	0.23	3.56	2	18.77	4.70	51.97	4	1.46	0.51	4.11
9. $100 to just under $500 million	1	3.49	0.48	21.37	5	5.34	2.22	12.27	2	15.24	3.77	45.23	8	5.06	2.30	10.75
10. $500 million or more	0	0.00	0.00	0.00	0	0.00	0.00	0.00	0	0.00	0.00	0.00	0	0.00	0.00	0.00
Don't know	0	0.00	0.00	0.00	2	1.58	0.34	7.03	0	0.00	0.00	0.00	2	0.81	0.18	3.66
No answer	8	4.31	2.09	8.66	11	8.69	4.59	15.86	1	7.62	1.03	39.47	20	6.73	4.20	10.61

[a]Estimated confidence interval for lower bound was less than zero so we truncated the interval.

Table D-11. Verbatims for Question 2.4: Why Does this Plant Not Follow Published GMPs?

Very Small

It is not a manufacturing facility. Just a sales and marketing site.

All products distributed are produced by other companies in facilities wholly within their control.

We sub-contract with packaging companies for actual supplement manufacturing. (We do not have production facility).

OEM customers do not want to pay for extensive costs, i.e. lab tests of raw materials even finished products.

Don't manufacture—we rely on manufacturers.

Not a plant.

We do not manufacture products, we distribute finished products only.

Proposed rule making not finalized.

Very expensive—we are small.

We don't manufacture.

Do not understand exact meaning.

We are not manufacturer in this place. Only office here.

Current program stronger than GMPs.

Not a manufacturer—only resell bulk ingredients.

We import products that are made overseas and depend on our suppliers to follow GMP standards.

Products produced by approved vendor.

Not sure how GMPs apply to my company. Too busy struggling to survive to find out.

Our plant is staffed by only two people—myself and my wife. We simply warehouse and re-ship products which are packed by private companies.

Not familiar.

We manufacture single herb tea grown on our biological reserve. As a small company with one product that we control from seed to mature plant.

Not familiar with them.

Not required.

(continued)

Table D-11. Verbatims for Question 2.4: Why Does this Plant Not Follow Published GMPs? (continued)

Very Small (continued)

It is not a manufacturing facility. Just a sales and marketing site.

Too costly and unnecessary in our situation.

Not applicable—we don't manufacture products.

Do not have enough information—will set up in 2000.

We do not manufacture.

We are just a sales and marketing office.

I don't think they are adequate for botanical identity.

It doesn't seem necessary. We know the contents/purity of the goods we make, and have our own standards for purity and sanitation.

Published procedures are generally not applicable or practical for an herbal manufacturing company of our size.

We do not trust the intent of the inspectors. We are afraid that they may acquire proprietary manufacturing practices from us.

I was told by an FDA staff member that GMPs did not apply to our operation.

Only because I don't have a copy of published GMPs and didn't know where to access this information.

Unavailable—guidelines not established.

GMP not readily available and the expense involved

Not a manufacturer.

Manufacturing is not done at this plant but items in question 2.3 are kept on file by our supplier

We employ the services of contract manufacturers for all our products Consequently, the questions in sections 3-7 are not applicable.

Small

I don't manufacture anything or encapsulate anything—I'm not a plant.

Distribution only

Limited resources

We are strictly a distributor and rely on our vendors to have GMPs.

We are a business office.

Current operations have proven adequate and safe over many years. Thousands of satisfied customers with very few complaints.

(continued)

Table D-11. Verbatims for Question 2.4: Why Does this Plant Not Follow Published GMPs? (continued)

Small (continued)
Not economically feasible.
Too costly to implement.
We handle 80-90% raw materials of herbs—only about 5 kinds of herbs that's all.
In development at this time.
Dietary supplement product lines are not extensive enough to warrant following a published GMP model.
We are not aware of published GMPs for importers who do not ever open drums. The producers follow published GMP.
We do not manufacture or bottle the product—Only private label and distribute.
We are not a manufacturer and this is not a plant.
We are in the process of implementing new procedures.
We follow specific procedures defined by clients and we are using our own GMP system.
We feel we have GMPs in place. They just aren't the GMPs that someone else established, they're are [*sic*] own.
Work in process. Goal to be by 6/2000.
None of the actual manufacturing done at this location.
We are not manufacturer. Our manufacturer follows China's and/or Australia's GMPs.
Raw ingredient supplier.
We are a distributor.
We are a farm and produce bulk herbs mostly.
Contract manufacturers—make and package our products—we repackage into point of sale displays only.
Local sanitation dept standards.

Appendix E: Weighted Results by Product Type

The results for each section of the survey are reported in a separate table (e.g., Table E-1 corresponds to Section 1 of the survey). For each question response item, we provide the number of respondents who circled that answer (n), the proportion of respondents who circled that answer (%), and the 95 percent confidence interval for the point estimate (Low and High values). Where appropriate, we report the mean response.

The totals for a question may not always sum to 100 percent due to rounding. We have indicated with an (*) when respondents could select more than one response.

Because of the skip patterns, the number of respondents varies by question. We excluded from the analysis respondents who appropriately skipped questions. For example, respondents who answered 2 (No) to Question 2.5 were not included in the frequency for Question 2.6.

Table E-1. Weighted Responses for Section 1: Products and Markets

	Vitamins and Minerals (n = 118)				Aminos/Proteins/Animal Extracts (n = 16)				Herbals and Botanicals (n = 97)				Other (n = 7)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
1.1* Which of the following describes the dietary supplement operations at this plant?																
1 Manufacturer—manufacture dietary supplements from ingredients, may package and label the product itself or transfer it to a repackager/relabeler/encapsulator or distributor	77	63.54	51.71	73.94	7	43.26	21.81	67.57	59	60.77	47.60	72.54	3	47.28	16.09	80.74
2. Repackager/relabeler/encapsulator—repackage, relabel, or encapsulate dietary supplements manufactured by another firm	50	42.57	31.63	54.29	3	17.92	5.70	44.08	13	16.47	7.93	31.09	1	17.58	2.37	65 22
3. Ingredient or input supplier—supply ingredients or bulk finished products used to manufacture dietary supplements at this plant or another firm	38	28.51	19.27	39.98	4	24.47	9.31	50.56	34	37.70	25.60	51.56	3	35.21	11.07	70.34
4. Distributor—distribute products manufactured by this plant or another firm	76	61.29	49.41	71.96	7	44.79	22.78	69.05	48	44.53	32 39	57.36	4	59.34	23.54	87.37
5. Importer—import either ingredients for further processing or finished products for distribution	36	32.37	22.35	44.32	5	30.73	13.23	56.37	30	24.89	16.93	35.01	2	23.67	5.68	61.47
6. Exporter—export either ingredients for further processing or finished products for distribution	46	36.88	26.53	48.59	4	24.18	9.04	50.57	29	30.32	19.57	43.76	1	12.12	1.63	53 50
7. Other	4	3.83	1.05	12.92	1	6.26	0.83	34.72	5	4.13	1.72	9.59	0	0.00	0.00	0.00
No answer	0	0.00	0.00	0.00	0	0.00	0.00	0.00	2	3.06	0.67	12.81	0	0.00	0.00	0.00

(continued)

Table E-1. Weighted Responses for Section 1: Products and Markets (continued)

	Vitamins and Minerals (n = 118)				Aminos/Proteins/Animal Extracts (n = 16)				Herbals and Botanicals (n = 97)				Other (n = 7)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
1.2 For your dietary supplement operations at this plant, what is the product type for your *primary line of business?*[a]																
1. Vitamins and minerals	60	53.24	41.82	64.32	0	0.00	0.00	0.00	0	0.00	0.00	0.00	0	0.00	0.00	0.00
2. Herbals and botanicals, not including extracts	16	15.70	8.54	27.10	1	5.97	0.82	32.74	41	39.36	28.12	51.84	0	0.00	0.00	0.00
3. Herbal and botanical extracts	21	15.44	8.92	25.38	2	11.66	2.91	36.72	41	37.19	26.96	48.71	0	0.00	0.00	0.00
4. Amino acids	1	0.35	0.05	2.48	3	18.79	6.12	45.06	0	0.00	0.00	0.00	0	0.00	0.00	0.00
5 Protein products	4	3.31	0.81	12.52	7	45.37	23.07	69.70	0	0.00	0.00	0.00	0	0.00	0.00	0.00
6. Animal extracts	0	0.00	0.00	0.00	0	0.00	0.00	0.00	0	0.00	0.00	0.00	0	0.00	0.00	0.00
7. Concentrates, metabolites, and constituents	2	2.50	0.41	13.77	0	0.00	0.00	0.00	0	0.00	0.00	0.00	2	29.64	7.09	69.93
8. Other	3	3.01	0.64	12.92	0	0.00	0.00	0.00	3	12.18	3.73	33.20	5	70.36	30.07	92.91
Respondent selected multiple responses	9	5.74	2.87	11.15	3	18.21	5.81	44.56	11	10.40	5.39	19.12	0	0.00	0.00	0.00
Non-dietary supplement product	2	0.72	0.18	2.87	0	0.00	0.00	0.00	0	0.00	0.00	0.00	0	0.00	0.00	0.00
No answer	0	0.00	0.00	0.00	0	0.00	0.00	0.00	1	0.88	0.12	6.12	0	0.00	0.00	0.00

(continued)

Table E-1. Weighted Responses for Section 1: Products and Markets (continued)

	Vitamins and Minerals (n = 118)				Aminos/Proteins/Animal Extracts (n = 16)				Herbals and Botanicals (n = 97)				Other (n = 7)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
1.3* What *other* product types, not including your primary line of business, *do you produce* at this plant? By produce we mean, manufacture, repack/relabel/ encapsulate, supply ingredients, distribute, import, or export.																
1. Vitamins and minerals	58	46.76	35.68	58.18	0	0.00	0.00	0.00	0	0.00	0.00	0.00	0	0.00	0.00	0.00
2. Herbals and botanicals, not including extracts	67	59.76	48.05	70.46	1	5.69	0.79	31.29	29	37.58	25.45	51.49	0	0.00	0.00	0.00
3. Herbal and botanical extracts	48	40.26	29.57	51.96	5	29.87	12.62	55.69	32	32.92	22.41	45.47	0	0.00	0.00	0.00
4. Amino acids	52	45.79	34.83	57.19	3	18.79	6.12	45.06	0	0.00	0.00	0.00	0	0.00	0.00	0.00
5. Protein products	39	34.84	24.78	46.45	2	12.24	2.95	38.98	0	0.00	0.00	0.00	0	0.00	0.00	0.00
6 Animal extracts	22	22.49	13.85	34.38	5	29.87	12.62	55.69	0	0.00	0.00	0.00	0	0.00	0.00	0.00
7 Concentrates, metabolites, and constituents	24	23.68	15.02	35.25	3	18.50	5.87	45.25	2	3.02	0.66	12.77	0	0.00	0.00	0.00
8. Other	3	0.95	0.30	2.96	2	12.52	3.07	39.25	2	2.16	0.51	8.61	1	12.12	1.63	53.50
Non-dietary supplement product	11	6.39	3.46	11.51	4	24.18	9.04	50.57	8	7.92	3.66	16.29	0	0.00	0.00	0.00
No other product types	10	9.08	4.15	18.74	3	21.18	6.90	49.36	29	24.18	16.47	34.03	6	87.88	46.50	98.37
1.4 Does this plant produce any food products other than dietary supplements?																
1. Yes	26	19.51	12.10	29.92	5	31.02	13.27	56.94	20	19.47	12.03	29.96	1	17.58	2.37	65.22
2. No	91	79.62	69.18	87.18	11	68.98	43.06	86.73	75	78.37	67.55	86.31	6	82.42	34.78	97.63
Don't know	0	0.00	0.00	0.00	0	0.00	0.00	0.00	1	0.88	0.12	6.12	0	0.00	0.00	0.00
No answer	1	0.87	0.12	6.02	0	0.00	0.00	0.00	1	1.28	0.18	8.71	0	0.00	0.00	0.00

(continued)

Table E-1. Weighted Responses for Section 1: Products and Markets (continued)

	Vitamins and Minerals (n = 118)				Aminos/Proteins/Animal Extracts (n = 16)				Herbals and Botanicals (n = 97)				Other (n = 7)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
1.5 Does this plant produce any over-the-counter (OTC) or prescription (Rx) drugs?																
1. Yes, OTC drugs	17	9.73	5.97	15.47	2	11.37	2.91	35.46	10	10.13	5.14	18.98	1	17.58	2.37	65.22
2. Yes, Rx drugs	0	0.00	0.00	0.00	0	0.00	0.00	0.00	0	0.00	0.00	0.00	0	0.00	0.00	0.00
3 Yes, OTC and Rx drugs	15	10.86	5.98	18.91	3	18.50	5.87	45.25	1	0.84	0.12	5.86	0	0.00	0.00	0.00
4. No	84	76.68	67.77	83.71	11	70.13	44.31	87.38	84	86.88	77.52	92.70	6	82.42	34.78	97.63
Don't know	0	0.00	0.00	0.00	0	0.00	0.00	0.00	1	0.88	0.12	6.12	0	0.00	0.00	0.00
No answer	2	2.73	0.62	11.15	0	0.00	0.00	0.00	1	1.28	0.18	8.71	0	0.00	0.00	0.00
1.6* Is this plant a member of any of the following trade organizations?																
1. American Herbal Products Association (AHPA)	30	16.48	11.15	23.68	1	5.97	0.82	32.74	52	46.70	34.81	58.98	0	0.00	0.00	0.00
2. Consumer Health Products Association (CHPA) (formerly known as Nonprescription Drug Manufacturers Association)	12	8.92	4.48	16.97	0	0.00	0.00	0.00	3	2.56	0.81	7.83	1	17.58	2.37	65.22
3. Council for Responsible Nutrition (CRN)	23	21.81	13.68	32.92	1	6.26	0.83	34.72	8	7.88	3.65	16.20	0	0.00	0.00	0.00
4. National Nutritional Foods Association (NNFA)	60	52.62	41.13	63.85	8	48.08	25.32	71.67	42	44.30	31.84	57.52	3	41.76	13.14	77.26
5. Utah Natural Products Alliance (UNPA)	5	2.12	0.83	5.30	0	0.00	0.00	0.00	1	2.18	0.31	13.97	0	0.00	0.00	0.00
6. Other	17	15.31	8.70	25.54	3	20.61	6.73	48.31	15	12.81	7.47	21.09	1	12.06	1.62	53.34
Not applicable	35	25.45	16.93	36.39	6	37.00	17.28	62.27	22	25.13	14.99	38.97	3	40.66	12.63	76.46
Don't know	0	0.00	0.00	0.00	0	0.00	0.00	0.00	1	0.88	0.12	6.12	0	0.00	0.00	0.00

[a]The primary line of business is the line of business that contributes to the majority of revenues—either greater than 50 percent of revenues or the greatest of several lines such as 35 percent if all other lines contribute less.

*Total may sum to greater than 100% because respondents could select more than one answer.

Table E-2. Weighted Responses for Section 2: Good Manufacturing Practices (GMPs)

	Vitamins and Minerals (n = 118)				Aminos/Proteins/Animal Extracts (n = 16)				Herbals and Botanicals (n = 97)				Other (n = 7)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
2.1 Does this plant follow a published *Good Manufacturing Practices (GMPs)* model for the dietary supplement products produced at this plant?																
1. Yes	89	67.58	55.79	77.50	10	61.18	36.00	81.54	57	59.31	46.23	71.18	3	41.24	12.85	76.97
2. No (Skip to question 2.3)	22	28.93	19.43	40.74	5	32.56	14.17	58.54	32	31.67	20.93	44.81	4	58.76	23.03	87.15
Not applicable (Skip to question 2.3)	4	1.41	0.53	3.66	1	6.26	0.83	34.72	3	2.96	0.91	9.19	0	0.00	0.00	0.00
No answer	3	2.07	0.62	6.72	0	0.00	0.00	0.00	5	6.06	2.32	14.90	0	0.00	0.00	0.00
2.2* [If 2.1 is Yes] Which of the following are your GMPs for dietary supplement operations patterned after?																
1. FDA Food CGMPs (21 CFR Part 110)	55	66.46	56.09	75.45	7	69.29	36.69	89.78	34	57.19	40.01	72.80	3	100.00	100.00	100.00
2. Advance Notice of Proposed Rulemaking for Dietary Supplements	28	34.87	23.31	48.52	0	0.00	0.00	0.00	13	26.21	13.28	45.18	0	0.00	0.00	0.00
3. National Nutritional Foods Association (NNFA) GMPs	23	26.75	16.52	40.26	2	19.06	4.80	52.36	13	31.86	16.47	52.56	1	29.40	3.51	82.65
4. FDA Drug CGMPs (21 CFR Parts 210 and 211)	36	37.37	25.72	50.70	4	40.94	16.67	70.62	8	11.20	5.40	21.80	0	0.00	0.00	0.00
5. U.S. Pharmacopeia (USP) GMPs	30	37.05	25.32	50.54	3	30.71	10.22	63.31	9	15.92	7.71	30.02	0	0.00	0.00	0.00
6. Other	5	5.83	1.97	16.03	1	10.24	1.33	49.11	11	23.01	10.27	43.83	1	27.99	3.30	81.58
Don't know	0	0.00	0.00	0.00	0	0.00	0.00	0.00	1	1.48	0.20	10.15	0	0.00	0.00	0.00
No answer	0	0.00	0.00	0.00	0	0.00	0.00	0.00	1	1.42	0.19	9.77	0	0.00	0.00	0.00
(Skip to question 2.5)																

(continued)

Table E-2. Weighted Responses for Section 2: Good Manufacturing Practices (GMPs) (continued)

	Vitamins and Minerals (n = 118)				Aminos/Proteins/Animal Extracts (n = 16)				Herbals and Botanicals (n = 97)				Other (n = 7)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
2.3* [If 2.1 is No] *If not* following published GMPs, how does this plant verify the identity, purity, and composition of dietary supplement products and ingredients?																
1. Sanitation standard operating procedures (SSOPs)	7	22.41	—	—[a]	1	16.13	—	—[a]	5	10.96	—	—[a]	1	29.92	—	—[a]
2. Other quality assurance (QA) program	6	24.54	—	—[a]	1	16.13	—	—[a]	12	29.03	—	—[a]	1	20.52	—	—[a]
3. Certificate of Analysis	19	83.97	—	—[a]	4	63.04	—	—[a]	20	47.49	—	—[a]	3	70.08	—	—[a]
4. Certificate of Identity	5	13.65	—	—[a]	3	46.91	—	—[a]	7	16.67	—	—[a]	1	20.52	—	—[a]
5. Other	11	44.07	—	—[a]	2	38.44	—	—[a]	11	25.96	—	—[a]	0	0.00	—	—[a]
Not applicable	2	2.21	—	—[a]	0	0.00	—	—[a]	5	27.29	—	—[a]	0	0.00	—	—[a]
No answer	1	1.22	—	—[a]	0	0.00	—	—[a]	0	0.00	—	—[a]	0	0.00	—	—[a]
2.4 [If 2.1 is No] Why does this plant *not* follow published GMPs?	(verbatims provided in Table E-11)															
2.5 Does this plant have standard operating procedures (SOPs)?																
1. Yes	102	82.13	70.56	89.81	10	60.32	34.91	81.16	79	78.10	63.91	87.77	4	58.82	23.07	87.19
2. No (Skip to Section 3)	10	11.49	5.42	22.74	1	5.97	0.82	32.74	10	13.32	5.53	28.74	3	41.18	12.81	76.93
Not applicable	2	0.67	0.17	2.63	1	8.66	1.25	41.58	3	2.96	0.91	9.19	0	0.00	0.00	0.00
Don't know	0	0.00	0.00	0.00	0	0.00	0.00	0.00	1	0.84	0.12	5.86	0	0.00	0.00	0.00
No answer	4	5.71	1.83	16.44	4	25.05	9.75	50.83	4	4.78	1.60	13.38	0	0.00	0.00	0.00

(continued)

Table E-2. Weighted Responses for Section 2: Good Manufacturing Practices (GMPs) (continued)

	Vitamins and Minerals (n = 118)				Aminos/Proteins/Animal Extracts (n = 16)				Herbals and Botanicals (n = 97)				Other (n = 7)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
2 6 [If 2.5 is Yes] Is there written documentation of the SOPs?																
1. Yes	88	82.94	70.68	90.75	8	80.19	45.17	95.21	60	80.39	70.11	87.75	3	70.12	18.37	96.07
2. No	6	8.96	3.52	20.98	1	9.43	1.30	45.20	11	11.42	6.18	20.13	1	29.88	3 93	81.63
Don't know	0	0.00	0.00	0.00	0	0.00	0.00	0.00	1	1.12	0.15	7.78	0	0.00	0.00	0.00
No answer	8	8.10	3.41	18.01	1	10.38	1.37	49.21	7	7.07	3.26	14.66	0	0.00	0.00	0.00

[a]Confidence interval could not be estimated because there was only one observation (respondent) in a stratum for that question.

*Total may sum to greater than 100% because respondents could select more than one answer.

Table E-3. Weighted Responses for Section 3: Personnel

	Vitamins and Minerals (n = 118)				Aminos/Proteins/Animal Extracts (n = 16)				Herbals and Botanicals (n = 97)				Other (n = 7)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
3.0 Do personnel at this plant or site handle raw materials, in-process materials, or finished products, including distribution of finished products?																
1. Yes	111	93.25	83.23	97.47	14	85.08	55.60	96.29	88	87.74	72.03	95.21	5	64.85	26.01	90.63
2. No (Skip to Section 4)	7	6.75	2.53	16.77	2	14.92	3.71	44.40	9	12.26	4.79	27.97	2	35.15	9.37	73.99
3.1 Are there written procedures for personnel on *disease control*?																
1. Yes	76	69.72	57.72	79.53	9	64.21	36.70	84.74	48	60.83	48.76	71.71	1	27.11	3.95	77.08
2. No	34	29.92	20.15	41.94	5	35.79	15.26	63.30	39	38.21	27.50	50.20	4	72.89	22.92	96.05
Not applicable	1	0.36	0.05	2.53	0	0.00	0.00	0.00	1	0.96	0.13	6.65	0	0.00	0.00	0.00
3.2 Are there written procedures for personnel on maintaining *personal cleanliness*?																
1. Yes	96	81.10	69.13	89.16	12	85.28	55.77	96.38	65	77.29	66.96	85.11	2	45.80	12.12	83.82
2 No	14	18.54	10.53	30.55	2	14.72	3.62	44.23	22	21.76	14.14	31.94	3	54.20	16.18	87.88
Not applicable	1	0.36	0.05	2.53	0	0.00	0.00	0.00	1	0.96	0.13	6.65	0	0.00	0.00	0.00
3.3 Are there written procedures ensuring that all personnel employed in the manufacturing process have the proper *education, training, or experience* needed to perform the assigned functions?																
1. Yes	82	67.90	55.42	78.26	12	85.62	56.03	96.53	51	57.02	43.93	69.19	2	45.80	12.12	83.82
2. No	27	29.33	19.38	41.74	2	14.38	3.47	43.97	33	38.40	26.63	51.72	3	54.20	16.18	87.88
Not applicable	1	0.36	0.05	2.53	0	0.00	0.00	0.00	4	4.58	1.65	12.07	0	0.00	0.00	0.00
No answer	1	2.41	0.33	15.71	0	0.00	0.00	0.00	0	0.00	0.00	0.00	0	0.00	0.00	0.00

(continued)

Table E-3. Weighted Responses for Section 3: Personnel (continued)

	Vitamins and Minerals (n = 118)				Aminos/Proteins/Animal Extracts (n = 16)				Herbals and Botanicals (n = 97)				Other (n = 7)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
3.4 Does plant management verify and keep records that the procedures for personnel on disease control, personal cleanliness, and training are being followed?																
1. Yes	79	67.54	55.40	77.71	9	63.88	36.62	84.40	42	47.92	35.28	60.83	2	45.80	12.12	83.82
2. No (Skip to question 3.6)	30	29.68	19.85	41.84	5	36.12	15.60	63.38	42	42.23	30.66	54.71	3	54.20	16.18	87.88
Not applicable	1	0.36	0.05	2.53	0	0.00	0.00	0.00	2	2.42	0.57	9.66	0	0.00	0.00	0.00
No answer	1	2.41	0.33	15.71	0	0.00	0.00	0.00	2	7.44	1.39	31.38	0	0.00	0.00	0.00
3.5 [If 3.4 is Yes] Are records made of any corrective actions taken if procedures are *not* followed?																
1. Yes, for some procedures	38	50.93	37 00	64.71	6	65.43	32.07	88.35	22	46.04	28.93	64.14	1	59.18	8.11	95.97
2. Yes, for all procedures	26	31.03	19.66	45.28	2	23.05	5.67	59.89	12	35.02	18.30	56.46	1	40.82	4.03	91 89
3. No	9	13.53	6.04	27.61	0	0.00	0.00	0.00	6	14.85	6.02	32.21	0	0.00	0.00	0.00
No answer	6	4.50	1.90	10.31	1	11.52	1.49	52.93	2	4 09	0 97	15.70	0	0.00	0.00	0 00
3.6 Are records maintained of personnel education, training, or experience?																
1 Yes	82	69.97	57.61	79.98	11	78.60	49.84	93.13	55	58.57	45.26	70.73	2	45.80	12.12	83.82
2. No (Skip to Section 4)	28	29.67	19.69	42.06	3	21.40	6.87	50.16	31	38.97	26.95	52.51	3	54.20	16.18	87.88
Not applicable	1	0.36	0.05	2.53	0	0.00	0.00	0.00	2	2.46	0.58	9 77	0	0.00	0.00	0.00

(continued)

Table E-3. Weighted Responses for Section 3: Personnel (continued)

	Vitamins and Minerals (n = 118)				Aminos/Proteins/Animal Extracts (n = 16)				Herbals and Botanicals (n = 97)				Other (n = 7)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
3.7 [If 3.6 is Yes] How long are records of personnel education, training, or experience maintained?																
1. Term of employment	52	63.94	—	—[a]	3	27.23	—	—[a]	31	50.06	—	—[a]	1	59.18	—	—[a]
2. ___ Year(s) after expiration date	6	7.31	—	—[a]	1	8.93	—	—[a]	3	7.09	—	—[a]	0	0.00	—	—[a]
3. ___ Year(s) from date of manufacture	3	3.21	—	—[a]	2	18.30	—	—[a]	3	12.50	—	—[a]	0	0.00	—	—[a]
4. Other	20	25.17	—	—[a]	3	28.09	—	—[a]	14	21.56	—	—[a]	1	40.82	—	—[a]
Don't know	0	0.00	—	—[a]	1	8.93	—	—[a]	0	0.00	—	—[a]	0	0.00	—	—[a]
No answer	1	0.38	—	—[a]	1	8.50	—	—[a]	4	8.79	—	—[a]	0	0.00	—	—[a]
Mean years after expiration date	6	2.20	—	—[a]	1	1.00	—	—[a]	3	3.97	—	—[a]	—[b]	—	—	—
Mean years from date of manufacture	3	4.18	—	—[a]	2	3.98	—	—[a]	3	2.86	—	—[a]	—[b]	—	—	—

[a]Confidence interval could not be estimated because there was only one observation (respondent) in a stratum for that question.

[b]Could not estimate because there were no respondents for that question.

Table E-4. Weighted Responses for Section 4: Buildings and Facilities

	Vitamins and Minerals (n = 118)				Aminos/Proteins/Animal Extracts (n = 16)				Herbals and Botanicals (n = 97)				Other (n = 7)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
4.0 Are raw materials, in-process materials, or finished products handled or stored at this plant or site?																
1. Yes	113	95.84	87.12	98.74	16	100.00	100.00	100.00	91	95.14	89.30	97.87	5	70.88	30.42	93.13
2. No (Skip to Section 5)	5	4.16	1.26	12.88	0	0.00	0.00	0.00	6	4.86	2.13	10.70	2	29.12	6.87	69.58
4.1 What percentage of plants are classified as owned vs. leased?[c] *(Include warehouse facilities located at this plant.)*																
a. Owned	59	51.18	39.58	62.65	9	55.21	30.93	77.23	46	48.85	35.67	62.19	4	83.72	36.26	97.89
b. Leased	54	48.82	37.35	60.42	7	44.79	22.77	69.07	45	51.15	37.81	64.33	1	16.28	2.11	63.74
Owned Facilities																
4.2 Are there written procedures on *maintenance of the grounds* about the plant?																
1. Yes	36	58.27	41.61	73.24	4	44.85	16.82	76.58	15	38.18	21.40	58.35	2	50.06	10.83	89.22
2. No	22	41.04	26.14	57.79	5	55.15	23.42	83.18	28	53.43	35.42	70.59	2	49.94	10.78	89.17
Not applicable	0	0.00	0.00	0.00	0	0.00	0.00	0.00	1	1.89	0.25	12.85	0	0.00	0.00	0.00
Don't know	1	0.68	0.09	4.79	0	0.00	0.00	0.00	0	0.00	0.00	0.00	0	0.00	0.00	0.00
No answer	0	0.00	0.00	0.00	0	0.00	0.00	0.00	2	6.50	1.42	25.21	0	0.00	0.00	0.00

(continued)

Table E-4. Weighted Responses for Section 4: Buildings and Facilities (continued)

	Vitamins and Minerals (n = 118)				Aminos/Proteins/Animal Extracts (n = 16)				Herbals and Botanicals (n = 97)				Other (n = 7)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
4.3 Are there written procedures on *general maintenance and sanitation of the buildings, fixtures, and other physical facilities* of the plant?																
1. Yes	49	80.52	64.18	90.51	6	66.49	31.36	89.61	27	65.39	49.58	78.40	2	50.06	10.83	89.22
2. No	9	18.79	8.94	35.30	3	33.51	10.39	68.64	18	32.72	20.01	48.60	2	49.94	10.78	89.17
Not applicable	1	0.68	0.09	4.79	0	0.00	0.00	0.00	1	1.89	0.25	12.85	0	0.00	0.00	0.00
4.4 Are there written procedures on the storage and use of *cleaning and sanitizing materials*?																
1. Yes	44	71.83	54.55	84.42	4	44.33	17.17	75.36	24	60.28	44.59	74.12	2	50.06	10.83	89.22
2. No	14	27.49	15.01	44.87	5	55.67	24.64	82.83	21	37.83	24.20	53.69	2	49.94	10.78	89.17
Not applicable	1	0.68	0.09	4.79	0	0.00	0.00	0.00	1	1.89	0.25	12.85	0	0.00	0.00	0.00
4.5 Are there written procedures on *pest control*?																
1. Yes	47	78.30	61.17	89.20	6	67.54	33.45	89.59	27	63.97	47.84	77.46	2	50.06	10.83	89.22
2. No	11	21.02	10.25	38.27	3	32.46	10.41	66.55	18	34.14	20.94	50.36	2	49.94	10.78	89.17
Not applicable	1	0.68	0.09	4.79	0	0.00	0.00	0.00	0	0.00	0.00	0.00	0	0.00	0.00	0.00
No answer	0	0.00	0.00	0.00	0	0.00	0.00	0.00	1	1.89	0.25	12.85	0	0.00	0.00	0.00

(continued)

Table E-4. Weighted Responses for Section 4: Buildings and Facilities (continued)

	Vitamins and Minerals (n = 118)				Aminos/Proteins/Animal Extracts (n = 16)				Herbals and Botanicals (n = 97)				Other (n = 7)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
4.6 Does plant management verify and keep records that procedures for buildings and facilities maintenance are being followed?																
1. Yes	45	78.78	63.12	88.95	6	67.01	32.30	89.64	21	53.13	36.05	69.50	2	50.06	10.83	89.22
2. No (Skip to Section 5)	14	21.22	11.05	36.88	3	32.99	10.36	67.70	24	44.98	28.97	62.11	2	49.94	10.78	89.17
No answer	0	0.00	0.00	0.00	0	0.00	0.00	0.00	1	1.89	0.25	12.85	0	0.00	0.00	0.00
4.7 [If 4.6 is Yes] Are records made of any corrective actions taken if procedures are *not* followed?																
1. Yes, for some procedures	20	44.10	26.86	62.90	4	66.15	24.63	92.12	10	37.66	16.91	64.21	1	59.18	7.93	96.06
2. Yes, for all procedures	19	39.53	23.38	58.34	1	16.93	1.96	67.53	5	22.84	7.90	50.54	1	40.82	3.94	92.07
3. No	4	8.29	3.09	20.40	0	0.00	0.00	0.00	3	9.49	2.59	29.23	0	0.00	0.00	0.00
No answer	2	8.08	1.64	31.70	1	16.93	1.96	67.53	3	30.01	7.73	68.69	0	0.00	0.00	0.00
Leased Facilities																
4.8 What is the *remaining* term of the lease?																
Years (mean response)	49	3.64	—	—[a]	5	1.01	—	—[a]	42	4.39	—	—[a]	1	0.17	—	—[a]
Open lease (%)	1	0.79	0.11	5.55	2	27.96	6.95	66.85	3	5.18	1.62	15.36	—[b]	—	—	—

(continued)

Table E-4. Weighted Responses for Section 4: Buildings and Facilities (continued)

	Vitamins and Minerals (n = 118)				Aminos/Proteins/Animal Extracts (n = 16)				Herbals and Botanicals (n = 97)				Other (n = 7)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
4.9 For leased facilities, who is primarily responsible for *maintaining the grounds* about the plant?																
1. Plant management (lessee)	30	47.54	30.97	64.67	2	26.03	6.38	64.50	16	36.74	20.08	57.32	0	0.00	0.00	0.00
2. Facility owner (lessor) (Skip to question 4.11)	23	47.65	30.56	65.30	5	73.97	35.50	93.62	28	58.77	38.74	76.27	1	100.00	100.00	100.00
No answer	1	4.81	0.63	28.80	0	0.00	0.00	0.00	1	4.48	0.62	26.15	0	0.00	0.00	0.00
4.10 [If 4.9 is 1 (lessee)] For leased facilities, are there written procedures on *maintenance of the grounds* about the plant?																
1. Yes	12	32.86	13.84	59.86	1	51.23	5.68	94.82	4	23.82	6.97	56.62	—[b]	—	—	—
2. No	17	66.03	39.32	85.36	1	48.77	5.18	94.32	9	40.46	16.60	69.87	—[b]	—	—	—
No answer	1	1.11	0.15	7.92	0	0.00	0.00	0.00	3	35.72	9.72	74.15	—[b]	—	—	—
(Skip to question 4.12)																
4.11 [If 4.9 is 2 (lessor)] Does plant management verify and keep records that the facility owner is properly *maintaining the grounds*?																
1. Yes	7	30.08	11.82	57.99	0	0.00	0.00	0.00	5	16.49	6.15	37.34	0	0.00	0.00	0.00
2. No	10	41.57	18.65	68.83	3	56.70	19.82	87.40	16	45.88	24.73	68.62	1	100.00	100.00	100.00
Don't know	0	0.00	0.00	0.00	0	0.00	0.00	0.00	1	3.07	0.38	20.75	0	0.00	0.00	0.00
No answer	6	28.35	9.73	59.22	2	43.30	12.60	80.18	6	34.56	12.81	65.48	0	0.00	0.00	0.00

(continued)

Table E-4. Weighted Responses for Section 4: Buildings and Facilities (continued)

	Vitamins and Minerals (n = 118)				Aminos/Proteins/Animal Extracts (n = 16)				Herbals and Botanicals (n = 97)				Other (n = 7)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
4.12 For leased facilities, who is primarily responsible for *general maintenance and sanitation of the buildings, fixtures, and other physical facilities* of the plant?																
1. Plant management (lessee)	45	76.73	56.78	89.22	6	86.02	40.22	98.25	33	78.59	63 24	88.68	0	0.00	0.00	0.00
2. Facility owner (lessor) (Skip to question 4.15)	8	18.46	7.69	38.09	1	13.98	1.75	59.78	12	21.41	11 32	36.76	1	100.00	100.00	100.00
No answer	1	4.81	0.63	28.80	0	0.00	0.00	0.00	0	0.00	0.00	0.00	0	0.00	0.00	0.00
4.13 [If 4.12 is 1 (lessee)] For leased facilities, are there written procedures on *general maintenance and sanitation of the buildings, fixtures, and other physical facilities* of the plant?																
1. Yes	27	48.54	32.12	65.29	1	14.76	1.90	60.79	19	65.91	44 08	82.59	—[b]	—	—	—
2. No	17	50.77	34.11	67.26	3	48.01	15.89	81.86	11	27.98	13.39	49.39	—[b]	—	—	—
No answer	1	0.69	0.09	4.88	2	37.23	9.47	77.09	3	6.11	1.75	19.20	—[b]	—	—	—
4.14 [If 4.12 is 1 (lessee)] For leased facilities, are there written procedures on the storage and use of *cleaning and sanitizing materials*?																
1. Yes	26	47.97	29.87	66.62	2	37.23	9.47	77.09	17	51.10	28.66	73.10	—[b]	—	—	—
2. No	17	50.41	31.94	68.76	3	48.01	15.89	81.86	13	42.79	21.82	66.72	—[b]	—	—	—
No answer	2	1.62	0.39	6.51	1	14.76	1.90	60.79	3	6.11	1.75	19.20	—[b]	—	—	—
(Skip to question 4.17)																

(continued)

Table E-4. Weighted Responses for Section 4: Buildings and Facilities (continued)

	Vitamins and Minerals (n = 118)				Aminos/Proteins/Animal Extracts (n = 16)				Herbals and Botanicals (n = 97)				Other (n = 7)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
4.15 [If 4.12 is 2 (lessor)] Does plant management verify and keep records that the facility owner is properly *maintaining the buildings, fixtures, and other physical facilities* of the plant?																
1. Yes	3	57.68	—	—[a]	0	0.00	—	—[a]	3	28.43	—	—[a]	0	0.00	—	—[a]
2. No	3	12.38	—	—[a]	1	100.00	—	—[a]	8	63.14	—	—[a]	1	100.00	—	—[a]
Don't know	0	0.00	—	—[a]	0	0.00	—	—[a]	0	0.00	—	—[a]	0	0.00	—	—[a]
No answer	2	29.94	—	—[a]	0	0.00	—	—[a]	1	8.43	—	—[a]	0	0.00	—	—[a]
4.16 [If 4.12 is 2 (lessor)] Does plant management verify and keep records that the *cleaning and sanitizing materials* used by the facility owner are being properly stored and used?																
1. Yes	3	57.68	—	—[a]	0	0.00	—	—[a]	4	36.50	—	—[a]	0	0.00	—	—[a]
2. No	3	12.38	—	—[a]	1	100.00	—	—[a]	7	55.07	—	—[a]	1	100.00	—	—[a]
Don't know	0	0.00	—	—[a]	0	0.00	—	—[a]	0	0.00	—	—[a]	0	0.00	—	—[a]
No answer	2	29.94	—	—[a]	0	0.00	—	—[a]	1	8.43	—	—[a]	0	0.00	—	—[a]

(continued)

Table E-4. Weighted Responses for Section 4: Buildings and Facilities (continued)

	Vitamins and Minerals (n = 118)				Aminos/Proteins/Animal Extracts (n = 16)				Herbals and Botanicals (n = 97)				Other (n = 7)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
4.17 For leased facilities, who is primarily responsible for *pest control*?																
1. Plant management (lessee)	45	73.78	54.19	87.00	6	86.02	40.22	98.25	31	74.24	57.86	85.81	0	0.00	0.00	0.00
2. Facility owner (lessor) (Skip to question 4.19)	8	21.41	9.49	41.46	1	13.98	1.75	59.78	13	24.04	12.97	40.19	1	100.00	100.00	100.00
Not applicable	0	0.00	0.00	0.00	0	0.00	0.00	0.00	1	1.73	0.23	11.89	0	0.00	0.00	0.00
No answer	1	4.81	0.63	28.80	0	0.00	0.00	0.00	0	0.00	0.00	0.00	0	0.00	0.00	0.00
4.18 [If 4.17 is 1 (lessee)] For leased facilities, are there written procedures on *pest control*?																
1. Yes	31	71.57	50.67	86.05	3	53.49	17.43	86.24	12	42.87	21.91	66.75	—[b]	—	—	—
2. No	14	28.43	13.95	49.33	3	46.51	13.76	82.57	15	48.95	26.64	71.69	—[b]	—	—	
No answer	0	0.00	0.00	0.00	0	0.00	0.00	0.00	4	8.18	2.72	22.13	—[b]	—	—	—
(Skip to question 4.20)																
4.19 [If 4.17 is 2 (lessor)] Does plant management verify and keep records that the facility owner is taking proper *pest control* measures?																
1. Yes	2	41.04	—	—[a]	0	0.00	—	—[a]	4	30.60	—	—[a]	0	0.00	—	—[a]
2. No	6	58.96	—	—[a]	1	100.00	—	—[a]	5	36.57	—	—[a]	1	100.00	—	—[a]
Don't know	0	0.00	—	—[a]	0	0.00	—	—[a]	1	7.19	—	—[a]	0	0.00	—	—[a]
No answer	0	0.00	—	—[a]	0	0.00	—	—[a]	3	25.64	—	—[a]	0	0.00	—	—[a]

(continued)

Table E-4. Weighted Responses for Section 4: Buildings and Facilities (continued)

	Vitamins and Minerals (n = 118)				Aminos/Proteins/Animal Extracts (n = 16)				Herbals and Botanicals (n = 97)				Other (n = 7)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
4.20 Does plant management verify and keep records that procedures for buildings and facilities maintenance are being followed?																
1. Yes	31	51.20	36.05	66.13	4	59.34	23.71	87.27	21	48.50	30.10	67.33	0	0.00	0.00	0.00
2. No (Skip to Section 5)	20	34.37	19.75	52.70	3	40.66	12.73	76.29	22	47.96	29.51	66.99	1	100.00	100.00	100.00
Not applicable	0	0.00	0.00	0.00	0	0.00	0.00	0.00	1	1.73	0.23	11.89	0	0.00	0.00	0.00
Don't know	0	0.00	0.00	0.00	0	0.00	0.00	0.00	1	1.80	0.24	12.36	0	0.00	0.00	0.00
No answer	3	14.43	4.97	35.22	0	0.00	0.00	0.00	0	0.00	0.00	0.00	0	0.00	0.00	0.00
4.21 [If 4.20 is Yes] Are records made of any corrective actions taken if procedures are *not* followed?																
1. Yes, for some procedures	16	57.69	38.78	74.58	2	43.86	9.36	85.54	11	43.27	19.93	70.04	—[b]	—	—	—
2. Yes, for all procedures	5	11.37	4.19	27.35	1	32.58	4.52	83.13	6	36.80	13.36	68.74	—[b]	—	—	—
3. No	7	22.14	9.37	43.88	1	23.56	2.90	76.06	3	16.37	4.41	45.36	—[b]	—	—	—
No answer	3	8.80	2.57	26.10	0	0.00	0.00	0.00	1	3.56	0.44	23.75	—[b]	—	—	—

[a]Confidence interval could not be estimated because there was only one observation (respondent) in a stratum for that question.

[b]Could not estimate because there were no respondents for that question.

[c]If 50% or more of the plant's facilities are *owned,* the respondent completed questions 4.2 through 4.7. If 50% or more of the plant's facilities are *leased,* the respondent completed questions 4.8 through 4.21.

Table E-5. Weighted Responses for Section 5: Equipment

	Vitamins and Minerals (n = 118)				Aminos/Proteins/Animal Extracts (n = 16)				Herbals and Botanicals (n = 97)				Other (n = 7)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
5.0 Is equipment at this plant or site used to process raw materials, in-process materials, or finished products?																
1. Yes	110	92.92	83.08	97.23	14	85.08	55.60	96.29	85	89.98	82.73	94.40	6	82.42	34.78	97.63
2. No (Skip to Section 6)	8	7.08	2.77	16.92	2	14.92	3.71	44.40	12	10.02	5.60	17.27	1	17.58	2.37	65.22
5.1 Are there written procedures on the *cleaning, sanitizing, and maintaining of equipment and utensils?*																
1. Yes	90	75.48	62.98	84.77	10	71.57	43.20	89.29	62	71.69	57.33	82.67	3	50.04	15.82	84.23
2. No (Skip to question 5.4)	20	24.52	15.23	37.02	4	28.43	10.71	56.80	23	28.31	17.33	42.67	3	49.96	15.77	84.18
5.2 [If 5.1 is Yes] Does plant management verify and keep records that these procedures are being followed?																
1. Yes	80	84.90	71.29	92.72	9	90.19	53.60	98.65	49	79.20	64.76	88.75	2	72.01	18.43	96.70
2. No (Skip to question 5.4)	9	14.37	6.72	28.09	0	0.00	0.00	0.00	12	19.84	10.49	34.32	1	27.99	3.30	81.57
No answer	1	0.73	0.10	5.10	1	9.81	1.35	46.40	1	0.96	0.13	6.74	0	0.00	0.00	0.00

(continued)

Table E-5. Weighted Responses for Section 5: Equipment

	Vitamins and Minerals (n = 118)				Aminos/Proteins/Animal Extracts (n = 16)				Herbals and Botanicals (n = 97)				Other (n = 7)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
5.3 [If 5.2 is Yes] Are records made of any corrective actions taken if procedures are *not* followed?																
1. Yes, for some procedures	30	34.67	22.70	48.95	4	44.04	16.86	75.33	22	39.11	23.80	56.91	0	0.00	0.00	0.00
2. Yes, for all procedures	37	50.16	36.82	63.47	3	34.21	11.19	68.21	18	37.39	21.20	57.00	2	100.00	100.00	100.00
3. No	13	15.18	8.24	26.28	1	11.40	1.46	52.86	7	10.80	4.83	22.43	0	0.00	0.00	0.00
No answer	0	0.00	0.00	0.00	1	10.35	1.44	47.81	2	12.70	2.42	46.01	0	0.00	0.00	0.00
5.4 Does this plant *validate* that equipment, instruments, and controls are *installed* correctly?																
1. Yes	67	57.08	45.33	68.08	11	79.27	51.39	93.26	63	74.18	59.58	84.84	3	57.36	21.49	86.87
2. No	38	39.11	28.50	50.87	3	20.73	6.74	48.61	20	18.61	11.72	28.26	2	28.63	6.77	68.92
No answer	5	3.81	1.53	9.14	0	0.00	0.00	0.00	2	7.21	1.32	31.11	1	14.00	1.83	58.68
5.5 Does this plant *validate* that equipment, instruments, and controls are *used* correctly?																
1. Yes	78	65.59	53.55	75.91	10	71.57	43.20	89.29	67	72.45	55.98	84.47	4	71.37	31.08	93.23
2. No	28	31.54	21.58	43.55	4	28.43	10.71	56.80	17	21.27	11.29	36.44	2	28.63	6.77	68.92
No answer	4	2.87	1.02	7.81	0	0.00	0.00	0.00	1	6.28	0.91	32.93	0	0.00	0.00	0.00

(continued)

Table E-5. Weighted Responses for Section 5: Equipment

	Vitamins and Minerals (n = 118)				Aminos/Proteins/Animal Extracts (n = 16)				Herbals and Botanicals (n = 97)				Other (n = 7)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
5.6 Does this plant *validate* the equipment used in quality control? Quality control equipment includes automatic, mechanical, electronic, and computer equipment, including hardware and software.																
1. Yes	77	65.52	53.07	76.16	9	64.89	37.65	84.98	58	68.03	53.62	79.67	3	57.36	21.49	86.87
2. No	28	29.18	19.25	41.60	4	28.43	10.71	56.80	21	20.73	13.18	31.06	2	28.63	6.77	68.92
No answer	5	5.30	1.80	14.57	1	6.68	0.93	35.29	6	11.23	3.62	29.87	1	14.00	1.83	58.68

Table E-6. Weighted Responses for Section 6: Quality Control and Laboratory Operations

	Vitamins and Minerals (n = 118)				Aminos/Proteins/Animal Extracts (n = 16)				Herbals and Botanicals (n = 97)				Other (n = 7)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
6.1 Is there a unit or person responsible for quality control?																
1 Yes	106	84.50	72.91	91.70	12	76.10	50.63	90.82	82	86.81	78.38	92.27	5	70.88	30.42	93.13
2. No (Skip to question 6.4)	8	10.29	4.54	21.69	4	23.90	9.18	49.37	3	3.44	1.10	10.27	1	11.54	1.53	52.22
Not applicable (Skip to question 6.4)	3	2.96	0.62	12.89	0	0.00	0.00	0.00	6	5.12	2.26	11 17	1	17.58	2.37	65.22
No answer	1	2.25	0.31	14.71	0	0.00	0.00	0.00	6	4.64	2.02	10.29	0	0.00	0.00	0.00
6.2 [If 6.1 is Yes] Are there written procedures on the responsibilities and procedures required of the quality control unit/person?																
1. Yes	86	84.39	73.75	91.23	9	72.16	40.22	90.90	54	67.43	52.82	79.29	2	41.90	10.00	82.40
2. No	15	12.26	6.18	22.87	1	8.23	1.07	42.62	25	29.58	18.07	44.44	2	41.81	9.96	82.35
No answer	5	3.35	1.26	8.60	2	19.61	4.89	53.63	3	2.99	0.94	9.07	1	16.28	2.11	63.74

(continued)

Table E-6. Weighted Responses for Section 6: Quality Control and Laboratory Operations (continued)

	Vitamins and Minerals (n = 118)				Aminos/Proteins/Animal Extracts (n = 16)				Herbals and Botanicals (n = 97)				Other (n = 7)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
6.3* [If 6.1 is Yes] For which of the following does the quality control unit/person have responsibility and authority?																
1. Approval/rejection of cleaning and maintenance procedures	75	70.63	58.49	80.41	9	72.16	40.22	90.90	60	70.62	56.10	81.89	4	75.20	24.16	96.65
2. Approval/rejection of procedures, specifications, controls, tests, and examinations for purity, quality, and composition	88	86.60	77.24	92.48	10	80.39	46.37	95.11	73	91.11	83 27	95.47	4	82.99	35.04	97 78
3 Approval/rejection of raw materials	88	81.59	69.79	89.47	11	88.62	50.54	98.34	74	82.17	62.39	92.76	4	82.99	35.04	97 78
4. Approval/rejection of packaging materials	83	73.37	60.77	83.04	11	88.62	50.54	98.34	66	75.29	60.45	85.86	5	100.00	100.00	100 00
5. Approval/reject on of labeling	82	76.21	64.37	85.03	11	91.77	57.38	98.93	66	76.84	62 16	87.01	3	58.92	18 05	90.33
6. Approval/reject on of finished dietary products	92	86.42	75.92	92.77	11	91.77	57.38	98.93	67	83.67	73.04	90.65	4	83 72	36.26	97.89
7. Other	6	3.69	1 56	8.47	0	0.00	0.00	0.00	3	3 04	0 99	8.93	1	24.80	3.35	75.84
No answer	7	5.41	2.44	11.56	0	0.00	0.00	0.00	2	1.98	0.48	7.83	0	0.00	0.00	0 00

(continued)

Table E-6. Weighted Responses for Section 6: Quality Control and Laboratory Operations (continued)

	Vitamins and Minerals (n = 118)				Aminos/Proteins/Animal Extracts (n = 16)				Herbals and Botanicals (n = 97)				Other (n = 7)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
6.4 Does this plant require suppliers to provide a *Certificate of Analysis*?																
1. Yes, from some suppliers	22	17.67	10.39	28.42	5	29.58	12.82	54.55	44	41.91	30.04	54.80	2	29.12	6.87	69.58
2. Yes, from all suppliers	83	70.67	58.93	80.19	9	55.49	31.66	77.04	30	33.66	22.90	46.42	3	41.76	13.14	77.26
3. No, do not require CofA from any suppliers (Skip to question 6.7)	3	2.94	0.61	12.90	1	6.26	0.83	34.72	13	10.89	6.14	18.57	0	0.00	0.00	0.00
4. Do not receive ingredients (Skip to question 6.7)	7	5.27	1.95	13.43	0	0.00	0.00	0.00	2	6.93	1.38	28.32	1	11.54	1.53	52.22
Don't know	0	0.00	0.00	0.00	0	0.00	0.00	0.00	2	1.72	0.42	6.80	0	0.00	0.00	0.00
No answer	3	3.46	0.84	13.08	1	8.66	1.25	41.58	6	4.90	2.14	10.80	1	17.58	2.37	65.22
6.5 [If 6.4 is Yes] Does this plant verify the reliability of the suppliers' *Certificate of Analysis*?																
1. Yes	78	76.87	65.09	85.55	10	72.25	44.68	89.35	50	73.11	61.11	82.47	3	66.70	25.15	92.28
2. No (Skip to question 6.7)	26	22.85	14.20	34.65	4	27.75	10.65	55.32	23	26.07	16.89	37.97	2	33.30	7.72	74.85
No answer	1	0.28	0.04	1.98	0	0.00	0.00	0.00	1	0.82	0.11	5.74	0	0.00	0.00	0.00

(continued)

Table E-6. Weighted Responses for Section 6: Quality Control and Laboratory Operations (continued)

	Vitamins and Minerals (n = 118)				Aminos/Proteins/Animal Extracts (n = 16)				Herbals and Botanicals (n = 97)				Other (n = 7)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
6.6* [If 6.5 is Yes] How is reliability of the suppliers' *Certificate of Analysis* verified?																
1. Conduct on-site review of suppliers' operations	39	44.79	31.51	58.85	3	30.09	9.46	63.95	18	39.07	22.89	58.08	2	62.82	11.47	95.66
2. Perform tests in-house to confirm results	46	54.50	40.61	67.73	7	69.91	36.05	90.54	26	55.00	36.92	71.85	0	0.00	0.00	0.00
3. Use off-site laboratory to confirm results	52	66.75	52.52	78.47	7	70.84	38.04	90.58	37	70.99	51.10	85.14	3	100.00	100.00	100.00
4. Require suppliers to conduct tests as part of supply specifications	32	46.77	33.45	60.57	2	20.37	4.88	56.07	19	42.87	25.47	62.23	1	37.18	4.34	88.53
5. Standard reference materials	32	38.43	25.81	52.81	2	20.37	4.88	56.07	19	30.46	18.01	46.63	1	25.64	3.14	78 58
6. Other	5	5.09	1.66	14.55	0	0.00	0.00	0.00	1	8.45	1.22	40.92	0	0.00	0.00	0.00
No answer	1	1.28	0.17	8.77	0	0.00	0.00	0.00	2	3.04	0.74	11.67	0	0 00	0.00	0.00
6.7* Does this plant conduct tests on any *raw materials*?																
1 Yes, in-house	67	53.90	42.55	64.86	10	61.18	36.12	81.46	53	52.06	39 36	64.50	3	46.70	15.70	80.47
2. Yes, off-site	68	56.91	45.32	67.80	4	24.47	9.29	50.63	45	43.31	31.23	56.23	3	41.24	12.85	76 97
3 No (Skip to question 6.14)	16	13.26	7.01	23.67	2	11.95	3.15	36.18	16	19.35	10.27	33.47	2	23.60	5.67	61 38
Not applicable (Skip to question 6.14)	2	2.59	0.45	13.57	1	8.66	1.25	41.58	4	3.40	1.25	8.90	0	0.00	0.00	0.00
No answer	2	3.12	0.67	13.41	1	6.26	0.83	34.72	6	4.67	2.04	10.37	1	17.58	2.37	65.22

(continued)

Table E-6. Weighted Responses for Section 6: Quality Control and Laboratory Operations (continued)

	Vitamins and Minerals (n = 118)				Aminos/Proteins/Animal Extracts (n = 16)				Herbals and Botanicals (n = 97)				Other (n = 7)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
6.8 [If 6.7 is Yes] What percentage of raw materials are sampled and tested? *(Provide average for all raw materials.)*																
% of lots (mean response)	98	68.52	58.25	78.80	12	77.81	61.56	94.06	65	64.04	51.27	76.82	3	36.66	0.00[b]	80.08
6.9* [If 6.7 is Yes] Which of the following testing techniques are used to confirm *identity of ingredients* for raw materials?																
1. Physical	88	89.36	78.48	95.08	10	83.27	51.35	95.91	56	71.74	52.91	85.15	2	59.76	17.66	91.14
2. Chemical	81	85.47	75.03	92.01	9	75.49	45.09	92.04	30	46.91	32.58	61.77	2	50.50	11.47	88.93
3. Microbiological	55	59.86	47.27	71.27	5	42.03	18.21	70.24	28	49.81	35.67	63.98	2	40.24	8.86	82.34
4. Visual (macroscopic or microscopic)	66	69.91	58.15	79.52	9	75.10	43.88	92.08	57	77.67	60.08	88.93	2	49.50	11.07	88.53
5. Organoleptic	52	49.33	36.94	61.79	3	24.90	7.92	56.12	42	57.78	42.53	71.67	1	29.88	3.92	81.64
6. No tests are conducted to confirm identity of ingredients	1	2.78	0.37	17.84	0	0.00	0.00	0.00	1	1.22	0.17	8.28	0	0.00	0.00	0.00
7. Other	6	5.48	1.76	15.77	1	7.78	1.08	39.36	6	6.74	2.86	15.09	0	0.00	0.00	0.00
No answer	0	0.00	0.00	0.00	0	0.00	0.00	0.00	1	0.85	0.12	5.98	0	0.00	0.00	0.00

(continued)

Table E-6. Weighted Responses for Section 6: Quality Control and Laboratory Operations (continued)

	Vitamins and Minerals (n = 118)				Aminos/Proteins/Animal Extracts (n = 16)				Herbals and Botanicals (n = 97)				Other (n = 7)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
6.10* [If 6.7 is Yes] Which of the following testing techniques are used for detecting *contamination* of raw materials?																
1 Physical	69	71.14	59.13	80.78	10	83.66	51.83	96.06	43	51.97	37.20	66.41	3	80.38	29.77	97.54
2. Chemical	57	58.33	45.63	70.01	7	59.15	31.25	82.19	26	39.57	25.86	55.15	1	20.61	2.61	71.53
3. Microbiological	74	71.89	58.67	82.16	8	67.32	37.65	87.54	43	68.88	56.60	78.98	3	70.12	18.36	96.08
4. Visual (macroscopic or microscopic)	70	73 56	61.75	82.74	8	67.32	37.65	87.54	55	74.75	57.62	86.57	2	49.50	11.07	88.53
5. Organoleptic	39	39.47	27.83	52.43	1	7.78	1.08	39.36	39	54.87	39.93	68.98	1	20.61	2 61	71.53
6. No tests are conducted to detect contamination	3	3.97	0.91	15.71	0	0.00	0.00	0.00	0	0.00	0.00	0.00	0	0.00	0.00	0.00
7. Other	3	1.32	0.44	3.91	1	7.78	1 08	39.36	2	2.37	0.57	9.31	0	0.00	0.00	0.00
No answer	1	1.07	0.15	7.38	0	0.00	0.00	0.00	1	0.85	0.12	5.98	0	0.00	0.00	0.00
6.11 [If 6.7 is Yes] Does this plant conduct chemical tests to determine *potency* of raw materials?																
1. Yes	71	72.17	59.45	82.10	8	67.72	38.99	87.32	29	38.41	25.94	52.61	1	29.88	3 92	81.64
2 No	26	26.76	16.99	39.47	4	32.28	12.68	61.01	39	51.80	37.23	66.07	3	70.12	18 36	96 08
No answer	1	1.07	0.15	7.38	0	0.00	0.00	0.00	3	9.79	2.12	35.29	0	0 00	0 00	0 00

(continued)

Table E-6. Weighted Responses for Section 6: Quality Control and Laboratory Operations (continued)

	Vitamins and Minerals (n = 118)				Aminos/Proteins/Animal Extracts (n = 16)				Herbals and Botanicals (n = 97)				Other (n = 7)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
6.12 [If 6.7 is Yes] For the most recent fiscal year, approximately what percentage of raw materials was rejected because of the wrong identity, contamination, or potency?																
% of lots (mean response)	98	3.08	1.79	4.37	12	1.52	0.00[b]	3.12	66	4.30	2.39	6.21	4	0.21	0.00[b]	0.58
6.13 [If 6.12 > 0] What was the reason(s) for the rejection? (mean response in %)																
1. Microbial contamination	65	34.76	24.37	45.15	7	47.77	11.42	84.11	48	20.78	10.31	31.26	1	100.00	100.00	100.00
2. Pesticide, herbicide, fungicide contamination	65	0.84	0.00[b]	1.89	7	7.24	0.00[b]	21.11	48	3.13	0.33	5.94	1	0.00	0.00	0.00
3. Other chemical contamination	65	4.94	1.03	8.85	7	14.48	0.00[b]	42.21	48	1.16	0.00[b]	2.65	1	0.00	0.00	0.00
4. Wrong ingredient	65	14.03	7.60	20.47	7	0.00	0.00	0.00	48	25.13	13.71	36.57	1	0.00	0.00	0.00
5. Subpotency	65	23.11	13.26	32.96	7	30.52	2.11	58.92	48	25.86	15.84	35.88	1	0.00	0.00	0.00
6. Superpotency	65	1.52	0.06	2.98	7	0.00	0.00	0.00	48	2.14	0.00[b]	5.64	1	0.00	0.00	0.00
7. Aflatoxin or other toxin	65	0.85	0.00[b]	2.30	7	0.00	0.00	0.00	48	1.16	0.00[b]	2.68	1	0.00	0.00	0.00
8. Other	65	19.93	12.23	27.64	7	0.00	0.00	0.00	48	20.62	8.38	32.86	1	0.00	0.00	0.00

(continued)

Table E-6. Weighted Responses for Section 6: Quality Control and Laboratory Operations (continued)

	Vitamins and Minerals (n = 118)				Aminos/Proteins/Animal Extracts (n = 16)				Herbals and Botanicals (n = 97)				Other (n = 7)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
6.14 Does this plant conduct tests on any *in-process materials and/or finished products*?																
1. Yes	92	75.01	63.15	84.02	12	75.82	49.43	90.96	54	54.06	41.20	66.40	4	58.82	23.07	87.19
2. No (Skip to question 6.21)	22	19.81	11.87	31.20	4	24.18	9.04	50.57	32	36.33	24.43	50.17	2	23.60	5.67	61.38
Not applicable (Skip to question 6.21)	3	2.92	0.61	12.91	0	0.00	0.00	0.00	6	5.52	2.40	12.19	0	0.00	0.00	0.00
No answer	1	2.25	0.31	14.71	0	0.00	0.00	0.00	5	4.09	1.67	9.68	1	17.58	2.37	65.22
6.15 [If 6.14 is Yes] What percentage of in-process materials and/or finished products are sampled and tested?																
In-process materials: % of batches (mean response)	91	55.38	43.74	67.02	12	58.30	34.93	81.67	52	60.06	45.21	74.91	4	73.11	28.75	117.46
Finished products: % of batches (mean response)	91	64.52	53.18	75.85	12	86.95	69.90	100.00[c]	52	66.02	52.70	79.33	4	43.22	0.00[b]	87.63

(continued)

Table E-6. Weighted Responses for Section 6: Quality Control and Laboratory Operations (continued)

	Vitamins and Minerals (n = 118)				Aminos/Proteins/Animal Extracts (n = 16)				Herbals and Botanicals (n = 97)				Other (n = 7)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
6.16* [If 6.14 is Yes] Which of the following testing techniques are used to confirm *identity of ingredients* for in-process materials and/or finished products?																
1. Physical	70	80.95	71.76	87.67	9	75.60	44.41	92.32	36	60.90	43.47	75.93	2	59.76	17.68	91.13
2. Chemical	65	72.29	59.13	82.47	9	72.44	40.75	90.94	22	45.06	30.23	60.82	1	20.61	2.61	71.54
3. Microbiological	34	39.51	27.59	52.82	6	48.42	22.47	75.25	18	38.63	23.80	55.92	2	40.24	8.87	82.32
4. Visual (macroscopic or microscopic)	58	62.92	49.63	74.51	7	59.84	31.08	83.12	38	68.78	53.32	80.95	3	70.12	18.26	96.10
5. Organoleptic	40	45.30	32.69	58.54	2	19.68	4.89	53.88	32	59.17	43.47	73.21	2	50.50	11.40	88.99
6. No tests are conducted to confirm identity of ingredients	1	0.33	0.05	2.33	1	7.88	1.08	40.03	2	3.19	0.77	12.22	0	0.00	0.00	0.00
7. Other	8	7.18	2.70	17.71	0	0.00	0.00	0.00	3	5.55	1.68	16.78	1	29.88	3.90	81.74
No answer	1	1.16	0.16	7.95	0	0.00	0.00	0.00	3	7.15	2.03	22.25	0	0.00	0.00	0.00

(continued)

Table E-6. Weighted Responses for Section 6: Quality Control and Laboratory Operations (continued)

	Vitamins and Minerals (n = 118)				Aminos/Proteins/Animal Extracts (n = 16)				Herbals and Botanicals (n = 97)				Other (n = 7)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
6.17* [If 6.14 is Yes] Which of the following testing techniques are used for detecting *contamination* of in-process materials and/or finished products?																
1. Physical	51	57.48	44.78	69.27	8	67.72	38.28	87.65	33	55 43	39.02	70.74	2	59.76	17 68	91.13
2. Chemical	42	45.27	32.82	58.34	7	56.68	28.62	81.02	18	29.28	17 83	44.14	2	50.50	11.40	88 99
3. Microbiological	66	74.12	61.60	83.65	6	48.42	22.47	75.25	32	63.42	48.94	75.83	2	40.24	8.87	82.32
4. Visual (macroscopic or microscopic)	51	59.71	46.59	71.57	7	59.84	31.08	83.12	37	69.57	54.41	81 41	3	70.12	18.26	96.10
5. Organoleptic	31	37.18	25.37	50.75	1	11.42	1.65	49.72	30	56.34	40.56	70.92	0	0.00	0.00	0.00
6. No tests are conducted to detect *contamination*	4	3.60	1 29	9.66	1	8.26	1.07	42.83	2	3 19	0 77	12.22	0	0.00	0.00	0.00
7. Other	0	0.00	0.00	0.00	0	0.00	0.00	0.00	0	0.00	0.00	0.00	0	0.00	0.00	0.00
No answer	1	1.16	0.16	7.95	0	0.00	0.00	0.00	4	8.77	2.94	23.37	0	0.00	0.00	0.00
6.18 [If 6.14 is Yes] Does this plant conduct chemical tests to determine *potency* of in-process materials and/or finished products?																
1 Yes	68	78.14	65.95	86.83	8	65.32	37.76	85.39	27	53.17	37 69	68.06	2	50.50	11 40	88 99
2. No	23	20.70	12.24	32.82	4	34.68	14.61	62.24	24	39.69	26.23	54.91	2	49.50	11 01	88.60
No answer	1	1.16	0.16	7.95	0	0.00	0.00	0.00	3	7.15	2.03	22.25	0	0 00	0.00	0.00

(continued)

Table E-6. Weighted Responses for Section 6: Quality Control and Laboratory Operations (continued)

	Vitamins and Minerals (n = 118)				Aminos/Proteins/Animal Extracts (n = 16)				Herbals and Botanicals (n = 97)				Other (n = 7)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
6.19 [If 6.14 is Yes] For the most recent fiscal year, approximately what percentage of in-process materials and/or finished products was rejected because of the wrong identity, contamination, or potency?																
In-process materials: % of batches (mean response)	71	1.57	0.54	2.59	9	13.89[d]	0.00[b]	35.27	41	1.37	0.78	1.95	4	0.50	0.00[b]	1.03
Finished products: % of batches (mean response)	77	3.81	0.77	6.86	12	9.82[d]	0.00[b]	25.72	46	3.23	0.00[b]	6.71	3	0.29	0.00[b]	0.80
6.20 [If 6.19 > 0] What was the reason(s) for the rejection?																
In-Process Materials (mean responses in %)																
1. Microbial contamination	34	13.72	0.00[b]	28.58	5	38.24	5.21	71.28	23	35.70	5.92	65.49	2	40.82	0.00[b]	100.00[c]
2. Pesticide, herbicide, fungicide contamination	34	0.08	0.00[b]	0.23	5	0.00	0.00	0.00	23	0.00	0.00	0.00	2	0.00	0.00	0.00
3. Other chemical contamination	34	5.11	0.00[b]	10.98	5	36.67	0.00[b]	80.54	23	0.27	0.00[b]	0.80	2	0.00	0.00	0.00
4. Wrong ingredient	34	13.67	1.14	26.20	5	1.85	0.00[b]	4.96	23	12.07	0.06	24 08	2	0.00	0.00	0.00
5. Subpotency	34	18.16	9.29	27.03	5	4.63	0.00[b]	12.41	23	24.64	6.27	43 02	2	59.18	0.00[b]	100.00[c]
6. Superpotency	34	4.03	0.79	7.28	5	0.00	0.00	0.00	23	0.72	0.00[b]	2.18	2	0.00	0.00	0.00
7. Formulation with missing ingredient	34	8.74	2.54	14.93	5	4.72	0.00[b]	10.88	23	10.44	0.00[b]	21.78	2	0.00	0.00	0.00
8. Aflatoxin or other toxin	34	0.00	0.00	0.00	5	0.00	0.00	0.00	23	1.80	0.00[b]	5.45	2	0.00	0.00	0.00
9. Other	34	36.50	20.57	52.43	5	13.89	0.00[b]	33.78	23	14.35	0.00[b]	29.11	2	0.00	0.00	0.00

(continued)

Table E-6. Weighted Responses for Section 6: *Quality Control and Laboratory Operations (continued)*

	Vitamins and Minerals (n = 118)				Aminos/Proteins/Animal Extracts (n = 16)				Herbals and Botanicals (n = 97)				Other (n = 7)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
6.20 (continued)																
Finished Products (mean responses in %)																
1. Microbial contamination	47	10.26	2.65	17.88	6	27.82	0.00[b]	57.31	24	41.94	18.12	65.76	1	0.00	0.00	0.00
2. Pesticide, herbicide, fungicide contamination	47	0.25	0.00[b]	0.75	6	0.00	0.00	0.00	24	0.79	0.00[b]	2.40	1	0.00	0.00	0.00
3. Other chemical contamination	47	3.48	0.00[b]	7.32	6	14.62	0.00[b]	42.46	24	1.03	0.00[b]	2.72	1	0.00	0.00	0.00
4. Wrong ingredient	47	13.57	4.55	22.60	6	19.75	0.00[b]	47.65	24	4.61	0.00[b]	10.45	1	100.00	100.00	100.00
5. Subpotency	47	21.99	10.08	33.90	6	9.38	0.00[b]	26.44	24	32.23	9.79	54.67	1	0.00	0.00	0.00
6. Superpotency	47	5.15	0.72	9.57	6	0.00	0.00	0.00	24	0.00	0.00	0.00	1	0.00	0.00	0.00
7. Formulation with missing ingredient	47	2.74	0.24	5.24	6	8.08	0.96	15.20	24	0.00	0.00	0.00	1	0.00	0.00	0.00
8. Aflatoxin or other toxin	47	0.00	0.00	0.00	6	0.00	0.00	0.00	24	0.00	0.00	0.00	1	0.00	0.00	0.00
9. Other	47	42.56	28.22	56.89	6	20.35	0.00[b]	46.18	24	19.40	2.86	35.93	1	0.00	0.00	0.00

(continued)

Table E-6. Weighted Responses for Section 6: Quality Control and Laboratory Operations (continued)

	Vitamins and Minerals (n = 118)				Aminos/Proteins/Animal Extracts (n = 16)				Herbals and Botanicals (n = 97)				Other (n = 7)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
6.21* Which of the following testing methods are generally used for testing of raw materials, in-process materials, or finished products?																
1. Association of Analytical Chemists (AOAC)	56	45.23	34.12	56.83	9	55.21	30.95	77.22	30	33.07	22.33	45.91	3	41.24	12.85	76.97
2. U.S. Pharmacopeia (USP)	78	69.57	58.15	79.00	10	61.18	36.12	81.46	24	21.86	14.09	32.30	1	17.58	2.37	65.22
3. Food Chemical CODEX (FCC)	43	38.97	28.31	50.79	9	55.49	31.66	77.04	8	10.06	4.75	20.07	1	17.58	2.37	65.22
4. American Chemical Society (ACS)	20	15.22	8.93	24.73	3	18.79	6.12	45.06	5	5.32	1.96	13.63	0	0.00	0.00	0.00
5. In-house methods	67	53.92	42.30	65.12	10	63.58	38.22	83.12	42	40.55	29.06	53.18	1	17.58	2.37	65.22
6 Other	18	12.16	6.78	20.85	3	17.64	5.69	43.18	29	35.46	23.46	49.62	2	23.67	5.68	61.47
7. No testing conducted (Skip to question 6.24)	10	8.73	3.89	18.46	1	5.97	0.82	32.74	16	18.81	9.83	32.99	1	11.54	1.53	52.22
Don't know	1	1.86	0.26	12.07	0	0.00	0.00	0.00	0	0.00	0.00	0.00	0	0.00	0.00	0.00
No answer	2	2.59	—	—[e]	0	0.00	—	—[e]	7	6.21	—	—[e]	2	29.64	—	—[e]
6.22 [If 6.2 is 1-6] Does your testing policy specify the use of standard reference materials?																
1 Yes	82	69.02	56.29	79.40	8	52.36	28.04	75.61	44	53.10	39.52	66.23	2	33.58	7.88	74.92
2. No (Skip to question 6.24)	17	20.01	11.56	32.38	6	40.98	19.62	66.39	27	35.26	23.02	49.79	2	33.50	7.85	74.87
Don't know	2	0.77	0.19	3.07	0	0.00	0.00	0.00	0	0.00	0.00	0.00	0	0.00	0.00	0.00
No answer	7	10.20	4.40	21.87	1	6.66	0.88	36.48	10	11.64	5.88	21.76	2	32.92	7.64	74.45

(continued)

Table E-6. Weighted Responses for Section 6: Quality Control and Laboratory Operations (continued)

	Vitamins and Minerals (n = 118)				Aminos/Proteins/Animal Extracts (n = 16)				Herbals and Botanicals (n = 97)				Other (n = 7)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
6.23* [If 6.22 is Yes] What is the source of the standard reference materials?																
1. Compendial reference standard	64	83.30	71.50	90.85	6	75.73	37.50	94.19	18	47.12	30.29	64.64	1	59 18	8 11	95.97
2. In-house *primary* reference materials	39	50.20	36.39	63.98	4	49.12	18.96	79.93	29	57.13	38 92	73.59	1	59.18	8.11	95.97
3. In-house *working* reference materials	42	46.39	33.33	59.98	4	49.12	18.96	79.93	24	49.48	32.00	67.09	1	59.18	8.11	95 97
4 Other	10	7.97	4.10	14.94	0	0 00	0.00	0.00	2	4.07	1 01	14.97	0	0.00	0 00	0.00
No answer	1	3.57	0.47	22.42	0	0.00	0.00	0.00	2	7.01	1.54	26.62	1	40.82	4.03	91.89
6.24 Does your plant hold representative reserve samples of each batch manufactured?																
1. Yes	95	77.41	65.74	85.95	13	82.08	55.92	94.30	68	70.15	56.97	80.66	3	41.76	13.14	77.26
2. No (Skip to question 6.26)	14	14.35	7.57	25.53	3	17.92	5.70	44.08	18	20.24	11.06	34.12	3	40.66	12.63	76.46
Not applicable (Skip to question 6.26)	3	2.92	0.61	12.91	0	0.00	0.00	0.00	5	4.68	1 88	11.20	0	0.00	0.00	0.00
No answer	6	5.32	1.94	13.75	0	0.00	0.00	0.00	6	4.93	2.17	10.84	1	17.58	2.37	65.22

(continued)

Table E-6. Weighted Responses for Section 6: Quality Control and Laboratory Operations (continued)

	Vitamins and Minerals (n = 118)				Aminos/Proteins/Animal Extracts (n = 16)				Herbals and Botanicals (n = 97)				Other (n = 7)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
6.25 [If 6.24 is Yes] How long do you hold representative reserve samples?																
1. ____ year(s) after expiration date	42	45.76	33.29	58.79	2	14.56	3.50	44.45	19	22.84	14.00	34.98	2	70.97	17.69	96.53
2. ____ year(s) from date of manufacture	42	42.3	30.34	55.24	8	62.55	34.82	83.93	36	59.47	45.16	72.33	1	29.03	3.47	82.31
3 Other	9	7.9	3.24	18.01	2	15.26	3.70	45.74	10	13.48	6.81	24.93	0	0.00	0.00	0.00
Don't know	0	0.00	0.00	0.00	0	0.00	0.00	0.00	1	1.83	0.25	12.19	0	0.00	0.00	0.00
No answer	2	4.03	0.85	17.06	1	7.63	1.00	40.41	2	2.40	0.59	9.28	0	0.00	0.00	0.00
Mean years after expiration date	42	1.99	1.40	2.59	2	3.86	0.00[b]	8.09	19	1.98	1.52	2.44	2	4.66	0.00[b]	10.81
Mean years from date of manufacture	42	4.52	3.81	5.22	8	3.70	2.44	4.96	36	4.04	3.40	4.68	1	6.00	6.00	6.00
6.26 Are there written procedures for *laboratory operations?*																
1. Yes	71	52.67	41.69	63.41	9	54.92	30.74	76.98	40	42.70	30.98	55.29	2	29.70	7.11	69.99
2. No (Skip to question 6.31)	11	11.66	5.70	22.35	3	17.92	5.70	44.08	17	14.11	8.67	22.14	0	0.00	0.00	0.00
3. Do not have laboratory operations (Skip to Section 7)	31	31.28	21.42	43.19	3	20.90	6.80	48.90	34	37.82	25.83	51.51	4	52.72	19.26	83.91
Don't know	0	0.00	0.00	0.00	0	0.00	0.00	0.00	1	1.28	0.18	8.71	0	0.00	0.00	0.00
No answer	5	4.39	1.38	13.04	1	6.26	0.83	34.72	5	4.09	1.67	9.68	1	17.58	2.37	65.22

(continued)

Table E-6. Weighted Responses for Section 6: Quality Control and Laboratory Operations (continued)

	Vitamins and Minerals (n = 118)				Aminos/Proteins/Animal Extracts (n = 16)				Herbals and Botanicals (n = 97)				Other (n = 7)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
6.27 [If 6.26 is Yes] Does plant management verify and keep records that these procedures are being followed?																
1. Yes	67	94.08	84.91	97.82	7	77.72	40.58	94.69	33	78.82	59.24	90.50	2	100.00	100.00	100.00
2. No (Skip to question 6.29)	3	4.27	1.32	12.92	2	22.28	5.31	59.42	6	16.07	6.57	34.27	0	0.00	0.00	0.00
No answer	1	1.65	0.22	11.13	0	0.00	0.00	0.00	1	5.11	0.71	28.77	0	0.00	0.00	0.00
6.28 [If 6.27 is Yes] Are records made of any corrective actions taken if procedures are *not* followed?																
1. Yes, for some procedures	25	36.14	22.79	52.05	4	55.99	21.28	85.69	18	62.43	43.67	78.08	1	59.18	8.06	96.00
2. Yes, for all procedures	36	56.18	40.82	70.44	3	44.01	14.31	78.72	11	27.34	14.49	45.53	1	40.82	4.00	91.94
3. No	6	7.67	3.26	17.03	0	0.00	0.00	0.00	4	10.23	3.62	25.71	0	0.00	0.00	0.00

(continued)

Table E-6. Weighted Responses for Section 6: Quality Control and Laboratory Operations (continued)

	Vitamins and Minerals (n = 118)				Aminos/Proteins/Animal Extracts (n = 16)				Herbals and Botanicals (n = 97)				Other (n = 7)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
6.29* [If 6.26 is Yes] Do your written procedures for laboratory operations include any of the following?																
1. Sample selection, method description, validation of methodology and results, acceptance/rejection criteria, and use of test results	64	89.99	75.01	96.42	9	100.00	0.00	0.00	33	82.99	65.97	92.47	2	100.00	100.00	100.00
2. Methods for determining ingredient identity and for detecting adulteration	54	80.44	66.54	89.48	7	78.77	45.13	94.36	29	71.86	53.79	84.85	2	100.00	100.00	100.00
3. Tests to assess the stability characteristics of products in determining appropriate storage conditions and expiration dating (include testing conducted at corporate headquarters)	43	62.29	47.14	75.37	6	66.32	31.55	89.37	20	54.07	35.72	71.38	2	100.00	100.00	100.00
4. Procedures for handling and filing test records	54	78.79	64.60	88.32	6	67.37	33.51	89.42	26	67.99	49.93	81.90	0	0.00	0.00	0.00
No answer	1	0.64	0.09	4.45	0	0.00	0.00	0.00	2	7.08	1.54	27.10	0	0.00	0.00	0.00

(continued)

Table E-6. Weighted Responses for Section 6: Quality Control and Laboratory Operations (continued)

	Vitamins and Minerals (n = 118)				Aminos/Proteins/Animal Extracts (n = 16)				Herbals and Botanicals (n = 97)				Other (n = 7)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
6.30 [If 6.26 is Yes] How long are records for laboratory operations retained?																
1. ___ year(s) after expiration date	29	43.60	29.59	58.72	1	10.35	1.45	47.51	7	12.83	5.85	25.85	1	59.18	8.09	95.98
2. ___ year(s) from date of manufacture	28	38.17	25.06	53.26	5	55.44	23.78	83.22	23	64.16	47.05	78.30	0	0.00	0.00	0.00
3. Other	14	18.23	9.36	32.49	3	34.21	11.08	68.44	7	13.96	6.54	27.34	1	40.82	4.02	91.91
No answer	0	0.00	0.00	0.00	0	0.00	0.00	0.00	3	9.05	2.54	27 49	0	0.00	0.00	0.00
Mean years after expiration date	29	2.32	__[a]	—	1	3.00	—	__[a]	7	2.01	—	__[a]	1	1.00	—	__[a]
Mean years from date of manufacture	28	4.74	3.87	5.61	5	5.00	3.57	6.43	23	5.05	3.67	6.44	__[f]	—	—	—
6.31 [If 6.26 is 1 or 2] Does this plant verify and keep records that laboratory equipment is calibrated correctly?																
1. Yes	68	77.90	63.53	87.70	9	75.40	44.43	92.15	38	68.35	53.75	80.05	2	100.00	100.00	100.00
2. No	11	19.66	10.37	34.09	2	16.01	4.07	46.11	19	31.65	19.95	46.25	0	0.00	0.00	0.00
Don't know	1	0.52	0.07	3.65	0	0.00	0.00	0.00	0	0.00	0.00	0.00	0	0.00	0.00	0.00
No answer	2	1.93	0.42	8.33	1	8.60	1.11	44.15	0	0.00	0.00	0.00	0	0.00	0.00	0.00

[a]Confidence interval could not be estimated because there was only one observation (respondent) in a stratum for that question

[b]Estimated confidence interval for lower bound was less than zero so we truncated the interval.

[c]Estimated confidence interval for upper bound was greater than 100 so we truncated the interval.

[d]One respondent in the aminos/proteins/animal extracts category entered 100% for question 6.19 for both in-process materials and finished products. The means excluding this response are 2.94 for in-process materials and 1.70 for finished products. (This respondent did not answer question 6.20.)

[e]Confidence interval could not be estimated because of matrix conformability error.

[f]Could not estimate because there were no respondents for that question.

*Total may sum to greater than 100% because respondents could select more than one answer.

Table E-7. Weighted Responses for Section 7: Production and Process Controls

	Vitamins and Minerals (n = 118)				Aminos/Proteins/Animal Extracts (n = 16)				Herbals and Botanicals (n = 97)				Other (n = 7)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
7.1 Are there written procedures for *receipt of dietary supplement ingredients?*																
1. Yes	88	74.37	62.79	83.30	8	49.23	26.41	72.38	55	60.31	47.41	71.92	1	17.58	2.37	65.22
2. No (Skip to question 7.6)	11	10.40	4.85	20.91	4	23.61	8.96	49.25	20	16.11	10.10	24.70	2	29.12	6.87	69.58
3. Do not receive dietary supplement ingredients (Skip to question 7.6)	16	11.78	6.21	21.19	3	18.50	5.87	45.25	17	19.53	10.46	33.51	3	35.73	11.21	70.99
No answer	3	3.46	0.84	13.08	1	8.66	1.25	41.58	5	4.06	1.64	9.68	1	17.58	2.37	65.22
7.2 [If 7.1 is Yes] Does plant management verify and keep records that these procedures are being followed?																
1. Yes	75	83.56	70.39	91.57	8	100.00	100.00	100.00	46	82.82	67.98	91.63	1	100.00	100.00	100.00
2. No (Skip to question 7.4)	13	16.44	8.43	29.61	0	0.00	0.00	0.00	8	13.56	6.30	26.80	0	0.00	0.00	0.00
No answer	0	0.00	0.00	0.00	0	0.00	0.00	0.00	1	3.62	0.50	21.78	0	0.00	0.00	0.00
7.3 [If 7.2 is Yes] Are records made of any corrective actions taken if procedures are *not* followed?																
1. Yes, for some procedures	34	43.79	30.10	58.50	3	36.99	11.60	72.42	23	41.39	25.27	59.60	1	100.00	100.00	100.00
2. Yes, for all procedures	31	43.78	30.25	58.30	4	50.29	19.12	81.24	12	27.56	13.31	48.52	0	0.00	0.00	0.00
3. No	10	12.43	6.24	23.22	1	12.72	1.57	57.05	10	19.74	9.64	36.20	0	0.00	0.00	0.00
No answer	0	0.00	0.00	0.00	0	0.00	0.00	0.00	1	11.31	1.70	48.49	0	0.00	0.00	0.00

(continued)

Table E-7. Weighted Responses for Section 7: Production and Process Controls (continued)

	Vitamins and Minerals (n = 118)				Aminos/Proteins/Animal Extracts (n = 16)				Herbals and Botanicals (n = 97)				Other (n = 7)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
7.4* [If 7.1 is Yes] Do your written procedures for receipt of dietary supplement ingredients include any of the following?																
1. Written acceptance criteria for dietary supplement ingredients developed by a competent individual	70	73.47	59.38	83.99	7	87.87	47.89	98.28	38	72.61	57.42	83.90	0	0.00	0.00	0.00
2. Certificate of Analysis specifications	84	97.55	92.68	99.21	6	75.15	36.88	93.99	42	80.14	66.46	89.15	1	100.00	100.00	100.00
3. Representative sample and authenticated plant reference held in an environmentally appropriate repository for each receiving and production lot/batch	55	60.59	46.85	72.85	3	36.99	11.71	72.20	26	50.76	34.23	67.12	1	100.00	100.00	100.00
4. Records linking the Certificate of Analysis to the identity of the unprocessed raw material and to the finished product	70	81.39	69.11	89.52	3	37.57	11.99	72.67	40	76.93	62.50	86.97	1	100.00	100.00	100.00
5. Records to trace and verify compliance with laws on harvest of wildcrafted botanicals	5	7.65	2.59	20.52	0	0.00	0.00	0.00	14	19.15	11.07	31.06	0	0.00	0.00	0.00
6. Audit records concerning the reliability of supplier Certificate of Analysis	30	37.73	26.01	51.09	4	50.29	19.29	81.07	14	27.53	14.45	46.06	1	100.00	100.00	100.00
7. Records for source of animal derived materials or products	17	21.31	12.24	34.44	5	61.84	26.97	87.67	1	7.74	1.11	38.63	0	0.00	0.00	0.00

(continued)

Table E-7. Weighted Responses for Section 7: Production and Process Controls (continued)

	Vitamins and Minerals (n = 118)				Aminos/Proteins/Animal Extracts (n = 16)				Herbals and Botanicals (n = 97)				Other (n = 7)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
7.4 [Continued]																
8. Records for fish and fishery demonstrating that FDA fish and fishery products HACCP regulations are followed	1	0.47	0.07	3.35	1	12.13	1.72	52.11	1	2.12	0.28	14.14	0	0.00	0.00	0.00
9. Records for raw materials to assure segregation of raw, in-process, and finished product and protection against adulteration	50	53.75	40.46	66.52	3	36.99	11.71	72.20	26	52.41	35.85	68.46	0	0.00	0.00	0.00
No answer	0	0.00	0.00	0.00	0	0.00	0.00	0.00	1	3.62	0.50	21.78	0	0.00	0.00	0.00
7.5 [If 7.1 is Yes] How long are records on receipt of dietary supplement ingredients retained?																
1. _____ year(s) after expiration date	28	32.25	21.26	45.64	2	24.27	5.82	62.46	15	21.35	12.17	34.72	1	100.00	100.00	100.00
2. _____ year(s) from date of manufacture	33	34.45	23.19	47.78	5	63.01	27.80	88.29	25	55.94	40.33	70.46	0	0.00	0.00	0.00
3. Other	25	29.10	18.44	42.70	1	12.72	1.60	56.59	11	14.91	8.04	25.99	0	0.00	0.00	0.00
Don't know	1	3.03	0.41	19.30	0	0.00	0.00	0.00	1	1.39	0.19	9.61	0	0.00	0.00	0.00
No answer	1	1.17	0.16	8.04	0	0.00	0.00	0.00	3	6.41	1.79	20.40	0	0.00	0.00	0.00
Mean years after expiration date	28	2.36	—	—[a]	2	2.90	—	—[a]	15	2.13	—	—[a]	1	1.00	—	—[a]
Mean years from date of manufacture	33	4.32	—	—[a]	5	5.00	—	—[a]	25	4.98	—	—[a]	—[b]	—	—	—

(continued)

Table E-7. Weighted Responses for Section 7: Production and Process Controls (continued)

	Vitamins and Minerals (n = 118)				Aminos/Proteins/Animal Extracts (n = 16)				Herbals and Botanicals (n = 97)				Other (n = 7)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
7.6 Are there written procedures for *production processes?*																
1. Yes	91	72.09	60.29	81.47	10	61.18	36.12	81.46	67	68.71	55.43	79.49	3	41.24	12.85	76.97
2 No (Skip to question 7.11)	7	4.65	1.58	12.90	4	23.90	9.18	49.37	12	11.62	6.34	20.34	1	17.58	2.37	65.22
3 No production processes conducted (Skip to Section 8)	15	19.10	10 99	31.10	1	6.26	0.83	34.72	13	15.58	7.28	30.27	2	23.60	5.67	61 38
No answer	5	4.16	1.26	12.88	1	8.66	1.25	41.58	5	4.09	1.67	9.68	1	17.58	2.37	65 22
7.7 [If 7.6 is Yes] Does plant management verify and keep records that these procedures are being followed?																
1 Yes	90	98.79	91.74	99.83	10	100.00	100.00	100.00	57	87.48	77.69	93.35	2	72.01	18.44	96.70
2. No (Skip to question 7.9)	1	1.21	0 17	8.26	0	0.00	0.00	0.00	8	10.01	4.92	19 32	1	27.99	3.30	81.56
No answer	0	0.00	0.00	0.00	0	0.00	0.00	0.00	2	2.50	0.60	9.82	0	0.00	0.00	0.00
7 8 [If 7.7 is Yes] *Are records made of any corrective actions taken if procedures are not followed?*																
1. Yes, for some procedures	36	40.36	28.39	53.61	3	28.83	9.47	61.06	31	58.04	41.72	72.78	0	0.00	0.00	0.00
2. Yes, for all procedures	42	47.92	35.62	60.49	6	60.94	30.04	85.00	16	26.75	15.47	42.15	2	100.00	100.00	100.00
3. No	12	11.71	6.20	21.03	1	10.24	1.32	49.38	10	15.21	7.77	27.65	0	0.00	0.00	0.00

(continued)

Table E-7. Weighted Responses for Section 7: Production and Process Controls (continued)

	Vitamins and Minerals (n = 118)				Aminos/Proteins/Animal Extracts (n = 16)				Herbals and Botanicals (n = 97)				Other (n = 7)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
7.9* [If 7.6 is Yes] Do your written procedures for production processes include any of the following?																
1. Master production and control records	83	90.02	77.22	96.01	7	69.77	36.37	90.31	50	77.65	65.27	86.53	1	29.40	3.52	82.63
2. Batch production and control records	88	95.66	82.56	99.03	10	100.00	100.00	100.00	61	92.43	83.79	96.65	3	100.00	100.00	100.00
3. Equipment use and cleaning records, including dates of use and product and lot number of each batch processed	77	81.59	68.84	89.90	9	89.76	50.65	98.68	47	74.98	63.17	83.97	2	72.01	18.44	96.70
4. Records that demonstrate that automatic equipment, including mechanical and electronic equipment (computers), used in the manufacturing process is designed, installed, tested, calibrated, validated, maintained, and checked to ensure that they are capable of and are performing the intended functions	46	49.03	36.39	61.79	5	50.24	21.91	78.42	28	43.67	29.44	59.03	2	72.01	18.44	96.70
5. Records for reprocessing of a product	66	71.65	58.21	82.09	9	89.76	50.65	98.68	36	54.31	39.20	68.67	1	29.40	3.52	82.63
6. Records to assure that correct labels and labeling and safe packaging materials are used	80	87.61	76.42	93.92	9	89.76	50.65	98.68	45	67.35	51.09	80.29	2	72.01	18.44	96.70
7. Records to permit tracking the history of the manufacturing process	87	94.98	82.87	98.66	9	90.71	55.66	98.70	57	86.70	75.79	93.14	2	72.01	18.44	96.70

(continued)

Table E-7. Weighted Responses for Section 7: Production and Process Controls (continued)

	Vitamins and Minerals (n = 118)				Aminos/Proteins/Animal Extracts (n = 16)				Herbals and Botanicals (n = 97)				Other (n = 7)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
7.9 [Continued]																
8. Reserve samples of each batch of dietary supplement product are retained and stored under conditions consistent with the product labeling	87	93.98	81.78	98.19	10	100.00	100.00	100.00	54	83.17	72.01	90.48	2	72.01	18.44	96.70
No answer	0	0.00	0.00	0.00	0	0.00	0.00	0.00	2	2.50	0.60	9.82	0	0.00	0.00	0.00
7.10 [If 7.6 is Yes] How long are records on production processes retained?																
1. _____ year(s) after expiration date	32	35.82	24.38	49.12	2	19 53	4.70	54.45	16	20.23	11.80	32.47	1	42.62	6.20	89.29
2 _____ year(s) from date of manufacture	39	42.66	30.42	55.87	6	60.00	28.78	84.77	38	63.86	50.02	75.72	1	29.40	3.52	82.63
3 Other	18	19.99	11.46	32.54	2	20.47	4 94	56.05	8	9.68	4.78	18.62	1	27.99	3.30	81.56
Don't know	1	0.82	0.11	5.78	0	0.00	0.00	0.00	0	0.00	0.00	0.00	0	0.00	0.00	0.00
No answer	1	0.71	0.10	4.96	0	0.00	0.00	0.00	5	6.23	2 54	14.49	0	0.00	0.00	0.00
Mean years after expiration date	32	2.36	—	—[a]	2	2.90	—	—[a]	16	3.00	—	—[a]	1	1.00	—	—[a]
Mean years from date of manufacture	39	4.42	—	—[a]	6	5.00	—	—[a]	38	5.40	—	—[a]	1	6.00	—	—[a]

(continued)

Table E-7. Weighted Responses for Section 7: Production and Process Controls (continued)

	Vitamins and Minerals (n = 118)				Aminos/Proteins/Animal Extracts (n = 16)				Herbals and Botanicals (n = 97)				Other (n = 7)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
7.11 [If 7.6 is NOT 3] Does this plant use production and process controls that identify the points, steps, or stages in the manufacturing process to prevent adulteration?																
1. Yes	79	76.31	63.91	85.42	10	65.27	39.09	84.62	49	56.48	43.00	69.07	3	61.88	19.92	91 38
2. No (Skip to Section 8)	17	16.12	8.66	28.03	3	18.81	6.36	44.15	22	25.45	16.33	37.39	0	0.00	0.00	0.00
No answer	7	7.57	3.02	17.73	2	15.92	3.95	46.57	13	18.07	8.57	34.17	2	38.12	8.62	80.08
7.12* [If 7.11 is Yes] Does this plant's production and process controls have specifications that must be met for identity, purity, quality, strength, and composition of components, ingredients, or dietary supplements and packing and labeling materials?																
1. Yes, for components	53	66.96	52.62	78.71	5	51.18	23.27	78.37	28	59.58	43.11	74.13	0	0.00	0.00	0.00
2. Yes, for ingredients	67	85.99	75.41	92.47	5	51.18	23.27	78.37	40	83.60	70.06	91.73	3	100.00	100.00	100.00
3. Yes, for dietary supplements	65	81.04	67.34	89.86	7	69.77	36.12	90.40	31	61.29	44.46	75.79	1	37.18	4.57	87.97
4. Yes, for packing and labeling materials	49	64.01	49.90	76.05	8	79.53	43.62	95.12	36	74.01	57 79	85.55	1	25.64	3.07	78.99
5. No, none of the above	1	3.01	0.42	18.53	0	0.00	0.00	0.00	4	7.59	2.63	19.98	0	0.00	0.00	0.00
No answer	0	0.00	0.00	0.00	0	0.00	0.00	0.00	1	1.76	0.24	11.94	0	0.00	0.00	0.00

(continued)

Table E-7. Weighted Responses for Section 7: Production and Process Controls (continued)

	Vitamins and Minerals (n = 118)				Aminos/Proteins/Animal Extracts (n = 16)				Herbals and Botanicals (n = 97)				Other (n = 7)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
7.13* [If 7.11 is Yes] Does this plant conduct tests to monitor the production and in-process control points, steps, or stages to ensure the identity, purity, quality, strength, and composition of components, ingredients, or dietary supplements?																
1. Yes, for components	41	45.87	32.55	59.80	5	51.18	23.27	78.37	20	34.97	22.30	50.19	1	25.64	3.07	78.99
2. Yes, for ingredients	50	61.22	47.06	73.70	7	69.77	36.12	90.40	33	59.63	41.53	75.44	2	62.82	12.03	95.43
3. Yes, for dietary supplements	53	64.83	50.35	77.01	6	60.47	29.32	84.94	28	55.45	39.00	70.79	2	62.82	12.03	95.43
4. No, none of the above	14	20.80	11.37	34.97	1	9.76	1.39	45.36	7	13.42	6.17	26.76	0	0.00	0.00	0.00
No answer	0	0.00	0.00	0.00	0	0.00	0.00	0.00	1	1.76	0.24	11.94	0	0.00	0.00	0.00

[a]Confidence interval could not be estimated because there was only one observation (respondent) in a stratum for that question.

[b]Could not estimate because there were no respondents for that question.

*Total may sum to greater than 100% because respondents could select more than one answer.

Table E-8. Weighted Responses for Section 8: Warehousing

	Vitamins and Minerals (n = 118)				Aminos/Proteins/Animal Extracts (n = 16)				Herbals and Botanicals (n = 97)				Other (n = 7)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
8.0 Does this plant or site have warehouses to store raw materials, in-process materials, or finished products?																
1. Yes	116	97.41	86.43	99.55	16	100.00	100.00	100.00	92	95.91	90.32	98.33	6	88.46	47.78	98.47
2. No (Skip to Section 9)	2	2.59	0.45	13.57	0	0.00	0.00	0.00	5	4.09	1.67	9.68	1	11.54	1.53	52.22
8.1* Does your warehouse have temperature or humidity controls?																
1. Temperature controls	82	73.34	62.15	82.17	6	39.40	18.80	64.60	61	68.84	56.27	79.14	3	53.45	17.91	85.80
2. Humidity controls	25	27.33	17.81	39.49	0	0.00	0.00	0.00	14	13.11	7.37	22.26	0	0.00	0.00	0.00
3. No temperature or humidity controls	34	26.66	17.83	37.85	10	60.60	35.40	81.20	31	31.16	20.86	43.73	3	46.55	14.20	82.09
8.2 Are there written procedures for *storage procedures* to control against physical, chemical, and microbial adulteration as well as deterioration of the product and container?																
1. Yes	75	63.90	51.97	74.32	7	42.40	21.01	67.06	51	56.88	43.57	69.26	2	33.58	7.92	74.82
2. No (Skip to question 8.7)	41	36.10	25.68	48.03	9	57.60	32.94	78.99	40	42.24	29.95	55.58	4	66.42	25.18	92.08
No answer	0	0.00	0.00	0.00	0	0.00	0.00	0.00	1	0.88	0.12	6.11	0	0.00	0.00	0.00

(continued)

Table E-8. Weighted Responses for Section 8: Warehousing (continued)

	Vitamins and Minerals (n = 118)				Aminos/Proteins/Animal Extracts (n = 16)				Herbals and Botanicals (n = 97)				Other (n = 7)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
8.3 [If 8.2 is Yes] Does plant management verify and keep records that these procedures are being followed?																
1. Yes	65	87.93	74.33	94.82	7	100.00	100.00	100.00	34	74.35	59.84	84.94	2	100.00	100.00	100.00
2. No (Skip to question 8.5)	10	12.07	5.18	25.67	0	0.00	0.00	0.00	16	24.51	14.24	38.84	0	0.00	0.00	0.00
No answer	0	0.00	0.00	0.00	0	0.00	0.00	0.00	1	1.13	0.15	7.96	0	0.00	0.00	0.00
8.4 [If 8.3 is Yes] Are records made of any corrective actions taken if procedures are *not* followed?																
1. Yes, for some procedures	24	32.93	20.10	48.93	3	41.60	13.44	76.57	17	48 84	27.43	70 69	1	59.18	8.06	96.00
2. Yes, for all procedures	36	58.05	42.12	72.46	4	58.40	23.43	86.56	12	33.54	15.83	57.52	1	40.82	4.00	91 94
3. No	4	7.43	2.11	23.03	0	0.00	0.00	0.00	4	12.24	3 92	32.27	0	0.00	0 00	0.00
No answer	1	1.59	0.22	10.79	0	0.00	0.00	0.00	1	5.38	0.74	30.34	0	0.00	0 00	0.00
8.5* [If 8.2 is Yes] Do your written procedures for warehousing include any of the following?																
1. Procedures and records for forward and backward tracing of product	68	92 18	79.58	97.27	7	100.00	100.00	100.00	47	94.65	85.85	98.10	2	100.00	100.00	100.00
2. Procedures and records for salvaged products that include product examination and reprocessing as appropriate	55	66.53	50.93	79.20	5	73.17	36.21	92.91	31	58.11	39.42	74.73	1	40.82	4.03	91 89
No answer	3	2.03	0.62	6.49	0	0.00	0.00	0.00	3	4.22	1.29	12.95	0	0.00	0.00	0.00

(continued)

Table E-8. Weighted Responses for Section 8: Warehousing (continued)

	Vitamins and Minerals (n = 118)				Aminos/Proteins/Animal Extracts (n = 16)				Herbals and Botanicals (n = 97)				Other (n = 7)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
8.6 [If 8.2 is Yes] How long are records on warehousing retained?																
1. _____ year(s) after expiration date	25	30.95	19.59	45.20	1	13.41	1.84	56.13	15	23.13	13.07	37.59	2	100.00	100.00	100.00
2. _____ year(s) from date of manufacture	24	30.63	18.80	45.72	4	57.05	21.70	86.42	26	62.21	46.54	75.68	0	0.00	0.00	0.00
3. Other	20	30.47	18.63	45.62	2	29.54	7.21	69.35	6	8.84	3.86	18.97	0	0.00	0.00	0.00
Don't know	0	0.00	0.00	0.00	0	0.00	0.00	0.00	1	1.61	0.22	11.01	0	0.00	0.00	0.00
No answer	6	7.94	3.66	16.37	0	0.00	0.00	0.00	3	4.22	1.29	12.95	0	0.00	0.00	0.00
Mean years after expiration date	25	2.03	—	—[a]	1	5.00	—	—[a]	15	3.15	—	—[a]	2	1.00	—	—[a]
Mean years from date of manufacture	24	4.00	—	—[a]	4	5.52	—	—[a]	26	5.24	—	—[a]	—[b]	—	—	—
8.7 Are there written procedures on proper precautions to *reduce the potential for mix-ups or adulteration or contamination* of ingredients, raw materials, or in-process formulations (e.g., safety controls and operating practices or separation of ingredients)?																
1. Yes	82	63.51	51.73	73.88	9	54.92	30.73	76.98	54	59.59	46.11	71.76	2	33.58	7.92	74.82
2. No (Skip to Section 9)	28	27.42	17.98	39.43	6	36.42	16.87	61.78	33	35.95	24.21	49.65	4	66.42	25.18	92.08
Not applicable	2	2.66	0.46	13.90	1	8.66	1.25	41.59	2	1.79	0.43	7.09	0	0.00	0.00	0.00
Don't know	0	0.00	0.00	0.00	0	0.00	0.00	0.00	2	1.79	0.43	7.09	0	0.00	0.00	0.00
No answer	4	6.41	2.19	17.29	0	0.00	0.00	0.00	1	0.88	0.12	6.11	0	0.00	0.00	0.00

(continued)

Table E-8. Weighted Responses for Section 8: Warehousing (continued)

	Vitamins and Minerals (n = 118)				Aminos/Proteins/Animal Extracts (n = 16)				Herbals and Botanicals (n = 97)				Other (n = 7)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
8.8 [If 8.7 is Yes] Does plant management verify and keep records that these procedures are being followed?																
1. Yes	75	93.20	85.60	96.93	8	89.12	51.06	98.47	44	83.52	69.69	91.79	2	100.00	100.00	100.00
2. No (Skip to Section 9)	7	6.80	3.07	14.40	1	10.88	1.53	48.94	9	14.94	7.11	28.72	0	0.00	0.00	0.00
No answer	0	0.00	0.00	0.00	0	0.00	0.00	0.00	1	1.54	0.21	10.52	0	0.00	0.00	0.00
8.9 [If 8.8 is Yes] Are records made of any corrective actions taken if procedures are *not* followed?																
1. Yes, for some procedures	31	42.54	28.84	57.49	4	48.82	18.87	79.65	24	44.29	27.08	63.00	1	59.18	8.10	95.97
2. Yes, for all procedures	38	49.14	35.04	63.39	3	38.38	12.47	73.15	12	29.03	14.22	50.25	1	40.82	4.03	91.90
3. No	6	8.31	3.20	19.90	1	12.79	1.62	56.68	7	14.84	6.34	30.99	0	0.00	0.00	0.00
No answer	0	0.00	0.00	0.00	0	0.00	0.00	0.00	1	11.83	1.78	49.83	0	0.00	0.00	0.00

[a]Confidence interval could not be estimated because there was only one observation (respondent) in a stratum for that question.

[b]Could not estimate because there were no respondents for that question.

*Total may sum to greater than 100% because respondents could select more than one answer

Table E-9. Weighted Responses for Section 9: Consumer Complaints

	Vitamins and Minerals (n = 118)				Aminos/Proteins/Animal Extracts (n = 16)				Herbals and Botanicals (n = 97)				Other (n = 7)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
9.1 Are there written procedures at the plant or corporate level for handling *consumer complaints*?																
1. Yes	86	74.55	63.17	83.34	10	60.89	35.42	81.55	51	58.13	46.01	69.33	3	41.24	12.85	76.97
2. No (Skip to question 9.6)	29	23.38	14.90	34.72	6	39.11	18.45	64.58	43	39.50	28.65	51.49	4	58.76	23.03	87.15
Not applicable (Skip to Section 10)	1	0.34	0.05	2.36	0	0.00	0.00	0.00	1	0.88	0.12	6.12	0	0.00	0.00	0.00
No answer	2	1.74	0.43	6.72	0	0.00	0.00	0.00	2	1.50	0.36	6.06	0	0.00	0.00	0.00
9.2 [If 9.1 is Yes] Does management verify and keep records that these procedures are being followed?																
1. Yes	81	92.98	81.55	97.55	9	90.19	53.57	98.65	45	91.58	81.41	96.43	3	100.00	100.00	100.00
2. No (Skip to question 9.4)	5	7.02	2.45	18.45	1	9.81	1.35	46.43	6	8.42	3.57	18.59	0	0.00	0.00	0.00
9.3 [If 9.2 is Yes] Are records made of any corrective actions taken if procedures are *not* followed?																
1. Yes, for some procedures	31	41.87	28.80	56.18	5	54.39	24.10	81.75	18	40.24	22.04	61.60	0	0.00	0.00	0.00
2. Yes, for all procedures	38	45.84	32.59	59.71	4	45.61	18.25	75.90	20	37.00	20.84	56.72	3	100.00	100.00	100.00
3. No	12	12.29	6.29	22.63	0	0.00	0.00	0.00	6	12.15	4.86	27.21	0	0.00	0.00	0.00
No answer	0	0.00	0.00	0.00	0	0.00	0.00	0.00	1	10.61	1.54	47.45	0	0.00	0.00	0.00

(continued)

Table E-9. Weighted Responses for Section 9: Consumer Complaints (continued)

	Vitamins and Minerals (n = 118)				Aminos/Proteins/Animal Extracts (n = 16)				Herbals and Botanicals (n = 97)				Other (n = 7)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
9.4* [If 9.1 is Yes] Do your written procedures for handling consumer complaints include any of the following?																
1. Procedures for handling all written and oral complaints	83	97.34	91.14	99.24	8	79.91	44.34	95.20	47	94.15	84.75	97.90	3	100.00	100.00	100.00
2. Records concerning the handling of complaints including any investigations, investigation findings, and follow-up action taken	75	83.17	69.03	91.64	10	100.00	100.00	100.00	43	79.72	56.08	92.37	2	72.01	18.40	96.71
3. Procedures for requiring reporting of serious adverse events to FDA MEDWATCH	15	16.82	9.07	29.07	1	9.34	1.29	44.72	5	9.22	3.32	23.09	0	0.00	0.00	0.00
Don't know	0	0.00	0.00	0.00	0	0.00	0.00	0.00	1	1.45	0.19	10.01	0	0.00	0.00	0.00
No answer	0	0.00	0.00	0.00	0	0.00	0.00	0.00	1	1.45	0.19	10.01	0	0.00	0.00	0.00
9.5 [If 9.1 is Yes] How long are records on consumer complaints retained at the plant or corporate headquarters?																
1 _____ year(s) after expiration date	31	37.04	25.06	50.87	2	19.62	4.70	54.70	14	29.05	14.29	50.15	1	42.62	6.19	89.32
2 _____ year(s) from date of manufacture	23	28.48	17.65	42.52	6	59.81	28.88	84.51	18	35.58	20.85	53.65	1	29.40	3.51	82.67
3. Other	30	30.66	20.14	43.68	2	20.57	5.02	55.94	14	28.08	13.72	48.94	1	27.99	3.29	81.60
Don't know	1	3.02	0.41	19.21	0	0.00	0.00	0.00	2	2.89	0.70	11.18	0	0.00	0.00	0.00
No answer	1	0.80	0.11	5.61	0	0.00	0.00	0.00	3	4.40	1.35	13.44	0	0.00	0.00	0.00
Mean years after expiration date	31	1.95	1.38	2.52	2	1.95	0.53	3.38	14	3.04	1.63	4.45	1	1.00	1.00	1.00
Mean years from date of manufacture	23	4.51	3.89	5.14	6	4.51	3.09	5.92	18	3.97	3.24	4.69	1	6.00	6.00	6.00

(continued)

Table E-9. Weighted Responses for Section 9: Consumer Complaints (continued)

	Vitamins and Minerals (n = 118)				Aminos/Proteins/Animal Extracts (n = 16)				Herbals and Botanicals (n = 97)				Other (n = 7)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
9.6* What are your procedures for handling adverse events associated with consumer complaints?																
1. Incident is reported to FDA	22	20.60	12.49	32.04	3	18.50	5.87	45.25	12	16.23	7.61	31.31	0	0.00	0.00	0.00
2. Product is tested for identity and composition	86	73.09	61.39	82.27	11	69.27	43.37	86.90	58	58.53	45.34	70.59	2	23.67	5.68	61.47
3. Product is reformulated	36	32.09	22.60	43.32	1	6.26	0.83	34.72	21	22.54	12.92	36.32	0	0.00	0.00	0.00
4. Product is recalled	68	59.29	47.59	70.03	12	75.24	48.75	90.66	58	63.36	51.57	73.74	2	29.70	7.11	69.99
5. Other	28	23.72	15.14	35.14	6	39.11	18.44	64.59	22	20.92	13.39	31.17	4	58.76	23.02	87.16
Don't know	1	0.34	0.05	2.37	0	0.00	0.00	0.00	1	0.85	0.12	5.91	0	0.00	0.00	0.00
No answer	2	1.47	0.36	5.86	1	6.26	0.83	34.72	9	8.99	4.43	17.41	0	0.00	0.00	0.00
9.7 Does this plant have a recall procedure in place?																
1. Yes	95	80.84	69.74	88.53	15	93.74	65.28	99.17	59	59.64	46.42	71.60	3	41.24	12.84	76.98
2. No	18	16.47	9.27	27.57	1	6.26	0.83	34.72	31	33.99	22.71	47.43	4	58.76	23.02	87.16
No answer	4	2.69	0.96	7.31	0	0.00	0.00	0.00	6	6.37	2.63	14.63	0	0.00	0.00	0.00

(continued)

Table E-9. Weighted Responses for Section 9: Consumer Complaints (continued)

	Vitamins and Minerals (n = 118)				Aminos/Proteins/Animal Extracts (n = 16)				Herbals and Botanicals (n = 97)				Other (n = 7)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
9.8* Who evaluates reports on consumer complaints?																
1. In-house medical personnel	14	11.11	5.75	20.40	1	5.69	0.79	31.30	14	11.69	6.87	19.20	2	29.64	7.09	69.94
2. In-house scientific personnel	56	46.04	35.04	57.44	6	36.42	16.87	61.78	25	28.03	17.95	40.95	2	29.70	7.11	69.99
3. In-house quality control personnel	96	78.67	66.87	87.07	12	73.13	46.05	89.67	65	65.39	51.92	76.77	3	41.76	13.14	77.26
4. In-house regulatory affairs personnel	41	33.45	23.57	45.02	6	36.71	17.00	62.16	17	16.06	9.60	25.63	1	12.12	1.63	53.50
5. Outside contractor	13	11.90	—[a]	—[a]	0	0.00	—[a]	—[a]	11	9.22	—[a]	—[a]	2	23.60	—[a]	—[a]
6. Other	22	18.46	10.93	29.47	4	26.58	10.26	53.41	21	23.21	13.50	36.93	4	58.76	23.02	87 16
Don't know	1	2.26	0.31	14.75	0	0.00	0.00	0.00	0	0.00	0 00	0.00	0	Q.00	0.00	0.00
No answer	0	0.00	0.00	0.00	0	0.00	0.00	0.00	4	4.60	1.50	13.19	0	0.00	0.00	0.00

[a]Confidence interval could not be estimated because of matrix conformability error.

*Total may sum to greater than 100% because respondents could select more than one answer.

Table E-10. Weighted Responses for Section 10: Your Plant

	Vitamins and Minerals (n = 118)				Aminos/Proteins/Animal Extracts (n = 16)				Herbals and Botanicals (n = 97)				Other (n = 7)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
10.1 What was the calendar year during which this plant was built? *(If multiple buildings, use date of oldest building.)*																
Year (mean response)	105	1979	1976	1983	12	1972	1962	1982	74	1979	1975	1984	3	1981	1964	1998
10.2 What was the calendar year during which the *dietary supplement operations* began at this plant? (If multiple buildings, use date of earliest operation.)																
Year (mean response)	107	1988	1986	1991	14	1985	1978	1992	85	1991	1988	1994	5	1995	1995	1996
10.3 What is the total square footage of this plant?																
Square feet (mean response)	110	93,846	46,297	141,395	14	66,028	19,580	112,475	77	27,515	12,529	42,501	3	9,667	0.00[a]	24,074
10.4 Are this plant's facilities connected to a city water supply?																
1. Yes (Skip to question 10.6)	102	84.30	73.18	91.35	11	69.27	43.63	86.77	70	78.33	69.03	85.43	3	41.76	13.14	77.26
2. No	11	9.66	4.56	19.32	4	24.47	9.29	50.63	21	16.51	10.54	24.94	2	29.12	6.87	69.58
Don't know	1	2.25	0.31	14.71	0	0.00	0.00	0.00	1	0.84	0.12	5.86	0	0.00	0.00	0.00
No answer	4	3.79	1.04	12.91	1	6.26	0.83	34.72	5	4.32	1.78	10.12	2	29.12	6.87	69.58

(continued)

Table E-10. Weighted Responses for Section 10: Your Plant (continued)

	Vitamins and Minerals (n = 118)				Aminos/Proteins/Animal Extracts (n = 16)				Herbals and Botanicals (n = 97)				Other (n = 7)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
10.5 [If 10.4 is No] Is the water supply at this plant potable?																
1. Yes	9	73.05	19.08	96.89	4	100.00	100.00	100.00	15	72.15	49.37	87.31	1	60.36	7.82	96.47
2. No	0	0.00	0.00	0.00	0	0.00	0.00	0.00	3	13.93	4 17	37.55	1	39.64	3.53	92.18
Don't know	0	0.00	0.00	0.00	0	0.00	0.00	0.00	1	5.09	0.63	31.23	0	0.00	0.00	0.00
No answer	2	26.95	3.11	80.92	0	0.00	0.00	0.00	2	8.84	1.94	32.17	0	0.00	0.00	0.00
10.6 Does your company own plants at other locations?																
1. Yes	38	30.70	21.32	42.00	5	30.16	12.83	55.88	14	13.86	7 70	23.68	1	17.58	2.37	65.22
2. No	74	63.31	51.76	73.52	10	63.58	38.47	82.98	77	79.65	68.83	87.40	6	82.42	34.78	97.63
No answer	6	5.99	2.15	15.59	1	6.26	0.83	34.72	6	6.50	2.69	14.88	0	0.00	0.00	0.00
10.7 How many employees are currently employed at this plant?																
1. Full-time (mean response)	112	136.94	68.21	205.67	14	65.14	26.67	103.60	88	32.87	13.00	52.75	4	10.44	0.00[a]	27.47
2. Part-time (mean response)	53	24.46	0.00[a]	49.64	3	16.26	0.00[a]	41.97	49	4.33	2.47	6.19	4	1.93	0.14	3.71
10.8 How many employees employed at this plant are working in *quality control*?																
1. Full-time (mean response)	101	13.28	6.48	20.08	14	5.82	2.84	8.80	72	2.64	1.98	3.31	3	1.75	0.00[a]	4.18
2. Part-time (mean response)	43	3.11	0.93	5.29	6	1.94	0.73	3.15	38	1.53	1.09	1 97	4	0.70	0.00[a]	1.46

(continued)

Table E-10. Weighted Responses for Section 10: Your Plant (continued)

	Vitamins and Minerals (n = 118)				Aminos/Proteins/Animal Extracts (n = 16)				Herbals and Botanicals (n = 97)				Other (n = 7)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
10.9 For the most recent fiscal year, provide the number of batches of *dietary supplement* product by product form.																
Mean response in batches																
a. Powder	86	95.00	62.44	127.56	10	101.81	0.00[a]	224.87	74	64.00	22.21	105.80	5	1.19	0.01	2.36
b. Liquid	86	48.98	12.86	85.11	10	18.01	0.00[a]	37.23	74	90.64	52.72	128.57	5	5.67	0.00[a]	12.71
c. Paste	86	1.27	0.00[a]	3.21	10	0.09	0.00[a]	0.26	74	19.96	0.00[a]	57.59	5	0.00	0.00	0.00
d. Capsule	86	126.77	78.88	174.67	10	3.82	0.00[a]	10.46	74	25.29	4.12	46.46	5	2.45	0.13	4.77
e. Tablet or caplet	86	166.60	101.32	231.87	10	0.89	0.00[a]	2.60	74	18.56	3.18	33.94	5	0.00	0.00	0.00
f. Gelcap	86	12.92	2.54	23.30	10	0.00	0.00	0.00	74	0.83	0.00[a]	1.87	5	0.00	0.00	0.00
g. Other	86	7.36	0.29	14.44	10	3.41	0.00[a]	8.46	74	29.42	9.55	49.29	5	0.98	0.00[a]	2.78
h. Other	86	0.00	0.00	0.00	10	0.00	0.00	0.00	74	6.13	0.00[a]	15.27	5	0.00	0.00	0.00
Total	86	458.92	334.11	583.72	10	128.04	11.19	244.88	74	254.83	168.54	341.12	5	10.29	0.87	19.70

(continued)

Table E-10. Weighted Responses for Section 10: Your Plant (continued)

	Vitamins and Minerals (n = 118)				Aminos/Proteins/Animal Extracts (n = 16)				Herbals and Botanicals (n = 97)				Other (n = 7)			
			95% CI				95% CI				95% CI				95% CI	
	n	%	Low	High	n	%	Low	High	n	%	Low	High	n	%	Low	High
10.10 What were the gross sales revenue for the *dietary supplement operations only* at this plant for the most recent fiscal year?																
1. Less than $500,000	22	16.19	9.41	26.45	5	30.45	12.83	56.56	38	34.10	24.25	45.53	4	58.76	23.03	87.15
2. $500,000 to just under $1 million	8	4.73	1.69	12.59	3	18.21	5.95	43.91	15	22.37	11.70	38.53	0	0.00	0.00	0.00
3. $1 to just under $2.5 million	13	19.93	11.65	31.97	1	8.66	1.25	41.58	14	13.13	7.40	22.24	1	12.12	1.63	53.50
4. $2.5 to just under $5 million	8	7.49	3.15	16.75	2	11.95	2.90	38.13	7	5.74	2.67	11.91	0	0.00	0.00	0.00
5. $5 to just under $10 million	19	15.81	9.14	25.95	0	0.00	0.00	0.00	9	10.14	3.92	23.78	0	0.00	0.00	0.00
6. $10 to just under $20 million	14	7.79	4.45	13.29	1	6.26	0.83	34.72	4	4.92	1.64	13.84	0	0.00	0.00	0.00
7. $20 to just under $50 million	11	11.04	5.52	20.84	1	6.26	0.83	34.72	4	4.70	1.57	13.24	0	0.00	0.00	0.00
8. $50 to just under $100 million	4	2.16	0.75	6.07	0	0.00	0.00	0.00	0	0.00	0.00	0.00	0	0.00	0.00	0.00
9. $100 to just under $500 million	8	7.51	3.40	15.80	0	0.00	0.00	0.00	0	0.00	0.00	0.00	0	0.00	0.00	0.00
10. $500 million or more	0	0.00	0.00	0.00	0	0.00	0.00	0.00	0	0.00	0.00	0.00	0	0.00	0.00	0.00
Don't know	1	0.87	0.12	6.02	1	5.69	0.79	31.29	0	0.00	0.00	0.00	0	0.00	0.00	0.00
No answer	10	6.47	3.40	11.97	2	12.52	3.07	39.25	6	4.90	2.14	10.80	2	29.12	6.87	69.58

[a]Estimated confidence interval for lower bound was less than zero so we truncated the interval.

Table E-11. Verbatims for Question 2.4: Why Does this Plant Not Follow Published GMPs?

Vitamins and Minerals

It is not a manufacturing facility. Just a sales and marketing site.

All products distributed are produced by other companies in facilities wholly within their control.

We sub-contract with packaging companies for actual supplement manufacturing. (We do not have production facility).

OEM customers do not want to pay for extensive costs, i.e., lab tests of raw materials even finished products.

Don't manufacture—we rely on manufacturers.

Not a plant.

We do not manufacture products, we distribute finished products only.

Proposed rule making not finalized.

Very expensive—we are small.

We don't manufacture.

Do not understand exact meaning.

We are not manufacturer in this place. Only office here.

I don't manufacture anything or encapsulate anything—I'm not a plant.

Distribution only.

Limited resources.

We are strictly a distributor and rely on our vendors to have GMPs.

We are a business office.

Current operations have proven adequate and safe over many years. Thousands of satisfied customers with very few complaints.

Not economically feasible

Too costly to implement.

We handle 80-90% raw materials of herbs—only about 5 kinds of herbs that's all.

In development at this time.

Dietary supplement product lines are not extensive enough to warrant following a published GMP model.

(continued)

Table E-11. Verbatims for Question 2.4: Why Does this Plant Not Follow Published GMPs? (continued)

Aminos/Proteins/Animal Extracts

Current program stronger than GMPs.

Not a manufacturer—only resell bulk ingredients.

We import products that are made overseas and depend on our suppliers to follow GMP standards.

Products produced by approved vendor.

We are not aware of published GMPs for importers who do not ever open drums. The producers follow published GMP.

We do not manufacture or bottle the product—Only private label and distribute.

Herbals and Botanicals

Not sure how GMPs apply to my company. Too busy struggling to survive to find out.

Our plant is staffed by only two people—myself and my wife. We simply warehouse and re-ship products which are packed by private companies.

Not familiar.

We manufacture single herb tea grown on our biological reserve. As a small company with one product that we control from seed to mature plant.

Not familiar with them.

Not required.

Too costly and unnecessary in our situation.

Not applicable—we don't manufacture products.

Do not have enough information—will set up in 2000.

We do not manufacture.

We are just a sales and marketing office.

I don't think they are adequate for botanical identity.

It doesn't seem necessary. We know the contents/purity of the goods we make, and have our own standards for purity and sanitation.

Published procedures are generally not applicable or practical for an herbal manufacturing company of our size.

We do not trust the intent of the inspectors. We are afraid that they may acquire proprietary manufacturing practices from us.

I was told by an FDA staff member that GMPs did not apply to our operation.

Only because I don't have a copy of published GMPs and didn't know where to access this information.

(continued)

Table E-11. Verbatims for Question 2.4: Why Does this Plant Not Follow Published GMPs? (continued)

Herbals and Botanicals (continued)
Unavailable—guidelines not established.
GMP not readily available and the expense involved.
We are not a manufacturer and this is not a plant.
We are in the process of implementing new procedures.
We follow specific procedures defined by clients and we are using our own GMP system.
We feel we have GMPs in place. They just aren't the GMPs that someone else established, they're are [*sic*] own.
Work in process. Goal to be by 6/2000.
None of the actual manufacturing done at this location.
We are not manufacturer. Our manufacturer follows China's and/or Australia's GMPs.
Raw ingredient supplier.
We are a distributor.
We are a farm and produce bulk herbs mostly.
Contract manufacturers—make and package our products—we repackage into point of sale displays only.
Other
Not a manufacturer.
Manufacturing is not done at this plant but items in question 2.3 are kept on file by our supplier.
We employ the services of contract manufacturers for all our products. Consequently, the questions in sections 3-7 are not applicable.
Local sanitation dept standards.