Wisconsin Department of Agriculture, Trade and Consumer Protection
Division of Food and Recreational Safety
Milk Certification Program
Wis. Admin Code § 65.32(2)(i)

REPORT OF CERTIFICATION

(Fabrication of Single-Service Containers and/or Closures for Milk and/or Milk Products)

FOR FDA USE ONLY				
1	2	3	4	5

IDENTIFICATION

1. NAME OF SINGLE-SERVICE FABRICATING PLANT	2. CITY	3. STATE / COUNTRY
ProAmpac	**Neenah**	**Wisconsin / USA**

4. STREET	5. MFG. CODE NO	6. CODE	
		PRODUCT CODE	MATERIAL CODE
1055 Winchester Rd	55- 4831		

7. AGENCY OR SINGLE-SERVICE CONSULTANT (SSC), AS APPLICABLE, PROVIDING ROUTINE INSPECTION
N/A

56	57	58	59	60	61	62
4	**8**	**3**	**1**	**3**		**3**

PRODUCT CODE (60)
1. Containers
2. Closures
3. Other products
4. Containers and closures
5. Containers and other products
6. Closures and other products
7. Containers, closures and other products

MATERIAL CODE (62)
1. Metal
2. Paper (Includes laminates)
3. Plastic
4. Metal and paper
5. Metal and plastic
6. Paper and plastic
7. Metal, paper and plastic
8. Glass
9. Rubber
10. Paper, metal, plastic, and glass
11. Ceramic

7.a. RATING/ CERTIFICATION PERSONNEL	7.b. DATE OF PLANT CERTIFICATION	7.d. EXPIRATION DATE*					
		11/30/25					
	11/13/2024	MONTH		DAY		YEAR	
☐ SHD ☐ Other ☑ SDA ☐ TPC ☐ SDL ☐ SSC	7.c. SANITATION COMPLIANCE RATING	67	68	69	70	72	72
	80	**1**	**1**	**3**	**0**	**2**	**5**

***EXPIRATION DATE**
Certification of single-service manufacturing plants may be valid for a period not to exceed twelve (12) or twenty-four (24) months plus the remaining days of the month. The expiration date is twelve (12) months or twenty-four (24) months plus the remaining days of the month in which the rating is due. NOTE: Certifications conducted by SSCs shall only be valid for a period not to exceed twelve (12) months plus the remaining days of the month.

8. SRO OR SSC
Michele Sobeck

9. CERTIFICATION RECOMMENDED ◉ YES ○ NO

9a. LISTING TYPE ○ FULL ◉ PARTIAL

LABORATORY CONTROL

10. NAME AND ADDRESS (OR CODE) OF APPROVED LABORATORY
N/A Goes on for further processing

11. **INSPECTION RESULTS** (Place an "X under Items debited)

1	2	3	4	5	6	7	8	9	10	11	12	13 a,b,c,f ,g,l,k	13 d,e, h,j	14	15	16 a	16 b,c	17 a,b, d,e	17 c	18	19	20 a,b,f	20 c,d,e	21	BACTI	COLI
		X	X					X	X			X			X			X								

12. PERMISSION TO PUBLISH

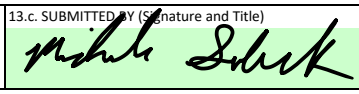
Signing this form is voluntary. If you choose not to sign this form, the single-service manufacturer plant will be withdrawn and removed from the Interstate Milk Shipper's (IMS) List. Permission is hereby granted by the undersigned to release and publish the above stated certification for use by Regulatory/Rating Agencies and prospective purchasers. Personally identifiable information you provide may be used for purposes other than that for which it was collected. Wis. Stat. § 15.04 (1)(m).

It is understood and agreed by the undersigned that the official Rating Agency or SSC, as applicable, may review and appraise the single-service fabricating plant at any time during the period of time the above certification is in effect. It is further understood that failure to maintain the above certification will subject this plant to withdrawal from the IMS Listing. We will notify the Rating Agency or SSC, as applicable, of any significant changes made in the operation of this plant. This would include, but not be limited to: changes in processing lines/equipment involved in processing IMS materials or changes to product types or materials manufactured.

12.a. NAME OF PLANT
ProAmpac

12.b. PLANT REPRESENTATIVE AUTHORIZING RELEASE (Signature)	12.c. TITLE
	Matt Peterson/ Manager

13. SUBMISSION OF REPORT BY MILK SANITATION RATING AGENCY OR SSC, AS APPLICABLE

13.a. DATE OF REPORT	13.b. RECOMMENDED CLASSIFICATION ACCEPTED	13.c. SUBMITTED BY (Signature and Title)
11/21/2024	◉ YES ○ NO	 MSRO

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13. DATE RECEIVED	15. PUBLICATION OF RATING RECOMMENDED ○ YES ○ NO (If "NO", indicate why.)
16. DATE TRANSMITTED	**17. SIGNATURE (FDA Regional Milk Specialist)**

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

MANUFACTURING PLANT INSPECTION REPORT

(Single-Service Containers and/or Closures for Milk and/or Milk Products)

INSPECTING AGENCY/TPC/ CERTIFICATION AGENCY/SSC
Wisconsin Department of Agriculture, Trade and Consumer Protection - Division of Food and Recreational Safety

NAME AND LOCATION OF PLANT
ProAmpac
1055 Winchester Rd
Neenah, WI 54956

1. FLOORS
Smooth; impervious; in good repair (a) ___
Joints between walls and floors tight; impervious (b) ___
Floor drains properly trapped; sloped to drain (c) ___

2. WALLS AND CEILINGS
In fabrication areas—smooth; cleanable; light-colored (a) ___
In fabrication and storage areas—good repair (b) ___
Openings in walls and ceilings effectively sealed (c) ___

3. DOORS AND WINDOWS
All outside openings protected against entrance of insects, rodents, dust, and airborne contamination (a) X
Outer doors tight, self-closing (b) ___

4. LIGHTING AND VENTILATION
Adequate light in all rooms (a) ___
Ventilation sufficient (b) ___
Pressure ventilation systems properly filtered (c) X

5. SEPARATE ROOMS
Fabrication areas separate from non-fabrication areas when required (a) ___
Regrinding plastic and paper trim shredding, packaging and baling conducted in separate room(s) from fabrication areas or as Appendix J permits (b) ___

6. TOILET FACILITIES-SEWAGE DISPOSAL
Disposal of sewage; other waste; in public sewage system or in compliance with Local and State Regulations (a) ___
All plumbing complies with Local and State plumbing Regulations (b) ___
Solid, tight-fitting, self-closing doors (c) ___
Toilet rooms and fixtures clean; in good repair (d) ___
Adequate light and ventilation; ducts vented to the outside (e) ___
Proper handwashing facilities (f) ___
Open windows effectively screened (g) ___
Employee handwashing signs posted (h) ___
Eating/food storage prohibited (i) ___

7. WATER SUPPLY
Safe; complies with bacteriological and construction requirements (a) ___
No direct or indirect connection between safe and unsafe water (b) ___
Sampled and examined as required (c) ___
Recirculated cooling water used in water baths complies with bacteriological standards, tested semi-annually (d) ___
Testing records maintained as required (e) ___

8. HANDWASHING FACILITIES
Hot and cold and/or warm running water, soap, individual towels or air dryers convenient to fabrication areas; covered trash containers when required; hand sanitizers used as Appendix J permits (a) ___
Handwashing facilities clean (b) ___

9. PLANT CLEANLINESS
Floors, walls, ceilings, overhead beams, fixtures, pipes and ducts clean in rooms as required (a) X
Plant free of evidence of insects, rodents and birds (b) ___
Machines and appurtenances clean (c) X

10. LOCKERS AND LUNCHROOMS
Separate from plant operation; self-closing doors (a) ___
Eating/storage of food prohibited in fabrication and storage areas (b) X
Locker and lunchrooms clean (c) X
Cleanable trash containers provided; properly labeled, covered (d) ___
Handwashing facilities convenient (e) ___
Employee handwashing signs posted (f) ___

11. DISPOSAL OF WASTES
Stored in covered, impervious, leak-proof containers; does not apply to production scrap (a) ___
Waste containers properly identified (b) ___
Storage of garbage/rubbish meets requirements (c) ___

12. PERSONNEL - PRACTICES
Hands washed as required (a) ___
Clean outer garments; hair restraints (b) ___
No person affected by disease in communicable form; while a carrier of such disease; or with inadequately protected wounds or lesions shall work in the fabrication areas (c) ___
Tobacco use in authorized areas only (d) ___
Unsecured jewelry not permitted in fabrication areas (e) ___

13. PROTECTION FROM CONTAMINATION
Product contact surfaces protected; all materials in process properly protected (a) X
Air under pressure directed at materials or product contact surfaces in compliance (b) ___
Air directed at materials or product contact surfaces by fans or blowers in compliance (c) ___
Pesticides approved; EPA registered (d) ___
Pesticides used in accordance with directions; precludes contamination of containers/closures (e) ___
Single-service articles in process protected from contamination (f) ___
Equipment cleaned after use of non-food-grade materials (g) ___
Cross contamination with non-food-grade material prevented (h) ___
No overcrowding of equipment and operations (i) ___
Toxic chemicals separated from raw materials and finished products (j) ___
Food containers manufactured by facility not used for storage of miscellaneous items or chemicals (k) ___

14. STORAGE OF MATERIALS AND FINISHED PRODUCT
Away from any wall; soiled outer turns or edges discarded (a) ___
Stored in clean, dry place, protected from splash, insects, and dust (b) ___
Containers and closures stored in original cartons and sealed until used; partially used cartons resealed during storage (c) ___
Containers for storage of resin, raw and reuse materials are covered, clean, impervious and properly identified (d) ___
In-process storage bins that touch the product contact surface constructed of cleanable, nonabsorbent material; clean (e) ___

15. FABRICATING EQUIPMENT
Contact surfaces clean; milk plant equipment utilized for preforming containers clean and sanitized prior to operation (a) ___
Makeshift devices not used; fasteners, guides, hangers, supports and baffles properly constructed; good repair (b) X
Take-off tables and other container contact surfaces properly constructed; clean; in good repair (c) ___
Grinders, shredders and similar equipment properly installed; protected from contamination (d) ___
Resin storage silos, other containers, constructed to protect resin from contamination; air vents filtered; air tubes good repair and properly protected (e) X

16. MATERIALS FOR CONSTRUCTION OF CONTAINERS AND/OR CLOSURES
Materials from approved source (a) ___
Food-grade lubricants used on contact surfaces; stored to prevent cross contamination; storage clean and ventilated (b) ___
Containers, closures or materials on floor not used (c) ___

17. WAXES, ADHESIVES, SEALANTS, COATING AND INKS
Handled and stored to prevent cross contamination with non-food-grade materials; storage areas clean and ventilated (a) ___
Unused materials covered, labeled and properly stored (b) X
Nontoxic; imparts no flavor or odor; non-contaminating; complies with 21 CFR Parts 174-178 (c) ___
Transfer containers clean; covered, properly identified (d) ___
Waxing, when used, performed as required; wax kept at proper temperature (e) ___

18. HANDLING OF CONTAINERS, CLOSURES AND EQUIPMENT
Handling of container and closure surfaces minimized (a) ___
Hands sanitized frequently or clean, single-use gloves worn; sanitizing dispensers convenient (b) ___

19. WRAPPING AND SHIPPING
Single-service articles properly containerized prior to shipping (a) ___
Packaged contents protected from contamination (b) ___
Transportation vehicles clean; in good repair; not used for unapproved uses (c) ___
Paperboard containers, wrappers and dividers not reused (d) ___
Packaging materials in compliance (e) ___

20. IDENTIFICATION AND RECORDS
Plant identification on outer wrapping as required (a) ___
Glass containers properly labeled (b) ___
Required bacteriological tests on file; maintained as required; and in compliance (c) ___
Required bacteriological and chemical test records for all component parts used in final assembled product on file (d) ___
Information on file from suppliers of raw materials, waxes, adhesives, sealants, coatings and inks indicating compliance (e) ___
Information on file from suppliers of packaging materials indicating compliance (f) ___

21. SURROUNDINGS
Surroundings neat and clean and free of breeding areas, conditions attracting or harboring flies, insects or rodents (a) ___
Driveways graded; no standing water (b) ___

REMARKS *(If additional space is required, please place information on the back of this Form or on a separate page.)*
See attached narrative report.

DATE	**SANITARIAN/SRO/SSC/RMS**
11/13/2024	Michele Sobeck

NOTE: This Form has been developed for use with Appendix J of the *Grade "A" Pasteurized Milk Ordinance* .

IMS SINGLE-SERVICE SURVEY

PLANT NAME: ProAmpac
PLANT #: 55-4831
DATE: November 13, 2024

A routine Interstate Milk Shippers (IMS) survey was conducted at this Single Service Manufacturing plant to determine compliance with the requirements of Appendix J of the Pasteurized Milk Ordinance (PMO). This survey was conducted by Michele Sobeck, WDATCP Milk Sanitation Rating Officer. Plant personnel accompanying this survey were Greg Porter, Compliance Manager; Dustin Lenz, Extruder Manager; and Matt Peterson, Manager.

ProAmpac is a plastic film extrusion laminating and slitting facility with a partial plant listing for IMS related products. Processing lines included in this plant's partial listing are: Extruder 1 and Winder 1.

The following violations were noted during the course of the survey.

A. DEBITED VIOLATIONS:

4c. Pressure ventilation systems properly filtered (2 points)

- The two small make-up air units that bring outside air into the air handling mezzanine adjacent to the main extrusion laminating processing room of the plant are not equipped with filters. The intake of all pressure ventilation systems in fabricating areas, whether they are positive or exhaust shall be properly filtered.

9a&c. Plant Cleanliness (3 points)

- There is an accumulation of dirt, debris, and scrap material on the floor in multiple areas near and beneath Extruder 1.
- Debris present throughout the walkways of the facility.

13a. Product contact surfaces protected; all materials in process properly protected (3 points)

- Several of the walkway cross-over platforms above the web path of Extrusion Laminator 1 have trap doors and open seams in them. The inside ledge of the trap doors and open seams in the deck plates are directly above the web path with no suitable protection in place whereby dirt and other contaminants will fall directly onto in-process materials below.

17b. Waxes, Adhesives, sealants, coating and inks (3 points)

- Cover for the primer sump is left open throughout the production runs.

3a Doors and Windows (2 points)

- Door #9 is damaged.
- A large opening is present between the dock door and the scrap trailer.

15b&e. Fabricating Equipment (5 points)

- The underside of the curing dryer of Extruder 1 has droplets of potential contaminants located directly over the web path.
- Resin wands aspirators are not equipped with filters.
- Gaylord box covers are ajar more than necessary for the transfer of resin.
- Tape is present on the resin hoses.

- Numerous resin hoses are located in a box structure without covers on the ends to protect them from contamination entering the hoses.

10b&c Lockers and Lunchrooms (2 points)

- Water bottles that required the touching of the drinking lip are present on workstations throughout the production floor.
- Accumulation of items located in the lunchroom behind the refrigerator.

B. NON-DEBITED VIOLATIONS:

2b Walls

- Several areas of the warehouse ceiling are separating at the seams.
- A hole is present in the wall near a side hallway in the received goods warehouse.

16b Food-grade Lubricants used on contact surfaces.

- Excessive lubrication is present on the roll pusher bar for winder 1.

11a Disposal of Wastes

- Open garbage cans that had items other than production scrap are present throughout the plant.

8a Hand Washing Facilities

- The main hand sink by extruder 1 is not equipped with warm water.

C. NOTES:

The thin gauge flexible plastic film produced under this plant's IMS listing is a 3-layer laminated structure that is used as the product contact sealant layer in the further construction/processing of end cap closures utilized on single service canister type containers (Huhtamaki- sour cream canisters). The film produced here is packaged in roll-stock form and is utilized in further manufacturing operations at another IMS listed plant. The IMS finished product number is #1060107.

Sani-Wipes are used as the final cleaner/sanitizer on product contact surfaces of equipment. This product is an EPA registered sanitizer and is a no-rinse sanitizer only requiring air dry before next use on product contact surfaces. A purging resin is utilized during change over before the resin for this specification is utilized.

Resin for the laminating process is received in Gaylord boxes. This resin forms the product contact layer on both sides of the 3-layer laminated film structure. The manufacturer's certification letter for this Marlex 1017 LDPE resin is maintained on file at this plant and states conformity to 21 CFR 177.1520(c)2.2.

The middle 4 mil CD901 PET layer of the 3 layer laminated film structure does not make contact with product or the product contact surface of the film structure. This middle layer sourced from Kolon Industries of Korea, which is not an IMS listed plant. This plant maintains certification documentation on file from the manufacturer of the film that the materials utilized in the film complies with 21 CFR 177.1630(f),(g) dated 1/15/2021.

Regrind is not used in the manufacture of IMS single service products at this plant.

A PEI primer A131X is used as part of the extrusion laminating process. This primer does not meet the specifications of 21 CFR 174-178. Therefore, this plant commissioned a migration study on 7/29/2015 which indicates that none of the components of the primer migrated through the 1017 LDPE layer establishing that layer as a functional barrier. The migration study tested for any detectable components of the primer on the external surface of the film and was conducted using the same film structure specifications that are utilized for the IMS listed film processed at this plant: 1 mil 1017 LDPE extruded layer, primer, 4 mil PET layer, primer, 1 mil 1017 LDPE extruded layer.

Resin silos are not utilized for the storage of resins used in the manufacture of IMS related products at this plant rather the resin comes in gaylord boxes.

Fan blown air (<15 PSI) in contact with in-process materials takes place at the turn bars in the Extrusion Laminator 1 processing line as well as the curing section of the Extrusion Laminator 1 processing line. The air intake for this fan blown air application is equipped with an air filter manufactured by Endustria Filter Manufacturers, Inc. which is rated 98% efficient at 10 microns or Beko with a rate of .5-1 micron at 99.9% efficiency. PMO Appendix H requirements for fan blown air specifies, “Intake air filter efficiency shall be at least 98% SAE J726, June 1987 using Air Cleaner (AC) coarse test dust” which correlates to the modern ISO 5011 standard of 20-120 micron test particles removed at a rate of 98%.

Compressed air is not utilized at this facility.

No processing aids are used on product or product contact surfaces of fabricating equipment in conjunction with IMS listed manufacturing operations at this plant.

Bacteriological testing of the plastic film manufactured here is not required by PMO Appendix J as this plant is not the final producer of the single service container/closure.

The stretch wrap overwrap material used over rolls of work in progress product is obtained from Berry Plastics of Evansville, IN distributed by Veritiv and has a letter of guarantee that the material complies with 21 CFR 174.5, 175.105, 175,300, 177.1340, 177.1430, 177.1520(c)2.1,2.2,3.1,3.2,3.1a,3.2a, 177.1640, 178.2010, and 178.3740. It was last tested on 8/21/23.

Food grade lubricants, which are NSF H1 listed, are used in applications where incidental contact with product or product contact surfaces may occur on the IMS listed processing lines at this plant. These lubricants are stored on carts and racking shelves in the maintenance supply storage area of the plant.

Outside make-up air for production areas of the plant is supplied via air handling equipment located on the utility mezzanine adjacent to the extrusion laminating processing room of the plant. The two smaller make-up air handling units that bring outside air into this mezzanine area (which opens directly into the processing room) are not currently equipped with intake air filters as mentioned above in this survey report.

Water for the plant is supplied by the Town of Neenah municipal water supply system.

There are no direct water bath cooling water applications utilized in conjunction with IMS listed processing operations at this plant. Recirculated cooling water is only utilized in thick walled chill rolls as part of processing operations at this plant.

There are 5 RPZ cross-connection control device(s) in place on the water distribution system in the plant that are regulated by the State’s water control authority (DSPS) and were last inspected on 7/03/2024.

In general, this is an under-one-roof facility with the following primary rooms: processing room including IMS extrusion laminating line and other non-IMS processing equipment, a maintenance room, a receiving dock and warehouse, and a winder/slitter processing room which also includes warehousing areas and the shipping dock. The non-production areas were found to be adequately cleaned and maintained to production room standards. Separate rooms for the office and break room facilities also exist at this plant.

Pest control services are provided by Valley Pest Control with routine service on a weekly basis. Pest control service records are maintained on file at this plant.

There are no offsite storage facilities utilized in conjunction with products processed at this plant.

The label applied to the outer wrap and inside the core of roll stock film prior to shipment out of this plant is properly labeled including the plant name “ProAmpac”, city “Neenah”, and state “WI” along with other material and production information.

REQUIRED DOCUMENTATION:

It is recommended that documentation supporting these items be maintained as applicable in an IMS binder to facilitate future IMS surveys.

1. Only resin in compliance with applicable sections of 21 CFR, Parts 174 – 178 may be used to produce IMS single-service items. Component materials and component parts must be manufactured in an IMS listed facility. Documentation, in the form of letters of guarantee, must be available at the plant.
2. Line cleaning and / or sanitization procedures (written SOP) after maintenance, after cleaning with non-food grade cleaners or after producing non-IMS product.
3. Pest control records.
4. Annual Cross Connection Control Performance Tests for testable backflow protection devices.
5. Verification letters indicating that waxes, adhesives, sealants, coatings, and inks meet the applicable requirements of 21 CFR, Sections 174–178.
6. Verification that materials, which do not meet the applicable requirements of 21 CFR, Parts 174–178, are not applied to, come into contact with, or migrate to a product contact surface or incidental product contact surface of a finished product. Migration testing may be utilized to establish that a functional barrier is present or that there is no set-off of lacquer / coating components when in rollstock or nested-container form.
7. Documentation that wraps and liners meet the applicable sections of 21 CFR, Sections 174 – 178 and the bacteriological testing criteria listed in Appendix J, Section C (minimum annual test).
8. Bacteriological product testing results (refer to PMO Appendix J, Section C), performed in an IMS listed laboratory, when applicable.
9. Compressed and fan blown air filter efficiency documentation, when applicable (refer to PMO Appendix H, Section II – Air Under Pressure – Filter Performance).
10. Private well water supply and recirculated cooling water bath bacteriological test results, when applicable.
11. Documentation that glycol is food grade or USP, if used as a cooling medium in a thin-walled heat exchanger or in a recirculated water bath.
12. Air intake systems for production areas and resin silos must be filtered and inspected. If the plant has a safety policy that precludes access to these areas an alternate approach may be utilized. On the day of the survey, plant personnel may take photos of silo intake filters and final filter banks for production area HVAC units. In addition, a HVAC filter change log which identifies the specific filters, the date(s) changed and the condition of the filter(s) should be maintained.

CONCLUSION:

Based upon a passing score of 80 it will be recommended that this plant continue to be included on the IMS List as a certified supplier of single service product(s). The findings of this survey were discussed with plant management at the conclusion of the plant visit. If you have questions or concerns pertaining to this survey, feel free to contact me at michele.sobeck@wisconsin.gov or (920) 400-0700.

U.S. Department of Health and Human Services
Food and Drug Administration

STATUS OF MANUFACTURING PLANTS

(SINGLE-SERVICE CONTAINERS AND/OR CLOSURES FOR MILK AND/OR MILK PRODUCTS)

Plant ProAmpac
Number 55-4831
Date of Certification 11/13/2024

Sanitation Compliance Rating[1] **80**

NAME OF PLANT		ITEMS OF SANITATION																											REMARKS
		Floors	Walls and Ceilings	Doors and Windows	Lighting and Ventilation	Separate Rooms	Toilet/Facilities-Sewage Disposal	Water Supply	Handwashing Facilities	Plant Cleanliness	Lockers and Lunchrooms	Disposal of Wastes	Personnel - Practices	Protection From Contamination		Storage of Materials and Finished Product	Fabrication Equipment	Materials for Construction of Containers and/or Closures		Waxes, Adhesives, Sealants, Coating and Inks		Handling of Containers, Closures and Equipment	Wrapping and Shipping	Identification and Records		Surroundings	Bacterial Count*	Coliform Count*	Total Debits[2]	
	ITEM	1	2	3	4	5	6	7	8	9	10	11	12	13 a,b,c, f,g,i,k	13 d,e,h,j	14	15	16 a	16 b,c	17 a,b, d,e	17 c	18	19	20 a,b,f	20 c,d,e	21				
	WEIGHT	1	1	2	2	3	3	4	2	3	2	2	3	3	11	3	5	11	3	3	11	2	4	3	11	2	5	10		
ProAmpac				**2**	**2**					**3**	**2**			**3**			**5**			**3**									**20**	
TOTALS				**2**	**2**					**3**	**2**			**3**			**5**			**3**									**20**	

Footnotes:

[1]Sanitation Compliance Rating = 100 – Total Debits

[2]Total Debits for each manufacturing plant are the sum of the weights of the Items violated. (NOTE: Any Item or sub-item violated, indicate by placing the debit value (weight) of that Item or an "X" under that Item.)

*Used only when not in compliance.

FORM FDA 2359e (11/15)