DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

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
Prolamina	**Neenah**	**Wisconsin / USA**

4. STREET: **1055 Winchester Rd**

5. MFG. CODE NO: 55- 4831

6. CODE

PRODUCT CODE				MATERIAL CODE		
56	57	58	59	60	61	62
4	**8**	**3**	**1**	**2**		**3**

7. AGENCY OR SSC, AS APPLICABLE, PROVIDING ROUTINE INSPECTION

Wisconsin Department of Agriculture, Trade and Consumer Protection
Division of Food Safety
PO Box 8911
Madison, WI 53708-8911

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

☐ SHD ☐ Other
☑ SDA ☐ TPC
☐ SDL ☐ SSC

7.b. DATE OF PLANT CERTIFICATION: **5/16/2017**

7.c. SANITATION COMPLIANCE RATING: **95**

7.d. EXPIRATION DATE*: **05/15/18**

MONTH		DAY		YEAR	
67	68	69	70	72	72
0	**5**	**1**	**5**	**1**	**8**

***EXPIRATION DATE**

Certification of single-service manufacturing plants may be valid for a period not to exceed one (1) or two (2) years from the earliest certification date. The expiration date is one (1) or two (2) years from the earliest certification date. **NOTE**: Certifications conducted by SSCs shall only be valid for a period not to exceed one (1) year from the earliest certification date.

8. SRO OR SSC: **Robert Carrier**

9. CERTIFICATION RECOMMENDED: ◉ YES ○ NO

9a. LISTING TYPE: ○ FULL ◉ PARTIAL

LABORATORY CONTROL

10. NAME AND ADDRESS (OR CODE) OF APPROVED LABORATORY

N/A - Further Processed

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														

12. PERMISSION TO PUBLISH

Permission is hereby granted to release and publish the above-stated certification for use by Regulatory/Rating Agencies and prospective purchasers.

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.

12.a. NAME OF PLANT: **Prolamina**

12.b. OFFICER AUTHORIZING RELEASE (Signature)

12.c. TITLE: Corey Peterson / Quality Assurance Manager

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

13.a. DATE OF REPORT: 5/22/2017

13.b. RECOMMENDED CLASSIFICATION ACCEPTED: ◉ YES ○ NO

13.c. SUBMITTED BY (Signature and Title) MSRO

FOR FDA USE ONLY

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 Safety

NAME AND LOCATION OF PLANT
Prolamina
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) ___
Outer doors tight, self-closing (b) ___

4. **LIGHTING AND VENTILATION**
Adequate light in all rooms (a) X
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) ___
Plant free of evidence of insects, rodents and birds (b) ___
Machines and appurtenances clean (c) ___

10. **LOCKERS AND LUNCHROOMS**
Separate from plant operation; self-closing doors (a) ___
Eating/storage of food prohibited in fabrication and storage areas (b) ___
Locker and lunchrooms clean (c) ___
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) ___
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) ___

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) ___
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**
5/16/2017	Robert Carrier

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

IMS SINGLE-SERVICE SURVEY

PLANT NAME: Prolamina (Neenah)
PLANT #: 55-4831
DATE: 5/16/2017

A routine Interstate Milk Shippers (IMS) survey was conducted at this Single Service Manufacturing facility to determine compliance with requirements of the Appendix J of Pasteurized Milk Ordinance (PMO). This survey was conducted by Robert Carrier, WDATCP Sanitation Rating Officer. Plant personnel accompanying this survey was Greg Porter and Corey Peterson.

Prolamina is an extruding, laminating, and slitting facility with a Partial plant listing for IMS related products. The following lines are included in the Partial plant IMS listing: Laminator 1 and Winder 1. The product produced is used as a component for a seal in a Grade A dairy product container closure/valve.

The following report contains violations noted and documents reviewed during the course of the survey. It is expected that all violations (debited and non-debited) are to be corrected prior to the next routine IMS audit.

A. DEBITED VIOLATIONS:

13a. Laminator 1: The trap doors on the crossover walkways above the web bath have open gaps and horizontal ledges that do not effectively preclude dirt and other contamination from falling through the trap door opening onto the exposed product below.

4c. Two supplemental air make-up units blow unfiltered outside air into the mechanical mezzanine, which is directly open to the production area as evidenced by dust accumulation on surfaces around these make-up air units.

4a. There is less than 5 foot-candles of light available along the south wall where boxed resins are stored.

B. NON-DEBITED VIOLATIONS:

N/A

C. NOTES:

1. The IMS plastic roll stock produced at this facility is shipped to customers for further processing and assembly prior to use in Grade A dairy product packaging applications. Therefore, no bacteriological testing of films manufactured here is required of or conducted by this establishment.
2. Prolamina has conducted a study on the plastic structures manufactured at this plant and certifies that a functional barrier exists between primers and coatings and the product contact side of the structure.
3. Resin is received boxed. Manufacturer's certification letters stating conformity to 21 CFR 174-178 were reviewed for these resins. Only virgin resins are utilized.
4. Roll stock shipped for IMS purposes are labeled with an outer label and a core label which include the plant name, city, and state for this plant.
5. Sani-Wipes (NSF rated sanitizing wipes) are used as the final cleaner/sanitizer on product contact surfaces of equipment.
6. A letter of guarantee is on file for the BASE Plastics bag used to overwrap finished film rolls.
7. Lubricants used for applications requiring food grade materials are properly labeled and stored segregated from non-food grade materials.
8. Final filters used in applications where compressed air is directed product meets PMO – Appendix H specifications.
9. Operations water is supplied by the Town of Menasha municipal water system.
10. The RPZ backflow protection devices in use in the plant and were last inspected on 7/20/2016.

1. Recirculated cooling water is used exclusively in chill rolls and not in any water baths or applications that may come into incidental contact with product.
2. This is an under-one roof facility with maintenance shop and break room areas open to the production areas. The non-production areas were found to be adequately cleaned and maintained to production room standards.

D. REQUIRED DOCUMENTATION:

The following documentation is required of all IMS listed single service manufacturing plants. It is recommended that documentation supporting these items be maintained in an IMS binder to facilitate future IMS audits.

01. Line cleaning/sanitization procedure prior to running IMS product.
02. Photos of resin silo air intake filters (as applicable for inaccessible filters).
03. Pest control records.
04. Annual RPZ back-flow preventer tests.
05. Approval letters for resin, colorants, and inks as applicable.
06. Documentation that wraps and liners that come into contact with resins or products comply with applicable sections of 21 CFR, Sections 174-178 and the bacteriological standards of the PMO, Appendix J, Section C.

E. CONCLUSION:

It is important that all documentation is available and all violations are corrected prior to the next routine IMS audit. Based upon a passing score of 95 it will be recommended that this facility be included on the IMS List as a certified supplier of single service product. This report was discussed with management at the conclusion of the survey. Should you have questions or concerns, feel free to contact me at Robert.Carrier@Wisconsin.gov or (608)-206-9172.

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 Prolamina
Number 55-4831
Date of Certification 5/16/2017

Sanitation Compliance Rating[1] **95**

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		
Prolamina					**2**									**3**															**5**	
TOTALS					**2**									**3**														**5**	

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)