

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 331-4900 Fax: (973) 331-4969 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 12/10/2008 - 01/13/2009*
	FEI NUMBER 2243677

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Dr. Mohamed S. Desoky, President and CEO

FIRM NAME Quality Formulation Laboratories, Inc.	STREET ADDRESS 110 Pennsylvania Ave
CITY, STATE, ZIP CODE, COUNTRY Paterson, NJ 07503	TYPE ESTABLISHMENT INSPECTED Dietary Supplement and Conventional Food Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

RELEASE

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED: REVIEWED: ~~2/3~~ 3/13/09
C.O. DATE

OBSERVATION 1

Effective measures are not being taken to exclude pests from the processing areas and protect against the contamination of food on the premises by pests.

For example:

1. On 12/11/2008, we observed that (b) (4) Agglomerated 80% WPC (Whey Protein Concentrate) lot# 8297CW was staged to be blended into the firm's lot# 811105. Upon cursory examination we found apparent rodent excreta pellets (REP's), urine stains (dry and wet) and holes apparently gnawed through to product. After observing our examination blending room employees removed the bags of product and used other bags of WPC for the lot. On 12/15/2008 a bag-by-bag examination was conducted and of 21 bags, 13 were observed to exhibit rodent contamination. Here is a description of the findings on each of the 13 bags.
 - a. Three apparently gnawed holes were observed on the upper right side of bag, two of which were through to product, and stains were observed around the holes. Another hole was observed at the bottom right side with urine stains. One of which appeared wet and a dropping was observed near the hole.
 - b. Three, apparently rodent gnawed, holes were observed in the front top to middle portion of the bag, the uppermost hole was through to product. Stains were observed from the top portion of the bag to about 18 inches below, with the heaviest apparent urine staining to the right of the apparently gnawed hole.
 - c. Two apparent REP's were found touching the bag.
 - d. Approximately six inches of staining was observed above, and to right of, the product label, which is located near the bottom front portion of the bag. Two apparent rodent pellets were found touching the bag.
 - e. One apparently gnawed hole, through to product, was observed on the lower right hand corner of the bag. Two apparent REP's were observed on the bag.
 - f. One apparent REP, two apparently gnawed holes through to product on upper left hand corner, and two spots of apparent urine stain were observed on the bag.
 - g. One apparent REP was observed on the bag.
 - h. Apparent REP's, too numerous to count, and staining on the bag approximately 12 inches from top of bag on right side, and approximately 4 inches from top of bag on the right side was observed.
 - i. Two apparently gnawed holes, through to product, were observed on lower left hand corner of bag with apparent urine

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stains around holes.

- j. Six apparent REP's were observed on the bag.
 - k. One apparent rodent dropping, apparent urine staining, and three apparently gnawed holes not to product on bottom of bag.
 - l. Apparent REP's, too numerous to count, concentrated on two spots, the upper left hand corner approximately four inches from the top of the bag and approximately six inches below that. Apparent urine stains observed between these two spots and below the second concentration of apparent REP's.
 - m. Apparent REP's, too numerous to count, concentrated on two spots: the upper left hand corner approximately four inches from the top of the bag and approximately six inches below that. Apparent urine stains observed between these two spots and below the second concentration of apparent REP's.
2. On 12/11/2008, upon examination of five bags of Alkalized Cocoa with Lecithin, lot number 3028 11013, we found that three of the five bags were apparently gnawed, through to product, three of five had apparent rodent urine stains, three apparent REP's were found on top of one bag, and approximately sixteen apparent REP's were observed in between three of the bags. Apparent REP's, too numerous to count, were found on the floor surrounding the bags.
3. On 12/11/2008, upon examination of 15 bags (b) (4) Pasteurized Grade A Sweet Whey, 08/25/08, we observed that four bags were apparently gnawed, through to product and three bags had apparent urine stains.
4. On 12/11/2008, at 1:28pm, a live rodent was observed running from under a table near Blender (b) (4) (B- (b) (4)) toward Blender 60 (B-60).
5. On 12/11/2008, at 4:05pm, a live rodent was observed running from the area of the blending room under pallets of bulk whey protein isolate.
6. On 12/16/2008, at 12:15pm, a live rodent was observed under pallets of product packaging including scoops, lids, and silver plastic bottles. The silver plastic bottles are used to package the Whey Protein Isolate product line. Numerous apparent REP's and a urine stain were also observed in this area.
7. On 12/10/2008, a dead rodent, apparently cut in half, was found on the motor platform of B- (b) (4) near a scoop.
8. On 12/11/2008, a dead rodent, surrounded by apparent rodent pellets, too numerous to count, was found in the southeast corner of the near finished product storage.
9. Evidence of rodent activity was observed in the blending room. For example:
- a. Apparent REP's, too numerous to count, and tracks were observed on the platform that holds the blender motor of B- (b) (4). Apparent REP's were also observed on the motor housing.
 - b. Apparent REP's, too numerous to count, were observed on blender (b) (4)'s (B- (b) (4)) support beam located on the side of the blender steps located only an inch or two from the bottom of the blender.
 - c. Apparent REP's were observed on the B- (b) (4) blender platform nearest to the blender and the steps
 - d. Apparent REP's were observed on the left hand side of the top step to B- (b) (4)

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- e. Apparent REP's and rodent tracks were observed on the horizontal supports of B (b) (4)
- f. Apparent REP's, too numerous to count, were observed on the windowsill in the northwest corner of the blending room near B (b) (4) and B (b) (4)
- g. Apparent REP's, too numerous to count, were observed in the southwest corner of the blending room.
- 10. Apparent REP's were observed on the floor and on the mechanical table in the blending room of the tableting department.
- 11. Apparent REP's and urine stains were observed along the cove molding and on the floor near the coding line, outside of the packaging room.
- 12. Apparent REP's were observed on the floor and on the drain board of the sink in the coating room.
- 13. Apparent REP's were noted on the floor and cove molding in the packaging room. Apparent urine was observed on the floor in the southeast corner of the packaging room.
- 14. Apparent REP's were noted throughout the warehouse.
- 15. The area in the northwest corner of the warehouse, along the eastern dividing wall where Whey Protein Concentrate was stored showed apparent urine staining and REP's. The staining was observed to be heavy, in a trail along the wall.
- 16. Apparent REP's were noted on a rack outside of the blending room where the bags that are used to line drums were stored.
- 17. Conditions in your warehouse are conducive to rodent harborage and are not conducive to adequate pest control activities. For example:
 - a. Your rack storage equipment is installed directly against the wall throughout the warehouse.
 - b. Pallets of raw materials, packaging, and finished product are being stored directly against rack storage.
 - c. Pallets of raw materials, packaging, and finished product were being stored directly next to each other in the northwest corner of the warehouse and in the Amitco storage area, such that, the rear of the Amitco area was inaccessible and the rear of the northwest area was only accessible by a small aisle.
 - d. Aisles in the south area of the warehouse had so many pallets stored in them that you could not walk through the aisles.
 - e. Holes were noted in the west wall of the blending room near B (b) (4) along the cove molding in the coating room, and on the east wall in the southern area of the warehouse.
 - f. A gap of approximately an inch was observed underneath the door located in the south area of the warehouse.

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OBSERVATION 2

Failure to clean food-contact surfaces and utensils as frequently as necessary to protect against contamination of food.

For example:

1. On at least 28 occasions from 04/10/2008 to present, your firm failed to conduct an effective cleaning in between products containing different allergens or between allergenic and non-allergenic products.
2. On 12/10/2008, after bringing the dead rodent (apparently cut in half) that was found on the motor platform of B^{(b) (4)} to the attention of the plant manager, employees were instructed by the plant manager to remove the rodent. Employees removed the cardboard that was lining the platform and replaced the cardboard. Rodent droppings, to numerous to count were observed under the original cardboard, but the platform was not cleaned before the cardboard was replaced.
3. Your drums, used to store finished product prior to final packaging, are not cleaned more than twice per year.

OBSERVATION 3

The procedure used for cleaning and sanitizing of equipment and utensils has not been shown to provide adequate cleaning and sanitizing treatment.

For example:

1. On 12/10/2008, B-60 was purportedly cleaned after processing Whey Strawberry lot # 81178, a milk containing product, but we observed a significant, white residue caked on the ribbon blades, a white accumulation on the bottom surface of the blender, and a white and pink accumulation on the horizontal surface located on the upper right hand corner of the blender. On 12/11/2008, the next batch of product was processed in this blender was "Euro Multi Vit Mineral" lot # 81187, a product that does not contain allergens.
2. On 12/10/2008, the exteriors of B^{(b) (4)} and B^{(b) (4)} was observed to be covered in a residue that shows wipe marks. The top of B-10 also had the marks as well and what appeared to be a hand mark.
3. Your firm is only using hot water to clean out the blenders after batches of allergenic products. Your blending room supervisor stated that detergent is only used when the blender is "sticky".
4. Your firm does not use any sanitizer or isopropyl alcohol when conducting cleaning.
5. Two firm employees were observed using rags that were made from clothing to dry the interior of B^{(b) (4)} and the food contact surface of the unloading port of B^{(b) (4)}. These rags were observed to be hanging on the chain link fence (surrounding the V blender in the northwest corner of the blending room) and on the edge of the unclean sink in the blending room. No

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assurance was provided that these rags were cleaned and laundered prior to use or that they were intended for use in a food establishment. These rags were also observed in the tableting room.

6. Your firm uses brooms, covered in plastic bags, to sweep out the blenders after processing.

- a. On 12/10/2008, the bag covering the broom located at B (b) (4) had a large hole in it and product residue was observed on the bristles.
- b. On 12/10/2008, the bag covering the broom located at B (b) (4) had a large hole.

7. Your firm only has two sinks where cleaning of items such as screens and scoops can be cleaned. The sink in the blending room was in an excessively unclean condition. The sink in the tablet room was observed to have apparent REP's on the drain board. Cleaning items such as mops, brushes, and buckets were also stored on the drain board, and the interior of the sink was in an unclean condition.

OBSERVATION 4

Failure to maintain equipment and utensils in an acceptable condition through appropriate cleaning and sanitizing.

For example:

- 1. The following conditions were observed at B (b) (4) on 12/10/2008:
 - a. B-10 was purportedly cleaned on 12/09/2008 after producing lot# 81186 Biogurt Magnesium; however, there was a white crystal like powder in the screen. Also there was a heavy brown, cocoa-colored accumulation behind the blender on the windowsill. The last time the firm produced a cocoa-containing product, American Soy Chocolate lot # 811112, was on 11/22/2008.
 - b. Surfaces on and near the port, from which blended product is unloaded, were covered with a tanish product residue.
 - c. Hoses above the opening to this blender were observed to be taped together and had a tanish product residue on them.
 - d. The motor covering, which is level and right next to the opening of the blender, was covered in a tanish residue.
 - e. Zip ties used to close bags are stored in a container that is not easily cleanable and is taped to one of the blender legs.
 - f. The holder for the broom is duct taped.
- 2. The following conditions were observed at B (b) (4) on 12/10/2008
 - a. The right side of B (b) (4) had a heavy accumulation of brown-colored and tan-colored residues
 - b. Duct tape was observed on the railing
 - c. The dust collection system hose, above the blender opening, was observed to be encrusted with product residue.
- 3. On 12/18/2008, on the deck of B (b) (4) a screen was observed to be in poor repair. The top and bottom was duct taped and

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the frame was separating from the screen itself.

4. The following conditions were observed at B (b) (4) on 12/10/2008, at the time of these observations the blender was purportedly cleaned after processing Whey Strawberry lot # 81178, a milk containing product. On 12/11/2008, the next batch of product was processed in this blender was "Euro Multi Vit Mineral" lot # 81187, a product that does not contain allergens.

- a. Surfaces near the opening of the blender such as the air hose which is above the blender, a flat surface on the exterior of the blender, and the railing were covered in a white to cream colored product residue.
- b. Cardboard was being used to line the deck and the deck was observed to be covered in a tan and brown-colored residue. Cardboard was also used to line the motor platform.
- c. A box cutter was observed to be covered in a slight product residue.
- d. The handle of a hook was observed to be covered with tape.
- e. The dust collection system hose, above the blender opening, was observed to be encrusted with white and tan-colored product residue.

5. The following conditions were observed at B (b) (4) on 12/10/2008

- a. The deck of this blender was observed to be covered in a tanish product residue.
- b. The motor covering on the left side was observed to be covered on a cream-colored residue.
- c. The broom holder and the blender switch box was duct taped. The switch box was covered with a white-colored residue.
- d. The handle of a hook was covered in tape.
- e. The storage container that holds the box cutters was found to have disposable gloves stored in it.
- f. A heavy accumulation of product residue was observed on the metal tubing to the right of the opening of B (b) (4)
- g. Heavy accumulation of residue on the right side of the blender and on the machine surfaces on the right side.
- h. Above the blender, the dust collection system was encrusted with product residue, cobwebs were observed, and surfaces such as pipes and a chain were covered with product residue.

6. Your firm continues to use box cutters, which are not easily cleanable, to open bags of raw materials.

OBSERVATION 5

Failure to manufacture, package, and store foods under conditions and controls necessary to minimize contamination.

For example:

- 1. On 12/10/2008, at B (b) (4) plastic bags used to cover the brooms prior to blender cleaning were observed to be covered in product residue.
- 2. On 12/15/2008 product residue was found on the inside of plastic bags staged at the filler. Residue appeared to be accumulating on the bags from the environment.

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3. On 12/11/2008, bags that were stored on a rack near the exterior of the blending room were found to have an accumulation of product residue on them. These bags are used to line the finished product drums. Apparent REP's were observed next to these bags.

4. Throughout the inspection, the drums that hold the plastic bags in place while loading product into them and are later used to hold the finished product, were covered in residue. The drums are reused repeatedly without regard to whether an allergenic product was stored in it before.

5. Your screens used to sift product in the blenders were stored directly on the floor.

6. You are not following your stated SSOP's to prevent the inadvertent inclusion of allergenic materials in non-allergenic products or products containing different allergens. Although your "Standard Operating Procedure Pharmacy and Blending Department" states,

"Blenders are assigned mainly for blending of the following products

Blender 1 (b) (4) cubic feet) for Whey products

Blender 2 (b) (4) cubic feet) for Mass Products

Blender 3 (b) (4) cubic feet) for Stamina products and Vitamins

Blender 4 (b) (4) cubic feet) for Egg products, Soy products, and Vitamins".

You have not dedicated blenders for specific products and, in fact, failed to adhere to your SSOP on at least 31 occasions between 12/01/2008 and 12/31/2008.

OBSERVATION 6

The function of supervising overall sanitation of the plant has not been designated to the supervision of one or more competent individuals assigned responsibility for this function.

Specifically, supervision of the blending procedure was inadequate, in that, at least 28 cleaning deviations were noted in the "Blending Department Recor for Cleanin Mixers Start Jan-1-2008" log book without detection by firm management.

OBSERVATION 7

Appropriate training in food handling techniques and food protection principles has not been provided to food handlers and supervisors.

Specifically, your blending supervisor was not properly trained to identify allergens or when to clean the blenders in between

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batches in order to minimize the cross contamination between products containing different allergens or between allergenic and non-allergenic products.

OBSERVATION 8

Failure to properly store toxic cleaning compounds and pesticide chemicals in a manner that protects against contamination of food, food-contact surfaces, and food-packaging materials.

For example:

1. Your firm had a non-acid bathroom cleaner and (b) (4) Hornet and Wasp Killer stored on the platform that holds the blender motor of B-60. The Hornet and Wasp Killer label states, "Do not use inside the home."
2. Your firm had (b) (4) Flying Insect Spray and (b) (4) stored on a shelf above product packaging materials outside of the blending room. The label states, "This product is for residential use."

*** DATES OF INSPECTION:**

12/10/2008(Wed), 12/11/2008(Thu), 12/15/2008(Mon), 12/16/2008(Tue), 12/18/2008(Thu), 12/30/2008(Tue), 01/13/2009(Tue)

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