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SUMMARY

This was an inspection of a manufacturer of infant formula pre-mixes. The inspection was conducted in accordance with Compliance Program 7321.006-"Infant Formula Program and DET-DO work plan FY '10 under FACTS Assignment # 1107400 and OP ID 4422647. The current inspection covered the processing, packaging, sanitation, and storage operations.

The previous inspection was conducted on 06/1-3/09 as a surveillance inspection of the firm's infant formula premixes and PAI for drug products. At the conclusion of the inspection, no FDA 483 was issued. Items discussed included the ongoing issue of unifying sampling and testing procedures with (b) (4) for Vitamin pre mixes, stability protocol not matching the inspectional standards, and clear identification of identity samples. Management promised corrections.

The current inspection was a routine surveillance inspection of the firm's infant formula pre mix manufacturing. No FDA 483 was issued. Items discussed included: recording amount of samples received and used for testing to assure correct amount was sampled, updating customer complaint log to correctly address fields used, and consistency when filling out forms. Management promised correction.

ADMINISTRATIVE DATA

Inspected firm:	Perrigo Holland Inc
Location:	13295 Reflections Dr Holland, MI 49424-8220
Phone:	616-738-8500
FAX:	
Mailing address:	13295 Reflections Dr. Holland, MI 49424
Dates of inspection:	4/20/2010
Days in the facility:	1
Participants:	Martha Sullivan Myrick, Investigator

FDA 482 Notice of inspection was issued to Dave Schrage, Site Director and the most responsible person on site.

HISTORY

This firm is a manufacturer of OTC drugs (Over-The-Counter liquids, tablets, and capsules), nutritional supplements, vitamins and vitamin pre-mixes. This firm was acquired by L. Perrigo Co. in September 2008. All shareholders sold stock as a result of the acquisition. No business has changed. Organizational charts were supplied for Manufacturing support (EXHIBIT 1), Quality Control- PMH (EXHIBIT 2) Global Quality Operation (EXHIBIT 3) and Global Quality and Compliance (EXHIBIT 4).

Normal office hours are 0800 Hrs. to 1630 Hrs. Monday through Friday. The firm's manufacturing plant operates (b) (4) (b) (4) .

Any inspectional correspondence should be directed to Mr. Dave Schrage at the firm's address.

INTERSTATE COMMERCE/JURISDICTION

The firms operations have not changed since the acquisition in September 2008.The percentage of sales are as follows:

(b) (4) Drug Sales (including prescription nutritionals)
(b) (4) Infant Formula
(b) (4) Nutritional Supplements

According to management, approximately (b) (4) % of products are shipped directly into interstate commerce. Management stated that almost all other products end up eventually going into interstate channels.

The vitamin pre-mixes intended for infant formula use are contract manufactured for (b) (4) (b) (4)) and are either shipped to (b) (4) plant or to other plants (b) (4) (b) (4) . The vitamin premixes manufactured at Perrigo Holland Inc. are packaged and shipped in bulk size containers.

The infant formula premix product list (EXHIBIT 5) was supplied. In addition, a list of all lots of infant formula lots produced since the last inspection was supplied. (EXHIBIT 6-10)

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

Mr. Dave Schrage, Site Director, stated he was the most responsible person at the firm at the time of the inspection.

Others present during the inspection included:
Gary Carlson, Compliance Manager
Paul Walker, Director of Quality
Gretchen Starr, Quality Assurance Manager
Jill Bronkema, Supply Chain Quality Manager
Kirk Walter, Director Operations
Micheal Schoonover, QC Microbiology Supervisor
Chad Neher, QC Lab Manager
Joseph Gannon, QC Finished Goods Supervisor

FIRM'S TRAINING PROGRAM

The firm continues to train the employees with classroom and OJT. In addition, trained employees go through periodic refresher courses.

MANUFACTURING/DESIGN OPERATIONS

INFANT FORMULA PRE MIXES

Raw Ingredient Weigh Operations:

Raw materials suppliers are approved by (b) (4) for the use in infant formula pre mixes. All raw ingredients meeting specifications is released in (b) (4) All of the firm's products are received under the same General Receiving Procedure. Each raw material purchased is identified by a code number. When a lot of raw material is received, it is inspected for damaged containers and identified with a label listing the name, code number, date and quantity received, manufacturer's lot number, and a reference number. The reference number (receiving number) is assigned in the order in which the material is received. The label also indicates the lot is quarantined. As of March 2009, the firm uses (b) (4) system to control the status of all materials from receipt to shipping.

The sample technician transfers the lot of raw ingredient to a sampling area. The amount of sample needed to be collected is determined by the laboratory. The Material Control Card and the sample of material are taken to the Quality Control Laboratory, where the sample is tested in accordance with established procedures. At minimum, description, identification, and foreign matter are performed each time a material is received, with other required testing accepted from the manufacturer's certificate of analysis. Testing accepted on certificate of analysis is verified on one lot (b) (4) for materials used in drug products, and for other materials on request. The Quality Control Laboratory has the capability to perform normal and reversed-phase HPLC, flame atomic absorption, and UV-Visible spectrophotometric assays, fluorimetry, titrimetric techniques, and dissolution testing. Compendial methods are used for these tests. As of the last inspection the firm now has use of (b) (4) scans.

Raw ingredients are weighed out as specified in the batch record and the amount weighed accounted for taken out of inventory in (b) (4). Each step of the weighing operation is checked by a second person in addition to the individual performing the weighing operation. Labels are attached to each container of bulk ingredients, identifying the contents by name, code number, and the product name, code number, and lot number for which they are to be used.

All ingredients needed for one batch of product are weighed and assembled on one pallet or group of pallets and transferred to a staging area located on the second floor for the appropriate manufacturing operation.

Infant formula Mixing Operations:

After the designated mixer is checked for cleanliness, staged ingredients are verified against the batch record, then added and processed according to the manufacturing instructions.

(b) (4) . The final packaged containers of vitamin pre-mixes are labeled and placed on pallets for shipment. The firm receives the (b) (4) liners from (b) (4) located in (b) (4). The (b) (4) liners are manufactured by (b) (4) located in (b) (4). The (b) (4) drums with (b) (4) lids and seals are manufactured and received from (b) (4). located in (b) (4).

This firm manufactures five vitamin premixes for (b) (4). A list for each product manufactured during the last year was provided. These are (b) (4) Vitamin Pre-Mix # (b) (4) (EXHIBIT 6) (b) (4) Vitamin Pre-Mix # (b) (4) (EXHIBIT 7), (b) (4) Vitamin Pre-Mix # (b) (4) (EXHIBIT 8), (b) (4) Vitamin Pre-Mix # (b) (4) (EXHIBIT 9), and (b) (4) (b) (4) Pre-Mix # (b) (4) (EXHIBIT 10).

During the discharging of the vitamin premix into the (b) (4) drums, the company employees select the first, middle, and last master container of finish product for lab testing. The three master containers of vitamin premix are shipped to the (b) (4) laboratory for full testing. The three containers serve as representative of the production lot. Perrigo Holland INC., collects samples of the vitamin premix and test for certain indicators in each lot before they are released. The indicators tested by Perrigo Holland INC., are Niacinamide, Riboflavin (Vitamin B2), Pyridoxine HCL (Vitamin B6) and Cyanocobalamin (Vitamin B12). A "Certificate of Analysis" (C.O.A.) is issued for each lot of finish product.

This firm has not made any formulation changes since the last inspection.

METAL DETECTION

There are currently metal detection units on all the packaging lines. The firm has completed installing portable metal detectors on all compression units. Magnets are currently used on the blenders. All bulk products are currently metal detected prior to shipping. Products that are packaged at Perrigo Holland Inc., are detected on the packaging line.

MANUFACTURING CODES

Perrigo Holland uses an internal lot coding system. i.e. 9H4755

9- Year

H- product month

4755- consecutive batch

COMPLAINTS

Infant formula complaints (EXHIBIT 11-12) were reviewed. The firm receives complaints directly from (b) (4) for vitamin pre-mixes. The firm continues to receive complaints for OOS results. Perrigo Holland Inc. reviews the product batch records and testing results to look for non conformances. The firm was not able to confirm any OOS result complaint received since the last inspection. Perrigo Holland Inc. stated they composite the samples before analysis and (b) (4) does not. This in turn can lead to differences in results.

RECALL PROCEDURES

Recalls for infant formula are handled by (b) (4) .

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

No FDA 483 was issued at the close of the inspection.

REFUSALS

No refusals were encountered during this inspection.

GENERAL DISCUSSION WITH MANAGEMENT

Individuals present during the closeout inspection including myself (representing the FDA) and the following persons for Perrigo Holland Inc.:

Gary Schrage, Site Director

Kirk M. Walter, Director Operations

Paul Walker, Director Quality

Jill Bronkema, Raw Material Supervisor

Gretchen Starr, Quality Assurance Manager

Gary R. Carlson, Director Quality Assurance

Items discussed during the close out inspection including the following:

1- Improving the customer complaint SOP (b) (4) (EXHIBIT 113-20) to more coldly reflect the meaning and instruction for use for the customer complaint log. Review of the customer complaint files found to in some instances the specification failure was checked no (EXHIBIT 21) but in other instances it was checked yes (EXHIBIT 22). In addition, the management review and sample returned field is not filled out.

2- On the firm Certificate of Analysis the Qty Lab Recd, the amount is not filled out with consistency. For (b) (4) the sample size collected is two samples of 50 grams each from 3 drums for a total of 300 grams (EXHIBIT 23). The

C of A for two lots showed a quantity received as 6 x 200g (EXHIBIT 24) and on another one `500g (EXHIBIT 25). For premix (b) (4) the sample size is 2 samples of 100grams each from 5 drums (EXHIBIT 26). The C of A's ranged for `500g (EXHIBIT 27) to `200g (EXHIBIT 28). I stressed to the firm the importance of consistency in filling out the required information.

Management promised corrections.

EXHIBITS COLLECTED

1- Manufacturing Support Organizational chart
2- Quality Control- PMH Org Chart
3- Global Quality Operations Org Chart
4- Global Quality and Compliance Org Chart
5- Product list for formula Pre mixes
6- Lots produced Material 9H7AA (b) (4)
7- Lots produced Material 9L2AA (b) (4)
8- Lots produced Material 9H3AA (b) (4)
9- Lots produced Material 9L5AA (b) (4)
10- Lots produced Material 9F3AA (b) (4)
11-12 Complaint list
13-20 SOP (b) (4) Customer Complaints
21-22 Customer Complaint Log
23- (b) (4) premix (b) (4) sampling instructions
24-25 C of A for (b) (4) Premix (b) (4)
26 (b) (4) premix (b) (4) sampling instructions
27-28 C of A for (b) (4) Pre mix (b) (4)

ATTACHMENTS

1- FDA 482 Notice of Inspection

Martha Sullivan Myrick, Investigator