

Establishment Inspection Report

Nestle USA, Inc.
Danville, VA 24540-5616

FEI: **1122474**
EI Start: 09/11/2006
EI End: 09/12/2006

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SUMMARY

The comprehensive inspection of this pasta and cookie dough manufacturer was conducted as an ad hoc inspection in accordance with FY-06 BLT-DO workplans and FACTS assignment #760403, OP ID #2969731 under CP 7303.803 (Domestic Food Safety Program, PACs: 03803 and 04803) and CP 7321.005 (NLEA, PAC: 21005). The previous inspection of this firm was conducted by FDA on 9-14-05 and was classified NAI with no deficiencies noted.

The current inspection found the firm continues to manufacture a variety of refrigerated pastas, pasta sauces, and cookie dough. The firm produces products which are regulated by USDA and FDA. The firm was manufacturing a variety of flat and stuffed pastas, pasta sauce, and cookie dough during the inspection.

Although no FDA-483 was issued, four deficiencies were verbally discussed with the firm. These were:

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- Three live ant-like insects were observed on a ledge along the W wall of the powdered sugar dump station in the cookie dough manufacturing area.
- Dirty stainless steel equipment and utensils were observed in a bin which was identified as "clean" in the cookie dough cleaning area.
- Water or other clear liquid was observed dripping from an overhead line in the liquid egg receiving bay.
- The knock off arm for the check weigher was improperly timed or otherwise not functioning properly to remove trays of cookie dough on line ten.

Management promised correction of all deficiencies.

No samples were collected during the inspection. The firm refused to provide the following:

- Percent of products which move in interstate commerce
- Review of complaint log
- Use of camera
- Review of pest control records
- Review of HACCP program
- Information on environmental testing program

The firm is registered with FDA in accordance with the Bioterrorism Act of 2002.

One reconciliation examination was performed during the inspection. No problems were noted.

ADMINISTRATIVE DATA

Inspected firm: Nestle USA
Location: 201 Airside Dr
Danville, VA 24540-5616
Phone: 434822-4000
FAX:
Mailing address: 201 Airside Dr
Danville, VA 24540-5616

Dates of inspection: 9/11/2006, 9/12/2006
Days in the facility: 2
Participants: Dennis L. Doupnik, Investigator

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On arrival at the firm, credentials were shown and the FDA-482 (Notice of Inspection) was issued to Mr. Donald P. Nodtvedt, Plant Manager, who is the most responsible individual for the firm. Mr. Nodtvedt was also provided with a copy of the Attachment to FDA-482, Resources for FDA Regulated Businesses, form.

Credentials were also shown to Mr. Floyd H. Caldwell, QA Manager.

The firm is also inspected by USDA. The USDA inspector was not at the plant during my inspection.

HISTORY

Nestle USA, Inc. is part of Nestle Holding Inc., Glendale, CA which is incorporated in Delaware. The top individual for Nestle Holding Inc. in the U.S. is Mr. Bradley Alford, COP/CEO. Mr. Alford maintains his office at:

Nestle Holding Inc.
800 North Brand Boulevard
Glendale, CA 91203

The firm operates two divisions under Nestle USA, Inc. at the Danville, VA facility. These are the Nestle Confections and Snacks Division which is responsible for the production of cookie dough and the Buitoni Division which is responsible for the manufacture of pastas and pasta sauces.

FDA has taken no legal action against this firm to date. The firm has not been involved in any product recalls since the previous inspection.

The firm operates (b) (4) depending on production needs. Production shifts run from (b) (4). Office hours are 8:00Am to 5:00PM on Monday through Friday.

The top individual at the Danville, VA facility is Mr. Donald P. Nodtvedt, Plant Manager. All correspondence should be addressed to Mr. Nodtvedt at the firm's physical address.

The firm is registered with FDA in accordance with the Bioterrorism Act of 2002.

INTERSTATE COMMERCE

The firm stated that their products are shipped in interstate commerce; however, they refused to identify the percentage of products which are shipped IS.

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The firm leases an outside warehouse in (b) (4) for the storage of ingredients.

The firm ships finished products to two outside warehouses in (b) (4) and one warehouse in (b) (4) for the storage of finished products. Identified as Exhibit #1 are the names and addresses of these warehouses.

JURISDICTION

The firm manufactures a variety of refrigerated pastas, pasta sauces, and cookie dough products. The types of pasta products produced by the firm include fettuccine, linguine, angel hair, ravioli, tortelloni, and tortellini. Seven meat filled pasta products are regulated by the USDA. Identified as Exhibit #2 is a list of the firm's products. The firm refused to provide the percentage of the types of products produced by volume or dollar amounts although the numbers of products produced by types can be determined on this product list.

Pasta and pasta sauces are all manufactured under the firm's own Buitoni® brand name. Cookie dough is manufactured under the firm's own Toll House® brand name. The firm does not manufacture any products for outside firms.

Identified as Exhibits #3-5 respectively are examples of product labels for pasta, pasta sauce, and cookie dough which were being manufactured during the inspection. A review of product labels found they were in compliance with the allergen and trans fat label regulations. The firm has no label agreements with outside firms.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

The most responsible individual for the firm is Mr. Donald P. Nodtvedt, Plant Manager. Mr. Nodtvedt is responsible to oversee all of the firm's operations. Identified as Exhibit #6 is an organizational chart which identifies those individuals who report directly to Mr. Nodtvedt. Mr. Nodtvedt reports to Ms. Louise DeFalco, Vice President of Operations for Nestle Confections and Snacks who maintains her office at Nestle Holding, Inc. in Glendale, CA.

Among the individuals reporting to Mr. Nodtvedt is Mr. Floyd H. Caldwell, QA Manager. Mr. Caldwell is responsible to oversee product adherence to quality specifications including ingredient and finished product testing, sanitation, the firm's HACCP program and regulatory compliance.

Among those individuals reporting to Mr. Caldwell is Mr. Larry G. Hundycz, Plant Hygienist. Mr. Hundycz is directly responsible to oversee the firm's pest control program, sanitation, the firm's HACCP program, and employee training.

Mr. Mike Stoppenbach, Operations Manager for Nestle Confections and Snacks, is responsible to oversee manufacturing operations for cookie dough. Mr. Stoppenbach reports to Mr. Nodtvedt.

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Mr. Keith Scruggs, Operations Manager for the Buitoni Division is responsible to oversee manufacturing operations for pasta and pasta sauce manufacturing operations. Mr. Scruggs reports to Mr. Nodtvedt.

Information for this report was provided by Mr. Nodtvedt; Mr. Caldwell; Mr. Hundycz; (b) (6), Operational Technologist; and (b) (6), Quality Specialist. I was accompanied throughout the inspection by Mr. Caldwell and (b) (6).

Prior to starting the inspection, Mr. Caldwell presented a form which detailed those areas which the firm refused to provide or permit per corporate policy. These included the use of a camera or recording devices in the plant, talking directly to line employees, copying product formulations or time temperature readings, and review of complaints among others.

I responded that observing times, temperatures, or other process parameters were a part of our routine inspectional methods and if I felt a problem existed where I needed to record this information I would; however, I went on to say that unless I felt a problem existed I would not do so.

FIRM'S TRAINING PROGRAM

All new employees are provided with classroom orientation which includes information relating to food safety, GMPs, and the firm's policies and procedures. Annually the employees are trained on specific quality related topics. Training is documented.

MANUFACTURING/DESIGN OPERATIONS

Employees and visitors are required to wear clean lab coats and hair nets and to wash and sanitize their hands (b) (4) before entering the plant. Foot baths containing quaternary ammonia are located in the pasta processing and packaging areas. Employees are also required to wear gloves when contacting food.

Products are received in various areas of the plant. Dry goods are received in one storage area. Liquid eggs on tanker trucks are received in an enclosed receiving bay. Canned goods are received and stored in a separate area.

The firm has separate, enclosed areas for the storage and/or preparation of products. These include the following areas:

- Dries room: storage for slower moving dry ingredients as well as ingredients brought into the room for weighing into production batches
- Allergen room: primarily used for weighing out pine nuts and walnuts for production batches
- Dairy cooler: used for short term storage of dairy ingredients such as cheeses which are weighed out for product batches (temperate found - 40°F)

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- Cooler prep: primarily used for weigh out of meats and some slurries for sauces (temperature found - 50°F)
- Cheese debox and trim room: weigh out of cheese for production batches (temperature found - 42°F)
- Vegetable debox: weigh out and preparation of vegetables for production batches (temperature found - 38°F)
- Freezer: used for the storage of various meats, vegetables, and some cheeses (temperature found 20°F)

In general, product batches are staged within one day of processing. The firm has limits as to how long product batches can be staged before being used.

Processing operations remain essentially the same as has previously been described in the previous EIR. Since the previous inspection, the firm has replaced the equipment on pasta lines (b) (4) and (b) (4). Previously, line (b) (4) was used to manufacture tortelloni and line (b) (4) was used to manufacture tortellini. The firm has replaced the equipment on these lines with a (b) (4) pasta machine which can make either tortelloni or tortellini. In addition, the firm has installed a mechanical shuttle system which supplies dough to these lines.

The firm uses the following lines for manufacturing products:

Pasta:

- (b) (4) Flat pasta (Firm was manufacturing fettuccini and linguini on this line during the inspection)
- (b) (4) not operational
- (b) (4) Ravioli (Firm was manufacturing four cheese ravioli and chicken and roasted garlic ravioli (USDA product) on this line during the inspection)
- (b) (4) Tortellini or tortelloni (Firm was manufacturing chicken tortellini (USDA product) and three cheese tortellini on this line during the inspection)
- (b) (4) Tortellini or toertelloni (Firm was manufacturing three cheese tortellini on this line during the inspection)
- (b) (4) not operational

Each line has various line controls and monitors. All lines have metal detectors with knock off arms which are located prior to the blanching step (lines (b) (4) and (b) (4)) or down stream after packaging (lines (b) (4) and (b) (4)). The metal detectors on all pasta lines are challenged hourly (documented) using (b) (4) mm ferrous standards as well as (b) (4) mm stainless steel standards (line 3) and (b) (4) mm stainless steel (lines (b) (4), (b) (4), and (b) (4)). According to Mr. Caldwell, all packages removed from the line by the metal detectors are examined for metal.

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The firm was requested to challenge the metal detector on line (b) (4) on 9-11-06. No problems were noted.

All pasta lines are also equipped with net weight sensors with knock off arms.

Each pasta container is flushed with nitrogen prior to sealing. Nitrogen is currently purchased in bulk from (b) (4) although Mr. Caldwell stated that they would be changing to a new supplier in the next several weeks. (b) (4) provides the firm with a continuing guarantee regarding the quality of the nitrogen received.

Mr. Caldwell stated that waste product (pasta and cookie dough) is sold to (b) (4) (b) (4)

Pasta Sauce:

The firm manufactures pasta sauces in two different rooms. Red and white sauces are manufactured in a sauce kitchen which has seven steam jacketed kettles. Depending on production runs, days are dedicated as "red" and "white" days. The firm was manufacturing alfredo sauce on the last day of the inspection.

Pesto sauce and bruschetta are manufactured in the (b) (4) room. Two (b) (4) mixers are used to manufacturer these products. There were no operations in progress in the (b) (4) room during the inspection sine the firm was manufacturing sauces in the sauce kitchen during this inspection.

The sauce line contains sensors with knock off arms. These sensors include fill detectors, check weighers, and metal detectors. Metal detectors for sauces in 7 oz, 10 oz, and 15 oz containers are challenged hourly (documented) with (b) (4) mm ferrous and (b) (4) mm stainless steel standards. Metal detectors for sauces in 20 oz containers are challenged hourly (documented) with (b) (4) mm ferrous and (b) (4) mm stainless steel standards. Metal detectors are located after product filling (sealing) and after cooling and the lid is applied.

Cookie Dough:

Cookie dough manufacturing is performed in a refrigerated area of the plant. Ingredients are maintained separate from pasta and pasta sauce ingredients.

The firm uses five lines for the manufacture of cookie dough. These are:

(b) (4) Chubs (This line was not in operation during the inspection)

(b) (4) Shapes (This line was used to manufacture animal cookie dough during the first day of the inspection)

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(b) (4) Break and bake cookie dough (This line was used to manufacture mini sugar cookies and chocolate chip fudge drizzles cookie dough during the inspection)

(b) (4) Break and bake cookie dough (This line was used to manufacture ultimate peanut butter lovers cookie dough during the inspection)

(b) (4) Break and bake cookie dough (This line was used to manufacture jumbo chocolate chip cookie dough and chocolate chunk cookie dough during the inspection)

Each line has various line controls and monitors. This includes check weighers and metal detectors with knock off arms. The metal detectors on all but the chub lines are challenged hourly (documented) with (b) (4) mm ferrous and (b) (4) mm stainless steel standards. The metal detector on the chub line is challenged hourly (documented) with (b) (4) mm ferrous and (b) (4) mm stainless steel standards.

Firm's Allergen Program:

The firm has identified six of eight allergens in their products. These are milk, soy, wheat, egg, peanuts, and tree nuts. The firm has a program in place for control of these allergens. The firm labels pallets of dry ingredients which contain these six allergens. The firm also has designated racking locations on the warehouse for allergen containing products. As previously stated, the firm has a separate allergen room which is used for the storage and/or preparation of product batches containing pine nuts and walnuts.

The firm has a sequencing plan in place for the manufacture of products containing allergens. The firm's QA department is responsible for reviewing production records to verify the correct run order of products prior to product release. Equipment is cleaned after use to prevent cross contamination with other allergens.

Employees are required to change their uniforms if working on different lines where allergens are an issue. In addition, in the cookie dough manufacturing area, employees working with allergen containing products are required to wear a blue hair net in order to differentiate these workers from workers who are working with products where allergens are not an issue. Workers not working with allergen containing products wear green hair nets.

A review of the firm's labels found they are in compliance with the allergen labeling regulations. Product labels specifically identify any allergens in the products following the ingredient statement.

According to the firm, they do not directly add any colors to their products.

Cleaning Compounds/Boiler Water Additives:

The firm has formal cleaning procedures in place for cleaning products. Designated employees perform equipment and utensil cleaning. Product tubs and totes are cleaned in designated areas using automated wash equipment. Equipment and utensils are also cleaned by hand or by CIP depending

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on the equipment. All of the firm's equipment cleaning compounds are purchased from (b) (4). Identified as Exhibit #7 is a list of the cleaning compounds which are used by the firm and the areas they are used.

Steam contacts the product in two areas of the firm's operations. Steam blanchers are used for all pasta products. Steam injection is also used during the manufacture of pesto sauce.

A review was made of boiler additives which are used by the firm. The boiler additives used by the firm are manufactured by (b) (4) and appear to be approved for use where steam can contact the product.

Pest Control:

The firm uses the services of (b) (4) for their pest control. According to the firm, this is accomplished two times per week. The firm uses bait stations on the exterior of the building and mechanical wind-up traps on the interior for rodent control. Insect control is performed using insecticides and pheromone traps (warehouse beetles and Indian meal moths). Fogging is used in the plant on an as needed basis only.

Flour and sugar silos are cleaned on a rotating basis every 4 to 6 weeks from approximately April through November.

The firm refused to allow review of their pest control records.

Three live ant-type insects were observed in the plant during the inspection. This observation is further discussed under the heading "Objectionable Conditions".

Calibration:

The firm uses the services of (b) (4) for the calibration of monitoring equipment including scales and temperature monitoring/recording devices. Scales are calibrated yearly. Temperature monitoring/recording devices are calibrated monthly. In addition, Mr. Caldwell stated that the firm performs a daily verification for scale or thermometer accuracy.

No problems were noted relative to calibration during the inspection.

Reconciliation Examination:

One reconciliation examination of instant potato granules in 50 lb bags from (b) (4) was performed during the inspection. No problems were noted.

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Label Examination:

An examination of representative product labels found the firm's labels are in compliance with the allergen and trans fat label regulations. No other label problems were noted.

MANUFACTURING CODES

An example of the firm's manufacturing code is as follows:

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

The firm also identifies the products with a use by date.

COMPLAINTS

The firm stated that complaints are not maintained at the Danville, VA facility. The firm refused to allow review of a complaint log. FACTS does not report any complaints against the firm's products since the last inspection.

RECALL PROCEDURES

The firm has a recall procedure in place. The firm has not had a recall of any products since the last inspection.

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

Although no FDA-483 was issued at the conclusion of the inspection, four objectionable conditions or deficiencies were discussed with the firm. These were:

- 1) Three live ant-like insects were observed on a ledge along the W wall of the powdered sugar dump station in the cookie dough manufacturing area.

Mr. Caldwell accompanied me when this observation was noted. Mr. Caldwell immediately informed Mr. Hundycz of this observation and requested him to inspect this area. None of these insects were observed near exposed product.

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- 2) Dirty stainless steel equipment and utensils were observed in a bin which was identified as "clean" in the cookie dough cleaning area.

Mr. Caldwell accompanied me when this observation was made. Mr. Caldwell moved the bin containing the dirty equipment and utensils to the wash area for re-cleaning.

- 3) Water or other clear liquid was observed dripping from an overhead line in the liquid egg receiving bay.

Mr. Caldwell accompanied me when this observation was made. Mr. Caldwell stated that maintenance would be contacted to determine why this pipe was leaking.

- 4) The knock off arm for the check weigher was improperly timed or otherwise not functioning properly to remove trays of cookie dough on line ten.

Mr. Caldwell and (b) (6) accompanied me when this observation was made. During an evaluation of the cookie dough processing operations, it was observed that knock off arm for the check weigher on line (b) (4) was not working properly which caused slabs of cookie dough to either not be kick off the line or to cause a line jam. Mr. Caldwell stated that maintenance would be contacted to correct this problem.

REFUSALS

The firm refused to provide the following:

- Percent of products which move in interstate commerce
- Review of complaint logs
- Use of camera
- Review of pest control records
- Review of HACCP program
- Information on environmental testing program

GENERAL DISCUSSION WITH MANAGEMENT

A closing discussion was held with Mr. Donald P. Nodtvedt, Plant Manager; Mr. Floyd H. Caldwell, QA Manager; Mr. Larry G. Hundycz, Plant Hygienist; (b) (6), Quality Specialist; and (b) (6), Operational Technologist, at the conclusion of the inspection.

Although no FDA-483 was issued, the four objectionable conditions were verbally discussed with Mr. Nodtvedt and the individuals in attendance. With respect to the ant-like insects noted in the powdered sugar dumping area, Mr. Hundycz stated that he had not seen any other insects in the area;

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however, he had called their extermination company to look at this area. Mr. Nodtvedt and Mr. Caldwell stated that the other deficiencies would be corrected immediately.

ADDITIONAL INFORMATION

None

SAMPLES COLLECTED

None

VOLUNTARY CORRECTIONS

NA

EXHIBITS COLLECTED

- 1) List of warehouses where firm stores ingredients and finished products
- 2) Product list
- 3-5) Product labels
- 6) Organizational chart
- 7) List of cleaning compounds

ATTACHMENTS

- FDA-482
- Regional OEI Checklist



Dennis L. Douppnik, Investigator

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SUMMARY

This comprehensive inspection of a refrigerated foods manufacturer was conducted in accordance with FY-05 BLT-DO workplans under FACTS assignment #566390, OP ID 2079619. This inspection was conducted under PAC codes 03803, 03803E, 04803, and 21105. The previous inspection of this firm was performed in July 2004 and classified NAI. Current inspection revealed the firm continues to manufacture various pastas, pasta sauces and cookie dough. Pasta and sauce products are marketed under the Buitoni label and cookie doughs are produced under the Nestle Toll House label. The firm produces both FDA and USDA regulated pastas. As such, a USDA inspector is located onsite. This inspector was not present during the current inspection. Since the last inspection, the firm has added a new cookie dough line that produces cookie shapes. The firm was processing alfredo sauce, various types of cookie dough and FDA regulated pastas during the current inspection. No deviations were noted and no FDA-483 was issued. The firm is registered under the Bioterrorism Act.

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ADMINISTRATIVE DATA

Inspected firm: Nestle Refrigerated Foods Company
Location: 201 Airside Dr
Danville, VA 24540-5616
Phone: 434 822-4000
FAX:
Mailing address: 201 Airside Dr
Danville, VA 24540-5616

Dates of inspection: 9/14/2005
Days in the facility: 1
Participants: Brian R Yaun, Investigator

Upon arrival to the firm, credentials were presented to Mr. Floyd H. Caldwell, QA Manager, Mr. Larry G. Hundycz, Plant Hygienist and (b) (6), QA Technologist. During the inspection, Mr. Donald P. Nordtvedt, Plant Manager was away from the firm. As such, Mr. Caldwell was issued the FDA-482. I also provided Mr. Caldwell with a copy of the "Resources for FDA Regulated Businesses" information sheet and a copy of the "Establishment and Maintenance of Records" under the Bioterrorism Act. After I issued the firm this paperwork, Mr. Caldwell read me a corporate statement that details certain items that the firm will refuse to provide during an inspection. Among these are the refusal to review the firm's consumer complaint file, refusal to permit photography, refusal to sign affidavits or receipts and refusal to provide specific information on interstate commerce. I attempted to obtain a copy of this document "Appendix J" but Mr. Caldwell stated that he would need to check with others in the organization before he could provide it.

The firm continues to operate (b) (4), (b) (4) and employees approximately (b) (4) people. Production occurs during (b) (4). Sanitation operations occur (b) (4). The firm does not have any labeling agreements with other companies.

HISTORY

The firm has recently undergone a name change due to corporate reorganization. There was some confusion over what the firm's correct legal name is. Mr. Caldwell stated he believed that the firm was called Nestle Refrigerated Foods however it may also be considered the Nestle Brands Company. Mr. Caldwell stated that Mr. Nordtvedt would know this, but he was currently away from the firm. Mr. Caldwell then stated that the plant in turn remain a part of Nestle, USA, Glendale CA

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Mr. Joe Weller, CEO and President is the top officer for Nestle USA. Mr. Weller maintains his office at:

Nestle USA
800 North Brand Boulevard
Glendale, CA 91203

Mr. Donald P. Nordtvedt, Plant manager remains the most responsible individual at the Danville, VA facility. Mr. Nordtvedt can be reached at the firm's physical address.

INTERSTATE COMMERCE

The firm refused to provide any specific information about Interstate Commerce or percentages of business. Mr. Caldwell did state that his firm does engage in interstate commerce but refused to provide further specifics.

JURISDICTION

The firm produces both FDA and USDA regulated products. According to Mr. Caldwell, the majority of products produced by the firm fall under FDA regulations. These include non-meat filled pastas, pasta sauces and cookie dough. A copy of the firm's current products is included as *Exhibit 1*. It should be noted that some of the products listed fall under USDA regulations.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

Mr. Donald P. Nordtvedt, Plant Manager remains the most responsible individual for the firm. Mr. Nordtvedt was not at the firm during the current inspection. As such, Mr. Floyd Caldwell, QA Manager stated that he was authorized to accept the FDA 482. Mr. Caldwell stated that the firm is currently undergoing a split in their management. During this reorganization, the cookie dough production (Toll House) and the pasta and sauce production (Buitoni) will fall under different Operations Managers. Mr. Ken McLeish will be the new operations manager for the Buitoni products. An operations manager for the Toll House products was not yet identified. However, Mr. Caldwell currently is the interim operations manager for this area of the plant. Both operations managers will report to Mr. Nordtvedt.

Mr. Caldwell's roles as the QA Manager includes oversight of all of the firm's products adherence to quality specifications. This includes ingredient and finished product testing and proper labeling of products. Mr. Caldwell reports to Mr. Nordtvedt.

Mr. Larry Hundycz, Plant Hygienist is responsible for pest control, supplier audits, sanitation operations, and training of employees under GMP and HACCP systems.

(b) (6), QA Technologist assists Mr. Caldwell and Mr. Hundycz.

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Information for this report was provided by Mr. Caldwell, Mr. Hundycz and (b) (6). I was accompanied throughout the inspection by Mr. Hundycz and (b) (6).

FIRM'S TRAINING PROGRAM

A review of the firm's training program was not performed during this EI.

MANUFACTURING/DESIGN OPERATIONS

Manufacturing operations remain essentially the same as the previous inspection. The firm currently has (b) (4) production lines in the plant. These are:

Line	Product	Line	Product
(b) (4)	Flat Pasta (fettuccini, linguini)	(b) (4)	Sauce line (Red or White)
(b) (4)	Not Operational	(b) (4)	Cookie Dough Chubs
(b) (4)	Raviloi (Meat or Cheese filled)	(b) (4)	Cookie Dough Shapes
(b) (4)	Tortelloni (large filled pasta)	(b) (4)	Break and Bake Cookie Dough
(b) (4)	Tortellini (small filled pasta)	(b) (4)	Break and Bake Cookie Dough
(b) (4)	Not operational	(b) (4)	Break and Bake Cookie Dough

During the inspection, the firm was processing various flat pastas, filled pastas, alfredo sauce and cookie doughs. Copies of labels are attached as *Exhibit 2*.

Allergens

The firm has an allergen control program in place. Mr. Hundycz stated the firm has identified the following allergens in their products: Milk, wheat, egg, soy, peanut, tree nuts. In general, the firm stages run order so that the most allergenic products are run last.

Cookie Dough Production

It should be noted that all cookie dough production lines are in a refrigerated area of the plant. I did not note the temperature during the inspection. Dry ingredients are weighed out in prep rooms according to recipe specifications. Ingredients are then transported in stainless steel tubs and added to one of several mixers located near the beginning of each production line. Dough is then transferred to a hopper and extruded into either a sheet or a tube (chubs). Dough then passes through a series of cooling tunnels and is either scored or stamped into different shapes depending on the production line. Rework from the cookie dough lines is collected in stainless steel drums and added back into the mixer for a subsequent batch. When I asked Mr. Hundycz about the timeframe that rework product could be used, he stated that the water activity of this product was quite low but did not indicate what the value was or how long rework could be reused.

The firm uses two metal detectors per line to test of the presence of metal after packaging. An exception to this is (b) (4) which packages product into chubs. These chubs are sealed with a metal

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clamp on the end. As a result, the metal detection occurs immediately prior to packaging. During the inspection, a line operator successfully challenged the first metal detector on (b) (4). The firm challenges all production lines hourly with (b) (4) mm ferrous and (b) (4) mm stainless steel.

The firm had recently installed new equipment on (b) (4) the Cookie Dough Shapes line. This line operates essentially the same as other cookie dough lines in the plant. However, dough on these lines are stamped with a shape. In general, these types of products are marketed around holidays. The firm was producing Gingerbread Cookie Shapes during the inspection. Whereas the other processing lines are highly automated, due to the recent addition of this line, several employees are located towards the packaging operations on this line.

Sauce Production

During the inspection, the firm was producing Alfredo sauce packaged in 10 oz. plastic tubs. Both white and red sauces are initially manufactured in the "sauce kitchen". Depending on production runs, days are either dedicated as "red" days or "white" days. This area consists of (b) (4) steam jacketed kettles. Operations are PLC controlled. Bulk ingredients are added and then followed by the addition of water or a liquid slurry. After the prescribed cook time, sauces are transferred to a common filling line. Product is then hot filled into plastic tubs, flushed with HEPA filtered air, closed and then tested for the presence of metal ((b) (4) mm stainless, (b) (4) mm ferrous). Following packaging, plastic tubs enter a cooling tower which consists of two vertical spirals that brings product temperature below 45 F prior to labeling. Packages then go through a second metal detector, coding and final packaging. During the EI, it was noticed that the line would occasionally stop and back up multiple containers of product past the air rejection station for the second metal detector. When this was pointed out to Mr. Hundycz, the line was challenged to see if all packages would be blown off the line if the detector went off. The detector and air jets successfully rejected the correct package.

A review of the pesto production was not performed during this EI as the line was not in operation. It should be noted that the pesto sauce uses direct steam injection for heating of the product.

Pasta Production

Pasta production continues as previously reported. For more details, see the 2004 and 2000 EIR. Ingredients are batched based on run orders and fillings are initially mixed in prep rooms. Dough is mixed, shaped, filled, blanched, dried, and cooled prior to entering weigh hoppers. Product is then MAP packaged (modified atmosphere packaging) into preformed trays that receive an oxygen scavenger polymer as the closure.

All products are generally shipped on the same day of production. The firm stores product in a refrigerated warehouse and sends finished product to satellite warehouses such as (b) (4)

Sanitation and Pest Control

Plant sanitation is carried out by dedicated personnel. Access to cleaning compounds including CIP chemical is controlled. The firm utilized (b) (4) chemicals which are authorized by corporate QA. The firm has (b) (4) flour silos. Each silo is cleaned on a rotating basis once every six weeks.

The firm continues to use (b) (4) for their insect and rodent control. Mr. Hundycz stated that the plant is visited twice per week (Tuesday and Friday) and that he occasionally audits the pest control personnel. In general, the firm uses bait traps on the exterior of the building, insecticutors, and pheromone traps on the interior. Fogging of the plant is not done on a routine basis.

Reconciliation Examination

One reconciliation exam was conducted on a lot of (32) – 30 lb. containers of domestic Riccotta cheese exp 10/06/05. No deviations were noted.

MANUFACTURING CODES

An example of the firm's manufacturing code is as follows:

USE BY 12 JAN 2006 (b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

COMPLAINTS

A review of FACTS revealed no complaints against the firm. Citing corporate policy, the firm refused to allow review of their complaint log.

RECALL PROCEDURES

The firm conducts mock recalls on an annual basis for both ingredients and finished product. Specific procedures were not discussed with the firm.

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

None.

REFUSALS

At the onset of the inspection, Mr. Caldwell read me a corporate statement that details certain items that the firm will refuse to provide during an inspection. Among these are the refusal to review the

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firm's consumer complaint file, refusal to permit photography, refusal to sign affidavits or receipts and refusal to provide specific information on interstate commerce.

GENERAL DISCUSSION WITH MANAGEMENT

At the conclusion of the inspection, a close out meeting was held with Mr. Floyd Caldwell, QA Manager, Mr. Larry Hundycz, Plant Hygienist and (b) (6), QA Technologist. I informed Mr. Caldwell that I had no objectionable conditions. One verbal observation was made in relation to a plastic covering placed over an air handler located above (b) (4). This air handler had a plastic covering taped over it. When asked the purpose of this covering, Mr. Hundycz stated that the firm was working on the air handling system to reduce condensation in the plant. There was no condensation visible on the covering during the inspection. During this meeting Mr. Caldwell stated that the work was designed to move air more efficiently in the plant and that work was to be completed on the air system within one week.

ADDITIONAL INFORMATION

None

SAMPLES COLLECTED

None

VOLUNTARY CORRECTIONS

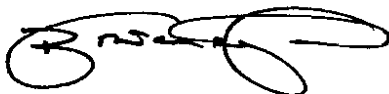
None

EXHIBITS COLLECTED

1. Product listing
2. Product labeling examples

ATTACHMENTS

- FDA 482
- Attachment C



Brian R Yaun, Investigator

Establishment Inspection Report

Nestle Prepared Foods Company
 Danville, VA 24540

BRY / DLD

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SUMMARY:

A comprehensive inspection of this refrigerated and frozen food manufacturer was conducted in accordance with BLT-DO workplans for FY-04 (FACTS assignment #460242; OP ID #1618547) under PAC codes 03803 and 04803. Previous FDA inspection of this firm was conducted in 8/2000 and classified NAI. Previous state inspection of this firm was performed 12/18/02 and classified VAI with several minor GMP deficiencies.

The current inspection found the firm continues to manufacture various pastas, pasta sauces and refrigerated cookie dough. The firm's pasta lines contain both meat and meatless products. A USDA inspector is located on-site for regulation of meat products. The firm was manufacturing alfredo sauces, and various pastas during the inspection.

Per corporate policy, the firm refused to provide information regarding follow up of two consumer complaints without consulting their corporate regulatory group, formulations and information regarding interstate commerce. Although no attempts were made during the current inspection, the firm will also refuse photography.

No deviations were noted and no 483 was issued.

ADMINISTRATIVE DATA

Inspected firm:	Nestle Prepared Foods Company
Location:	201 Airside Drive Danville, VA 24540
Phone:	(434) 822-4000
Fax:	
Mailing Address:	201 Airside Drive Danville, VA 24540
Dates of Inspection:	7/14/04
Days in the Facility:	1
Participants:	Brian R. Yaun, Investigator Dennis L. Doupnik, Investigator

The firm operates (b) (4). The (b) (4).
 (b) (4). The (b) (4).
 (b) (4). The firm generally operates (b) (4) days a
 week, (b) (4).
 (b) (4).

The firm has registered with FDA under the Bioterrorism Act.

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I was accompanied by CSO Doupnik on this inspection. This report was written by CSO Yaun.

Upon arrival to the firm, credentials were shown to Mr. Donald P. Nordtvedt, Plant Manager, Floyd H. Caldwell, Quality Assurance Manager and Larry G. Hundycz, Plant Hygienist.

The FDA 482 and the accompanying "Resources for FDA Regulated Businesses" was issued to Mr. Donald P. Nordtvedt, Plant Manager. We were accompanied by Mr. Caldwell and Mr. Hundycz throughout the inspection. All three gentleman provided information for this report.

HISTORY

Nestle Prepared Foods, Co is a division of Nestle Prepared Foods, Solon, OH which in turn is part of Nestle, USA, Glendale CA. Nestle USA is owned by Nestle S.A., Vevey, Switzerland. The addresses for the above listed firms are:

Nestle Prepared Food Company
3003 Bainbridge Road
Solon, OH 44139

Nestle USA
800 North Brand Boulevard
Glendale, CA 91203.

The CEO and President for Nestle USA is Joe Weller. Mr. Weller maintains his office in Glendale, CA.

INTERSTATE COMMERCE

Information regarding interstate commerce was refused during this inspection. The firm only stated that they do enter product into interstate commerce but refused to elaborate as to what percentages.

JURISDICTION

The firm manufacturers various refrigerated pastas, sauces and cookie dough which are covered under the Food, Drug and Cosmetic Act.

Pastas and sauces are produced under the Buitoni brand name.

Cookie dough is produced under the Nestle Toll House brand name.

RESPONSIBILITY

Upon arrival to the firm, credentials were shown to Mr. Donald P. Nordtvedt, Plant Manager, Floyd H. Caldwell, Quality Assurance Manager and Larry G. Hundycz, Plant Hygienist.

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FDA 482 and the accompanying "Resources for FDA Regulated Businesses" was issued to Mr. Donald P. Nordtvedt, Plant Manager the most responsible individual for the firm. We were accompanied by Mr. Caldwell and Mr. Hundycz throughout the inspection. All three gentleman provided information for this report.

Mr. Floyd H. Caldwell, Quality Assurance Manager is responsible for overseeing quality operations relating to the testing of ingredients and finished product as well as ensuring that products are properly labeled. Mr. Caldwell reports to Mr. Nordtvedt.

Mr. Larry G. Hundycz, Plant Hygienist is responsible for pest control, supplier audits, sanitation, employee training, GMPs and food safety and HACCP systems for the firm. Mr. Hundycz, reports to Mr. Caldwell.

OPERATIONS, PERSONNEL AND EQUIPMENT

Since the last inspection of 9/15/00, operations remain essentially the same. The firm maintains (b) (4) lines for flat pasta products (b) (4) lines for filled pasta products, (b) (4) sauce filling line and (b) (4) lines of production for cookie dough products. Production on the cookie dough lines was not being preformed during the current inspection. As such, no evaluation was performed on this manufacturing operation. However, the lines were visually inspected for process flow. These lines were also not in production during the last FDA inspections in 2000 or in 1999.

Raw ingredients

As previously reported, raw ingredients are received and placed in a quarantine status where they await various forms of testing prior to release. Product release may be based on combinations of any of the following tests depending on the ingredient: sensory, label verification, thermal process verification, certificate of analysis, seal integrity, vehicle condition, temperature specifications, box integrity. Other tests may also be utilized for ingredient release. Once ingredients are released for use, they are mixed in one of several mixing rooms prior to addition to the production lines.

Production Lines

The firm maintains (b) (4) pasta lines, (b) (4) sauce line and (b) (4) cookie lines. The lines are as follows:

Line	Product
(b) (4)	Flat pasta (fettuccini, linguini)
(b) (4)	Not operational
(b) (4)	Ravioli (meat or cheese filled)
(b) (4)	Tortelloni (large pasta filled with meat or cheese)
(b) (4)	Tortellini (small pasta filled with meat or cheese)
(b) (4)	Flat pasta

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(b) (4)	Sauce line
(b) (4)	Cookie dough chubs (18 oz. and 32 oz.)
(b) (4)	Does not exist, former Chub line that was taken out
(b) (4)	Break and Bake Bar line
(b) (4)	Bar line
(b) (4)	Bar line

During the inspection, the firm was processing:

- Portobello Mushroom and Cheese Tortelloni
- Three Cheese Tortellini (Coded 01 OCT 2004 419600513)
- Four Cheese Ravioli (Coded 01 OCT 2004 4196000313)
- Fettuccini
- Alfredo Sauce

Pasta production

Pasta production in general begins in one of several staging rooms. Fillings are initially mixed in prep rooms. Ingredients are batched based on run orders. Fill ingredients are then transferred to the production line. Dough is mixed, rolled, and allowed to set. Pasta is then formed, filled, cut, blanched, separated, dried and filled by weight into packaging units prior to receiving a nitrogen flush resulting in a Modified Atmosphere Package (MAP). Packages are then labeled, coded, case packed and finally packed by hand onto pallets.

Product generally leaves the firm in a matter of hours and is stored in warehouses. These are: (b) (4) and various satellite warehouses.

Sauce production

Sauce production occurs in an area referred to as the Sauce Kitchen. Various red (marinara), white (alfredo) sauces are mixed in (b) (4) steam jacketed kettles. Bulk ingredients are added, followed by a liquid slurry, water and other ingredients. Red and White sauces are then pressure cooked.

Pesto sauces do not undergo pressure cooking and are instead steam injected for their heat process

Sauces then enter a filling operation where product is hot filled into plastic tubs . Plastic tubs of the same diameter but various heights allow the filler to process various size containers. HEPA filtered air flushes the headspace of containers prior to sealing. Tub then pass thru a metal detector (b) (4) mm stainless steel, (b) (4) mm ferrous) prior to entering chillers. After cooling, product is checked for fill, labeled and case packed.

A review of the metal detector operations on the sauce line noted no deficiencies.

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Cookie Dough Production

Although the firm was not processing any cookie dough during the inspection, the lines were visually inspected. A typical process is as follows: Dough is pumped, extruded, cooled, cut, (metal detector) placed on paperboard, wrapped, sealed (metal detector) and then case packed.

Metal detection on the cookie dough line is for (b) (4) mm Ferrous and (b) (4) mm stainless steel.

Allergens

The firm stated that they handle six of the "Big Eight" allergens. These are: wheat, dairy, egg, soy, tree nuts and peanuts. Run order is staged so that the most allergenic products are run last during production.

Salvage / Rework

Pasta that is cut during the shaping operation is re-circulated to the pressing machine and utilized again. Once the shift ends, all remaining dough is considered waste. The firm utilizes (b) (4) to receive bakery waste.

Pest Control and Sanitation

The firm utilizes (b) (4) for insect and rodent control. (b) (4) generally visits the firm two times per week. The firm invokes insecticutors, bait stations (exterior) and mechanical wind up traps. Additionally, some pheromone traps are used for Indian Meal Moths and previously for beetles in the warehouse.

The firm uses two (b) (4) oil or gas fired boilers to generate steam. A review of the boiler additives and cleaning compounds is included as *Exhibit 2*.

Reconciliation Exam

A reconciliation exam was performed on Imported Parmesan Cheese (Lot 41660101, packed on 6/14/04) received from (b) (4). No deficiencies were noted.

PRODUCTS

The firm manufactures refrigerated pastas packaged under a modified atmosphere (nitrogen flushed), refrigerated pasta sauces including various types of marinara, alfredo and pesto sauces, cookie dough bars, chubs and break and bake cookie dough.

Attached as *Exhibit # 1* is a three page list of products produced by the firm. It should be noted that some USDA regulated products are also listed.

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Labeling for new products manufactured in the last year are included as *Exhibit 3* (12 pages). Labeling was requested during the inspection, and the firm subsequently mailed the labels to the RNK-RP after the inspection was complete.

MANUFACTURING CODES

The firm currently utilizes the same product coding system as previously reported. An example follows:

"USE BY DATE" *** "(b) (4)"

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

The firm is in the process of designing a new coding system that will be able to incorporate all of the global Nestle manufacturing facilities. It is anticipated that a new coding system will be implemented in approximately 6 months.

COMPLAINTS / PRODUCT DEFECTS

An attempt was made to follow up on two consumer complaints during the inspection. These were:

- CC #16689 which involved a foreign object found in cookie dough
- CC #20099 which involved insects found in cookie dough.

The firm refused to offer details on these complaints. For additional information, see the section labeled REFUSALS.

OBJECTIONABLE CONDITIONS

No objectionable conditions were noted during this inspection.

REFUSALS

Per corporate policy, the firm refused to provide information regarding follow up of two consumer complaints without consulting their corporate regulatory group, formulations and information regarding interstate commerce. Although no attempts were made during the current inspection, the firm will also refuse photography.

Consumer Complaints:

The firm maintained that all information regarding consumer complaints is kept at Nestle USA and that there were no records kept onsite. The firm is notified of complaints regarding injuries of products produced at their plant.

When asked by CSO Doupnik about the status of the above listed complaints, i.e. if other similar complaints on the same lots were reported, the firm contacted a member of the Nestle organization located off-site. Later during the inspection,

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the firm notified the Investigators that if we wished to pursue the matter, a formal request should be issued in writing to Mr. Donald P. Nordtvedt, Plant Manager or Mr. Floyd H. Caldwell who would then forward the request to the appropriate parties. As the inspection revealed no apparent insect infestation or foreign objects, we chose not to pursue the matter further.

Interstate Commerce

At the onset of the inspection, the firm read a statement regarding corporate policy during inspections. Among other items, it was noted that the firm will refuse information on interstate commerce, except to state that they do enter into interstate commerce.

GENERAL DISCUSSION WITH MANAGEMENT

At the conclusion of the inspection, a close out discussion was held with Floyd H. Caldwell, Quality Assurance Manager and Larry G. Hundycz, Plant Hygienist. At the time, we informed the firm that we had no objectionable conditions.

ADDITIONAL INFORMATION

N / A

VOLUNTARY CORRECTIONS

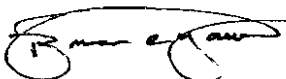
The firm had voluntarily corrected all GMP deviations noted on the previous VDACS inspection.

EXHIBITS AND SAMPLES COLLECTED

1. UPC Case Codes , Abbreviations and Shelf Life (3 pages)
2. Nestle Danville Cleaning Chemicals
3. Product labels (12 pages)

ATTACHMENTS

1. FDA form 482



Brian R. Yaun
Investigator
Roanoke, VA RP



Dennis L. Douppnik
Investigator
Roanoke, VA RP