

Food and Drug Administration Establishment Inspection Report

Date Assigned: 12/11/2008 **Inspection Start Date:** 03/12/2009 **Inspection End Date:** 03/12/2009
Firm Name & Address: Nestle USA, Inc. , 201 Airside Dr Danville, VA 24540-5616 US
Firm Mailing Address: 201 Airside Drive, Danville, VA 24540 United States
FEI: 1122474 **JD/TA:** 3F **County:** DANVILLE **Est Size:** (b) (4)
Phone: (434)822-4000 **District:** BLT-DO **Profiled:** No
Conveyance Type: **% Interstate:** (b) (4) **Inspectional Responsibility:** State Contract and Joint FDA/USDA

Endorsement

"This was a routine contract inspection of a manufacturer / processor. (Products: Pasata Sauces, Pasta, Cookie Dough)

The previous 7/22/2008 inspection was classified NAI and findings included: No objectionable conditions were observed during the inspection. Corrections since last insp: N/A.

The firm's operation hours are (b) (4). Office hours are 8:00am - 5:00pm - Mon - Fri. Approximately (b) (4) of products under FDA's coverage are distributed interstate. Wholesale output is (b) (4). Establishment size = (b) (4). There have been no establishment changes.

The firm is registered. Food security and BT Registration Act information was provided to the firm.

CURRENT FINDINGS: No unsanitary conditions noted. See state inspection report for list of observed GMP deficiencies. General areas of deficiencies observed include: FALSE. Coporate policy on refusal to sign inspection report. No samples were collected.

A report of this inspection was provide to Ms. Jan Harris - Plant Manager - Floyd Caldwell - Quality Assurance Manager. Corrections during inspection and/or promised: N/A

NOTE: No unsanitary conditions noted.

Firm inspected by: Bud Anderson
Inspection Classified: NAI
Follow-up Inspection: Routine Coverage 3/2010
FDA Distribution: Orig to BLT file."
SCM Remarks for State Inspection:

Endorsement Location:

Inspector Name	Date & Time of Signature	Supervisor Name	Date & Time of Signature
	ET	Nathaniel R Esaw	03/24/2009 05:28 PM ET

Food and Drug Administration Establishment Inspection Report

FEI: 1122474

Inspection Start Date: 03/12/2009

Inspection End Date: 03/12/2009

Firm Name & Address: Nestle USA, Inc. , 201 Airside Dr Danville, VA 24540-5616 US

Related Firm FEI: Name & Address of Related Firm:

Registration Type

FFR Food

Registration Dates

10/30/2003

Establishment Type

M Manufacturer
M Manufacturer
M Manufacturer
M Manufacturer
WZ Warehouse-Ambient, Refrigerated, and Frozen Storage

Industry Code

03 Bakery Prod/Dough/Mix/Icing
04 Macaroni/Noodle Prod
25 Vegetables/Vegetable Products
37 Mult Food Dinner/Grav/Sauce/Special
47 Multiple Food Warehouses

District Use Code:

1 TO BE EDITED
2 TO BE EDITED

Food and Drug Administration Establishment Inspection Report

FEI: 1122474

Inspection Start Date: 03/12/2009

Inspection End Date: 03/12/2009

Firm Name & Address: Nestle USA, Inc. , 201 Airside Dr Danville, VA 24540-5616 US

Inspection Basis: Surveillance

Inspected Processes & District Decisions

PAC	Establishment Type	Products/ Process	MQSA	Reschedule Insp Date	Re-Inspection Priority	Inspection Conclusions
03S001	Manufacturer	03 M G C				No Action Indicated (NAI)

Final Decision?	District Decision Date	District Decision Type	District Decision Made By	Org Name
	03/24/2009	No Action Indicated (NAI)	Agency, State	BLT-DO

Remarks:

Final Decision?	District Decision Date	District Decision Type	District Decision Made By	Org Name
Y	03/24/2009	No Action Indicated (NAI)	Esaw, Nathaniel R	BLT-DO

Remarks:

PAC	Establishment Type	Products/ Process	MQSA	Reschedule Insp Date	Re-Inspection Priority	Inspection Conclusions
03S001	Manufacturer	37 J H N				No Action Indicated (NAI)

Final Decision?	District Decision Date	District Decision Type	District Decision Made By	Org Name
	03/24/2009	No Action Indicated (NAI)	Agency, State	BLT-DO

Remarks:

Final Decision?	District Decision Date	District Decision Type	District Decision Made By	Org Name
Y	03/24/2009	No Action Indicated (NAI)	Esaw, Nathaniel R	BLT-DO

Remarks:

PAC	Establishment Type	Products/ Process	MQSA	Reschedule Insp Date	Re-Inspection Priority	Inspection Conclusions
03S001	Manufacturer	04 A G T				No Action Indicated (NAI)

Final Decision?	District Decision Date	District Decision Type	District Decision Made By	Org Name
	03/24/2009	No Action Indicated (NAI)	Agency, State	BLT-DO

Remarks:

Final Decision?	District Decision Date	District Decision Type	District Decision Made By	Org Name
Y	03/24/2009	No Action Indicated (NAI)	Esaw, Nathaniel R	BLT-DO

Remarks:

Food and Drug Administration Establishment Inspection Report

FEI: 1122474

Inspection Start Date: 03/12/2009

Inspection End Date: 03/12/2009

Firm Name & Address: Nestle USA, Inc. , 201 Airside Dr Danville, VA 24540-5616 US

Products Covered

Product Code	Est Type	Description	Additional Product Description
03 M G C 04	Manufacturer	Toll House Cookie, Biscuit, Wafer Dough; Plastic, Synth; Raw, Fresh, Refrigerated	
04 A G T 05	Manufacturer	Spaghetti; Plastic, Synth; Packaged Food (Not Commercially Sterile)	
37 J H N 99	Manufacturer	Sauces, n.e.c.; Nonflex Plastic; Heat Treated	

Assignees Accomplishment Hours

Employee Name	Position Class	Hours Credited To	PAC	Establishment Type	Process	Hours
Agency, State	STA	BLT-DO	03S001	Manufacturer	03 M G C	4
Agency, State	STA	BLT-DO	03S001	Manufacturer	37 J H N	4
Agency, State	STA	BLT-DO	03S001	Manufacturer	04 A G T	4
Total Hours:						12

Food and Drug Administration Establishment Inspection Report

FEI: 1122474

Inspection Start Date: 03/12/2009

Inspection End Date: 03/12/2009

Firm Name & Address: Nestle USA, Inc., 201 Airside Dr Danville, VA 24540-5616 US

Inspection Result

EIR Location

Trips Num

Inspection Summary

"LEGAL STATUS OF FIRM: Incorporated in Delaware.

CORPORATE INFORMATION: Nestle Inc. - 800 North Brand Blvd. - Glendale, CA 81203 - Mr. Bradley Alford COP/CEO

PRIOR REGULATORY ACTIONS / WARNINGS: N/A

RECALLS / PRODUCT REMEDIATION: B/A

MOST RESPONSIBLE PERSON IN CHARGE: Ms. Jan Harris - Plant Manager - Floyd Caldwell - Quality Assurance Manager

ESTABLISHMENT CHANGES: None

NUMBER OF EMPLOYEES AND OVERVIEW OF OPERATIONAL PROCEDURES: Nestle employs approximately (b) (4) employees. The company operates (b) (4). The plant manufactures pasta and pasta sauces under the Buitoni brand name and cookie dough under the Tollhouse brand name. The company has (b) (4) pasta processing production lines, (b) (4) pasta sauce processing production lines, and (b) (4) cookie dough processing production lines. Nestle processes meat filled pasta on-site and is under USDA/VDACS inspection. They receive most goods via (b) (4) transport and have three silos outside the firm for grain storage. Nestle also has another off site warehouse for storage of packaging materials. Nestle does process peanut cookies with the peanut products being purchased and supplied by (b) (4) (b) (4) - PRODUCTS - Peanut Butter (smooth) - Peanut Butter paste. "

IB Suggested Actions

Action	Remarks
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Referrals

Org Name	Mail Code	Remarks
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Refusals

Inspection Refusals: No refusal

Samples Collected

Sample Number

Recall Numbers

Recall Number

Related Complaints

Consumer Complaint Number

FDA 483 Responses

483 Issued?: 483 Location:

Date: 06/22/2009

Page: 5 of 6

Food and Drug Administration Establishment Inspection Report

FEI: 1122474

Inspection Start Date: 03/12/2009

Inspection End Date: 03/12/2009

Firm Name & Address: Nestle USA, Inc. , 201 Airside Dr Danville, VA 24540-5616 US

Response Type	Response Mode	Response Date	Response Summary
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Food and Drug Administration Establishment Inspection Report

Date Assigned: 11/27/2007 **Inspection Start Date:** 11/01/2007 **Inspection End Date:** 11/02/2007
Firm Name & Address: Nestle USA, Inc. , 201 Airside Dr Danville, VA 24540-5616 US
Firm Mailing Address: 201 Airside Drive, Danville, VA 24540 United States
FEI: 1122474 **JD/TA:** 3F **County:** DANVILLE **Est Size:** (b) (4)
Phone: (434)822-4000 **District:** BLT-DO **Profiled:** No
Conveyance Type: **% Interstate:** (b) (4) **Inspectional Responsibility:** State Contract and Joint FDA/USDA

Endorsement

"This was a routine contract inspection of a manufacturer and warehouse. (Manufactured - Refrigerated pasta, pasta sauces and cookie dough; Warehoused - Refrigerated pasta, pasta sauces and cookie dough)

The previous 2/21/2007 inspection was classified VAI and findings included: ""Toll House"" preparation: 1-Miscellaneous tools/equipment stored in hand washing sink. 2-The drain from the hand washing sink was leaking onto the floor. 3-The control pedal for the cold water was missing from the sink in the ""powdered sugar"" room. (b) (4) #14"": 4-Water was dripping from the valve on the cold water line. 5-A hole was found in the steam line above was exposing fibrous insulation. ""Toll House Receiving"": 6-The perimeter of the floors in the ""shipping warehouse"" and the hallway were peppered with wood splinters, dust, cardboard lint, and unidentifiable particles. Corrections since last insp: Corrected items marked on last inspection.

The firm's operation hours are (b) (4) depending on production needs. Approximately (b) (4) of products under FDA's coverage are distributed interstate. Wholesale output is (b) (4). Establishment size = (b) (4). See INSPECTION SUMMARY for details of establishment changes.

The firm is registered. Food security and BT Registration Act information was provided to the firm.

CURRENT FINDINGS: See state inspection report for list of observed GMP deficiencies. General areas of deficiencies observed include: Equipment, Employee Practices. Refusal to allow photography, review of production records, processing controls, complaint files. Samples Collected: #04500026 - Marinara Sauce - One 15 oz plastic container.

A report of this inspection was provide to Mr. Larry Hundycz - Plant Hygienist (b) (6) - QA Tech. Corrections during inspection and/or promised: Corrected concerns with metal detector on pasta sauce line. Replished hand towles at handsink on cookie dough processing line (shut down at time of inspection).

Firm inspected by: Bud Anderson

Inspection Classified: 37

Follow-up Inspection: Routine Coverage 11/2008

FDA Distribution: Orig to BLT file."

SCM Remarks for State Inspection: REPORT: \\Orsrbldo01\blt teams\State Reports\VDACS\2007 - 2008\Nestle USA Inc 07-11-02.xls

Endorsement Location:

Inspector Name	Date & Time of Signature	Supervisor Name	Date & Time of Signature
	ET	Nathaniel R Esaw	06/13/2008 02:31 PM ET

Food and Drug Administration Establishment Inspection Report

FEI: 1122474

Inspection Start Date: 11/01/2007

Inspection End Date: 11/02/2007

Firm Name & Address: Nestle USA, Inc. , 201 Airside Dr Danville, VA 24540-5616 US

Related Firm FEI: Name & Address of Related Firm:

Registration Type

FFR Food

Registration Dates

10/30/2003

Establishment Type

M Manufacturer
M Manufacturer
M Manufacturer
M Manufacturer
WZ Warehouse-Ambient, Refrigerated, and Frozen Storage

Industry Code

03 Bakery Prod/Dough/Mix/Icing
04 Macaroni/Noodle Prod
25 Vegetables/Vegetable Products
37 Mult Food Dinner/Grav/Sauce/Special
47 Multiple Food Warehouses

District Use Code:

1 TO BE EDITED
2 TO BE EDITED

Food and Drug Administration Establishment Inspection Report

FEI: 1122474

Inspection Start Date: 11/01/2007

Inspection End Date: 11/02/2007

Firm Name & Address: Nestle USA, Inc. , 201 Airside Dr Danville, VA 24540-5616 US

Inspection Basis: Surveillance

Inspected Processes & District Decisions

PAC	Establishment Type	Products/ Process	MQSA	Reschedule Insp Date	Re-Inspection Priority	Inspection Conclusions
03S001	Manufacturer	03 M G C				No Action Indicated (NAI)

Final Decision?	District Decision Date	District Decision Type	District Decision Made By	Org Name
	04/23/2008	No Action Indicated (NAI)	Agency, State	BLT-DO

Remarks:

Final Decision?	District Decision Date	District Decision Type	District Decision Made By	Org Name
Y	06/13/2008	No Action Indicated (NAI)	Esaw, Nathaniel R	BLT-DO

Remarks:

PAC	Establishment Type	Products/ Process	MQSA	Reschedule Insp Date	Re-Inspection Priority	Inspection Conclusions
03S001	Manufacturer	04 A G T				No Action Indicated (NAI)

Final Decision?	District Decision Date	District Decision Type	District Decision Made By	Org Name
	04/23/2008	No Action Indicated (NAI)	Agency, State	BLT-DO

Remarks:

Final Decision?	District Decision Date	District Decision Type	District Decision Made By	Org Name
Y	06/13/2008	No Action Indicated (NAI)	Esaw, Nathaniel R	BLT-DO

Remarks:

PAC	Establishment Type	Products/ Process	MQSA	Reschedule Insp Date	Re-Inspection Priority	Inspection Conclusions
03S001	Manufacturer	37 J H N				No Action Indicated (NAI)

Final Decision?	District Decision Date	District Decision Type	District Decision Made By	Org Name
	04/23/2008	No Action Indicated (NAI)	Agency, State	BLT-DO

Remarks:

Final Decision?	District Decision Date	District Decision Type	District Decision Made By	Org Name
Y	06/13/2008	No Action Indicated (NAI)	Esaw, Nathaniel R	BLT-DO

Remarks:

Food and Drug Administration Establishment Inspection Report

FEI: 1122474

Inspection Start Date: 11/01/2007

Inspection End Date: 11/02/2007

Firm Name & Address: Nestle USA, Inc. , 201 Airside Dr Danville, VA 24540-5616 US

Products Covered

Product Code	Est Type	Description	Additional Product Description
03 M G C 04	Manufacturer	Toll House Cookie, Biscuit, Wafer Dough; Plastic, Synth; Raw, Fresh, Refrigerated	
04 A G T 05	Manufacturer	Spaghetti; Plastic, Synth; Packaged Food (Not Commercially Sterile)	
37 J H N 99	Manufacturer	Sauces, n.e.c.; Nonflex Plastic; Heat Treated	

Assignees Accomplishment Hours

Employee Name	Position Class	Hours Credited To	PAC	Establishment Type	Process	Hours
Agency, State	STA	BLT-DO	03S001	Manufacturer	03 M G C	4
Agency, State	STA	BLT-DO	03S001	Manufacturer	04 A G T	4
Agency, State	STA	BLT-DO	03S001	Manufacturer	37 J H N	4
Total Hours:						12

Food and Drug Administration Establishment Inspection Report

FEI: 1122474

Inspection Start Date: 11/01/2007

Inspection End Date: 11/02/2007

Firm Name & Address: Nestle USA, Inc. , 201 Airside Dr Danville, VA 24540-5616 US

Inspection Result

EIR Location

Trips Num

Inspection Summary

"LEGAL STATUS OF FIRM: Incorporated in Delaware.

CORPORATE INFORMATION: Nestle Holding Inc. - 800 North Brand Blvd. - Glendale CA 91203 Mr. Bradley Alford
COP/CEO

PRIOR REGULATORY ACTIONS / WARNINGS: N/A

RECALLS / PRODUCT REMEDIATION: Company has both an internal and external recall process. All product is coded for recall. All in-house product is held until concerns can be corrected.

MOST RESPONSIBLE PERSON IN CHARGE: Mr. Jason M. Mabert

ESTABLISHMENT CHANGES: Size (b) (4)

NUMBER OF EMPLOYEES AND OVERVIEW OF OPERATIONAL PROCEDURES: Approximately (b) (4) employees. There are (b) (4) employees. The plant manufactures refrigerated pasta sauces and pasta under the Buitoni brand name and cookie dough under the Tollhouse brand name. The company has (b) (4) pasta, (b) (4) pasta sauce and (b) (4) cookie dough production lines. Nestle processes some meat filled pasta on-site and is under USDA/VAS inspection (Mr. Ernie Spies and Ms. Heather Stumbo). Nestle also has an in-house allergen program. They receive most goods via transport and have (b) (4) silos outside for flour storage. They also have another off site warehouse for storing packaging. "

IB Suggested Actions

Action	Remarks
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Referrals

Org Name	Mail Code	Remarks
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Refusals

Inspection Refusals: No refusal

Samples Collected

Sample Number

Recall Numbers

Recall Number

Related Complaints

Consumer Complaint Number

FDA 483 Responses

483 Issued?: 483 Location:

Date: 06/22/2009

Page: 5 of 6

Food and Drug Administration Establishment Inspection Report

FEI: 1122474

Inspection Start Date: 11/01/2007

Inspection End Date: 11/02/2007

Firm Name & Address: Nestle USA, Inc. , 201 Airside Dr Danville, VA 24540-5616 US

Response Type	Response Mode	Response Date	Response Summary
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Food and Drug Administration Establishment Inspection Report

Date Assigned: 06/29/2007 **Inspection Start Date:** 02/20/2007 **Inspection End Date:** 02/21/2007
Firm Name & Address: Nestle USA, Inc. , 201 Airside Dr Danville, VA 24540-5616 US
Firm Mailing Address: 201 Airside Drive, Danville, VA 24540 United States
FEI: 1122474 **JD/TA:** 3F **County:** DANVILLE **Est Size:** (b) (4)
Phone: (434)822-4000 **District:** BLT-DO **Profiled:** No
Conveyance Type: **% Interstate:** (b) (4) **Inspectional Responsibility:** State Contract and Joint FDA/USDA

Endorsement

EIR link - H:\State Reports\VDACS\06-07\Nestle USA Inc - VAI.xls

This was a routine contract inspection.

CURRENT FINDINGS:

- 1-Miscellaneous tools/equipment were being stored in the hand washing sink in the "Toll House" preparation area.
- 2-The drain from the hand washing sink in the "Toll House" preparation area was leaking onto the floor.
- 3-The control pedal for the cold water flow at the hand washing sink was missing from the hand washing sink in the "powdered sugar" room.
- 4-Water was dripping from the valve on the cold water line above the "(b) (4) #14".
- 5-A hole was found in the steam line above the "(b) (4) #14" which was exposing fibrous insulation.
- 6-The perimeter of the floors in the "shipping warehouse" and the "Toll House Receiving" hallway were peppered with wood splinters, dust, cardboard lint, and unidentifiable particles

No refusals No samples were collected.

A report of this inspection was provide to Mr. Floyd Caldwell, Quality Assurance Manager. Corrections during inspection and/or promised: Tools/equipment were removed from the hand sink and management stated that they would correct the other cited issues.

NOTE: Due to certificates of free sale the plant shall be inspected at no more than 6 month intervals. Previous inspection was conducted by FDA in 09/2006. USDA inspector on site in facility also.

Firm inspected by: C.A.Thackston/B.Anderson
Inspection Classified: VAI
Follow-up Inspection: Routine Coverage 8/2007
FDA Distribution: Orig to BLT file.

Endorsement Location: FACTS

Inspector Name	Date & Time of Signature	Supervisor Name	Date & Time of Signature
Cntrctmnr Esaw	06/29/2007 04:34 PM ET	Nathaniel R Esaw	06/29/2007 05:13 PM ET

Food and Drug Administration Establishment Inspection Report

FEI: 1122474

Inspection Start Date: 02/20/2007

Inspection End Date: 02/21/2007

Firm Name & Address: Nestle USA, Inc. , 201 Airside Dr Danville, VA 24540-5616 US

Related Firm FEI: **Name & Address of Related Firm:**

Registration Type

FFR Food

Registration Dates

10/30/2003

Establishment Type

M Manufacturer
M Manufacturer
M Manufacturer
M Manufacturer
WZ Warehouse-Ambient, Rcfrigerated, and Frozen Storage

Industry Code

03 Bakery Prod/Dough/Mix/Icing
04 Macaroni/Noodle Prod
25 Vegetables/Vegetable Products
37 Mult Food Dinner/Grav/Sauce/Special
47 Multiple Food Warehouses

District Use Code:

1 TO BE EDITED
2 TO BE EDITED

Food and Drug Administration Establishment Inspection Report

FEI: 1122474

Inspection Start Date: 02/20/2007

Inspection End Date: 02/21/2007

Firm Name & Address: Nestle USA, Inc. , 201 Airside Dr Danville, VA 24540-5616 US

Inspection Basis: Surveillance

Inspected Processes & District Decisions

PAC	Establishment Type	Products/ Process	MQSA	Reschedule Insp Date	Re-Inspection Priority	Inspection Conclusions
03S001	Manufacturer	03 M G C		08/2007	Surveillance	Correction Indicated (CI)
Final Decision?	District Decision Date	District Decision Type		District Decision Made By		Org Name
Y	06/29/2007	Voluntary Action Indicated (VAI)		Esaw, Nathaniel R		VA-VDACS

Remarks:

PAC	Establishment Type	Products/ Process	MQSA	Reschedule Insp Date	Re-Inspection Priority	Inspection Conclusions
03S001	Warehouse-Ambient, Refrigerated, and Frozen Storage	47		08/2007	Surveillance	Correction Indicated (CI)
Final Decision?	District Decision Date	District Decision Type		District Decision Made By		Org Name
Y	06/29/2007	Voluntary Action Indicated (VAI)		Esaw, Nathaniel R		VA-VDACS

Remarks:

Food and Drug Administration Establishment Inspection Report

FEI: 1122474

Inspection Start Date: 02/20/2007

Inspection End Date: 02/21/2007

Firm Name & Address: Nestle USA, Inc. , 201 Airside Dr Danville, VA 24540-5616 US

Products Covered

Product Code	Est Type	Description	Additional Product Description
03 M G C 04	Manufacturer	Toll House Cookie, Biscuit, Wafer Dough; Plastic, Synth; Raw, Fresh, Refrigerated	

Assignees Accomplishment Hours

Employee Name	Position Class	Hours Credited To	PAC	Establishment Type	Process	Hours
Esaw, Cntrctmnr	STA	BLT-DO	03S001	Manufacturer	03 M G C	6
Esaw, Cntrctmnr	STA	BLT-DO	03S001	Warehouse-Ambient, Refr	47	6
Total Hours:						12

Food and Drug Administration Establishment Inspection Report

FEI: 1122474

Inspection Start Date: 02/20/2007

Inspection End Date: 02/21/2007

Firm Name & Address: Nestle USA, Inc. , 20I Airside Dr Danville, VA 24540-5616 US

Inspection Result

EIR Location
FACTS

Trips Num

Inspection Summary
See enodrsement.

IB Suggested Actions

Action	Remarks
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Referrals

Org Name	Mail Code	Remarks
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Refusals

Inspection Refusals:

Samples Collected

Sample Number

Recall Numbers

Recall Number

Related Complaints

Consumer Complaint Number

FDA 483 Responses

483 Issued?:

483 Location:

Response Type	Response Mode	Response Date	Response Summary
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