

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

<small>DISTRICT ADDRESS AND PHONE NUMBER</small> 6000 Metro Drive, Suite 101 Baltimore, MD 21215 (410) 779-5454 Fax: (410) 779-5707 Industry Information: www.fda.gov/oc/industry	<small>DATE(S) OF INSPECTION</small> 06/18/2009 - 07/09/2009*
	<small>FEI NUMBER</small> 1122474

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Janice E. Harris, Factory Manager

<small>FIRM NAME</small> Nestle USA, Inc.	<small>STREET ADDRESS</small> 201 Airside Drive
<small>CITY, STATE, ZIP CODE, COUNTRY</small> Danville, VA 24540-5616	<small>TYPE ESTABLISHMENT INSPECTED</small> 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.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

The workmanship of equipment does not allow proper cleaning.

Specifically, inside the "Toll House" brand cookie dough preparation room, dry ingredients are placed inside hoppers. The dry ingredients are gravity fed to blending mixers through gate valves that are installed on the hoppers.

As a result of this investigation, the firm disassembled all gate valves from all hoppers on production lines 8, 10, 11, and 12. The gate valves appear to have food contact surfaces that are not easily cleanable as evidenced by rough, pitted and discolored cast metal alloy.

OBSERVATION 2

Lack of appropriate design to enable manufacturing systems to be maintained in an appropriate sanitary condition.

Specifically, as "Toll House" brand cookie dough was mixed on 6-18-09, ice build-up surrounded pipes that transport a processing aid to mixers on production lines 8, 10, 11, and 12. On line 8, condensate from the ice dripped onto a metal rake that personnel then used to scrape cookie dough from the mixer into a dough trough for transport to the filling line.

*** DATES OF INSPECTION:**

06/18/2009(Thu), 06/19/2009(Fri), 06/22/2009(Mon), 06/23/2009(Tue), 06/24/2009(Wed), 06/25/2009(Thu), 06/26/2009(Fri), 07/07/2009(Tue), 07/08/2009(Wed), 07/09/2009(Thu)

SEE REVERSE OF THIS PAGE	<small>EMPLOYEE(S) SIGNATURE</small> Gale L. Glinecki, Investigator Dianne H. Milazzo, Investigator Joey C. West, Investigator Carrie L. Doupnik, Investigator	<small>DATE ISSUED</small> 07/09/2009
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