

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

DISTRICT ADDRESS AND PHONE NUMBER

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Industry Information: [www.fda.gov/oc/industry](http://www.fda.gov/oc/industry)

DATE(S) OF INSPECTION

01/27/2010 - 02/03/2010\*

FEI NUMBER

2650141

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

**TO:** Nuria Ramez Ordonez, General Manager

FIRM NAME

Mcneil Healthcare, Llc

STREET ADDRESS

Rd # 183 Km 19.8  
Bo. Montones

CITY, STATE, ZIP CODE, COUNTRY

Las Piedras, PR 00771

TYPE ESTABLISHMENT INSPECTED

Drug 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 I OBSERVED:**

**Facility and Equipment System**

**OBSERVATION 1**

Equipment and utensils are not maintained at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically, your firm failed to assure that products manufactured after cleaning validation activities are free from active ingredients and detergent (b)(4). During the inspection, I found that your firm lacked procedures in place for periodic cleaning monitoring of active ingredients and detergent residues to avoid product cross-contamination and to challenge cleaning effectiveness. The following are some examples of cleaning methods validated for non-dedicated manufacturing equipment without on-going monitoring program:

- a. Protocol No. (b)(4) "Cleaning Validation Protocol for the CT Meltaways Area" approved on 08/10/04
- b. Protocol No. (b)(4) "Cleaning Validation Protocol for the Campaing Lenth Extension of the CT Meltaways Area" Approved on 12/16/06
- c. Protocol No. (b)(4) "Cleaning Validation Assessment for Benadryl Ultratab Equipment Train" Approved on 03/12/08
- d. Protocol No. (b)(4) "Cleaning Validation Waiver for Sudafed PE Nasal Decongestant Tablets" Approved on 09/29/08

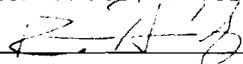
**\* DATES OF INSPECTION:**

01/27/2010(Wed), 01/28/2010(Thu), 02/03/2010(Wed)

**SEE REVERSE  
OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Ramon A Hernandez, Investigator



DATE ISSUED

02/03/2010