DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
466 Fernandez Juncos Ave. San Juan, PR 00901-3223 (787)-474-9500 Fax:(787) 729-6809 Industry Information: www.fda.gov/oc/industry	01/27/2010 - 02/03/2010* FEI NUMBER 2650141

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Nuria Ramíez Ordóñez, General Manager

FIRM NAME	STREET ADDRESS
Mcneil Healthcare, Llc	Rd # 183 Km 19.8 Bo. Montones
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Las Piedras, PR 00771	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 manaufactured 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	DATE ISSUED
	Ramon A Hernandez, Investigator	02/03/2010