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	07/22/2008 - 08/06/2008* FEI NUMBER 2650141

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Nuria Ramírez Ordóñez, General Manager

FIRM NAME	STREET ADDRESS
McNeil Healthcare, LLC	Carretera 183, Km 19.8 Bo. Montones
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Las Piedras, PR 00771	Human OTC 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 WE OBSERVED:

LABORATORY SYSTEM

OBSERVATION 1

Established sampling plans and test procedures are not documented at the time of performance.

Specifically,

Procedure (b) (4) describes the requirements for the microbiological surface monitoring program of manufacturing equipment. Swabbing, (b) (4) contact plates, and rinse water are the methods allowed in the procedure to perform the sampling. I reviewed documents related to the 2007 & 2008 monitoring of the granulation and packaging areas, which was conducted using the swab technique. I observed that the elapsed time between the monitoring of different equipment parts was (b) (4) An interview held with an employee who performs the monitoring revealed that the required sampling is not documented immediately in the corresponding laboratory worksheet. Details such as sampling time, sampling date, location, and equipment are documented in the test tube which contains the swab. The test tube is discarded upon transcribing the information into the laboratory worksheet. Based on the detailed explanation provided by the employee regarding the sampling procedure, as well as other steps that would be necessary to take the sample, such as moving from one part of the equipment to another, the inspection disclosed that it is physically impossible to have an elapsed time of (b) (4) between different swab samples.

OBSERVATION 2

Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that components and drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically,

The microbiological surface monitoring of equipment is conducted following the frequencies and sampling methods specified in the SOP (b) (4) The monitoring conducted using the swabbing method comprises the immersion of a sterile (b) (4) containing (b) (4) Once a sample is taken, the swab is returned to the (b) (4) and (b) (4) is (b) (4) and (b) (4) and (b) (4) However, the validation data

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available to support the swab monitoring technique is inadequate since it comprises the processing of the sample using the (b) (4) nd (b) (4) described in your test procedure.

SEE REVERSE OF THIS PAGE

AMENDED

JLL

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08/06/2008

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*** DATES OF INSPECTION:**
07/22/2008(Tue), 07/23/2008(Wed), 07/29/2008(Tue), 07/30/2008(Wed), 07/31/2008(Thu), 08/01/2008(Fri), 08/04/2008(Mon), 08/06/2008(Wed)

FDA EMPLOYEES' NAMES, TITLES, AND SIGNATURES:

Jorge L Lajara, Investigator

Iraida Ortiz, Chemist

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AMENDED

DATE ISSUED
08/06/2008

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or

2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgement, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."