

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

<b>DISTRICT ADDRESS AND PHONE NUMBER</b> 466 Fernandez Juncos Ave. San Juan, PR 00901-3223 (787) 729-6854 Fax: (787) 729-6747	<b>DATE(S) OF INSPECTION</b> 08/20/2002 - 09/09/2002*
	<b>FEI NUMBER</b> 2650141

**NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED**  
**TO:** Oray B. Boston, General Manager

<b>FIRM NAME</b> McNeil Consumer & Specialty Pharmaceuticals	<b>STREET ADDRESS</b> Km 19.8 Rd 183 Bo. Montones
<b>CITY, STATE, ZIP CODE, COUNTRY</b> Las Piedras, PR 00771	<b>TYPE ESTABLISHMENT INSPECTED</b> OTC Drug Manufacturer

**DURING AN INSPECTION OF YOUR FIRM I OBSERVED:**

**QUALITY SYSTEM**

**OBSERVATION 1**

Established sampling plans are not followed.

Specifically,

- 1) Stability sampling plan for Motrin IB Gelcaps 100 count for year 2001 was not followed in accordance with NDA commitments and SOP (b) (4) Stability Study Design and Acquisition," in that the first lot (b) (4) of the first three marketed lots was not placed on stability.
- 2) The first lots of each product packaged with caps with a new liner were not placed on stability in accordance with Change Control record (b) (4) The products involved include:
  - Extra Strength Tylenol caplets 24 count, lot FBA 224
  - Extra Strength Tylenol gelcaps 24 count, lot FBA 233
  - Regular Strength Tylenol 100 count, lot FBA 246
  - Extra Strength Tylenol tablets 30 count, lot FBA 247
  - Tylenol PM geltabs 24 count, FBA 219
  - Tylenol PM gelcaps 24 count, lot FBA 251
  - Motrin tablets 24 count, lot FBA 294
  - Motrin caplets 24 count, lot FBA 304
  - Tylenol Soft Chewable Grape tablets 30 count, lot FCA002

**OBSERVATION 2**

Deviations from written sampling plans are not recorded.

Specifically, a Nonconformance Investigation Report (NCR) was not generated after the Regulatory Affairs Department discovered that the first marketed lot of Motrin IB gelcaps, lot (b) (4) was not placed on stability in accordance to NDA requirements and written procedures.

<b>SEE REVERSE OF THIS PAGE</b>	<b>DATE ISSUED</b> 09/09/2002
---------------------------------	----------------------------------

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER 466 Fernandez Juncos Ave. San Juan, PR 00901-3223 (787) 729-6854 Fax: (787) 729-6747	DATE(S) OF INSPECTION 08/20/2002 - 09/09/2002* FEI NUMBER 2650141
---	--

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED  
TO: Oray E. Boston, General Manager

FIRM NAME McNeil Consumer & Specialty Pharmaceuticals	STREET ADDRESS Km 19.8 Rd 183 Bo. Montones
CITY, STATE, ZIP CODE, COUNTRY Las Piedras, PR 00771	TYPE ESTABLISHMENT INSPECTED OTC Drug Manufacturer

**DURING AN INSPECTION OF YOUR FIRM I OBSERVED:**

**OBSERVATION 3**

Written records of investigations into the failure of a batch or any of its components to meet any of its specifications ~~and~~ do not include the conclusions and followup.

Specifically,

Nine (9) investigations in years 2001 & 2002 related to out of specification yield values after the reconciliation of Tylenol products lot #'s: (b) (4) and (b) (4) were attributed to an (b) (4). A study titled (b) (4) was conducted and completed on 1/28/02. The study concluded that there was a significant difference between the current cubicle factors and the ones obtained in the study and recommended to change them since this "could be the major cause of the yield values out of parameters." This preventive action of replacing the old cubicle values with the new values in the (b) (4) and (b) (4)

**OBSERVATION 4**

Changes to written procedures are not reviewed and approved by the quality control unit.

Specifically, a form to verify major cleaning of equipment was created and implemented in September 2001 by production personnel without the review and approval of the quality control unit.

**OBSERVATION 5**

Written production and process control procedures are not followed in the execution of production and process control functions.

Specifically, (b) (4) investigation reports reviewed were generated (b) (4) According to SOP (b) (4)

<b>SEE REVERSE OF THIS PAGE</b>	DATE ISSUED 09/09/2002
---------------------------------	---------------------------

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER

466 Fernandez Juncos Ave.  
San Juan, PR 00901-3223  
(787) 729-6854 Fax: (787) 729-6747

DATE(S) OF INSPECTION

08/20/2002 - 09/09/2002\*

FEI NUMBER

2650141

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Oray B. Boston, General Manager

FIRM NAME

McNeil Consumer & Specialty  
Pharmaceuticals

STREET ADDRESS

Km 19.8 Rd 183  
Bo. Montones

CITY, STATE, ZIP CODE, COUNTRY

Las Piedras, PR 00771

TYPE ESTABLISHMENT INSPECTED

OTC Drug Manufacturer

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

\* DATES OF INSPECTION:

08/20/2002 (Tue), 08/22/2002 (Thu), 08/23/2002 (Fri), 08/26/2002 (Mon),  
08/27/2002 (Tue), 08/28/2002 (Wed), 09/03/2002 (Tue), 09/04/2002 (Wed), 09/09/2002 (Mon)

FDA EMPLOYEE'S NAME, TITLE, AND SIGNATURE:



Ileana Barreto-Pettit, Investigator

SEE REVERSE  
OF THIS PAGE

DATE ISSUED

09/09/2002 