DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Customhouse, Rm 900 2nd & Chestnut St Philadelphia, PA 19106 (215) 597-4390 Fax:(215) 597-0875	02/11/2008 - 02/19/2008* FEI NUMBER 2510184

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Gaston G. Barua, Director, Plant Operations

FIRM NAME	STREET ADDRESS
McNeil Consumer Healthcare, Div of McNeil-PPC, Inc.	7050 Camp Hill Road
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Fort Washington, PA 19034	Pharmaceutical 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:

QUALITY SYSTEM

OBSERVATION 1

Complaint records are deficient in that they do not include the findings of the investigation and follow-up.

Specifically, investigations into complaints are not always complete. For example:

a) QN (Quality Notification) [redacted] documenting investigation into two complaints of (b)(4) [redacted] found in a bottle of [redacted] that uncovered that [redacted] was in fact packaged on the same packaging line prior to [redacted] was incomplete in that there was no medical evaluation conducted to assess the risk to consumers if they were to ingest a (b) (4) [redacted] as opposed to (b) (4) [redacted] In addition, QN (b) (4) [redacted] was not initiated until approximately 6 months after the second complaint was received on (b) (4) [redacted]

b) Investigation [redacted] into a complaint of (b) (4) [redacted] found in a bottle of (b) (4) [redacted] was incomplete in that there was no evaluation of products that were packaged on parallel or adjacent packaging lines during packaging of lot (b) (4) [redacted] to identify a possible source of the product mix-up. During this inspection, on 2/14/08, as part of an additional investigation into this complaint it was determined that [redacted] was packaged on one of the packaging lines concurrently with packaging of [redacted]

c) Investigation [redacted] into a complaint of (b) (4) [redacted] found in a bottle of [redacted] received on (b) (4) [redacted] was incomplete in that there was no evaluation of products that were manufactured prior to production of bulk lot (b) (4) [redacted] which were packaged into finished lot (b) (4) [redacted] utilizing the same processing (i.e. compression, coating, and printing) equipment to identify a possible source of the product mix-up. In addition, there was no assessment of products that were packaged on parallel or adjacent packaging lines during packaging of lot [redacted]

SEE REVERSE OF THIS PAGE	Vlada Matusovsky	DATE ISSUED 02/19/2008

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Customhouse, Rm 900 2nd & Chestnut St Philadelphia, PA 19106 (215) 597-4390 Fax:(215) 597-0875	02/11/2008 - 02/19/2008* FEI NUMBER 2510184

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Gaston G. Barua, Director, Plant Operations

FIRM NAME	STREET ADDRESS
McNeil Consumer Healthcare, Div of McNeil-PPC, Inc.	7050 Camp Hill Road
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Fort Washington, PA 19034	Pharmaceutical manufacturer

d) Investigation (b) (4) into a complaint of (b) (4) found in a bottle of (b) (4) was incomplete in that there was no evaluation of products that were manufactured prior to production of bulk lot (b) (4) which was packaged into finished lot (b) (4) utilizing the same processing (i.e. compression) equipment to identify a possible source of the product mix-up. In addition, there was no assessment of products that were packaged on parallel or adjacent packaging lines during packaging of lot (b) (4).

OBSERVATION 2

Investigations of an unexplained discrepancy did not extend to other drug products that may have been associated with the specific failure or discrepancy.

Specifically, QN (Quality Notification) (b) (4) documenting an investigation into an observed shortage of Purified Water USP during processing (b) (4) recorded on the Batch Mixing Report for (b) (4) (b) (4) was incomplete in that the root cause of the deviation and its possible impact on the product batches processed during the affected time period were not documented.

OBSERVATION 3

Complaint records are deficient in that they do not document the reason and the individual making the decision not to conduct a complaint investigation.

Specifically, no formal investigation was initiated in response to a complaint alleging that there was an error in the children's dosing schedule chart on the official Tylenol website. The complaint was received on (b) (4)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Customhouse, Rm 900 2nd & Chestnut St Philadelphia, PA 19106 (215) 597-4390 Fax:(215) 597-0875	02/11/2008 - 02/19/2008* FEI NUMBER 2510184

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Gaston G. Barua, Director, Plant Operations

FIRM NAME	STREET ADDRESS
McNeil Consumer Healthcare, Div of McNeil-PPC, Inc.	7050 Camp Hill Road
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Fort Washington, PA 19034	Pharmaceutical manufacturer

*** DATES OF INSPECTION:**
02/11/2008(Mon), 02/12/2008(Tue), 02/13/2008(Wed), 02/14/2008(Thu), 02/15/2008(Fri), 02/19/2008(Tue)

FDA EMPLOYEE'S NAME, TITLE, AND SIGNATURE:

Vlada Matusovsky

Vlada Matusovsky, Investigator

SEE REVERSE OF THIS PAGE

DATE ISSUED
02/19/2008