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	01/04/2006 - 01/12/2006
	FEI NUMBER 2510184

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Colin F. Watts, President

FIRM NAME	STREET ADDRESS
McNeil Consumer & Specialty Pharmaceuticals, Division of McN	7050 Camp Hill Rd
CITY, STATE, ZIP CODE, COUNTRY Fort Washington, PA 19034-2210	TYPE ESTABLISHMENT INSPECTED 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 WE OBSERVED:

QUALITY SYSTEM

OBSERVATION 1

There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been thoroughly distributed.

Specifically, investigations are not always timely and/or complete. For example,

a) There was no adequate investigation to determine the root cause of the unsuccessful Cleaning Validation to demonstrate the removal of Ibuprofen residues from the (b)(4) Granulator Unit. The cleaning procedure used during this unsuccessful cleaning validation is currently utilized (with minor changes) to clean the (b)(4) Granulator Unit after manufacturing of various OTC pharmaceuticals, including Ibuprofen containing products.

b) Nonconformance Investigation NC # (b)(4) into the end of batch Ibuprofen assay Out of Specification (OOS) result for Children's Motrin Suspension Dye-Free 4 oz. batch # (b)(4) does not contain complete documentation of the records reviewed to determine the most likely root cause of this OOS. The investigation was initiated on (b)(4) and was not completed until (b)(4)

c) Nonconformance Investigation NC # (b)(4) into foreign material found in Children's Motrin Suspension 4 oz batch # (b)(4) does not document the reason for exceeding (b)(4) days time limit as required by SOP (b)(4) (b)(4) Procedure. The investigation was initiated on (b)(4) and was not completed until (b)(4)

d) Nonconformance Investigation NC # (b)(4) into the acid-stage dissolution OOS result for St. Joseph Enteric Coated Tablets batch # (b)(4) does not document the reason for exceeding (b)(4) days time limit as required by SOP (b)(4) The investigation was initiated on (b)(4) and was not completed until (b)(4)

RELEASE
Reviewed by: _____ 5/12/10
C.O. DATE
F#_____ GEN. ☑ SPEC. ☐

SEE REVERSE OF THIS PAGE	Vlada Matusovsky	DATE ISSUED 01/12/2006

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OBSERVATION 2

The responsibilities and procedures applicable to the quality control unit are not fully followed.

Specifically, SOP (b) (4) was not followed in that APR (Annual Product Review) for Flexeril Tablets - 10 mg, review period: (b) (4) approved on (b) (4) was not reviewed and approved within (b) (4) days of the review period ending date.

OBSERVATION 3

The establishment of laboratory control mechanisms including any changes thereto, are not reviewed and approved by the quality control unit.

Specifically, there is no documentation of review/approval by the QA unit of the changes made to the (b) (4) (b) (4) Logbook to correct the Form FDA-483 Observation documented during the previous 6/04 FDA Establishment Inspection.

FDA EMPLOYEES' NAMES, TITLES, AND SIGNATURES:

Vlada Matusovsky, Investigator

Anita R. Michael, Investigator

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DATE ISSUED
01/12/2006