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	05/17/2004 - 06/07/2004* FEI NUMBER 2510184

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: William L. McComb, President

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

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, complete, or do they include documentation of quality review, examples include:

1. Nonconformance report (NCR) (b) (4) was created (b) (4) for excess broken and moddled caplets from Tylenol Sinus Severe, batch (b) (4) the event occurred (b) (4) On (b) (4) QA deleted the description on the investigation and entered (b) (4) Quality System Report (b) (4) was created (b) (4) there is no documentation of any investigation until the closure of the investigation on (b) (4).

2. The investigation into the follow-up Field Alert submitted (b) (4) for the incorrect dosing for the Children's Motrin Grape Chewable lot (b) (4) fails to include an evaluation of retention samples for all lots packaged with the implicated outer carton vendor lots. Notably, retains of packaged lots (b) (4) had not been evaluated.

3. Nonconformance report (b) (4) was generated (b) (4) for a weighing error incident that occurred (b) (4) The investigation is silent as to when the error was discovered, other lots previously weighed, and any consideration for additional samples. The investigation was closed by QA on (b) (4)

4. Quality System Reports (QSR) investigations are initiated and remain open without documentation as to the status of the investigation. For example (b) (4) was initiated (b) (4) the extent of documentation was a memo written (b) (4) to cancel the QSR. Notably, (b) (4) QSR investigations were opened in 2003 and remain open.

5. NCR (b) (4) was generated (b) (4) for a foreign product, Tylenol 8 hour Geltab, was discovered on (b) (4) on bottle line (b) (4) after packaging Mylanta Gelcap lot (b) (4) On (b) (4) QA rejected the batch, there was no further documentation of Quality involvement on the NCR although the packaging Team Leader on 11/12/03 had updated the NCR that corrective actions have been completed.

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Susan F Laskin

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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.

1. Out of specification investigation (b) (4) was initiated (b) (4) for the microbiological excursion identified as gram (b) (4) (b) (4) on the purified water system sample from (b) (4) fails to include among other items an assessment of product impact.

2. Out of specification investigation (b) (4) was initiated (b) (4) for the (b) (4) (b) (4) contamination of Children's Motrin Suspension Grape Flavor lot (b) (4) that was analyzed on (b) (4) The documented investigation evaluated released Children's Motrin Suspension Grape Flavor lots only. NCR (b) (4) was created (b) (4) and closed (b) (4) the root cause of the (b) (4) contamination was undetermined.

3. Out of specification investigation (b) (4) was initiated (b) (4) for the out of specification (b) (4) that was dicovered on (b) (4) The investigation failed to identify the (b) (4) lots of finished product that were tested with the out of specification media.

OBSERVATION 3

Evidence of reserve drug product sample deterioration was not investigated.

Specifically, there has been no evaluation or summary reports generated in 2004, 2003, or 2002 for the category (b) (4) results of visual inspections, which includes product or packaging material exhibiting noncritical irregularities or retained samples not found.

OBSERVATION 4

Reserve samples from representative sample lots or batches of drug products selected by acceptable statistical procedures are not examined visually at least once a year for evidence of deterioration.

Specifically, the 2003 annual visual inspection for the following lots was not performed for Childrens Tylenol Strawberry Lot (b) (4) Childrens Tylenol Strawberry Lot (b) (4) Simply Sleep 24 caplets Lot (b) (4)

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OBSERVATION 5

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

Specifically, NDA Field Alert procedure , effective (b) (4) is not followed in that Field Alert investigations fail to include complete documentation. Among other items the investigations fail of to include documentation from the (b) (4) (b) (4) and notification to the Johnson & Johnson affiliates possibly impacted by the field alert condition.

OBSERVATION 6

Written procedures are not established for evaluations done at least annually and including provisions for a review of complaints, returned or salvaged drug products, and investigations conducted for each drug product.

Specifically:
1. Annual product reviews fail to include among other items; an evaluation of all returned goods, a documented review of all complaints, quality system reports, all analytical investigations into out of specifications results and an evaluation of the retention samples.

2. The procedure for Annual Product Review, effective (b) (4) fails to include, among other items, a requirement that all returns, all investigations and all complaints are evaluated.

OBSERVATION 7

Strict control is not exercised over labeling issued for use in drug product labeling operations.

Specifically, labels for drug product are staged in a locked, limited access cage although access is not restricted to only those designated to handle labeling.

OBSERVATION 8

Labeling and packaging materials are not representatively sampled and examined upon receipt and before use in packaging and labeling of a drug product.

Specifically, complete incoming label inspection is conducted on the first receipt only of a vendor lot.

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Packaging System

OBSERVATION 9

Reprocessing was performed without the review and approval of the quality control unit.

Specifically, bottles removed from the packaging lines are placed in rework bins and reworked by packaging operators without the review and approval of the quality control unit. On (b) (4) the following unlabeled bottles were in re-work bins awaiting rework; unlabeled bottles of St. Joseph's Aspirin lot (b) (4) were for rework on line (b) (4) unlabeled bottles of Tylenol Arthritis lot (b) (4) were for rework on line (b) (4) Notably, there is no in-process trending for the amount of reworks generated during packaging.

OBSERVATION 10

Batch production and control records do not include complete information relating to the production and control of each batch.

Specifically,

1. There was no documentation in the packaging records for St. Joseph's Aspirin lot (b) (4) packaged on (b) (4) for the (b) (4) scale set-up which was used to verify the bottle count.

2. Uncontrolled records are issued to the packaging line without complete information for example; on (b) (4) lot (b) (4) was being packaged, pages (b) (4) of the packaging production record failed to include batch numbers or product codes.

Laboratory System

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OBSERVATION 11

Laboratory records do not include a description of the sample received for testing, the source or location from where the sample was obtained, the quantity of the sample, the date the sample was taken, and the date the sample was received for testing.

Specifically, there is no documentation either in the log book for samples entered into the laboratory or on the analyst worksheets for the quanity of samples received, source of the sample and the date the sample was taken.

OBSERVATION 12

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

Specifically, the alert level specifications of (b) (4) for the purified water use points and non use points have not been evaluated or adjusted based on the historical results.

Facilities and Equipment System

OBSERVATION 13

Written procedures are not established and followed for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product.

Specifically, the dirty hold time of (b) (4) prior to cleaning, had been exceeded on (b) occasions from liquids holding tank (b) (4) to packaging line (b) (4) in the new manufacturing area during the period of (b) (4)

Materials Handling System

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OBSERVATION 14

Representative samples are not taken of each shipment of each lot of components for testing or examination.

Specifically, samples of incoming material are not collected randomly. For example (b)(4) drums of (b)(4) Starch lot (b)(4) were received on (b)(4) pallets on (b)(4) all (b)(4) samples were collected from (b)(4) pallet.

* DATES OF INSPECTION:
05/17/2004(Mon), 05/18/2004(Tue), 05/19/2004(Wed), 05/20/2004(Thu), 05/21/2004(Fri), 05/24/2004(Mon), 05/25/2004(Tue), 05/26/2004(Wed), 05/27/2004(Thu), 05/28/2004(Fri), 06/04/2004(Fri), 06/07/2004(Mon)

FDA EMPLOYEE'S NAME, TITLE, AND SIGNATURE:

Susan F Laska

Susan F Laska, M.S., Investigator

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Susan F. Laska

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