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SUMMARY

This inspection of a human drug manufacturer was conducted in response to FACTS Assignment ID # 875276, Operation ID # 3416033 as part of the FY'08 PHI-DO performance goal under Tier 1 high risk inspectional system. This inspection was conducted in accordance with C.P. 7356.002, Drug Manufacturing Inspections. In addition, the DQRS's were covered during this inspection under C.P. 7356.021, Drug Quality Reporting System NDA Field Alert Reporting.

The previous 10/18-26/06 inspection revealed the following deficiencies, which were verbally discussed with the firm's management at the conclusion of the inspection: investigation was not initiated when the Dissolution Apparatus exhibited an Out of Trend (OOT) calibration result, FW (Fort Washington) plant manufacturing investigation into an OOS result was not initiated in a timely manner and (b) (4) SOP's were not clear as to when adjustments and/or PM (Preventative Maintenance) of the (b) (4) would be warranted if the labeling information (i.e. lot number and expiration date) on the pouches becomes

illegible. Corrections implemented by the firm to address these deficiencies were assessed during the current inspection. There was no Form FDA-483, Inspectional Observations, issued and the inspection was classified (b) (4)

The current inspection revealed the following deficiencies, which were documented on the Form FDA-483, Inspectional Observations: incomplete investigations into complaints and manufacturing deviations and formal investigation into a complaint was not initiated. The firm's management promised corrections. Quality and Production systems were assessed. The inspection focused on production activities associated with St. Joseph Safety (enteric) Coated Aspirin 81 mg and Concentrated Tylenol Infants' Drops, ½ fl. oz., Cherry Flavor. There were no samples collected and no refusals were encountered during this inspection.

ADMINISTRATIVE DATA

Inspected firm:	McNeil Consumer Healthcare, Div of McNeil-PPC, Inc.
Location:	7050 Camp Hill Road Fort Washington, PA 19034
Phone:	215-273-7000
FAX:	(215)273-4124
Mailing address:	7050 Camp Hill Rd Fort Washington, PA 19034
Dates of inspection:	2/11/2008, 2/12/2008, 2/13/2008, 2/14/2008, 2/15/2008, 2/19/2008
Days in the facility:	6
Participants:	Vlada Matusovsky, Investigator Frank W. Perrella, Ph.D., Sr. Staff Fellow

On 2/11/08, the Form FDA-482, Notice of Inspection, with attachment was issued and credentials were presented to Gaston G. Barua, Director, Plant Operations, who identified himself as the most responsible official for the FW plant. Jerome J. Hayes, QA Manager, Product Assurance, Timothy A. Bauer, QA/QC Plant Manager, and Binoy Varghese, QA Team Leader were also present. Vlada Matusovsky, FDA Investigator and Frank W. Perrella, Ph.D., Sr. Staff Fellow from CDER, Office of Compliance, Division of Manufacturing & Product Quality, New and Generic Drug Manufacturing, represented FDA. Dr. Perrella participated in the inspection from 2/11/08 to 2/15/08. Investigator Matusovsky was present for the entire course of the inspection.

Mr. Barua stated that Ashley McEvoy, President, who is the most responsible individual for McNeil Consumer Healthcare, whose office is also located at the FW facility was off-site at the time of issuance of the Form FDA-482. Mr. Barua explained that FW site houses both the FW

manufacturing plant and the McNeil Consumer Healthcare Corporate Headquarters. Ms. McEvoy introduced herself on 2/12/08.

On 2/19/08, the Form FDA-483, Inspectional Observations, was issued to Mr. Barua. Mr. Bauer; Larry Constable, VP, Manufacturing; Mr. Hayes; and Robert Miller, Ph.D., VP, Global QA, OTC were also present.

The firm's hours of operations are 24 hours a day, 7 days a week over (b) (4) (b) (4) weekday. The firm's hours of business are 8:00 am to 5:00 pm, Monday through Friday. There are currently a total of approximately (b) (4) employees at the FW site (manufacturing plant and Corporate HQ), including (b) FW Plant manufacturing and QA employees.

I confirmed the firm's current drug registration # 2510184, stamped as registered by FDA on 3/16/07.

This report was written by Investigator Matusovsky in its entirety.

HISTORY

Mr. Barua confirmed that the history of the firm documented during the previous 10/06 inspection is accurate and complete. As was reported in 10/06, McNeil Consumer Healthcare, Division of McNeil – PPC, Inc. can trace its origins to the storefront pharmacy Robert McNeil opened in the Kensington section of Philadelphia in 1879. In 1904, Robert McNeil's only son, Robert Lincoln McNeil, joined the family business. Under his management, the business shifted away from retail operations and into the expanding pharmaceutical market. In 1933, the drug store was incorporated as McNeil Laboratories Inc. This new corporation specialized in the direct marketing of prescription pharmaceuticals to doctors and hospitals. By the early '50s, McNeil Laboratories had become a national concern employing more than (b) people and manufacturing more than (b) products.

In 1955, McNeil Laboratories introduced an aspirin-free prescription analgesic – TYLENOL Elixir for children.

In 1959, McNeil Laboratories was acquired by Johnson & Johnson. Soon after the acquisition, McNeil moved to its present location, a (b) (4) site in Fort Washington, PA.

In 1978, the company was divided into two separate organizations – McNeil Consumer Products Company, to provide OTC products for retail sales; and McNeil Pharmaceuticals, now part of Ortho-McNeil Pharmaceutical Corporation to market prescription drugs.

On 6/26/06, Johnson & Johnson publicly announced its acquisition of Pfizer PHC (Pharmaceutical Healthcare) Division.

McNeil Consumer Healthcare is a diversified OTC and pharmaceutical company, augmenting the firm's base business of TYLENOL with a cold and sinus line of products, a gastrointestinal line, including IMODIUM, as well as MOTRIN and ADHD focused CONCENTRA. In addition to the FW headquarters, there are McNeil Consumer Healthcare facilities in Las Piedras, Puerto Rico, and Guelph, Ontario, Canada. The addresses of the firm's related facilities are listed on Exhibit 1.

McNeil Consumer Healthcare Headquarters facility is located at the FW site.

Johnson & Johnson Worldwide Corporate Headquarters facility is located at One Johnson & Johnson Plaza, New Brunswick, NJ 08933. Johnson & Johnson Consumer Products Inc. Headquarters is located at 199 Grandview Rd., Skillman, NJ 08558.

According to Mr. Barua, there have been no changes to the firm's history of business since the previous 10/06 inspection except for the organizational changes within McNeil Consumer Healthcare, Division of McNeil – PPC, Inc. associated with the acquisition of Pfizer PHC, which were implemented in approximately 12/06.

INTERSTATE COMMERCE

According to Mr. Hayes, approximately (b) (4) of the firm's products are shipped outside of Pennsylvania.

Mr. Barua stated that all of the finished products manufactured at the FW Plant are transported to the off-site (b) (4) Warehouse located at (b) (4) From the (b) (4) warehouse the finished goods are shipped to the firm's (b) (4) Distribution sites located in (b) (4) Exhibit 2 represents a list of the Distribution Centers and their addresses.

JURISDICTION

Exhibit 3 represents a list of the products manufactured and/or packaged at the FW plant. All of the products produced by the firm are OTC pharmaceuticals. The only exception is Flexeril 5 mg and 10 mg tablets that is an Rx product. This product was acquired by the McNeil FW facility from another company under NDA 17-821. Mr. Hayes indicated that some of the firm's OTC products also have approved NDA's. NDA numbers are also listed on Exhibit 3. Mr. Hayes stated that solid oral dosage forms (except for capsules) and liquid/suspension products are manufactured at the FW plant.

Exhibit 9 represents a list of new product launches projected for 2008. Mr. Hayes explained that these products are being transferred to the FW site as the result of the acquisition of Pfizer PHC.

Exhibit #'s 4 and 5 represent labeling for St. Joseph Safety (enteric) Coated Aspirin 81 mg and Concentrated Tylenol Infants' Drops, ½ fl. oz., Cherry Flavor, respectively.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

Exhibit 6 represents the firm's Organizational Chart.

According to Mr. Hayes, due to the Pfizer PHC Divisional acquisition by Johnson & Johnson on 6/26/06, there have been some changes within the McNeil and Johnson & Johnson structural management organization. Exhibit 7 lists the changes within McNeil Consumer Healthcare associated with the acquisition that has occurred after 10/06.

Exhibit 8 lists management changes within the FW Plant Operations and QC/QA departments, respectively, since the previous 10/06 inspection.

According to Ms. McEvoy, she is the most responsible official on site representing McNeil Consumer Healthcare corporate division. She stated that she has an ultimate responsibility for manufacturing, sales and marketing of the firm's products produced at all of the McNeil Consumer Healthcare sites including FW. Ms. McEvoy reports to Rose Crane, Company Group Chairman, Consumer Pharmaceuticals and Nutritionals. Ms. Crane in turn reports to Marc Robinson, Company Group Chairman, Consumer Healthcare. Mr. Robinson reports to Colleen Goggins, World Wide Chairman, Consumer Group of Companies. Ms. Goggins reports to William C. Weldon, CEO and Chairman of the Board, Johnson & Johnson, who is the most responsible individual for Johnson & Johnson Corporation. Ms. Crane, Mr. Robinson, Ms. Goggins, and Mr. Weldon's offices are located at Johnson & Johnson Corporate Headquarters address.

According to Ms. Nieradka, she is responsible for the oversight of manufacturing, financial planning, contact manufacturing, strategic planning, facilities and engineering groups at the McNeil Consumer Healthcare sites, including FW. Ms. Nieradka reports to Ms. McEvoy.

FW Plant Operations

According to Mr. Barua, he is the most responsible individual for the FW site. He is ultimately responsible for all day to day operations of the plant, hiring and firing of the firm's employees and making decisions on major financial expenditures. Mr. Barua directs the plant production activities, which include manufacturing, plant engineering, maintenance, labor regulations and regulatory compliance. He is responsible for coordinating manufacturing activities with QA, Finance, Planning and Purchasing/Scheduling groups to ensure control and proper reporting. Mr. Barua reports to Mr. Constable, who in turn reports to Ms. Nieradka.

According to Brian Lipsitz, Interim Manager, Process Excellence & Project Management, he is responsible for identifying, delivering and managing process performance improvement and all Process Excellence projects across the plant, oversight of process design, change management, business case definition, and program communications, working with multiple business units to identify key business requirements/drivers and develop innovative solutions through the use of Process Excellence methodologies and tools, and developing Process Excellence capabilities within the FW plant on all functional teams. Mr. Lipsitz is also responsible for managing individual project managers including overall project team activities/priorities, development of scope/objectives, delivering and tracking critical milestones, facilitating team decisions, and ensuring individual accountabilities as well as issue resolution and risk management. Mr. Lipsitz reports to Mr. Barua.

According to Michael Faughey, Manager, Solid Dose Processing, he is responsible for managing the Solid Dose Processing operations for Chemical Weighing, Granulation, Compression, Coating, Printing, and Geldipping in the FW Plant. He also develops goals and strategies for improvement of safety, compliance, cost and people development. Mr. Faughey reports to Mr. Barua.

According to Lauren Kruse, Solid Dose Packaging Manager, she is responsible for managing the operations of the Solid Dose Packaging area in the FW Plant, which includes the bottling, blistering, and pouching technologies. Ms. Kruse reports to Mr. Barua.

According to Douglas P. Buddle, Liquids Manufacturing Manager, she is responsible for managing and operations of the Liquids Mixing and Packaging areas in the FW Plant. She develops goals and strategies for improvement of safety, compliance, cost, and people development. She partners with Quality, Engineering, Planning, and Human Resources to help develop and execute the strategies for the Liquids Area and the FW Plant. Ms. Bond reports to Mr. Barua.

According to Juan Carlos Lugo, FW Product Supply Manager, he is responsible for managing production planning, scheduling, and procurement of materials for Liquid and Solid products manufactured at the FW Plant. His primary responsibility is to ensure product continuity for the firm's customers. Mr. Lugo sets strategic direction for employees in his area and provides development opportunities for his direct reports. He is responsible for compliance, safety, cost, and customer service goals. Mr. Lugo reports to Rick Olsen, Product Supply Director (dotted line) and Mr. Barua.

According to Holly Bolan, Plant Engineering Manager, she is responsible for managing the facilities of the FW Site including the FW Manufacturing Plant. She oversees the areas of housekeeping, grounds maintenance, site security and utilities, mail services and central copying centers at the FW Site. In addition, Ms. Bolan provides support to the environment compliance group. She develops goals and strategies for improvement of safety, compliance, cost and people development. Ms. Bolan reports to Mr. Barua.

According to Robert Wilkerson, Warehousing Operations Manager, he is responsible for managing the operations of the Warehouse in the FW plant, as well as the (b) (4) warehouse, including the receipt, storage, and removal of raw materials including chemicals and components, and the movement of finished goods from the FW plant to the (b) (4) warehouse facility. In addition, Mr. Wilkerson manages the operations that coordinate the movement of finished goods from the (b) (4) warehouse to the approved Johnson & Johnson distribution centers. Mr. Wilkerson reports to Mr. Barua.

FW Quality Operations

According to Robert Miller, Ph.D., VP, Global QA OTC, he is responsible for setting the company's strategy and establishing global compliance priorities. Dr. Miller oversees the development of policies and requirements for quality systems and processes in order to ensure GMP compliance. He has global quality oversight of the McNeil OTC manufacturing plants located in Fort Washington, PA, Lancaster, PA, and Las Piedras, PR. Dr. Miller provides direction, insight, and expectations to senior company management related to emerging compliance trends and issues and makes recommendations on their resolution. Dr. Miller reports to Ms. Crane.

According to Paul-Michel Di Paolo, Director, QA, OTC, US/PR, he is responsible for the oversight of QA/QC activities at US and Puerto Rico manufacturing sites. He ensures that site personnel are adequately trained and versed in regulatory requirements. Mr. Di Paolo provides guidance to the Site Quality Leaders and assists them in developing and maintaining quality systems and processes to optimize GMP Regulatory Compliance. He is responsible for ensuring continuous enhancement of existing quality compliance systems and communication of the GMP regulatory concerns to the firm's management. Mr. Di Paolo reports to Dr. Miller.

According to Mr. Bauer, he is responsible for the administration of the QA functions at the FW facility. These functions include testing of all components, packaging materials, labeling, in-process materials, bulk and finished product. He is responsible for the maintenance of test records, batch records and specifications, reviewing and approving of SOPs, oversight of cGMP training and periodic contact with Regulatory agencies. Mr. Bauer also coordinates department programs where cooperation between departments is required. He represents the firm externally in matters relating to quality and compliance. Mr. Bauer reports to Mr. Di Paolo.

According to Mr. Hayes, he is responsible for the QA support functions for the Solid Dosage and Liquids Operations, which entails review and coordination of the initiation and closure of QN (Quality Notification) Investigations, development of SOP's, implementation of change control system, implementation/enhancement of quality systems and leading of Quality Personnel that support the solid dose manufacturing and packaging operations. Mr. Hayes also is a site contact for the DEA and provides support to the Product Assurance Function. He reports to Mr. Bauer.

According to Edward Chan, QA Manager, Validation, he is responsible for managing the Validation Services department in the FW plant. He manages the group responsible for review and approval of al validation and qualification documents for the FW site from a quality perspective. This includes all process validation, equipment qualification, facilities/utilities qualification and cleaning validation. He develops goals and strategies for improvement validation activities, compliance and people development. Mr. Chan reports to Mr. Bauer.

According to Tracy Cooper, QA Manager, Quality System, she is responsible for managing of the Quality aspects of the incoming sampling and inspection department, oversight of retain samples of finished packaged product and chemical components, label issuance and control process, approval of QN investigations, Annual Product Reviews (APRs) compilation (for all products), oversight of change control system and FW consumer complaint process. Ms. Cooper also participates, hosts and/or leads all audits of the FW Plant. She reports to Mr. Bauer.

According to Fred Bryant, Analytical Laboratory Manager, he is responsible for analytical testing of raw materials, bulk and finished products, oversight of marketed products stability testing and program management, ensuring that the laboratory adheres to cGMPs and safety requirements, ensuring that all laboratory equipment is maintained in a steady state of compliance, representing the laboratory during internal and external audits, oversight of professional development of all departmental personnel and final laboratory approval of all departmental investigations. Mr. Bryant reports to Mr. Bauer.

According to David R. Bonilla, QC Microbiology Manager, he is responsible for managing the QC Micro Laboratory staff and R&D Microbiology testing, management and development of QC Micro Laboratory employees, management of QC Micro Laboratory projects, initiation and approval of investigations relating to the Micro Laboratory testing issues, review and approval of SOPs, serving

as technical advisor during regulatory audits and representing the firm on matters relating to Microbiology. Mr. Bonilla reports to Mr. Bauer.

Exhibit 10 represents a list of McNeil-PPC, Inc. corporate officers.

Exhibit 11 represents a list of McNeil Consumer Healthcare Management Board members.

Exhibit 12 represents a list of Johnson & Johnson Board of Directors members.

Mr. Bauer, Mr. Barua, Ms. Cooper, and Mr. Hayes accompanied me during this inspection and provided me with most of the essential information and documentation. If further explanation was needed they referred me to appropriate individuals in accordance with their respective area of expertise. Exhibit 13 represents a list of FW plant employees interviewed during this inspection and the corresponding topic discussed.

MANUFACTURING OPERATIONS

According to Mr. Bauer, the firm is a manufacturer of solid (with the exception of capsules) and liquid oral dosage forms. There are approximately (b) (4) Bulk Product Formulas and (b) (4) Finished Package Codes produced at the FW Plant. Major Solid Dose Processing Equipment include (b) (4) (b) (4) (b) (4) Major Solid Dose Packaging (b) (4) Mr. Hayes stated that the firm is in the process of qualifying (b) (4) (b) (4) Major Liquids Processing and Packaging Equipment include (b) (4) (b) (4)

Exhibit 14 represents the FW Site diagram. Mr. Hayes stated that the facility, which includes the FW manufacturing plant and McNeil Consumer Healthcare, Division of McNeil-PPC, Inc. Corporate Headquarters, is situated on (b) (4) of land.

Exhibit 15 represents the FW Plant floor plan. According to Mr. Barua, the FW facility occupies approximately (b) (4) feet of space with approximately (b) (4) feet occupied by the FW manufacturing plant, comprised of (b) (4) feet production areas; (b) (4) feet analytical and microbiological laboratories; (b) (4) feet warehouse; (b) (4) areas; and (b) (4) feet miscellaneous areas.

According to Mr. Barua, all of the raw materials and packaging components are received and stored at the FW Main Warehouse. FW Plant Receiver inspects overall conditions of raw materials and packaging components during unloading of a trailer. All of the received materials are verified against a packaging list. A McNeil batch number is internally assigned by the (b) (4) system to each lot of raw materials and components listed on the Packaging Order. (b) pallet of the material is placed in the Incoming Inspection Area to be inspected and sampled. Next, the information on the packaging list is entered into the (b) (4) system. (b) (4) (b) (4) Status is assigned to all of the received materials. S/I (Sampling/Inspection) inspector logs each unique lot of raw materials and components into the (b) (4) system, which (b) (4) S/I technician completes an inspection of each lot in accordance with the appropriate SOPs/material specifications. Then the Inspector records the data on the (b) (4) generated inspection record which is reviewed by a Senior Inspector or Team Leader in S/I. If inspection requirements meet approval, the Senior Technician/Team Leader will approve the inspection record and disposition the material in (b) (4) status. If inspection does not meet requirements, the Senior Technician/Team Leader will reject the material and a QN (Quality Notification) will be generated to address the failure.

St. Joseph Enteric Coated Aspirin Tablets

Exhibit 16 represents the process flow diagram for St. Joseph Enteric Coated Aspirin Tablets.

Mathew A. Howard, Ph.D., Manager, Pharmaceutical Technology, provided me with an overview of the St. Joseph Enteric Coated Aspirin Tablets manufacturing process, as follows:

(b) (4)

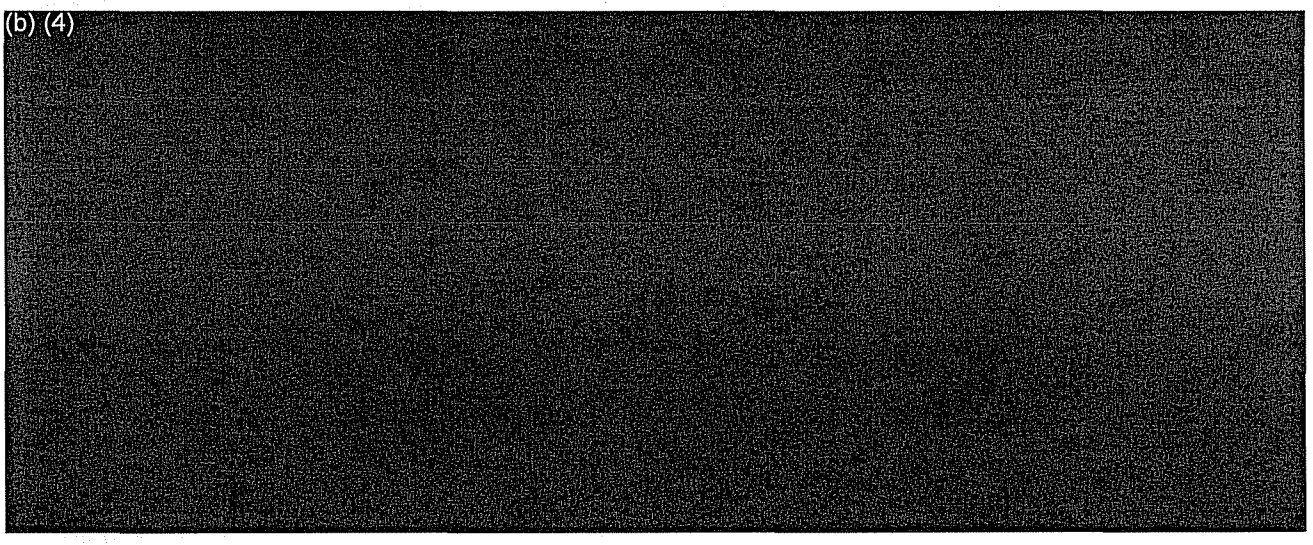
(b) (4)

Infant's Tylenol Drops Suspension, Cherry Flavor

Exhibit 17 represents the process flow diagram for Infant's Tylenol Drops Suspension, Cherry Flavor.

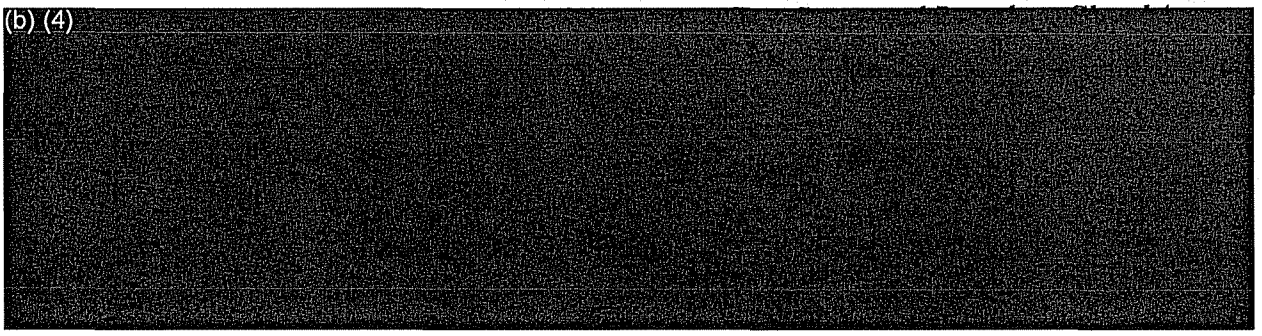
John J. Burke, Manager, Pharmaceutical Technology, provided me with an overview of Infant's Tylenol Drops Suspension, Cherry Flavor manufacturing process, as follows:

(b) (4)



Liquid Manufacturing Control System (LMCS)

According to Cherian (Reggie) George, Program Manager Compliance, Global QA, OTC, the LMF (Liquid Manufacturing Facility) is designed as a (b) (4) (b) (4) (b) (4) Exhibit 18 represents the process flow diagram of the LMCS. Exhibit 19 represents the manufacturing floor plan and equipment platform utility piping arrangement in the LMF. Mr. George continued that mixing area operators (b) (4) LMCS. LMCS also controls the (b) (4) (b) (4)



(b) (4)

Mr. George continued that the LMCS is (b) (4)
(b) (4)

Mr. George indicated that the (b) (4)
(b) (4)

On 2/11/08, during the physical inspection of the plant we observed processing of the following products:

- Mixing of Children's Tylenol Suspension, Strawberry flavor, lot # (b) (4)
(b) (4)
- Mixing of Tylenol Dye Free Cherry Suspension, lot # (b) (4)
- Granulation of Tylenol Sinus Night Time, lot # (b) (4)
- Granulation of Immediate Release Acetaminophen lot # (b) (4)
- Compression of Simply Sleep Tablets, lot # (b) (4)
- Compression of Tylenol Arthritis 650 mg Geltabs, lot # (b) (4)

- Coating of Tylenol Allergy Night Time, lot # (b) (4)
- Printing of St. Joseph Aspirin Enteric Coated (EC) Tablets, lot # (b) (4) (b) (4)
- Packaging of Tylenol Sinus Severe Tablets, lot # (b) (4)

There were no deficiencies observed.

During this inspection, I reviewed the following documentations associated with production of St. Joseph Safety (enteric) Coated Aspirin 81 mg and Concentrated Tylenol Infants' Drops, ½ fl. oz., Cherry Flavor: list of manufacturing and laboratory deviation/OOS (Out of Specification) investigations dated from 10/06 to 2/08 and select investigations from this list; process validation for St. Joseph Safety (enteric) Coated Aspirin 81 mg; master batch production records; list of change controls; select batch production records; qualification of the LMCS system; and Annual Product Review reports. In addition, select SOP's, list of complaints received from 10/06 to 2/08 and select complaint investigations from this list, list of rejected batches dated from 10/06 to 2/08 and select investigations from this list were reviewed. My review of these documents was unremarkable in that there were no apparent deficiencies observed, except as documented under the OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE and GENERAL DISCUSSION WITH MANAGEMENT Sections of this report.

MANUFACTURING CODES

According to SOP (b) (4) at Fort Washington, effective date 2/4/08 (Exhibit 20), the Scheduling Batch Record Coordinator assigns a unique batch number to each Master Record using the batch numbering codes referenced on page 5 of the Exhibit.

(b) (4)

According to Mr. Barua, raw materials and components used for in-house production are also assigned batch numbers. (b) (4)

(b) (4)

COMPLAINTS

During this inspection, I reviewed SOP (b) (4) (b) (4) effective date 6/25/07, SOP (b) (4) (b) (4) effective date 3/19/07, list of complaints received between 10/06 and 2/08 and select complaint investigations from this list.

During this inspection, I also inquired about the firm's investigations into complaint #'s 58242, 57797, 56879, 55244, 41691, 40239, 39929, 39290, 39415, 39286, and 38890 received by the FDA. After searching the firm's database for these complaints, Ms. Cooper provided me with their status (Exhibit 21). According to Exhibit 21, no investigations could be found into complaint #'s 57797, 41691, and 40239; complaint #'s 56879 and 39929 were investigated by the McNeil Las Piedras, PR plant since that is where the products documented in the complaints were manufactured and/or packaged; complaint # 58242 was investigated by the McNeil's Benefits Risk Management (BRM) group (Please note that this investigation was not covered during this inspection) and no investigation was conducted by the FW plant; investigations into complaint #'s 55244, 39290, 39415, 39286, and 38890 were performed by the FW plant and were reviewed during this inspection. My review of these documents was unremarkable in that there were no apparent deficiencies observed.

In addition, DQRS #'s (b) (4) were covered. Ms. Cooper provided me with Exhibit 22 documenting the status of each DQRS. According to this Exhibit, no investigations could be found into DQRS #'s (b) (4) (b) (4) DQRS #'s (b) (4) were investigated by the FW plant and the investigations were reviewed during this inspection; and DQRS # (b) (4) was not investigated although the corrective action was implemented in response to the complaint received prior to the DQRS notification (Please refer to the OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE Section of this report, under Observation # 3 for the details on this deficiency).

RECALL PROCEDURES

According to Mr. Hayes, there were no NDA field alerts filed since the previous 10/06 inspection and there were no product recalls. He stated that there was a market withdrawal of Concentrated Tylenol Infants' Drops Plus Cold, Concentrated Tylenol Infants' Drops Plus Cold, and various PediaCare Infant products due to a possibility of misuse of this products by the parents leading to incidences of overdose in children under 2 years of age (Exhibit 23). Documentation related to this market withdrawal was reviewed and no apparent deficiencies were observed.

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

Observations listed on form FDA 483

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) #(b) (4) initiated on 3/19/07, documenting investigation into two complaints of (b) (4) found in a bottle of (b) (4) (b) (4) lot # (b) (4) (expiration date 5/30/07) that uncovered that (b) (4) lot # (b) (4) was in fact packaged on the same packaging line prior to (b) (4) lot # (b) (4) was incomplete in that there was no medical evaluation conducted to assess the risk to consumers if they were to ingest a (b) (4) as opposed to (b) (4) (b) (4) In addition, QN # (b) (4) was not initiated until approximately 6 months after the second complaint was received on 9/21/06.**

b) **Investigation # (b) (4) into a complaint of (b) (4) found in a bottle of (b) (4) lot # (b) (4) received on 5/30/07, 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) 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 (b) (4) (b) (4) lot (b) (4) was packaged on one of the packaging lines concurrently with packaging of (b) (4) lot (b) (4)

c) **Investigation # (b) (4) into a complaint of (b) (4) (b) (4) found in a bottle of (b) (4), lot # (b) (4), received on 11/13/06, was incomplete in that there was no evaluation of products that were manufactured prior to production of bulk lot #'s (b) (4) (b) (4) and (b) (4) which were packaged into finished lot # (b) (4) 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 # (b) (4)**

d) **Investigation # (b) (4) into a complaint of (b) (4) (b) (4) found in a bottle of (b) (4) lot # (b) (4), received on 11/15/06, 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)**

Reference: 21 CFR 211.198(b)(2)

Supporting Evidence and Relevance:

Observation 1(a)

Exhibit 24 represents the investigation report for complaint # (b) (4) received on 7/19/06. Investigation report was initiated on 7/21/06 and finalized on 10/24/06. According to Exhibit 24, chewable tablets were found in a bottle of (b) (4) lot # (b) (4) The sample was requested from the consumer and was received by the firm on 8/1/06. It is further documented that the examination of the returned sample found the carton to be labeled as (b) (4) (b) (4) lot # (b) (4) However the returned sample bottle was labeled as St. (b) (4), lot # (b) (4) The bottle contained 12 light orange tablets with (b) debossed on one side. These tablets were identified as (b) (4) There were no (b) (4) present in the bottle. The investigation into the complaint revealed

that (b) (4) lot # (b) (4) was packaged immediately prior to packaging of (b) (4), lot # (b) (4) on packaging line # (b) The investigation concluded that the root cause of the product mix-up could not be determined.

Exhibit 25 represents the investigation report for complaint # (b) (4) received on 9/21/06. Investigation report was initiated on 9/22/06 and finalized on 11/27/06. According to Exhibit 25, mixed product was found in a bottle of (b) (4) lot # (b) (4) The sample was requested from the consumer and was received by the firm on 10/19/06. It is further documented that the examination of the returned sample found the bottle labeled as (b) (4) (b) (4) lot # (b) (4) to contain 1 light orange tablet with (b) debossed on one side. This tablet was identified as (b) (4) There were no (b) (4) (b) (4) found in the returned bottle. The investigation into the complaint revealed that (b) (4) (b) (4) lot # (b) (4) was packaged immediately prior to packaging of (b) (4) (b) (4) lot # (b) (4) on packaging line # (b) It is also documented that there were no prior related complaints against lot # (b) (4). The investigation concluded that the root cause of the product mix-up could not be determined.

According to Ms. Cooper, (b) (4) lot # (b) (4) expired on 5/30/07. She presented with the production history for this lot (Exhibit 27). According to Exhibit 27, manufacturing of bulk batch #'s (b) (4) (b) (4) (granulation batch #'s (b) (4) and (b) (4)) that were combined into finished lot # (b) (4) was performed between 6/12/05 and 8/11/05. Lot # (b) (4) was packaged from 8/13/05 to 8/18/05 and released on 8/29/05.

Exhibit 26 represents (b) (4) report (a.k.a. Quality Notification (QN) report) # (b) (4) initiated on 3/19/07 and finalized on 4/5/07. According to this Exhibit, the investigation was initiated to address complaint #'s (b) (4) It is further documented that on 3/12/07, the QA Manager was performing a trend analysis on customer complaints and discovered the two similar complaints against (b) (4) lot # (b) (4) therefore it was decided to initiate a QN investigation into the complaints. Ms. Cooper explained that it was not realized that there were two similar complaints against lot # (b) (4) due to the fact that when the sample from complaint # (b) (4) was returned it was discovered that the carton was labeled with the lot number (b) (4) that did not match the bottle labeling (lot # (b) (4) (as described above). The firm's policy at the time was to only enter (b) (4) (b) (4). Therefore when complaint # (b) (4) was received for lot # (b) (4) it was not automatically flagged as a duplicate complaint during the complaint trend analysis, which caused the delay in the decision to initiate a QN investigation.

According to Exhibit 26, packaging of (b) (4), lot # (b) (4) was completed during the (b) (4) shift on 8/12/06 on bottle packaging line (b) (b) (4) lot # (b) (4) started during the (b) shift on 8/13/06 on bottle packaging line (b) after it was cleaned and approved

by Operation and QA for further processing on 8/13/06. The investigation concluded that based on the all line clearance inspections, the set up of the packaging line, the results of all in-process inspections, the shift-to-shift challenges, and other factors it is unlikely that the event occurred at the FW plant. I pointed out to Mr. Hayes that since a lot of (b) (4) was packaged immediately prior to (b) (4) lot # (b) (4) the possibility that (b) (4) (b) (4) could have been introduced during packaging of (b) (4) lot # (b) (4) should have been entertained especially since not only one but two similar product mix-up complaints have been received against the lot. I asked Mr. Hayes if a medical evaluation was conducted to assess the risk to consumers if they were to ingest a (b) (4) as opposed to (b) (4) He indicated that this was not done. Mr. Hayes explained that it was not considered due to the fact that both (b) (4) and (b) (4) (b) (4) I asked if the risk of GI (Gastrointestinal) side effects (i.e. bleeding) was considered in individuals taking (b) (4) Mr. Hayes stated that this possibility was not considered.

On 2/14/08, I was presented with the document, entitled "Medical Assessment of (b) (4) (b) (4) (Exhibit 28). Mr. Hayes stated that this document was prepared by Andre Mann, MD, Safety Officer, OTC, Safety & Risk Management in response to my inquiry regarding the medical assessment made on 2/13/08. According to Exhibit 28, due to the fact that dosing recommendations are identical for (b) (4) and (b) (4) that (b) (4) preparations do not appear to influence the risk of major bleeding in the upper GI tract, and that there were no serious adverse events associated with (b) (4) lot # (b) (4) ingestion of (b) (4) instead of (b) (4) would not pose a clinical safety risk when taken as directed.

On 2/15/08, I was presented with QN # (b) (4) initiated on 2/13/08 and completed on 2/15/08 during this inspection (Exhibit 29). Mr. Hayes explained that this addendum to QN # (b) (4) was initiated to address my concerns regarding the conclusions made in QN # (b) (4) absence of medical evaluation, and delay in the initiation of QN # (b) (4) According to Exhibit 29, based on the addition investigation, which included the review of the Consumer Complaints Database for any additional mixed product complaints against (b) (4) lot # (b) (4) and a medical evaluation (Exhibit 28), no change is required to the original disposition decision to release the batch and no market action is to be taken against (b) (4) lot # (b) (4)

Observation 1(b)

Exhibit 30 represents the investigation report for complaint # (b) (4) received on 5/30/07. The investigation was initiated on 5/31/07 and finalized on 10/26/07. Ms. Cooper explained that the complaint was initially closed on 6/20/07 but had to be re-open to clarify/add some information relevant to the investigation. The initial closure date is documented on page 11 of the record, entitled "Audit History" for complaint # (b) (4) (Exhibit 31). According to Exhibit 30, two

different types of tablets were found in a bottle of (b) (4) lot # (b) (4) Some tablets were observed to be light orange in color and had (b) (4) marking on them and the rest of the tablets were darker in color and had (b) (4) marking on them. The sample was requested from the consumer and was received by the firm on 6/14/07. It is further documented that the examination of the returned sample revealed the bottle labeled as St. Joseph Enteric Coated Tablets, lot # (b) (4) to contain 6 light orange tablets with (b) debossed on one side. These tablets were identified as (b) (4) The rest of the tablets in the returned bottle were identified as (b) (4) (b) (4) My review of the investigation (Exhibit 30) revealed that the evaluation of products that were packaged on parallel or adjacent packaging lines during packaging of lot # (b) (4) to identify a possible source of the product mix-up was not performed. The investigation concluded that "Based on sample analysis, packaging and bulk documentation review and the absence of any prior related complaint against this batch, it cannot be determined what may have contributed to this reported incident."

On 2/15/08, Ms. Cooper presented me with an addendum to the investigation report for complaint # (b) (4) (Exhibit 32). She stated that the investigation was re-opened on 2/14/08 during this inspection to add the information on the products that ran on the adjacent packaging lines during packaging of (b) (4) lot # (b) (4) According to Exhibit 32, (b) (4) (b) (4) lot # (b) (4) was packaged on Packaging Line (b) from (b) (4) on 8/14/06 to (b) (4) on 8/15/06. It is further documented that (b) (4) lot # (b) (4) were packaged on Packaging Line (b) from (b) (4) on 8/11/06 to (b) (4) on 8/14/06. It is also documented that there was one Solid Dose Packaging Employee that performed activities for both batches. The investigation concluded that due to fact that each packaging line has physical barriers to prevent introduction of foreign product into the product stream and that each employee undergoes the on-the-job training and training in the Solid Dose Packaging SOP's that have controls to (b) (4) (b) (4) it is unlikely that the event occurred at the FW plant. According to Ms. Cooper there have been no additional mixed product complaints received against (b) (4) lot # (b) (4) which will expire on 6/30/08.

Observation 1(c)

Exhibit 33 represents the investigation report for complaint # (b) (4) received on 11/13/06. The investigation was initiated on 11/13/06 and finalized on 2/12/08. Ms. Cooper explained that the complaint was initially closed on 2/2/07 but had to be re-open to clarify/add some information relevant to the investigation. The initial closure date is documented on page 6 of the record, entitled "Audit History" for complaint # (b) (4) (Exhibit 34). According to Exhibit 33, the complainant found 2 white long tablets marked (b) (4) in a bottle of (b) (4) (b) (4) lot # (b) (4) The sample was requested from the consumer and was received by the firm on 11/30/06. It is further documented that the examination of the returned sample revealed the bottle labeled as (b) (4) ot # (b) (4) to contain 1 (b) (4) and 2 (b) (4) (b) (4) My review of the investigation report for complaint # (b) (4) (Exhibit 33)

revealed that there was no evaluation of products that were manufactured prior to production of bulk lot(s) of (b) (4) which were packaged into finished lot # (b) (4) utilizing the same processing 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) Ms. Cooper stated that both (b) (4) (b) (4) undergo the compression, coating and printing processing and therefore might share the same pieces of production equipment. The investigation (Exhibit 33) concluded that "Based on sample evidence, batch documentation review and the absence of any prior related complaints against this batch, it cannot be determined what may have contributed to this reported incident."

On 2/15/08, Ms. Cooper presented me with an addendum to the investigation report for complaint # (b) (4) (Exhibit 35). She stated that the investigation was re-opened on 2/13/08 during this inspection to add the information on the products that were processed on same processing equipment prior to manufacturing of (b) (4) lot # (b) (4) and were packaged on the adjacent packaging lines during packaging of (b) (4) (b) (4) lot # (b) (4) The investigation (Exhibit 35) identified four bulk lots (#'s (b) (4) which were packaged into finished lot # (b) (4) According to Exhibit 35, there were no (b) (4) (b) (4) manufactured immediately prior to (b) (4) bulk lots #'s (b) (4) In addition, there were no (b) (4) packaged on the adjacent packaging lines during packaging of (b) (4) ot # (b) (4)

Observation 1(d)

Exhibit 36 represents the investigation report for complaint # (b) (4) received on 11/15/06. The investigation was initiated on 11/17/06 and finalized on 4/13/07. Ms. Cooper explained that the complaint was initially closed on 1/23/07 but had to be re-open to clarify/add some information relevant to the investigation. The initial closure date is documented on page 10 of the record, entitled "Audit History" for complaint # (b) (4) (Exhibit 37). According to Exhibit 36, orange and purple tablets were found in a bottle of (b) (4) lot # (b) (4) The sample was requested from the consumer and was received by the firm on 12/11/06. It is further documented that the examination of the returned sample revealed the bottle labeled as (b) (4) lot # (b) (4) to contain 4 orange (b) (4) (b) (4) and 2 ½ purple (b) (4) flavor. My review of the investigation report for complaint # (b) (4) (Exhibit 36) revealed there was no evaluation of products that were manufactured prior to production of bulk lot(s) which was packaged into finished lot # (b) (4) utilizing the same processing 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) Ms. Cooper stated that both (b) (4) undergo the

compression processing and therefore might share the same pieces of production equipment. The investigation (Exhibit 36) concluded that "Based on sample analysis, batch documentation review and the absence of an (*sic*) prior related complaints against this batch, it cannot be determined what may have contributed to this reported incident."

On 2/15/08, Ms. Cooper presented me with an addendum to the investigation report for complaint # (b) (4) (Exhibit 38). She stated that the investigation was re-opened on 2/13/08 during this inspection to add the information on the products that were processed on same processing equipment prior to manufacturing of (b) (4) lot # (b) (4) and were packaged on the adjacent packaging lines during packaging of (b) (4) , lot # (b) (4) The investigation (Exhibit 38) identified bulk lot # (b) (4) which was packaged into finished lot # (b) (4) . According to Exhibit 38, there were no (b) (4) , manufactured immediately prior to (b) (4) (b) (4) bulk lots # (b) (4) . There was however one lot (# (b) (4) of (b) (4) packaged on the adjacent packaging line # (b) during packaging of (b) (4) lot # (b) (4) . The addendum investigation report is silent as to what impact this finding would have on the investigational conclusion. A follow up call by Mr. Hayes on 2/22/08 after the completion of this inspection revealed that (b) (4) , lot # (b) (4) was documented in the addendum investigation report in error. Mr. Hayes stated that (b) (4) (b) (4) , lot # (b) (4) (the lot in question) was packaged on packaging line # 13 from 12/2-4/05 and not (b) (4) lot # (b) (4) He confirmed that there were no lots of (b) (4) packaged on any of the adjacent or parallel packaging lines concurrently with (b) (4) (b) (4) lot # (b) (4)

Observations 1(a), (b), (c), and (d)

Exhibit 39 represents SOP (b) (4) (b) (4) , effective date 6/25/07, that was current at the time of the initiation of this inspection on 2/11/08. On 2/13/08, Mr. Hayes presented me with SOP (b) (4) entitled "(b) (4) effective date 2/14/08 (Exhibit 40, select pages). He explained that this SOP was revised during the inspection to address my concerns regarding completeness and timeliness of the complaint investigations. For example, section (b) was modified to include the requirement for the Quality Systems Manager or designee to review and approve all (b) (4) (b) (4) investigations that may require additional time. Section (b) was added to include requirements and procedures to follow when (b) (4)
(b) (4)

Discussion with Management:

During the discussion of the Form FDA-483, Inspectional Observations, Observation 1(a), Dr. Miller asked me to clarify if they should make it a requirement to conduct the medical evaluation in the case of mixed product complaints. I explained to Dr. Miller that it would have to be determined on the case-by-case basis whether a medical evaluation would be warranted. I indicated that in the case of Observation 1(a) it should have been performed since not only two mixed product complaints were received against (b) (4) lot # (b) (4) but there was packaging of (b) (4) (b) (4) lot on the same packaging line immediately prior to the product lot in question, which would increase the possibility that the product mix-up could have occurred at the FW plant. I also stated that I thought that the conclusion documented in QN report # (b) (4) that the product mix-up could not have occurred at the firm was not fully supported by the investigation.

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) (addendum # (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) bulk batch # (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.

Reference: 21 CFR 211.192

Supporting Evidence and Relevance:

Exhibit 41 represents QN report # (b) (4) initiated on 1/30/07 and finalized on 2/23/07. According to this QN, during the review of (b) (4) of the Batch Mixing record on 1/29/07, the operator observed a shortage in the addition of Purified Water, USP during mixing of (b) (4) (b) (4) bulk batch # (b) (4) on Mix Tank (b on 1/26/07. Bulk batch # (b) (4) was packaged into finished lot # (b) (4) . The firm's investigation yielded the conclusion that the observed shortage in the addition of Purified Water USP was caused by the (b) (4) (b) (4) that only occurs immediately following the (b) (4) process. According to Douglas P. Buddle, Business Unit Manager, Liquids Manufacturing, testing

performed as part of the investigation did not yield a specific root cause for this event and it was decided to schedule an on-site technical assessment by (b) (4) (Exhibit 41, page 27). According to page 26 of Exhibit 41, lot # (b) (4) was recommended to be released (Please note that lot # (b) (4) is incorrectly documented as lot # (b) (4) this error was corrected in QN report # (b) (4) which is an addendum to QN report # (b) (4) Mr. Buddle stated that the on-site assessment by (b) (4) was completed in March of 2007. As the result of this assessment and an on-going investigation by McNeil, engineering department concluded that the root cause of the (b) (4) could be attributed to the installation of a new (b) (4) on Mix Tank (b He continued that the (b) (4) (b) (4) Therefore the (b) (4) to the (b) (4) It was determined that the (b) (4) (b) (4) was causing the (b) (4) Mr. Buddle explained that the tank is situated on (b) (4) located under the (b) (4) and the location of the (b) (4) relation to the (b) (4) when the (b) (4) during and following the (b) (4) According to the Change Implementation Form for Change Control # (b) (4) was installed on (b) (4) on 10/12/06 (Exhibit 43). I asked Mr. Hayes and Mr. Buddle, whether the (b) (4) as the root cause of the incident was documented as part of the investigation and whether the batches manufactured from 10/12/06 (the date when the (b) (4)) and 1/26/07 (the date of the incident) were evaluated and this evaluation was documented as part of the event investigation. They stated that this was not done.

According to Mr. Buddle, only two products are being manufactured on (b) (4) (b) (4) . He indicated that an evaluation by the firm's Pharm Tech team concluded that in the event of (b) (4) undetected by the operators, the worst case (b) (4) (b) process) would result in a (b) (4) during manufacturing of (b) (4) during manufacturing of (b) (4) This could result in an overage of approximately (b) (4) (b) (4) for batches manufactured in LMF. Mr. Buddle stated that it was therefore concluded that this overage would have no impact on the finished product. Please refer to Exhibit 41, pages 20 and 21, for the documentation of the Pharm Tech team assessment. According to Mr. Buddle, a (b) (4) was established from the end of the (b) (4) process to the beginning of (b) (4) as part of the corrective action (Exhibit 41, page 24). Mr. Buddle explained that it was determined during the investigation that at the end of the (b) (b) (4) k should (b) (4)

Exhibit 42 represents documentation associated with Change Control (b) (4) Mr. Buddle explained that this change control was initiated in 3/07 to implement the (b) (4) (b) (4) process prior to the initiation of (b) (4) He indicated that based on the further studies performed by the firm, the (b) (4) process was (b) (4)

(b) (4) The target completion date for Change Control (b) (4) is documented as 6/30/08 (Exhibit 42, page 1).

Exhibit 44 represents QN report # (b) (4) initiated on 4/9/07 and finalized on 4/12/07. Mr. Buddle explained that this report was initiated as an addendum to QN report # (b) (4) to correct the error in batch numbers (b) (4) and to change the recommended disposition of lot # (b) (4) from the release status to the reject status.

On 2/15/08, Mr. Buddle presented me with QN report # (b) (4) initiated on 2/15/08 and finalized on 2/15/08, which he identified as another addendum to QN report # (b) (4) (Exhibit 45). Mr. Buddle stated that this document was initiated to include the root cause of the incident (b) (4)) and the assessment of the batches that were manufactured on Mix Tank (b) from 10/12/06 to 1/26/07. According to Exhibit 45, pages 5 and 6, there were (b) lots of (b) (4) processed on Mix Tank (b) from 10/12/06 to 1/26/07. It is further documented that (b) of these (b) batches were observed to be manufactured with (b) (4) process and the (b) (4) (b) (4) It was however confirmed that the (b) (4) (a worst case scenario achieved during investigation into the incident as documented above). Page 6 of Exhibit 45 documents that "There are no batches impacted as a result of failure to perform the impact statement for the (b) (4) on Mix Tank# (b) from 10/12/06 and 1/26/07."

Discussion with Management:

During the discussion of the Form FDA-483, Inspectional Observations, the firm's management agreed with this observation and there were no further comments.

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 7/26/07 (DQRS # (b) (4)

Reference: 21 CFR 211.198(b)(3)

Supporting Evidence and Relevance:

During this inspection I requested to see an investigation associated with DQRS (b) (4) (attached to this report). According to DQRS (b) (4) received by FDA on 9/26/07, on the official Tylenol website the dose for (b) (4) (b) (4)

According to Christine Wysocki, Associate Director, QA, (b) (4) (b) (4) received a call from a nurse on 7/26/07 reporting incorrect dosing for (b) (4) on the Tylenol.com website (Exhibit 46). According to Exhibit 46, which is a print out of a record from the (b) (4) database documenting the call from a nurse on 7/26/08, the complaint was incorrectly coded as (b) (4) Ms. Wysocki stated that this code does not normally transfer to the (b) (4) system, which is the (b) (4) (b) (4) that need to be investigated by the FW plant, since complaints coded as (b) (4) (b) (4) are not considered to be product quality complaints, but are rather inquiries. Since the complaint was never transferred into the (b) (4) the Complaint Coordinator wasn't aware of it and the investigation into this complaint had not been initiated.

On 7/26/07, the (b) (4) Project Manager sent an e-mail message to the Medical Communications department at McNeil to alert them of the issue, who forwarded the message on 7/26/07 to the IM (Information Management) Lead for the Custom Marketing department (Exhibit 47).

According to Mr. George, service request # (b) (4) was initiated on 7/26/07 to correct the dosing from 1.5 ml to 15 ml (Exhibit 48). This change was implemented on the Tylenol.com website on 7/27/07.

Ms. Wysocki indicated that DQRS (b) (4) was received by the firm on 10/24/07 (Exhibit 49). She indicated that the DQRS report was verbally investigated and it was determined that the change to the website had already occurred. Ms. Wysocki stated that the DQRS report was misplaced and was not entered into the (b) (4) database until 2/14/08, during this inspection.

On 2/14/08, Ms. Wysocki presented me with complaint investigation report # (b) (4) which she indicated was initiated on 2/14/08 and finalized on 2/14/08, during this inspection to address my concern regarding the firm's failure to initiate the investigation into the complaint in question (Exhibit 50).

Discussion with Management:

During the discussion of the Form FDA-483, Inspectional Observations, the firm's management agreed with this observation and there were no further comments.

REFUSALS

There were no refusals encountered during this inspection.

GENERAL DISCUSSION WITH MANAGEMENT

The following deficiency was verbally discussed with the firm's management at the conclusion of this inspection:

According to Ms. Cooper, there is currently (b) (4) QA employee that is responsible for initiating and completing investigations into customer complaints. She indicated that there is (b) (4) person to take over the duties of this (b) employee in case of her absence (due to vacation or illness). I asked Ms. Cooper, Mr. Hayes, and Mr. Bauer if this arrangement could result in delays in the initiation and/or completion of the investigations. They indicated that it is possible.

On 2/14/08, Mr. Bauer presented me with a memo dated 2/14/08 (Exhibit 51), documenting that an employee has been identified to cross train in the Consumer Complaint System to support the complaint and investigation process. Once trained this individual is expected to provide an alternate, trained resource to backfill as necessary during times of vacation or illness, or to support in the event of increased complaint volume. The employee's training in the Consumer Complaint System is expected to be completed by the end of March 2008.

SAMPLES COLLECTED

There were no samples collected during this inspection.

VOLUNTARY CORRECTIONS

Corrections implemented by the firm in response to the deficiencies verbally discussed during the previous 10/06 inspection were evaluated during the current inspection. My review of these corrective actions was unremarkable in that there were no apparent deficiencies observed.

In addition, I was presented with and verified the corrective actions instituted by the firm to address the deficiencies observed and documented on the Form FDA-483, Inspectional Observations, during the current inspection. Please refer to the OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE and GENERAL DISCUSSION WITH MANAGEMENT Sections of this report for the details of these corrective actions.

EXHIBITS COLLECTED

1. List of McNeil Companies (1 page);
2. List of Distribution Centers (1 page);
3. Product list (2 pages);
4. St. Joseph Safety Coated Aspirin Tablets labeling (1 page);
5. Concentrated Tylenol Infant's Drops labeling (1 page);
6. Organizational Charts (11 pages);
7. List of McNeil Consumer Healthcare Corporate Management Changes (1 page);
8. List of FW Plant Operations Management Changes (1 page);
9. List of FW 2008 Product Launches (1 page);
10. List of McNeil-PPC, Inc. Corporate Officers (1 page);
11. List of McNeil Consumer Healthcare Management Board members (1 page);
12. List of J&J Board of Director members (1 page);
13. List of FW Plant employees interviewed during the inspection (2 pages);
14. FW Site Diagram (1 page);
15. FW Plant floor plan (1 page);
16. Process flow diagram for St. Joseph Safety Coated Aspirin Tablets (1 page);
17. Process flow diagram for Concentrated Tylenol Infant's Drops (1 page);
18. LMF Process Flow diagram (1 page);
19. LMF Manufacturing Floor Plan and Equipment Platform Utility Piping Arrangement (1 page);
20. SOP (b) (4) (12 pages);
21. Status of FDA complaint investigations (1 page);
22. Status of FDA DQRS Investigations (1 page);
23. Memo, entitled "Market Withdrawal Summary" (2 pages);
24. Complaint investigation report # (b) (4) (3 pages);
25. Complaint investigation report # (b) (4) (3 pages);
26. QN report # (b) (4) (13 pages);

27. Batch (b) (4) history (1 page);
28. Medical Assessment memo (1 page);
29. QN report # (b) (4) (14 pages);
30. Complaint investigation report # (b) (4) (4 pages);
31. Audit History for complaint investigation report # (b) (4) (14 pages);
32. Addendum to complaint investigation report # (b) (4) (4 pages);
33. Complaint investigation report # (b) (4) (3 pages);
34. Audit History to complaint investigation report # (b) (4) (8 pages);
35. Addendum to complaint investigation report # (b) (4) (3 pages);
36. Complaint investigation report # (b) (4) (4 pages);
37. Audit History to complaint investigation report # (b) (4) (15 pages);
38. Addendum to complaint investigation report # (b) (4) (4 pages);
39. SOP (b) (4) (23 pages);
40. Select pages from SOP (b) (4) (5 pages);
41. QN report # (b) (4) (29 pages);
42. Change Control # (b) (4) (21 pages);
43. Change Implementation Form for Change Control # (b) (4) (2 pages);
44. QN report # (b) (4) (24 pages);
45. QN report # (8 pages);
46. Print out from the (b) (4) database (2 pages);
47. Copy of e-mail messages dated 7/26/07 (1 page);
48. Service request # (b) (4) (5 pages);
49. Copy of the 1st page of DQRS # (b) (4) stamped as received by the firm 10/24/07 (1 page);
50. Complaint investigation report # (b) (4) (2 pages);
51. Memo dated 2/14/08 (2 pages).

ATTACHMENTS

- Complaint #'s 57797, 56879, 55244, 41691, 40239, 39929, 39290, 39415, 39286, and 38890 received by the FDA that were covered during this inspection;
- DQRS #'s MSB- (b) (4) that were covered during this inspection;
- Form FDA-482, Notice of Inspection, dated 2/11/08;
- Form FDA-483, Inspectional Observations, dated 2/19/08.

Vlada Matusovsky

Vlada Matusovsky, Investigator