TABLE OF CONTENTS

SUMMARY

This inspection of a human drug manufacturer was conducted in response to FACTS Assignment ID # 762373, Operation ID # 2977100 as part of the FY'07 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 and an NDA Field Alert were covered during this inspection under C.P. 7356.021.

The previous 1/4-12/06 GMP inspection revealed the following deficiencies, which were documented on the Form FDA-483, Inspectional Observations, issued to the firm's management at the conclusion of the inspection: incomplete and untimely documented investigations, failure to follow SOP and no documented review and approval by the QA unit of the changes made to the laboratory sample login logbook. The inspection was classified (b) (2) Corrections implemented by the firm to address these deficiencies were assessed during the current inspection.

The current inspection revealed the following deficiencies which were 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 Solid Dose Start-Up and Packaging Inspection SOP's were not clear as to when adjustments and/or PM (Preventative Maintenance) of the embossing coder wheel would be warranted if the labeling information (i.e. lot number and expiration date) on the pouches becomes illegible. The firm's management promised corrections. There was no Form FDA-483, Inspectional Observations, issued and no samples were collected during the current inspection. Quality and Materials Systems were evaluated. Quality and raw material and packaging component receipt, inspection, sampling and disposition activities associates with Concentrated Motrin Infant Drops Oral Suspension, Flexeril (cyclobenzaprine HCl) 5 mg Tablets and Tylenol Cold Multi-Symptom Nighttime Caplet were covered. The following documentation was also reviewed during the inspection: investigations into select consumer complaints, deviation and OOS (Out of Specification)/OOT results, raw material and packaging components qualification and vendor audits, Purified Water System qualification and analytical/microbiological testing, (b) (4) inventory system validation and studies on container/closure system compatibility with finished products.

ADMINISTRATIVE DATA

Inspected firm:	McNeil Consumer Healthcare, Div of McNeil-PPC, Inc.
Location:	7050 Camp Hill Rd Fort Washington, PA 19034-2210
Phone:	215273-7000
FAX:	(215)273-4124
Mailing address:	7050 Camp Hill Rd Fort Washington, PA 19034
Dates of inspection:	10/18/2006, 10/19/2006, 10/20/2006, 10/23/2006, 10/24/2006, 10/25/2006, 10/26/2006
Days in the facility:	7
Participants:	Vlada Matusovsky, Investigator

On 10/18/06, I issued the Form FDA-482, Notice of Inspection, with attachment and presented my credentials to Maria M. Nieradka, VP, Operations, who identified herself as the most responsible individual on site at the time. Ms. Nieradka stated that she represents McNeil Consumer Healthcare corporate division. Gaston Barua, Director, Plant Operations, who was also present at the time, identified himself as the most responsible official for the FW site. John A. Salvagno, FW (Fort Washington) Plant Manager of Quality Compliance and QA Operations, Lawrence Constable, Executive Director, Operations, Tracy Cooper, QA Manager, Liquids, Tracy Panella, QA Manager, Validations, and Jerome Hayes, QA Manager, Solid Dose, were also present. Ms. Nieradka stated

that Ashley McEvoy, President, who is the most responsible official for McNeil Consumer Healthcare, was off-site at the time. I met Ms. McEvoy on 10/19/06.

Please note that on 10/19/06 I was informed that the current full legal name of the firm is McNeil Consumer Healthcare, Division of McNeil – PPC, Inc. and not just McNeil Consumer Healthcare, which was the name that was provided to me on 10/18/06 prior to issuance of the form. As the result, the Form FDA-482 (both the original and copy) was corrected on 10/19/06.

At the conclusion of the inspection on 10/26/06, a verbal discussion of the deficiencies noted during the inspection was held with the firm's management. The following individuals were present during this discussion: Ms. Nieradka, Mr. Constable, Mr. Barua, Mr. Salvagno, Ms. Cooper and Robert Miller, VP, Quality Services & Compliance (via telephone).

The firm's hours of operations are 24 hours a day, 7 days a week over 5 shifts with the first shift from 8:00 am to 4:00 pm, Monday through Friday, the second shift from 4:00 pm to 12:00 am, Monday through Friday, the third shift from 12:00 am to 8:00 am, Monday through Friday, the fourth shift from 12:00 am to 12:00 pm, Saturday and Sunday & one additional assigned weekday and the fifth shift from 12:00 pm to 12:00 am, Saturday and Sunday & one additional assigned weekday. The firm's hours of business are 8:00 am to 5:00 pm, Monday through Friday. There are currently a total of (b) (4) employees at the FW site (manufacturing plant and Corporate HQ), including (b) (4) FW Plant manufacturing and QA employees.

I confirmed the firm's current drug registration # 2510184, stamped as received by FDA on 2/26/06.

HISTORY

According to Mr. Constable the firm's history has not changed since the last 1/06 inspection, except for the following:

- In January, 2006, the firm's name changed from McNeil Consumer & Specialty Pharmaceuticals to McNeil Consumer Healthcare, Division of McNeil – PPC, Inc.;
- McNeil's plant in Round Rock, Texas has closed;
- On 6/26/06, Johnson & Johnson publicly announced its acquisition of Pfizer PHC (Pharmaceutical Healthcare) Division, which is currently awaiting FTC approval. Once approval is finalized, some organizational changes are expected within McNeil Consumer Healthcare, Division of McNeil – PPC, Inc. The firm is currently going through the integration planning.

Mr. Constable confirmed that the history of the firm documented during the previous 1/06 inspection is accurate and complete. As was reported in 1/06, 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) (4) people and manufacturing more than 75 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 110-acre 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.

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.

The firm's 2005 Gross Annual Sales associated with product processing were approximately (b) (4) (b) (4) US dollars.

INTERSTATE COMMERCE

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

JURISDICTION

Exhibit 2 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 Consumer & Specialty Pharmaceuticals FW facility from another company under NDA 17-821. Mr. Salvagno indicated that some of the firm's OTC products also have approved NDA's. NDA numbers are also listed on Exhibit 2. Mr. Salvagno stated that solid oral dosage forms (except for capsules) and liquid/suspension products are manufactured at the FW plant.

Exhibit 12, 13 & 14 represents labeling for Concentrated Motrin Infants Drops Oral Suspension 50 mg per 1.25 mL, Tylenol Cold Multi-Symptom Nighttime Caplets and Flexeril (Cyclobenzaprine Hydrochloride) 5 mg Tablets (generic and brand versions), respectively.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

Exhibit 3 represents the firm's Organizational Chart.

According to Mr. Salvagno, due to the Pfizer PHS Divisional acquisition by Johnson & Johnson which was publicly announced on 6/26/06, there have been some interim changes within the McNeil and Johnson & Johnson structural management organization. He stated that some additional changes are expected prior to and following FTC approval of the acquisition. Exhibit 4 lists the changes within McNeil Consumer Healthcare associated with the acquisition. Mr. Salvagno explained that in 10/06, Ashley McEvoy, who was the General Manager of McNeil Consumer Healthcare, became the firm's President, replacing Colin Watts.

Exhibit #'s 5 & 6 list management changes within the FW Plant Operations and QC/QA departments, respectively, since the previous 1/06 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 Christine Poon, Vice Chairman. Ms. Poon 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, Ms. Poon and Mr. Weldon 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 Drew Bradley, Manager, Process Excellence, he is responsible for development, deployment, implementation and providing strategic direction and oversight of Operational Equipment Effectiveness training, development and directing implementation of Process Excellence strategy, providing technical support across the McNeil Supply Chain and performing assessment of J&J operating companies as a member of J&J Corporate LEAN assessment team. Mr. Bradley reports to Mr. Barua.

According to Douglas P. Buddle, Solid Dose Processing Manager, he is responsible for managing the operations of the Coating, Printing and Geldipping workcenters in the FW plant. Mr. Buddle also develops business plan goals and strategies for improvement of safety, compliance, cost, and people development. Mr. Buddle 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, and Compression 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 Sipra Bond, 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 Karen Ulmer, Equipment Maintenance Manager, she is responsible for managing the Equipment Maintenance function to provide safe, compliant, reliable and cost effective processing and packaging operations that are maintained in accordance with all company and government guidelines. Ms. Ulmer reports to Mr. Barua.

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

According to Michael Liddy, Plant Projects Manager, he is responsible for managing individual project managers with responsibilities including overall project team activities, development of clear project scope and objectives, delivering and tracking critical milestones, establishing contingency plans, facilitating team decisions and ensuring individual accountability as well as issue resolution and risk management. The projects include safety, ergonomics, new product launches, new equipment upgrades and efficiency improvements. Mr. Liddy reports to Rafael Menda director of Operations Strategic Planning 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, environment compliance, site security and utilities for the FW Site. She develops goals and strategies for improvement of safety, compliance, cost and people development. Ms. Bolan reports to Mr. Barua.

FW Quality Operations

According to Robert Miller, Ph.D., VP, Quality Sciences & Compliance Division, he is responsible for setting the company's goals, priorities, and challenges. He develops policies and requirements for quality systems and processes in order to maximize GMP Regulatory Compliance. Dr. Miller has quality oversight for three McNeil Consumer Healthcare sites, FW, Lancaster, PA and Las Piedras, Puerto Rico. He also provides recommendations to company management and internal organization based on regulatory policies and expectations to ensure a clear understanding of compliance related issues. Dr. Miller is responsible for contacting internal legal resources to address critical regulatory issues. He reports to Ms. McEvoy.

According to Mr. Salvagno, 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. Salvagno also coordinates department programs where cooperation between departments is required. He represents the firm externally in matters relating to quality and compliance. Mr. Salvagno reports to Dr. Miller.

According to Mr. Hayes, he is responsible for the QA support functions for the Solid Dosage Operations, which entails review and coordination of the initiation and closure of QN (Quality Notification) Investigations, development of SOP's, 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. Salvagno.

According to Ms. Panella, she is responsible for managing the Validation Services department in the FW plant. She 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. She is also responsible for the site change control process. She develops goals and strategies for improvement validation activities, compliance and people development. Ms. Panella reports to Mr. Salvagno.

According to Ms. Cooper, she is responsible for managing the Quality aspect of Liquids manufacturing, packaging, batch records review and product release, all 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) and approval (liquid products) and FW consumer complaint process. Ms. Cooper also participates, hosts and/or leads all audits of the FW Plant. She reports to Mr. Salvagno.

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. Salvagno.

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. Salvagno.

Exhibit 7 represents a list of McNeil Consumer Healthcare Division of McNeil-PPC, Inc. corporate officers.

Exhibit 8 represents a list of McNeil-PPC, Inc. corporate officers.

Exhibit 9 represents a list of McNeil Consumer Healthcare Management Board members.

Exhibit 10 represents a list of Johnson & Johnson Board of Directors members.

Mr. Salvagno, Mr. Barua, Ms. Cooper, Ms. Panella 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 11 represents a list of FW plant employees interviewed during this inspection and the corresponding topic discussed. Please note that Mr. Hayes's name was inadvertently left out of this list. Mr. Hayes provided me with the information and documentation throughout the inspection.

MANUFACTURING OPERATIONS

According to Mr. Salvagno, the firm is a manufacturer of solid (with the exception of capsules) and liquid oral dosage forms. There are approximatel(b) (4)Bulk Product Formulas and 165 Finished Package Codes produced at the FW Plant. Major Solid Dose Processing Equipment include (b) (4) Fluid Bed Granulator, (b) (4) Fluid Bed Granulators, (b) (4) High Shear Granulators, (b) (4) (b) (4) Compression Machines, (b) (4) Coaters, (b) (4) High Coaters, (b) (4) Inclined Printers, (b) (4) Gelcap an(b) (4) Geltab Machines (for (b) (4) operations). Major Solid Dose Packaging Equipment includes (b) (4) Solid Dose Bottle Lines, (b) (4) Lines an(b) (4) Pouching Line. Major Liquids Processing and Packaging Equipment includ(b) (4) Mix Tanks (b) (4) Hold Tanks (b) (4) (b) (4)), 2 Drops Bottle Packaging Lines (b) (4) Syringe or Integrated Droppers Bottle Packaging Line an(b) (4) Suspension Bottle Packaging Lines.

Exhibit 15 represents the FW Site diagram.

Exhibit 16 represents FW Plant floor plant. According to Mr. Salvagno, the plant occupies approximately 814,000 square feet of space with approximately 449,000 square feet occupied by the manufacturing areas.

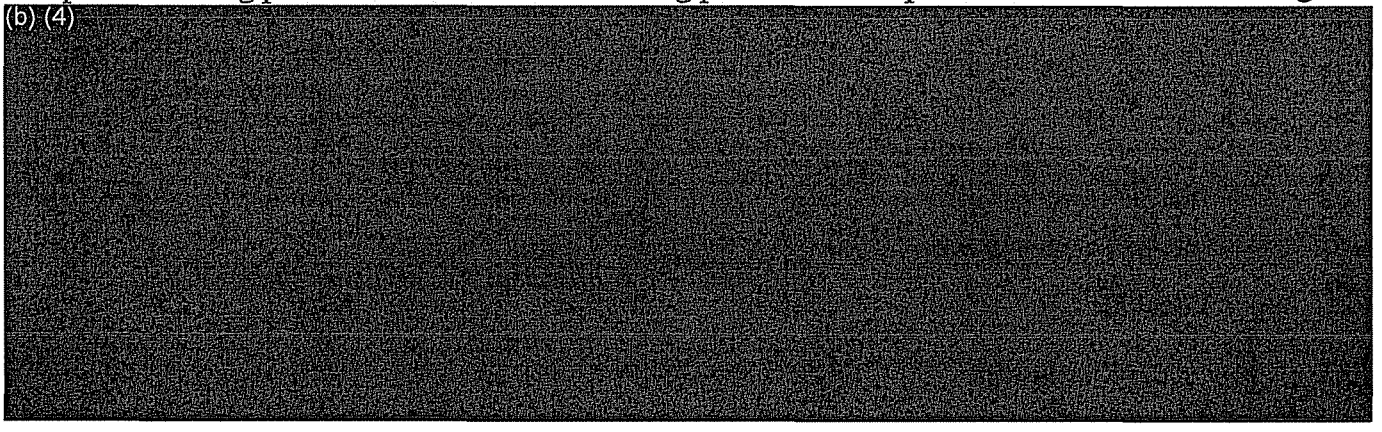
According to Robert Schlegel, Manager, Product Supply, all of the raw materials and packaging components are received and stored at the FW Main Warehouse. FW Plant Receiver inspects overall conditions of raw materials and packaging components during unloading of a trailer. All of the received materials are verified against a packaging list. A McNeil batch number is internally assigned by the SAP controlling system to each lot of raw materials and components listed on the Packaging Order (b) (4) 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 SAP electronic system. SAP QI (Quality Inspection) 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 LIMS tracking system, which generates an inspection record. 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 LIMS 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.

According to Mr. Schlegel, all of the finished products manufactured at the FW Plant are transported to the off-site (b) (4) (b) (4) Upon arrival at G&A Warehouse, shipping documents are received from the driver. The trailer seal is inspected to verify that it is intact and that the number matches the number on the Bill of Lading. Date and time of trailer unloading is recorded on the Bill of Lading. The received materials are verified to ensure that there is no damage and the shipment is reconciled against the shipping documents. The product is then moved to an assigned warehouse location. Location is verified physically and in SAP to ensure it contains only one lot of product and one SAP status. From th (b) (4) warehouse the finished goods are shipped to the firm's (b) (4) Distribution sites located in (b) (4)

Concentrated Motrin Infants Drops Oral Suspension 50 mg per 1.25 mL

Exhibit 17 represents a process flow diagram for Concentrated Motrin Infants Drops Oral Suspension 50 mg per 1.25 mL. The manufacturing process for this product consists of establishing (b) (4)



Tylenol Cold Multi-Symptom Nighttime Caplets

Exhibit 18 represents a process flow diagram for Tylenol Cold Multi-Symptom Nighttime Caplets. The (b) (4) (b) (4) is prepared in a

(b) (4) The (b) (4) Fluid Bed Granulator is (b) (4) in the following order: (b) (4) The raw materials are pre-blended and once the (b) (4) the active (b) (4) addition is started. At the completion of the (b) (4) is used to rinse the tank, pump lines and nozzle assemblies. Upon completion of the rinse cycle, the (b) (4) (b) (4) until the product temperature reaches the specified temperature. The (b) (4) (b) (4) After the granulation is dried, dry-add components (b) (4) are added, the material is passed through a (b) (4) Sieve and then blended in a tote bin blender. The granulation is then compressed on a (b) (4) tablet press. The film coating operation of the caplets is performed using a (b) (4) coating pan. The caplets are (b) (4) to an established set point. When the set point is achieved, an (b) (4) onto the (b) (4) tablet bed. After the specified amount of (b) (4) has been applied, the caplets are (b) (4) and (b) (4) The caplets are (b) (4) and discharged from the coating pan. The caplet printing process is performed using (b) (4) printers equipped with (b) (4) rolls.

Flexeril (Cyclobenzaprine Hydrochloride) 5 mg Tablets.

Exhibit 19 represents a process flow diagram for Flexeril (Cyclobenzaprine Hydrochloride) 5 mg Tablets. Granulation is manufactured using a (b) (4) granulation process in a (b) (4) unit followed by (b) (4) drying. The raw materials (b) (4) for the granulation are pre-weighed and added to the bowl of the (b) (4) unit. A (b) (4) step is used to mix the ingredients. (b) (4) (b) (4) is then sprayed on the moving product bed. This causes the powders to (b) (4) and (b) (4) The bottom (b) (4) and (b) (4) are allowed to work the granulation for (b) (4) after spraying. At the completion of the granulation process, the granulation is discharged into the (b) (4) bowl for drying. The granulation is dried to a target LOD (Loss on Drying). The granulation is then combined with (b) (4) (b) (4) The final granulation is passed through the (b) (4) (b) (4) Sieve into an (b) (4) tote bin. Finally, the granulation is blended using a (b) (4) blender. The granulation is (b) (4) on the (b) (4) The film coating operation is conducted in an (b) (4) coating pan. The tablets are pre-heated to an established set point. When the set point is achieved, an (b) (4) coating (b) (4) onto the moving product bed and dried in a continuous process. After all of the (b) (4) has been applied the product is (b) (4)

SAP Computer System.

According to Cherium (Reggie) George, QA Manager, Information Management (IM) Compliance and Rae Ann Delay, QA Director, IM Compliance, the (b) (4) client server software is installed on

(b) (4)

version (b) (4) is a current validated version. The (b) (4) modules include Production Planning-Process Industry (PP/PI), Material Management (MM), Controlling (CO), Financial Accounting (FI) and Plant Maintenance (PM). PP/PI module was implemented for bill of materials, recipes, process orders, operational strategic planning, master scheduling, tactical scheduling, detail plant floor scheduling, and material planning. MM module was implemented for material master maintenance, inventory management, purchasing inventoried items, and internal warehouse management. CO module was implemented for product cost development, standard cost budget development, and cost center accounting to support product cost and product planning. FI module was implemented for actual production accounting, and inventory valuation and management. PM module was implemented for master data maintenance of existing/new equipment, inventory, and resources; maintenance notification and work orders for processing of corrective maintenance and planning for preventative maintenance; material planning, capacity requirements planning, purchasing of materials, and cost monitoring. Exhibit 20 represents the (b) (4) system diagram. According to this Exhibit, users log into the (b) (4) which then connects via the Local Area Network (LAN) into the server that is located at the FW site data center. The Citrix server connects to the (b) (4) production database server through LAN and returns the requested data back to the user via LAN. The data is stored on the (b) (4) production data base server.

USP Purified Water (b) (4) System

Exhibit 21 represents the USP Purified Water Generation System flow diagram. According to Michael A. Vlasic, Manager, Process Engineering, the USP Purified Water (b) (4) System at the FW plant feeds incoming city water through a series of (b) (4) high efficiency prefilters to a cation bed, an anion bed and a mixed bed. The deionized water is then filtered through a (b) (4) particulate filter and (b) (4) filter and (b) (4) UV sanitizing units. The Purified Water is then fed to a (b) (4) storage tank, which delivers USP Purified Water to the facility via (b) (4) separate distribution loops. The USP Purified Water is sent through a series of UV lights before being delivered to the various points of use in the facility. The USP Purified Water is recirculated from the storage tank throug (b) (4) UV lights (b) (4) heat exchangers and the (b) (4) system, when the storage tank level reaches its fill point. This allows the water to constantly circulate through the cation, anion and mixed beds reducing the possibility of microbial growth. The heat exchangers provide cooling to the recirculation loop using chilled water. This prevents the recirculation loop from generating excessive heat from the recirculation pump and the UV lights during periods of no use. Loop pressure is maintained using a backpressure control valve at the return point. The backpressure control valves are designed to maintain operating pressure during peak flow conditions. The storage tank and the four distribution loops are sanitized every (b) (4) using an (b) (4) generator. A (b) (4) bank of UV lights, which are turned off during sanitization, serve as an (b) (4) destruction system subsequent to the loop sanitization cycle and reduce an ongoing bio-burden during normal conditions. The Microbiology Laboratory samples the USP Purified Water points of use utilized for product manufacturing (b) (4) The Microbiology Laboratory samples the

remaining points of use (b) (4) The Analytical Laboratory samples (b) (4) of use for TOC and conductivity on a (b) (4) basis.

The following documentation associated with Concentrated Motrin Infant Drops Oral Suspension, Flexeril (cyclobenzaprine HCl) 5 mg Tablets and Tylenol Cold Multi-Symptom Nighttime Caplet and other products was reviewed during the inspection: investigations into select consumer complaints, DQRS's, deviation and OOS (Out of Specification)/OOT results, raw material and packaging components qualification and vendor audits, Purified Water System qualification and analytical/microbiological testing, SAP inventory system validation, select SOP's, raw material and packaging component receipt, inspection, sampling and disposition activities and studies on container/closure system compatibility with finished products.

During the physical inspection of the plant on 10/18/06, I observed processing of the following products:

- Tylenol blend # (b) (4) in Aeromatic 1 Room;
- Extra Strength Tylenol Chewable Tablets blend lot # (b) (4) in the Dry Blend Room;
- Motrin (IB) 100 mg Children's Caplets lot # (b) (4) in Compression Room 105;
- Tylenol Cold Severe Cool Burst Caplets lot # (b) (4) in Accela Coating Room 1;
- St. Joseph Enteric Coated Aspirin lot # (b) (4) in Printing Room 1;
- Tylenol Extra Strength Caplets lot # (b) (4) in Pouching Room, Packaging Line 19;
- Children's Tylenol Plus Cold Suspension lot # (b) (4) mixing) in Room MIX-1;
- Children's Motrin (IB) Suspension Bubble Gum Flavor lot (b) (4) on Liquid Packaging Line 3.

MANUFACTURING CODES

According to SOP 20-OP-MFS-015, Version 4.0, Issuance of Batch Records at Fort Washington, effective date 6/8/06 (Exhibit 22), 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. Batch numbers for semi-finished/in-process (i.e. granulation, blend, etc.) goods are automatically created within the (b) (4) controlling system and manually assigned to the process order. It is a (b) (4) (b) (4) number, where the (b) (4) represents the (b) (4) the (b) (4) represents the (b) (4) the (b) (4) represents the (b) (4) is always (b) (4) and the remaining (b) (4) represent the (b) (4) For example, (b) (4) means that it is the (b) in-process batch manufactured in (b) (4) Batch number for finished products is a (b) (4) number, where the (b) (4) represents the (b) (4) the (b) (4) represents the (b) (4) the (b) (4) represents the (b) (4) is always (b) (4)) and the remaining (b) (4)

represent the (b) (4) For example, (b) (4) means that it is the (b) (4) finished product batch manufactured in (b) (4) in the (b) (4) plant.

According to Ms. Cooper, raw materials and components used for in-house production are also assigned batch numbers. It is a (b) (4) assigned by the (b) (4) system, where the first number represents the (b) (4) and the remaining (b) (4) represent the (b) (4) For example, (b) (4) means that it is the (b) (4) of raw material/component received in (b) (4) plant.

COMPLAINTS

During this inspection, I reviewed SOP 20-QA-QA-046, Version 3, Fort Washington Complaint Receipt and Investigation, effective date 12/14/05 and investigations into select consumer complaints dated between 1/06 and 10/06.

I also reviewed the firm's investigations into DQRS's, MSB File #'s (b) (4) (b) (4)

In addition, investigation associated with an NDA Field Alert into (b) (4) (b) (4) 18-month stability acid stage dissolution failure. Please refer to the 1/06 Establishment Inspection Report for the background information and results of the initial investigation into this failure.

My review of these documents was unremarkable in that there were no apparent deficiencies observed.

REFUSALS

There were no refusals encountered during the current inspection.

GENERAL DISCUSSION WITH MANAGEMENT

At the conclusion of the inspection on 10/26/06, a verbal discussion of the deficiencies noted during the inspection was held with the firm's management. The following individuals were present during this discussion: Ms. Nieradka, Mr. Constable, Mr. Barua, Mr. Salvagno, Ms. Cooper and Robert Miller, VP, Quality Services & Compliance (via telephone).

The deficiencies were discussed as follows:

1. On 10/19/06, during my inspection of the Analytical Laboratory I observed that (b) (4) Dissolution apparatus, bath # (b) (4) was affixed with the out of service label dated from

8/27/06. According to Mr. Bryant, the apparatus was taken out of service on 8/27/06 to be calibrated (Exhibit 23, Maintenance Logbook for DR (Dissolution Rate) (b) (4) . Mr. Bryant presented me with Calibration Work Order # 90508421 for Dissolution Rate Apparatus ID # (b) (4) executed on 8/27/06 (Exhibit 24). Mr. Bryant explained that during calibration, the result for position 6 for the Prednisone Calibrator tablet did not meet the specification of (b) (4) as required by SOP 20-QA-IPAP-043, Version 4.0, Dissolution Rate Apparatus, effective date 12/16/05 (Exhibit 25). According to page 2 of Exhibit 24, the obtained result was (b) (4) Mr. Bryant stated that according to SOP 20-QA-IPAP-043 (Exhibit 25), if dissolution fails using USP calibrator tablets, the dissolution system has to be examined and appropriate adjustments are to be made. Mr. Bryant indicated that this was performed at the time of the calibration failure but was not documented. According to SOP 99-QA-QA-021, Version 11.0, Calibration Monitoring System, effective date 12/12/05 (Exhibit 26), when the laboratory equipment is found to be out of calibration, the department using the device is required to initiate a Deviation Report immediately to investigate the out of calibration condition and determine the impact to product quality. I asked Mr. Bryant if the investigation was initiated into the dissolution apparatus calibration failure. He replied no. Mr. Bryant explained that a QN was not generated at the time of occurrence because the entire assessment/adjustments of the instrument were not complete and the nature of the failure had not yet been determined. He stated that when the internal assessment did not uncover the root cause of the calibration failure, (b) (4) Dissolution Systems vendor was called for service. (b) (4) Dissolution Systems did not come out to service the instrument until 10/5/06. Their assessment work completed on 10/8/06 did not reveal any instrument discrepancies and only minor adjustments were made (Exhibit 28, (b) (4) Dissolution Systems Lab Services Field Order and Work Report). Mr. Bryant also presented me with the Calibration Work Order for Dissolution Rate Apparatus 2876 documenting that the last successful calibration on this piece of instrument was completed on 2/28/06 (Exhibit 27). On 10/25/06, Mr. Bryant presented me with QN 605200340, which was initiated on 10/19/06 during this inspection to address the Dissolution Rate Apparatus calibration failure (Exhibit 29). He stated that this investigation revealed that the initial calibration result was found to be invalid due to the fact that the paddles on the Dissolution Rate Apparatus were allowed to be rotated during equilibration, which is discouraged by the USP certificate (Exhibit 29, pages 29 & 30). According to Exhibit 29, the Dissolution Rate Apparatus bath (b) (4) was repeated on 10/19/06 and the results were found to be within the acceptance criteria. In addition, Mr. Bryant stated that SOP 20-QA-IPAP-043 was updated to clarify the steps of when and how to initiate the investigation into the instrument calibration failure (Exhibit 30, select pages).

2. During this inspection, I reviewed Laboratory QN 605200147 into the buffer stage dissolution failure of St. Joseph Enteric Coated Tablets, lot # (b) (4) initiated on 4/12/06 and completed on 4/28/06 (Exhibit 31). The result of (b) (4) did not meet the stage 3 USP dissolution requirements of no unit less then (b) (4) The OOS result was found to be valid. According to Jennifer Nocito, Contract Quality Manager, this product lot was granulated and compressed by the FW plant; however the enteric coating operation was performed by a

contractor, (b) (4) According to COQM (Contract Operations Quality Management) Investigation Report CIR # (b) (4) (Exhibit 32), a formal request for manufacturing investigation was submitted by Ms. Nocito to (b) (4) on 4/28/06 (Exhibit 32). It is further documented that (b) (4) completed their investigation # (b) (4) on 5/11/06 (Exhibit 33). No root cause for the failure was determined. According to Ms. Nocito, on 5/16/06, she forwarded (b) (4) QIR (Quality Incident Report) (b) (4) to the FW QA/Product Assurance Manager, (b) (4) who in turn contacted FW Solid Dose Compression Manager, (b) (4) stated that although he requested a FW manufacturing investigation of the OOS, it was not initiated within (b) (4) as required by SOP 20-QA-QA-009, Version 9.0, Deviation Investigation Procedure (Exhibit 34) (b) (4) explained that the investigation was not initiated due to the fact that (b) (4) was out of the office from 5/23/06 to 5/31/06. On 5/31/06, QN 603200283 was initiated to investigate the possible root cause of the dissolution OOS at the FW plant (Exhibit 35). This investigation was completed on 9/7/06. (b) (4) stated that this QN was approved to extend beyond the (b) (4) time requirement on 6/30/06 per SOP 20-QA-QA-067, Quality Notification Monitoring, to obtained more information regarding the details of (b) (4) manufacturing investigation. (b) (4) indicated that there were no other documented (b) (4) (b) extensions to document the reason(s) for the delay in QN completion. The investigation concluded that the buffer stage failure is not a possible likely outcome of the compression or blending process. The possible root cause was theorized to be a possible blunt force trauma to the tablet during the coating and printing operations at the contractor. (b) (4) explained that based on the firm's R&D studies, the surface damage of the tablet caused by the trauma was sufficient to promote greater than normal diffusion of the acidic media across the polymeric film causing undesired hydration of non-water soluble portions of the (b) (4) thus resulting in a gelatinous mass capable of entrapping a fragment of the aspirin and retarding its release in the buffer stage. According to QN 603200283, batch (b) (4) was recommended for destruction. COQM Investigation Report was not finalized until 10/23/06 (Exhibit 32). (b) (4) presented me with SOP 23-NQA-CC-003, Version 1.0, Contract Operation Quality Management Investigation Procedure, effective date 9/29/06 (Exhibit 36) and stated that there is no specified time frame for the completion of the COQM Investigation Report. On 10/25/06, (b) (4) presented me with the revised version of SOP 23-NQA-CC-003 (Exhibit 37, select pages). She explained that this SOP now requires the CIR to be completed within (b) (4) from the receipt of hard copies of the approved investigation reports from all affected sites. In addition, SOP 20-QA-QA-067 was revised on 10/25/06 to limit QN extensions to (b) (4) and to require Plant management approval for extensions exceeding (b) (4) (Exhibit 38, select pages). SOP 20-QA-QA-009 was also updated on 10/25/06 to require concurrent investigation from the internal workcenters (FW manufacturing departments), external contractors, suppliers, etc. and addressing the investigation extensions exceeding (b) (4) Exhibit 39, select pages).

3. On 10/18/06, during my inspection of the Solid Dose Packaging department, Pouching Line 19, I observed that some of the characters and/or digits on the lot number and expiration date being embossed on the pouches containing Tylenol Extra Strength Caplets, lot # (b) (4)

expiration date 07/10, appeared to be not very legible (Exhibit 40). On 10/19/06, Mr. Salvagno informed me that the embossing wheels on the packaging line were inspected and the coding pins were found to be worn off, which was causing lighter then usual impressions on the pouches. Ms. Kruse stated that the current SOP's on the packaging equipment start-up and packaging inspection operations do not contain instructions for the operations on how to recognize illegible coding information on the pouches. These SOP's are 20-MF-PG-002, Version 34.0, Solid Dose Packaging Start-Up/Completion Procedures, effective date 8/2/06 (Exhibit 41) and 20-MF-PG-014, Version 40.0, Solid Dose Packaging Inspection Procedure, effective date 7/12/06 (Exhibit 42). On 10/26/06, Ms. Kruse presented me with revised versions of SOP's 20-MF-PG-002 (Exhibit 43, select pages) and 20-MF-PG-014 (Exhibit 44, select pages). She explained that the definition of Legibility was added to both of the procedures and the requirement to verify the legibility of the coding against the approved visual coding standard during the packaging start-up and in-process inspections was added to the corresponding SOP.

SAMPLES COLLECTED

There were no samples collected during this inspection.

VOLUNTARY CORRECTIONS

Corrections implemented by the firm in response to the deficiencies documented on the Form FDA-483, Inspectional Observations, issued during the previous 1/06 inspection were evaluated during the current inspection. Corrections of the verbal discussion items from the previous inspection were also verified. 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 discussed with the firm's management during the current inspection. Please refer to the GENERAL DISCUSSION WITH MANAGEMENT Section of this report for the details of these corrective actions.

EXHIBITS COLLECTED

1. List of McNeil Companies (1 page);
2. Product list (2 pages);
3. Organizational Charts (13 pages);
4. McNeil Consumer Healthcare Management Changes (1 page);
5. FW Plant Operations Management Changes (1 page);
6. FW Plant QC/QA Management Changes (1 page);
7. List of McNeil Consumer Healthcare Corporate Officers (1 page);
8. List of McNeil-PPC, Inc. Corporate Officers (2 pages);

9. List of McNeil Consumer Healthcare Management Board members (1 page);
10. List of J&J Board of Director members (1 page);
11. List of FW Plant employees interviewed during the inspection (3 pages);
12. Labeling for Concentrated Motrin Infants Drops Oral Suspension 50 mg per 1.25 mL (1 page);
13. Labeling for Tylenol Cold Multi-Symptom Nighttime Caplets (1 page);
14. Labeling for Flexeril (Cyclobenzaprine Hydrochloride) 5 mg Tablets (generic and brand versions) (2 page);
15. FW Site Diagram (1 page);
16. FW Plant floor plan (1 page);
17. Process Flow Diagram for Concentrated Motrin Infants Drops Oral Suspension 50 mg per 1.25 mL (1 page);
18. Process Flow Diagram for Tylenol Cold Multi-Symptom Nighttime Caplets (1 page);
19. Process Flow Diagram for Flexeril (Cyclobenzaprine Hydrochloride) 5 mg Tablets (1 page);
20. SAP System diagram (1 page);
21. Purified Water System, USP diagram (1 page);
22. SOP 20-OP-MFS-015, Ver. 4.0 (11 pages);
23. Select pages from QC Analytical Lab Maintenance Logbook for DR Bath (b) (4) (2 pages);
24. Calibration Work Order 90508421 (15 pages);
25. SOP 20-QA-IPAP-043, Ver. 4.0 (14 pages);
26. SOP 99-QA-QA-021, Ver. 11.0 (14 pages);
27. Calibration Work Order 90452222 (2 pages);
28. Varian Dissolution Systems Lab Services Field Order and Work Report (10 pages);
29. QN 605200340 (33 pages);
30. Select pages from SOP 20-QA-IPAP-043, Ver. 5.0 (6 pages);
31. QN 605200147 (18 pages);
32. CIR 2006-009 (3 pages);
33. QIR 06WJC015 (3 pages);
34. SOP 20-QA-QA-009, Ver. 9.0 (26 pages);
35. QN 603200283 (11 pages);
36. SOP 23-NQA-CC-003, Ver. 1.0 (9 pages);
37. Select pages from SOP 23-NQA-CC-033, Ver. 1.4 (4 pages);
38. Select pages from SOP 20-QA-QA-067, Ver. 1.9 (4 pages);
39. Select pages from SOP 20-QA-QA-009, Ver. 10.3 (5 pages);
40. Tylenol Extra Strength Caplets, lot (b) (4) Pouch (1 page);
41. SOP 20-MF-PG-002, Ver. 34.0 (40 pages);

42. SOP 20-MF-PG-014, Ver. 40.0 (25 pages);
43. Select pages from SOP 20-MF-PG-002, Ver. 34.5 (5 pages);
44. Select pages from SOP 20-MF-PG-014, Ver. 40.4 (6 pages).

ATTACHMENTS

DQRS report MSB File # (b) (4)
DQRS report MSB File # (b) (4)
DQRS report MSB File # (b) (4)
DQRS report MSB File # (b) (4)
Field Alert and associated documentation for (b) (4)
Tablets, lot # (b) (4)
Form FDA-482, Notice of Inspection, dated 10/18/06.

Vlada Matusovsky

Vlada Matusovsky, Investigator