

RELEASE

Reviewed by: [Signature] 5/10/2010  
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SUMMARY

*This section of the report was written by Investigator Whetstone.*

This inspection of a human drug manufacturer was conducted in response to FACTS Assignment ID # 976293, Operation ID # 3853339 as part of the PG 9M FY'09 Drug 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 2/11-15 and 19/08 inspection resulted in the issuance of the Form FDA-483, Inspectional Observations, for the following cGMP deficiencies: incomplete investigations into complaints and manufacturing deviations and formal investigation into a complaint was not initiated. The following deficiency was verbally discussed with management: lack of adequate number of employees trained to perform complaint investigations in a timely manner. A Form FDA-483,

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Inspectional Observations, was issued to the firm and the inspection was classified [REDACTED]. Corrections from the previous inspection were verified during the current establishment inspection. b2

The current inspection revealed the following deficiencies, which were documented on the Form FDA-483, Inspectional Observations: incomplete investigations into contamination of raw material [REDACTED] and manufacturing deviations and formal investigation into a complaint were not initiated. The firm's management promised corrections. Quality and Laboratory systems were assessed. The inspection focused on quality activities associated with Children's Motrin Suspension, Zyrtec Sugar-Free Syrup Bubblegum Flavor and Benadryl Allergy and Cold KapGels. No refusals were encountered during this inspection. Documentary sample # 536243 was collected to document the interstate movement of Tylenol Infants' Drop Dye Free Cherry Suspension, Lot # [REDACTED]. b4 b4

*End Investigator Whetstone*

#### 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: 5/19/2009, 5/20/2009, 5/21/2009, 5/22/2009, 5/26/2009, 5/27/2009,  
5/28/2009, 5/29/2009, 6/4/2009  
Days in the facility: 9  
Participants: Vlada Matusovsky, Investigator  
Hala L. J. Whetstone, Investigator  
Linda M. Hoover, Investigator  
George Pyramides, Chemist

*This section of the report was written by Investigator Hoover.*

*This section of the report was written by Investigator Hoover.*

Investigators Matusovsky, Whetstone, Chemist Pyramides and I (Investigator Hoover) issued a Form FDA-482, Notice of Inspection and presented credentials on 5/19/09 to Lawrence R. Constable, Vice

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President of Manufacturing, North American OTC who identified himself as the most responsible corporate official on-site at the initiation of the inspection. Jerome J. Hayes, Associate Director of Quality, Paul-Michel DiPaolo, Senior Director of QA, and Pragnesh Desal, Team Leader QA, were also present. All FDA representatives were present at the firm for the duration of the inspection except for Investigator Matusovsky who was absent on 5/22/09.

Gaston G. Barua, Director of Plant Operations, arrived later on 5/19/09 and identified himself as the most responsible person for the Fort Washington (FW) site. Both Mr. Constable and Mr. Barua were present for all days of the inspection.


Mr. Constable stated that Peter B. Luther, President of McNeil Consumer Healthcare, 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 the issuance of the Form FDA-482, Notice of Inspection. Mr. Luther introduced himself on 5/20/09.

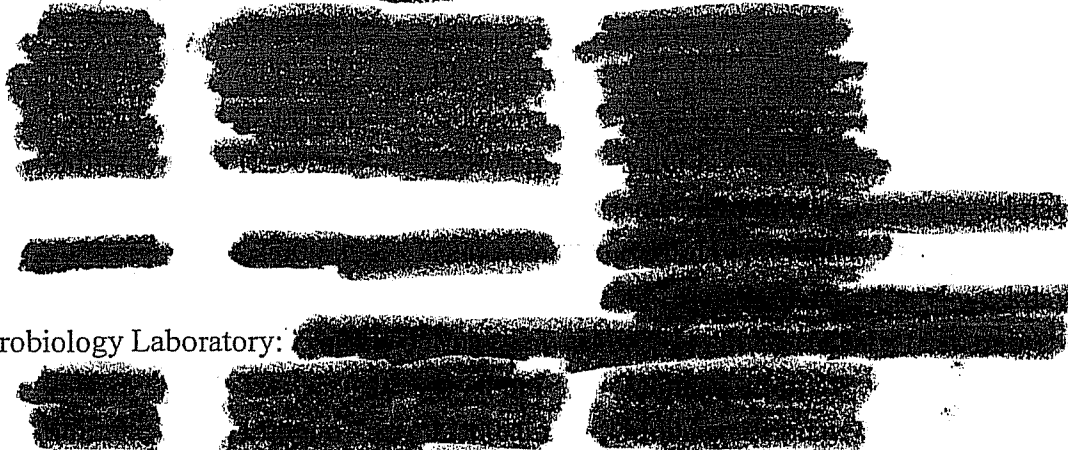
Correspondence should be sent to Timothy Bauer, Fort Washington (FW) Quality Site Leader, at the above address. He initiates the process for handling all correspondence received according to their QA Internal Distribution protocol.

On 6/4/09, the Form FDA-483, Inspectional Observations, was issued to Mr. Luther. Also present were Mr. Constable, Mr. Barua, Mr. Bauer, Mr. Hayes, Mr. DiPaolo, Maria Nieradka, Vice President, North American Supply Chain for McNeil, and Robert Miller, Ph. D., VP, Global QA OTC. Representing the FDA were Investigators Matusovsky, Whetstone, Hoover, and Chemist Pyramides.

The firm's hours of operations are as listed below:

Hours of Business: 8:00 am - 5:00 pm Monday - Friday

Production: 7 days a week over 



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[REDACTED]  
Analytical Laboratory ("Wet Lab") [REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

} b4

According to Mr. Barua, there are currently a total of approximately [REDACTED] employees at the FW site (manufacturing plant and Corporate HQ), including [REDACTED] FW Plant manufacturing and QA employees (with plans to reduce this latter number to approximately [REDACTED] in the near future). Exhibit LMH-1 represents a breakdown of the "Fort Washington Plant Headcount."

b4  
b4  
b4

According to Mr. Barua, the breakdown of managers is as listed below:

Manufacture of Liquids:	[REDACTED] Team Leaders	[REDACTED] Manager	b4
Solid Dose Processing	[REDACTED] Team Leaders	[REDACTED] Manager	b4
Solid Dose Packaging:	[REDACTED] Team Leaders	[REDACTED] Manager	b4
Planning / Warehouse:	[REDACTED] Leaders	[REDACTED] Managers	b4
Maintenance:	[REDACTED] Maint Mgrs	[REDACTED] Manager	b4
QA (not labs):	[REDACTED] Team Leaders	[REDACTED] Manager	b4
QC Analytical Lab:	[REDACTED] Team Leaders	[REDACTED] Manager	b4
Microbiology Lab:	[REDACTED] Team Leader	[REDACTED] Manager	b4

Robert Jerez, QA Manager, Compliance provided a copy of the current drug registration FEI # 2510184 / ID # 002347102 in the form of a printout from electronic submission entitled "Drug Firm Annual Registration Status" which shows "Current Registration Year" of 2009 (Exhibit LMH-2).

According to Mr. Barua, the annual volume of sales for this plant is approximately [REDACTED] for 2008 but he expects a lesser amount for 2009 due to the recent economic downturn.

b4

End Investigator Hoover.

**HISTORY**

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Mr. Barua confirmed that the history of the firm documented during the previous 02/2008 inspection is accurate and complete. As was reported in the 02/2008 establishment inspection report, McNeil Consumer Healthcare, Division of McNeil – PPC, Inc., can trace it's 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 1950's, McNeil Laboratories had become a national company, employing more than [redacted] people and manufacturing more than 75 products. b4

In 1955, McNeil Laboratories introduced 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 113-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.

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

McNeil consumer Healthcare, is a diversified OTC 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. They no longer market the ADHD-focused CONCENTRA as McNeil Consumer Healthcare now reports to the Consumer Sector and has pulled away from the pharmaceutical sector. According to Mr. Constable there are several McNeil facilities in addition to FW which include those McNeil Consumer Healthcare facilities located in Lancaster, PA, Las Piedras, Puerto Rico, and Guelph, Ontario, Canada. Exhibit LMH-3 represents the addresses of the firm's related facilities as "McNeil Companies".

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

McNeil Consumer Healthcare is one of the many Johnson & Johnson companies that handles consumer healthcare products. The Johnson & Johnson Worldwide Corporate Headquarters facility is located in New Brunswick, NJ and Johnson & Johnson Consumer Products, Inc., Headquarters is located in Skillman, NJ. Exhibit LMH-3 represents a list of Johnson & Johnson Corporate and Consumer Sector Office locations. According to Mr. Barua, Johnson & Johnson owns

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approximately [redacted] companies in several countries. Exhibit LMH-4 represents the "Subsidiaries". Exhibit LMH-5 represents the "List of countries where McNeil Consumer Healthcare does business" of which some are "sales only" and do not manufacture. b4

According to Mr. Barua there have been no changes to the firm's history of business since the 2/2008 inspection except for the organizational changes within McNeil Consumer Healthcare, Division of McNeil-PPC, Inc. and the completion of the addition of the Pfizer PHC products which were implemented in approximately 12/06.

*End Investigator Hoover.*

### INTERSTATE COMMERCE

*This section of the report was written by Investigator Hoover.*

According to Mr. Barua, approximately [redacted] of the firm's products go to a Distribution Center outside of Pennsylvania and [redacted] go to a Distribution Center within Pennsylvania. He stated that, including the products that are distributed from the Pennsylvania Distribution Center to other states, approximately [redacted] of the firm's products are sold outside of Pennsylvania. b4  
b4  
b4

Mr. Barua confirmed that all of the products manufactured at the FW Plant are transported to the off-site [redacted] Warehouse, located in Fort Washington, PA. From the [redacted] Warehouse the products are shipped to the firm's [redacted] Distribution sites located in Tobyhanna, PA, Olive Branch, MS, and Fontana CA. Mr. Barua provided a list of the addresses of the "Distribution Centers and Warehouse" hand wrote this title across the top of the page (Exhibit LMH-7) b4  
b4

*End Investigator Hoover.*

### JURISDICTION

*This section of the report was written by Investigator Hoover.*

Exhibit LMH-8 represents a list of the products manufactured and / or packaged at the FW plant. Mr. Barua provided the list, calling it the [redacted] and stated that [redacted] represents the finished good code which can be cross-referenced with the [redacted]. According to Mr. Barua, all of the products produced by the firm are OTC pharmaceuticals with the exception of Flexeril 5 mg and 10 mg tablets which is the only prescription product. This product was acquired by the McNeil FW facility from another company under [redacted] (J&J PRD NDA). Exhibit LMH-9 b4  
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represents a "List of NDA/ANDA that tie in Fort Washington" with product descriptions and FW responsibility.

Exhibit LMH-10 represents a list of "New Product Launches" for 2009.

Exhibits LMH-11, LMH-12, and LMH-13 represent labeling for the products listed below, respectively. These are examples of labels of McNeil Healthcare products. The labels were defaced by Mr. Barua, according to their protocol.

- Children's Motrin, Oral Suspension, 100 mg per 5 ml, 4 Fl. Oz., Berry Flavor.
- Benadryl, Severe Allergy Plus, Sinus Headache, 20 caplets.
- Children's Zyrtec Allergy, 1 mg / ml oral solution, 4 Fl. Oz., Bubble Gum Syrup

*End Investigator Hoover.*

#### INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

*This portion of the report was written by Investigator Hoover.*

Exhibit LMH-14 represents the firm's Organizational Charts. They were provided by Mr. Barua who highlighted specific personnel to demonstrate relationships. These Organizational Charts include Corporate Officers, McNeil Consumer Healthcare Management Board Members, and Johnson & Johnson Board of Directors Members.

According to Mr. Barua there have been some changes within the McNeil and Johnson & Johnson structural management organization. Exhibit LMH-15 lists the "Management Changes after February 2008".

According to Peter B. Luther, President of McNeil Consumer Healthcare, on 5/20/09, he is the most responsible official on-site representing McNeil Consumer Healthcare Corporate Division. He confirmed that he 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. Mr. Luther 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. Mr. Luther's office is located at the FW site. Ms. Goggins', Mr. Robinson's and Mr. Weldon's offices are located at the Johnson & Johnson Corporate Headquarters.

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According to Maria Nieradka, Vice President, North American Supply Chain for McNeil, who introduced herself on 5/26/09, she was out of the country at the time of the initiation of this inspection. She stated 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. She stated she is also responsible for supply and demand planning. Ms. Nieradka reports to Mr. Luther. She stated that she is part of Mr. Luther's Management Board.

According to Mr. Constable, he is responsible for overall oversight of all manufacturing for all sites in North America which include Fort Washington, PA, Lancaster, PA, Las Piedras, PR, and Guelph, Canada. He is responsible for all manufacturing activities they pertain to the North American network. He is also the manufacturing liaison to the Management Board and the most responsible operations leader for all manufacturing within the network. He reports to Ms. Nieradka.

### **FW Plant Operations**

According to Mr. Barua, he is the most responsible individual and top executive of the FW Operations. 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, 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. He leads the tactical and strategic site specific activities. Mr. Barua reports to Mr. Constable.

According to Mr. Barua, the personnel responsible for the production lines are the Team Leaders for each line; the Liquid train and the Solid train. The Team Leaders supervise all employees and activities in their work center to ensure compliance with GMPs, safety, environmental and quality standards, production schedules, labor relations, and employee performance. The Team Leaders report to Mr. Barua. Group Leaders report to the Team Leaders. Group Leaders aid in resolving any technical related issues related to the manufacture of the product to ensure meeting the daily production schedules under the GMP guidelines.

According to Robert Washington, Manager, Process Excellence & Project Management, he is responsible for identifying, delivering and managing process performance improvements 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. Washington is 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



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individual accountabilities as well as issue resolution and risk management. Mr. Washington reports to Mr. Barua.

According to Brian Lipsitz, he was the Interim Manager, Process Excellence & Project Management with the above-described responsibilities during the inspection of 02/2008 and is currently a Project Manager in Projects Operations.

According to James W. Moore, Manager, Solid Dose Processing, he is responsible for managing the Solid Dose Processing operations for Chemical Weighing, Granulation, Compression, Coating, and Printing in the FW plant. He also develops goals and strategies for improvement of safety, compliance, cost and human development. Mr. Moore reports to Lauren Kruse.

According to Mr. Barua, Michael Faughy, Manager, Solid Dose Processing during the 2/2008 establishment inspection, transferred to engineering.

According to Lauren Kruse (a.k.a. Lauren Kruse-Kedzierski) Solid Dose Business Unit Manager, (formerly the Solid Dose Packaging Manager) she is responsible for managing the operations of the Solid Dose Processing and Packaging areas in the FW plant, which includes the bottling, blistering, pouching, granulation, compression, coating, printing, and geldipping technologies. Ms. Kruse reports to Mr. Barua.

According to Douglas P. Buddle, Solid Dose Packaging and Geldip Manager, he is responsible for managing the operations of the Solid Dose, Geldipping, and Packaging areas in the FW Plant, which includes the bottling, blistering, and pouching technologies. He develops goals and strategies for improvement of safety, compliance, cost, and human resources. He partners with Quality Engineering, Planning, and Human Resources to develop and execute the strategies for the Solid Dose and Packaging areas of the FW plant. During the 2/2008 establishment inspection, Mr. Buddle was Acting Business Unit Manager, Liquids Manufacturing while Sipra Bond was on leave. Mr. Buddle reports to Ms. Kruse.

According to Sipra Bond, Business Unit Manager Liquid Manufacturing, she is responsible for managing the operations of the Liquids, Mixing, and Packaging areas in the FW Plant. She develops goals and strategies for improvement of safety, compliance, cost, and human resources. She partners with Quality Engineering, Planning, and Human Resources to develop and execute the strategies for the Liquid Manufacturing, Mixing, and Packaging areas of the FW plant. Ms. Bond reports to Ms. Kruse.

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. Mr. Lugo heads the Supply Planning Organization which is in charge

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of ordering raw materials and ingredients. He receives the specifications for the raw materials and ingredients from QA, based on R&D and Pharmaceutical Technology. 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 Mr. Barua. He also reports to Hakan Erdamir, Product Supply Director, who reports to Ms. Nieradka. (During the 2/2008 establishment inspection, Hakan Erdamir's position was held by Rick Olsen who is now in charge of the SAP System, as Director of Supply Chain Access and Reporting (National).

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 G&A satellite warehouse, including the receipt, inspection, storage, and removal of raw materials including chemicals and components, and the movement of finished goods from the FW plant to the G&A warehouse facility. If rejected materials are to be destroyed, Mr. Wilkerson witnesses the destruction of the materials after the Destruction Order is approved by QA. In addition, Mr. Wilkerson manages the operations that coordinate the movement of finished goods from the G&A warehouse to the approved Johnson & Johnson distribution centers. Mr. Wilkerson reports to Juan Carlos Lugo.

According to Holly Bolan, Plant Engineering Manager, she is responsible for managing the facilities of the FW Site including the FW Manufacturing Maintenance Department and Maintenance Engineering. She oversees the areas of housekeeping, grounds maintenance, site security and utilities, mail services, air handling system, 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, and human development. Ms. Bolan 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. He stated that he is responsible for the release of products for distribution. Dr. Miller reports to Peter Luther.

According to Paul-Michel DiPaolo, Senior Director, QA, OTC, US/PR, he is responsible for the oversight of QA/QC activities at US and Puerto Rico manufacturing sites and other sites outside of the U. S. He ensures that site personnel are adequately trained and versed in regulatory requirements. Mr. DiPaolo provides guidance to the Site Quality Leaders and assists them in developing and maintaining quality systems and processes to optimize GMP Regulatory

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Compliance. He is responsible for ensuring continuous enhancement of existing quality compliance systems and communicating of the GMP regulatory concerns to the firm's management. Mr. DiPaolo reports to Dr. Miller.

According to Timothy Bauer, Quality Site Leader, 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 products. 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. DiPaolo.

According to Jerome Hayes, Associate Director of QA, he is responsible for the QA support functions for the Solid Dosage and Liquid Operations, which entails review and coordination of the initiation and closure of QN (Quality Notification) Investigations, development of SOPs, implementation / enhancement of quality systems and leading of Quality Personnel that support the plant operations. He is in charge of day to day operational oversight for Quality issues and is an alternate Site Leader for Quality. Mr. Hayes is also a site contact for the DEA. He reports to Mr. Bauer.

According to Edward Chan, QA Manager, Validation, he is responsible for managing the Validation Services Department, Quality Systems, Change Control, training (overseeing ComplianceWire computerized training system), Complaint Systems, and Annual Product Review Compilation in the FW plant. He manages the group responsible for review and approval of all validation and qualification documents for the FW site from a quality perspective. This includes all process validations, equipment qualification, facilities / utilities qualification and cleaning validation. He develops goals and strategies for improvement validation activities, compliance, and human development. Mr. Chan reports to Mr. Bauer.

According to Robert Jerez, QA Manager, Compliance, he is responsible for managing the Quality aspects of the supplies / components entering the Sampling and Inspection Department, oversight of retained Samples of finished packaged products and chemical components, label issuance and control process, approval of QN Investigations. He also participates, hosts and / or leads all audits of the FW plant. He reports to Mr. Bauer.

According to Mr. Barua, the person who held the position of QA Manager, Compliance at the time of the 2/2008 establishment inspection, Tracy Cooper, transferred to Central QA as Associate Director, Quality on 1/19/09.

According to Frederick Bryant, QA Manager, Analytical Laboratory, he is responsible for analytical testing of raw materials, bulk and finished products, oversight of marketed products stability testing

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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, QA Microbiology Laboratory Manager, he is responsible for managing the QC Microbiology 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 tactical advisor during regulatory audits and representing the firm on matters relating to Microbiology. Mr. Bonilla reports to Mr. Bauer.

### General

According to Mr. Barua, training is coordinated by the Site Trainer, Courtney Harris. He stated the SOP for training in each Department is written by each Department and then reviewed and approved by QA.

According to Mr. Barua, any functional head has the authority to purchase equipment. The responsibility for the maintenance, calibration, and repair of the equipment belongs to Maintenance. While Maintenance is responsible for the overall Calibration System, the Laboratories and the Sampling & Inspection Department are responsible for calibrating their own equipment. The equipment is logged into the [REDACTED] system. b4

According to Mr. Barua, production and production schedules are developed by the Supply Planning Team and the National Planning Team which forecasts product demand. The schedule sets the priority for what products are to be manufactured, however, if there is a sudden high demand for a product, it will be moved up on the production schedule.

According to Mr. Barua, the QA department is responsible for reject and rework.

According to Mr. Barua, the personnel who run the equipment are responsible for cleaning the equipment with a few dedicated to totes. An outside contractor is used to clean the overall plant. There are verification processes in place and SOPs for the manufacturing processes and records which demonstrate effective cleaning.

According to Mr. Barua, the Regulatory Department is responsible for the content of labels. The Supply Team is responsible for ordering the labels through the [REDACTED] system. There is a computerized labeling check system which involves the overlay of labels received over approved b4

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label templates called the [REDACTED]. The labels are secured and reconciled according to SOP. b4

According to Mr. Barua, the personnel responsible for the formulation of the firm's products are the Pharmaceutical Tech Group. They are also in charge of validation and change control.

Mr. Bauer, Mr. Barua, Mr. Jerez, and Mr. Hayes accompanied us during the inspection and provided us with most of the essential information and documentation. If further explanation was needed they referred us to the appropriate individuals in accordance with their respective area of expertise. Exhibit LMH-16 represents a list of FW plant employees interviewed during this inspection and the corresponding topic discussed.

*End Investigator Hoover.*

*This portion of the report was written by Chemist Pyramides.*

The following individuals provided me with the requested information and documentation during this inspection:

- Gaston Barua, Director Plant Operations, McNeil Consumer & Specialty Pharmaceuticals. Mr. Barua was present through out the inspection.

- Timothy A. Bauer, QA/QC Plant Manager, McNeil Consumer Healthcare. Mr. Bauer was present through out the inspection and provided information regarding the Laboratory Operations, Plant Operations including the Purified Water System. Mr. Bauer arranged for many of the firm staff with specific background information to discuss the various topics with me.

- James V. Corrigan, Manufacturing Dept. Manager, Facilities Projects, McNeil Consumer Healthcare. Mr. Corrigan was present during the engineering discussions relating to the plant infrastructure and provided schematics and diagrams of the purified water systems that are in place in the production and laboratory areas of the plant.

- Frederick Bryant, Manager Analytical QC Laboratory, McNeil Consumer Healthcare. Mr. Bryant was present during most of the discussions relating to chemical/physical analysis of raw materials and finished dosage forms.

- David R. Bonilla, Microbiology Manager, McNeil Consumer Healthcare. Mr. Bonilla is the Director of the Microbiology Laboratory and he provided information about the [REDACTED] instrument used to determine unknown microbes to the genus level. b4

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- Lawrence R. Constable, Vice President, Manufacturing North American OTC, McNeil Consumer Healthcare. Mr. Constable was present during the morning discussions and afternoon wrap up meetings. Mr. Constable was present during the walk through review of the Research & Development areas at the site.
- Paul-Michel DiPaolo, Senior Director Quality Assurance, McNeil Consumer Healthcare. Mr. DiPaolo was present during the morning discussions and afternoon wrap up meetings.
- Peter Luther, President, McNeil Consumer Healthcare. Mr. Luther made a short presentation during the inspection and was present during the close out meeting.
- Holly Bolan, Manager Plant Engineering, McNeil Consumer Healthcare. Ms. Bolan was present during the purified water system engineering discussions and provided documents relating to the filter and valve types used on the purified water system.
- Etienne J. Mapily, Utilities Manager, McNeil Consumer Healthcare. Mr. Mapily was present during the detailed walk through review of the purified water system. Mr. Mapily provided technical information regarding the purified water system.
- Pragnesh Desai, Team Leader Quality Assurance, McNeil Consumer Healthcare. Mr. Desai acted as the scribe and assisted with the document requests. Mr. Desai also provided information relating to the Out Of Specification (OOS) Investigations he was personally involved with.
- Bob Wilkerson, Warehouse Manager, McNeil Consumer Healthcare. Mr. Wilkerson was present during the walk through of the warehouse areas and provided detailed information regarding warehouse operations. Mr. Wilkerson also was present during an audit of several raw materials and determined the physical locations of the materials. He arranged for his staff to move the materials from the upper rack storage locations to allow us a closer look at the labels.
- Scott Monks, Quality Assurance Team Leader, McNeil Consumer Healthcare. Mr. Monks was present during the warehouse walk through.
- Com Miece, Senior Inspector, Sampling & Inspection/Warehouse, McNeil Consumer Healthcare. Mr. Miece demonstrated the [REDACTED] used to verify labels used in the production areas during the warehouse walk through.

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- Mike Chendorain, Materials Services Specialist, Sampling & Inspection/Warehouse, McNeil Consumer Healthcare. Mr. Chendorain was present during the warehouse walk through and provided information regarding the [REDACTED] area procedures. b4

- Lauren Kruse, Business Unit Manager, McNeil Consumer Healthcare. Ms. Kruse was present during the warehouse walk through; she provided information regarding the [REDACTED] area procedures. b4

- Jim Moore, Manufacturing Department Manager, Solids Dosage Processing, McNeil Consumer Healthcare. Mr. Moore was present during the warehouse walk through; he provided information regarding the [REDACTED] area procedures. b4

- Jack Nouri, Liquid Mixing Team Leader, Operations, McNeil Consumer Healthcare. Mr. Nouri was present during all Liquid Products physical reviews in the liquids production areas.

- Eric Hilton, Gel Dip Operations, McNeil Consumer Healthcare. Mr. Hilton was present during the physical review of the Gel Dip production areas and provided information regarding the [REDACTED] tablet coating equipment. b4  
b4

- Doug Buddle, Manufacturing Department Manager, McNeil Consumer Healthcare. Mr. Buddle was present during the physical review of the packaging area operations.

- Mike Butler, Liquids Production Area Team Leader, McNeil Consumer Healthcare. Mr. Butler was present during the physical review of the packaging area operations.

- Sipra Bond, Business Unit Manager, Liquids Packaging, McNeil Consumer Healthcare. Ms. Bond was present during the physical review of the liquids production area operations. Ms. Bond also provided information regarding all liquids production business practices and operations.

- Tanner Lauderbaugh, Liquids Production Engineering Team Leader, McNeil Consumer Healthcare. Mr. Lauderbaugh was present during physical reviews of the liquids production areas.

- Tracey Shultz, Quality Assurance Marketed Products Stability Coordinator, McNeil Consumer Healthcare. Ms. Shultz was present during the Stability Chamber physical reviews. Ms. Shultz provided information regarding the stability sample storage processes.

- Bryan Hill, Research & Development Laboratory Technician, McNeil Consumer Healthcare. Mr. Hill was present during the Stability Chamber physical reviews. Mr. Hill provided information regarding the stability sample storage processes.

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- Marilia Cavaco, Director of Compliance, Global Quality Assurance, OTC/Nutritionals, McNeil Consumer Healthcare. Ms. Cavaco was present during the discussions with the Information Technology group and provided information regarding the computer Local Area Network and electronic [REDACTED] b4

- Bethany Fish, Processing Team Leader, McNeil Consumer Healthcare. Ms. Fish was present during the physical reviews of the Gel Coat areas and provided information regarding the purified water sampling ports in the production areas.

- Bryan Mummal, Quality Assurance Laboratory Team Leader, McNeil Consumer Healthcare. Mr. Mummal was present during the Chemistry Quality Control Laboratory physical review.

- Sherri Gregg, Quality Assurance Laboratory Team Leader, McNeil Consumer Healthcare. Ms. Gregg was present during the Chemistry Quality Control Laboratory physical review.

- Bob Miller, Vice President Global Quality Assurance OTC Products, McNeil Consumer Healthcare. Mr. Miller stopped in to the conference room where I was working to introduce himself on May 21, 2009. Mr. Miller was also present during the final close out meeting.

- Matt Johns, Fort Washington Site LIMS Administrator, McNeil Consumer Healthcare. Mr. Johns was present during the Quality Control Laboratory [REDACTED] discussion. b4

- John Geist, Quality Assurance Central Organization Analytical Services, McNeil Consumer Healthcare. Mr. Geist supports the [REDACTED] operations at three sites including the Fort Washington site and was present during the [REDACTED] discussions. b4 b4

- Thomas Abramek, Information Management, McNeil Consumer Healthcare. Mr. Abramek was present during some of the computer system discussions.

- Kimberly Bui, Information Technology, McNeil Consumer Healthcare. Ms. Bui was present during some of the computer system discussions and provided information regarding the computer networked [REDACTED] b4

- Claudia Bernada, System Administrator for all [REDACTED] Ms. Bernada provided information regarding the server end of the [REDACTED] b4 b4

- Rudy Fox, System Administrator for all [REDACTED] Mr. Fox provided information regarding the server end of the [REDACTED] b4 b4



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- John Humble, Employee Service Delivery Director, McNeil Consumer Healthcare. Mr. Humble provided information regarding the computer systems minimum requirements for all users at the Fort Washington site.

- Gerard P. McNally, Vice President Research & Development, McNeil Consumer Healthcare. Mr. McNally was present during the discussions regarding the R & D group.

- Thomas Markey, Head of Pharmaceutical Technology, McNeil Consumer Healthcare. Mr. Markey was present during the discussions regarding the Pharmaceutical Technology group.

- Minoj Shaw, Senior Director Research & Development, McNeil Consumer Healthcare. Mr. Shaw was present during the physical review of the R & D laboratory and production areas.

- David Rodgers, Research Fellow Research & Development, McNeil Consumer Healthcare. Mr. Rodgers was present during the R & D physical review of the R & D Laboratories and provided information regarding the analytical testing equipment.

- Eleanor Freeman, Manager Stability Research & Development, McNeil Consumer Healthcare. Ms. Freeman was present during the R & D physical review of the R & D Laboratories and provided information regarding the analytical testing equipment.

- Michael Nee, Operation Validations, McNeil Consumer Healthcare. Mr. Nee was present during the purified water system discussions.

- Edward Chan, Quality Assurance, McNeil Consumer Healthcare. Mr. Chan was present during the purified water system discussions.

- Robert Jacobs, Operations, McNeil Consumer Healthcare. Mr. Jacobs was present during the purified water system discussions.

- Kelly Culbertson, Pharmaceutical Technology, McNeil Consumer Healthcare. Ms. Culbertson was present during the discussions regarding investigations into product failures.

- William Witta, Operations, McNeil Consumer Healthcare. Mr. Witta was present during discussions regarding the purified water systems.

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- Robert Reenhalgh, Quality Assurance Team Leader, McNeil Consumer Healthcare. Mr. Reenhalgh was present during discussions regarding investigations into product failures.

- Doug Errett, Operations Validations, McNeil Consumer Healthcare. Mr. Errett was present during discussions regarding the purified water systems.

- Michael Lash, Manager Research & Development, McNeil Consumer Healthcare. Mr. Lash was present during discussions regarding the follow up complaint. He provided documentation in regards to the complaint follow up.

Lauren Longhitano, Director Product Development Quality Assurance, McNeil Consumer Healthcare. Ms. Longhitano was present during discussions regarding the follow up complaint. He provided documentation in regards to the complaint follow up.

- John Rateike, Analytical Services Quality Assurance Team Leader, McNeil Consumer Healthcare. Mr. Rateike was present during discussions regarding the follow up complaint. He provided documentation in regards to the complaint follow up.

*End Chemist Pyramides.*

## OPERATIONS

*The following portion of this section of the report was written by Investigator Hoover.*

According to Mr. Barua, the firm is a manufacturer of solid (with the exception of capsules) and liquid oral dosage forms. There are approximately [REDACTED] Bulk Product Formulas (with the recently added [REDACTED] products included) and [REDACTED] Finished Packaged Codes produced at the FW plant. Major Solid Dose Processing Equipment includes [REDACTED] (for gelpipping operations). Major Solid Dose Packaging Equipment includes 3 Solid Dose Bottle Lines, and [REDACTED] Blister Lines [REDACTED]. Major Liquids Processing and Packaging Equipment includes [REDACTED] Mix Tanks [REDACTED] Hold Tanks [REDACTED] Drop Bottle Packaging Lines [REDACTED] Syringe or Integrated Droppers Bottle Packaging Lines and [REDACTED] Suspension Bottle Packaging Lines. During this inspection I observed one bottling line operating under PQ assessment. Exhibit LHM-17 represents a "Listing of all Major Equipment".

Mr. Barua confirmed that the facility, which includes the FW manufacturing plant and McNeil Consumer Healthcare, Division of McNeil-PPC, Inc. Corporate Headquarters, is situated on [REDACTED]

of land. According to Mr. Barua, the FW facility occupies approximately [REDACTED] with approximately [REDACTED] occupied by the FW manufacturing plant, comprised of [REDACTED] production areas; [REDACTED] Analytical and Microbiological Laboratories; 83,300 sq. ft. Warehouse; [REDACTED] R&D areas, and [REDACTED] miscellaneous areas. Exhibit LMH-18 represents the Manufacturing Building, First Floor, Facility Floor Plan. Exhibit LMH-19 represents the Microbiology Laboratory Floor Plan. Exhibit LMH-20 represents the Analytical Laboratory Floor Plan.

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Exhibit LMH-21 represents a production schedule for Solid Dose products for 5/17/09 – 5/24/09. According to Mr. Barua, [REDACTED] granulation batches can be used in one compression batch and [REDACTED] compression batches can be used in one packaging batch. In the section for “Granulation” the Granulation product number is listed along with the batch number in a coordinating color. This must be cross-referenced on the table in Exhibit LMH-22.

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- For example, on Exhibit LMH-21 the [REDACTED] under [REDACTED] is [REDACTED] and granulation batch number [REDACTED] (both highlighted in [REDACTED]). On Exhibit LMH-22-3, under the column header for [REDACTED]; this granulation number cross references with material description Tylenol Sinus Severe CG Caplet 24, bulk code [REDACTED] Type [REDACTED] (finished goods), and [REDACTED] (column header) [REDACTED].
- For example, on Exhibit LMH-21, under the [REDACTED] section, for compression bay [REDACTED] the bulk code is [REDACTED] with batch code [REDACTED] (both highlighted in [REDACTED] column). On Exhibit LMH-22-1, under the column header for [REDACTED], this bulk code cross references with Material Description Multi Symptom Benadryl Severe Allergy Sinus Headache Caplet 20 and [REDACTED]. We observed compression of batch [REDACTED] in this bay during the physical inspection of the plant.
- For example, on Exhibit LMH-21, under the [REDACTED] section, for compression bay [REDACTED] the bulk code is [REDACTED] with batch code [REDACTED] (both highlighted in [REDACTED]). On Exhibit LMH-22-1, under the column header for [REDACTED], this bulk code cross references with Material Description St. Joseph Aspirin tablets. We observed compression of batch [REDACTED] during the physical inspection of the plant.
- For example, on Exhibit LMH-21, under the [REDACTED] section, for bottle line [REDACTED] the finished good code is [REDACTED] batch [REDACTED] (both highlighted in [REDACTED]). On Exhibit LMH-22-1, under the column header [REDACTED] for finished goods, this finished goods code cross references with Material Description St. Joseph Aspirin Enteric Coated Tablets 100. We observed bottling in Bottle Line [REDACTED] under Performance Qualification of Batch [REDACTED] expiration date [REDACTED] during the physical inspection of the plant.

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The bulk numbers can also be cross-referenced with the Family Code, the Product Name, and the Formula number via the table listed in SOP [REDACTED] effective date [REDACTED] [REDACTED] (Exhibit LMH-23).

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Exhibit LMH-24 represents a production schedule for Liquid products for 5/18/09 – 5/22/09; the week of this inspection. Each production line is listed with the Batch number, the Material number

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and the product description. The Material Number may be cross-referenced to the product description on the table entitled [REDACTED], Exhibit LMH-25.

- For example, packaging line [REDACTED] notes Batch number [REDACTED] and Material Number [REDACTED] for product description Children's Tylenol Suspension 4 oz. Bubblegum flavor. This Material Number cross-references on the table to this same product description and form as [REDACTED] (finished goods). We observed packaging of [REDACTED], expiration date [REDACTED] during the physical inspection of the plant.

During this inspection I reviewed the following documentation: select SOP's, Annual Product Review (APR) reports for Children's Motrin Suspension, training records for select employees, and data associated with Method Validation Preparatory Testing for Tylenol Suspension products. My review of these documents was unremarkable in that there were no apparent deficiencies observed.

*End Investigator Hoover.*

*This portion of the report was written by Investigator Whetstone.*

According to Mr. Robert Wilkerson, 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 the unloading of a trailer. All of the received materials are verified against a packaging list. A McNeil batch number is internally assigned by the [REDACTED] controlling system to each lot of raw materials and components listed on the Packaging Order. 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 [REDACTED] system. [REDACTED] is assigned to all of the received materials. The S/I (Sampling/Inspection) Inspector logs each unique lot of raw material and component into the [REDACTED] tracking system, which generates an inspection record. S/I Inspector will perform an inspection of each lot in accordance with the appropriate SOP's/material specifications. Then the Inspector records the data on the [REDACTED] 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 of the material in [REDACTED] and move it to [REDACTED] status. If product does not meet requirements, the Senior Technician/Team Leader will reject the material and a [REDACTED] will be generated to address the failure.

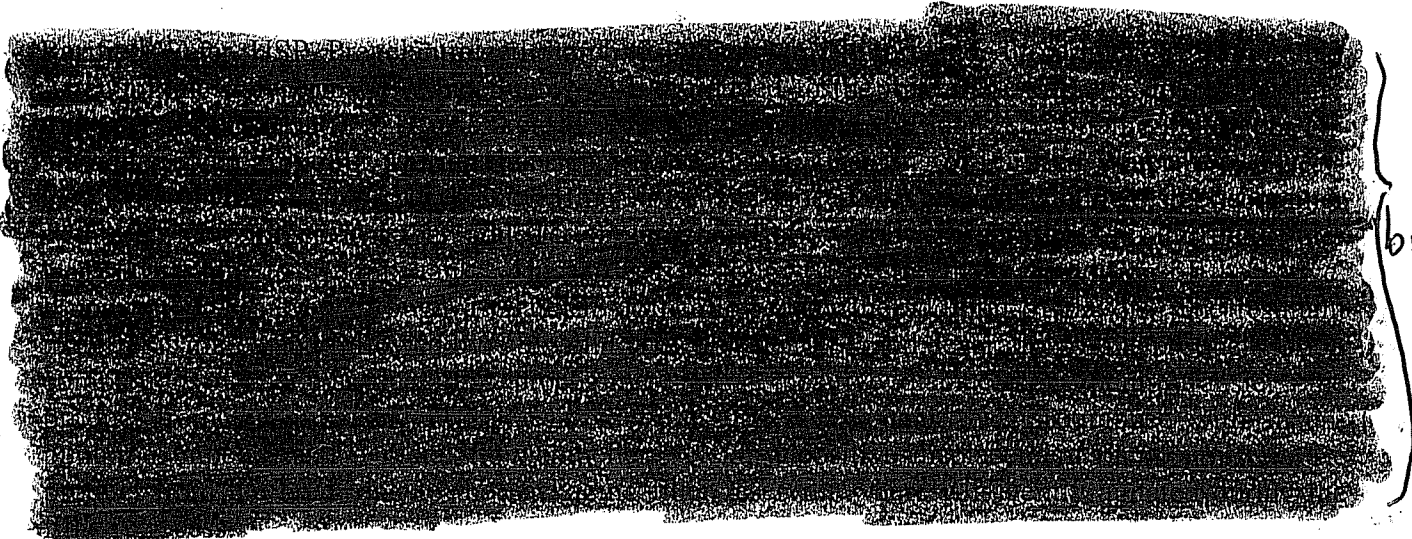
#### Children's Motrin Suspension

Exhibits HLJW-1 & HLJW-2 represents the process description and process flow diagram for Children's Motrin Suspension.

Mr. Jerome Hayes, Assoc. Director of Quality, provided me with a description of the Children's Motrin manufacturing process, as follows:

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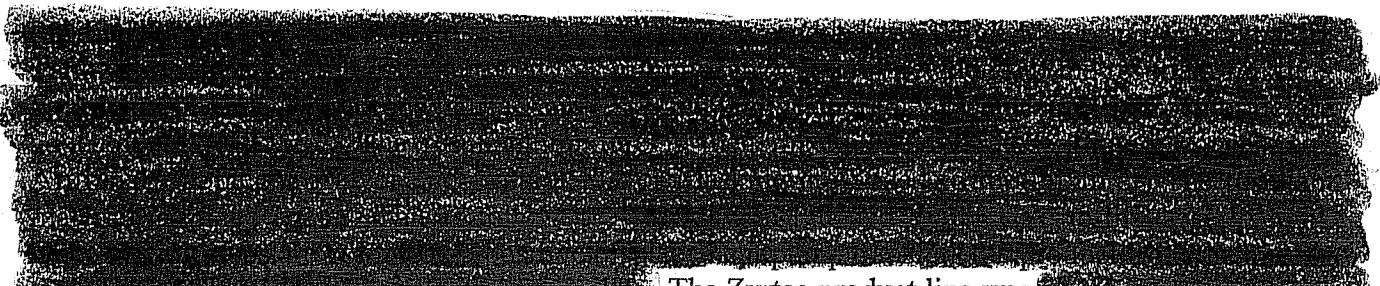
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Zyrtec Sugar Free Syrup-Bubblegum Flavor

Exhibits HLJW-3 and HJLW-4 represents the process description and process flow diagram for Zyrtec Sugar Free Syrup-Bubblegum Flavor.

Mr. Hayes provided me with a description of the Zyrtec Sugar Free Syrup-Bubblegum Flavor manufacturing process, as follows:



The Zyrtec product line was [redacted] to McNeil Fort Washington. The Zyrtec bubblegum 1/2 oz sample and 4 oz. bottle are the only products manufactured at the Fort Washington site that are currently marketed.

Benadryl Allergy and Cold KapGels

Exhibits HLJW-5 and HLJW-6 represent the process description and process flow diagram for Benadryl Allergy and Cold KapGels.

Jerome Hayes, Assoc. Director of Quality, provided me with a description of the Benadryl Allergy and Cold KapGels as follows:

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Benadryl Allergy and Cold KapGels are manufactured using a [REDACTED]

[REDACTED]

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On 5/19/09, during the physical inspection of the plant we observed processing of the following products:

- Granulation of Single layer Benadryl M/S Severe Allergy in [REDACTED] bulk lot# [REDACTED]
- Compression of St. Joseph's Enteric Coated Tablets in [REDACTED], bulk lot # [REDACTED]
- Mixing of Children's Tylenol Cough plus Runny Nose in [REDACTED] bulk lot# [REDACTED]

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During the physical inspection, I observed in the Dry Granulation/Dry Blend area, the metal beam above Bowl #2 had the appearance of a leak due to the presence of rust and chipping paint. The uncovered equipment was located directly under the affected area. Management initiated a work order to have the facility repaired (EXHIBIT HLJW- 7).

During this inspection, Investigator Matusovsky and I reviewed the following documentations associated with production of Children's Motrin Suspension, Zyrtec Sugar-Free Syrup Bubblegum Flavor and Benadryl Allergy and Cold KapGels: list of manufacturing and laboratory deviation/OOS (Out of Specification) investigations dated from 2/08 to 5/09 and select investigations from this list and list of change controls. In addition, select SOP's, list of complaints received from [REDACTED] and select complaint investigations from this list, list of rejected batches dated from [REDACTED] 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.

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End Investigator Whetstone.

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*This portion of the report was written by Chemist Pyramides.*

**Quality Control Laboratory-**

The Quality Control Laboratory consists of two main groups. There is the Analytical Chemistry Laboratory and the Microbiological Sciences Laboratory. Both Quality Control Laboratories are located in the same building. This large building also houses the Manufacturing Operations for the firm and is very close to an adjacent building. These two buildings are connected by walkways and hallways giving the impression from inside the buildings that they are a single building.

The Chemistry Laboratory currently has [redacted] analytical staff. The laboratory is in operation seven (7) days per week. The Laboratory has staff working [redacted] from Monday through Friday but is staffed for one day shift during the weekend. Exhibit GP#5 is the organizational charts for the Chemistry Laboratory. These organizational charts list the management and analytical staff that was part of the firm during the time frame of the inspection.

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The QC Chemistry Laboratory relies on electronic data systems and uses single paper sheets for data results and summaries. This laboratory does not use bound notebooks for a majority of their work.

**Physical Layout of the Analytical Chemistry Laboratory-**

The Analytical Chemistry Laboratory is situated in one main area of the building and is divided in to several rooms. The Chemistry Laboratory is organized along instrumental and analytical functions. The following areas/rooms were physically reviewed during a walk through; Room [redacted] Wet Chemistry Lab, [redacted] glassware washing room, Powder Room- Sieving, Room [redacted] Validation Sample Area/ Standards Storage Area, Room [redacted] Solvents- Acids/Bases, Sonication Room (Testing of Suspensions).

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The QC Analytical Chemistry Laboratory has [redacted] HPLC's, most with [redacted] Detectors but there are [redacted] Detectors, [redacted] Gas Chromatographs, [redacted] Dissolution Apparatus (all either apparatus [redacted] Infrared Spectrometers [redacted] is located in the raw materials area, [redacted] Ultraviolet/Visible Spectrophotometers, [redacted] Karl Fisher Auto-Titrators, [redacted] Polarimeter and an assortment of apparatus commonly found in Pharmaceutical Chemistry Laboratories such as balances, pH meters, ovens, etc.

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**OOS Laboratory Investigations Reviewed-**

[Large redacted block of text]

} b4

[REDACTED] } b4

[REDACTED] and [REDACTED] b4  
[REDACTED] b4

[REDACTED] b4

The QC Laboratories have a [REDACTED] based computerized [REDACTED] b4  
[REDACTED]. This system was installed in the late 1990's. This system consists of both hardware b4  
and software that is a commercially available product. The [REDACTED] is a package from [REDACTED] It is b4  
[REDACTED]. This system is configured by [REDACTED] for the firm b4  
based on their needs and specifications.

The [REDACTED] is a [REDACTED]. During the inspection the two server side b4  
System Administrators, Claudia Bernada and Rudy Fox, provided information and documents  
regarding the structure of the [REDACTED]. The firm also has Information Technology staffs that are the b4  
client side System Administrators. The QA unit [REDACTED] is running on [REDACTED] which b4  
consist of [REDACTED] computers running [REDACTED]. The [REDACTED] b4  
uses terminals that use emulation protocols to access the [REDACTED] b4

### Chromatography Based Data Management System-

The [REDACTED] has its own security system to limit access. This hardware/software uses b4  
unique username/password combinations as the security system.

The firm is currently running a [REDACTED] chromatography based computer b4  
network. The [REDACTED] system is connected to the [REDACTED]. Both the [REDACTED] and b4  
chromatography network are accessed by users at various computers or terminals throughout the QC  
Laboratories.

The [REDACTED] software has its own security level with user name/password combinations required to b4  
access the system.

All the chromatographic instrumentation (HPLC, GC) are operated and controlled using the b4  
[REDACTED]. There are no stand alone chromatographic b4  
instruments in the QC Chemistry Laboratory. The [REDACTED] system was installed and b4



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configure in 2005. Between 2001 and 2005 the firm had a previous version of the [REDACTED] chromatography based [REDACTED] called [REDACTED]

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There is a System Administrator for the [REDACTED] system and two back up System Administrators. These three report to the Information Technology group and are not based in the Quality Assurance Unit. The System Administrators have full access to all the configurable features available in the [REDACTED] system. There are other user levels with less access to the configurable features of the system. They consist of Senior Analyst and Analyst. The Senior Analyst level access has access to some features that the Analyst level access does not have.

b1

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The [REDACTED] data management system is used to control the HPLC and GC instruments, analyze the resulting chromatographs, and create summaries of the analytical results.

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#### Physical Layout of the Microbiological Sciences Laboratory-

The Microbiological Sciences Laboratory is located in the same building as the QC Chemistry Laboratory and the Manufacturing operations. This laboratory is in smaller space than the QC Laboratory. The Microbiological Laboratory is made up of several rooms that are all connected.

There is the instrumentation area and this room has the sample refrigerators. There is the back testing room [REDACTED], a stock room with an unrestricted storage area, a biohazard room with autoclaves and a smaller lab [REDACTED]. The Microbiology Laboratory has a [REDACTED] instrument they use to identify unknown microbial organisms to the genus level.

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The Microbiological Laboratory uses bound notebooks for most of their analytical results and data. They do also use in some cases single paper sheets generated from electronic data.

#### Research & Development Laboratories and Pilot Manufacturing Facilities-

The Research & Development Laboratories and Pilot Plants are spread out over [REDACTED] buildings. The R & D groups are designated as [REDACTED]

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A small portion of the R & D Laboratory is located in the same main buildings as the QC Laboratories and the Manufacturing Operations. This is [REDACTED]. This area of R & D is where the stability chambers/rooms are physically located. The R & D group monitors and operates the stability chambers/rooms.

b4

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The main R & D group is housed in their own building with [REDACTED]. The [REDACTED] are where the analytical laboratories are located with the [REDACTED] Manufacturing suites and facilities on the [REDACTED]

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Part of the R & D group is also located in a [REDACTED] building in close proximity to the other [REDACTED] buildings.

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The R & D group performs cGMP work and is quite large in comparison to the chemistry and microbiology QC Laboratories. The R & D group consists of approximately [REDACTED] staff. This group is multi-disciplined and is staffed by both analytical and manufacturing personnel. The R & D group cGMP functions include NDA submittals, stability analysis of commercial products, analytical support for QC and Manufacturing issues and problems.

b4

The R & D group was not covered in detail during this inspection.

Purified Water System –

The firm has a large fairly complex Purified Water System with two main parts. One part is the [REDACTED] the other part is the [REDACTED] This purified water system feeds the manufacturing operations and laboratory areas.

b4

The [REDACTED] are physically separate through out the plant areas but most of the purified water is made in one room that contains the pumps, filters, de-ionization apparatus, the reverse osmosis units, Ultraviolet light systems, monitoring equipment, chemical sanitization system, storage tanks, ozone generator and water softening systems.

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Exhibit GP#6 is a schematic diagram of the purified generation room and the systems that are inside this room.

The [REDACTED] consists of [REDACTED] that feed specific area of the manufacturing. The [REDACTED] also consists of [REDACTED] that also feed manufacturing areas. The Liquids Production areas create their own [REDACTED] The firm stated that the Liquids Production have to [REDACTED] to feed their systems because that area does not have the [REDACTED] The Liquids Production group uses a [REDACTED] in their own area. The solids production wash area also creates its own [REDACTED] in the production wash area.

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The Purified Water Systems feed the following areas:

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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Exhibit GP#7 is a large schematic diagram of the entire building where the manufacturing operations, QC Laboratories and R & D Stability areas. This diagram contains the Purified Water System sampling points and table of areas that the water system feeds.

*End Chemist Pyramides.*

**MANUFACTURING CODES**

*This section of the report was written by Investigator Hoover.*

According to Mr. Jerez, raw materials and components used for in-house production are assigned batch numbers. The batch number consists of a [REDACTED] assigned by the [REDACTED] system, where:

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- [REDACTED]
- [REDACTED]

and the remaining [REDACTED] represent the [REDACTED]. For example: Raw material [REDACTED] was given the McNeil batch number [REDACTED] upon receipt on [REDACTED].

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According to Mr. Jerez and SOP [REDACTED] effective date [REDACTED] (Exhibit LMH-26) the Scheduling Batch Record Coordinator assigns a unique batch number for in-process products to each Master Record using batch number 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 [REDACTED] controlling system and manually assigned to the process order. It is a [REDACTED] where, for the [REDACTED] characters:

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- [REDACTED]
- [REDACTED]
- [REDACTED]

} b4

and the remaining [REDACTED] For example, [REDACTED] is the [REDACTED] batch manufactured in the [REDACTED] plant in [REDACTED]

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According to Mr. Jerez and SOP [REDACTED] effective date [REDACTED] (Exhibit LMH-27) the packaging batch number for all products packed as one item number during a continuous period is assigned as described by page 2 of the Exhibit. It is a [REDACTED] where:

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- [REDACTED]
- [REDACTED]
- [REDACTED]

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and the remaining [REDACTED] represent the [REDACTED] As on page 3 of the Exhibit, the expiration, assigned to the master packaging record for each product, is determined by using the [REDACTED] plus the [REDACTED]. For example, if Children's Tylenol Suspension 4 oz. Bubblegum flavor was [REDACTED]

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End Investigator Hoover.

## COMPLAINTS

This portion of the report was written by Investigator Whetstone.

During this inspection, I reviewed SOP [REDACTED] effective date [REDACTED] (Exhibit HLJW-8) and a list of complaints received between [REDACTED] and select complaint investigations from this list.

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I also inquired about the firm's investigations into complaint #'s [REDACTED]

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received by the FDA. According to Ms. Cooper, no investigations could be performed into complaint #'s [REDACTED], and [REDACTED] due to a lack of information and lot number. Complaint # [REDACTED] related to a product that is not manufactured at the Fort Washington facility and was therefore not investigated. 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 Section of this report, under Observation # 5.

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In addition, DQRS #'s [REDACTED] were covered. Ms. Cooper provided me with a spreadsheet showing the status of the complaints and DQRS (Exhibit HLJW-9) documenting the status of each DQRS. According to this Exhibit, no investigations could be found into DQRS #'s [REDACTED] and complaint #'s [REDACTED] and [REDACTED] as these were not received by the firm; Information related to DORSs not previously received by the firm was provided during the inspection. Complaint #'s [REDACTED] and [REDACTED] required additional information to perform the investigation. All previously mentioned DQRS and complaints were investigated by the FW plant and the investigations were reviewed during this inspection. My review of these documents was unremarkable in that there were no apparent deficiencies observed.

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*End Investigator Whetstone.*

*This portion of the report was written by Chemist Pyramides.*

A complaint was sent to the Agency by email and this was followed up at the firm. The email listed some information about a batch that was analyzed in the Research & Development Group. The product was Zyrtec Chewable Tablets, 10 mg Cetirizine Dihydrochloride Study [REDACTED] and Study [REDACTED]

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The R & D staff described this product and studies as very early in the process to commercialization of the product. The R & D staff stated that they did their own [REDACTED] studies on products they hoped to bring to commercial level manufacturing. The studies listed above were to [REDACTED]

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[REDACTED]

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When I requested documents relating to this batch of product the R & D staff initially did not want to provide copies. The firm was concerned about the proprietary nature of the information. After some discussion the R & D staff did provide the documents and hand wrote "Proprietary R & D" in red on all the pages. Exhibit GP#8 is copies of the R & D summaries of the studies and results.

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End Chemist Pyramides.

### OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

The following portion of the report was written by Investigator Matusovsky.

On 6/4/09, the Form FDA-483, Inspectional Observations, was issued to Mr. Luther. Also present were Mr. Constable, Mr. Barua, Mr. Bauer, Mr. Hayes, Mr. DiPaolo, Maria Nieradka, Vice President, North American Supply Chain for McNeil, and Robert Miller, Ph. D., VP, Global QA OTC. Representing the FDA were Investigators Matusovsky, Whetstone, Hoover, and Chemist Pyramides. The firm promised to submit a written response to FDA documenting the firm's corrective action by June 30<sup>th</sup>, 2009.

End Investigator Matusovsky.

Observations listed on form FDA 483

### MATERIALS SYSTEM

#### OBSERVATION 1

Failure to reject any lot of components that did not meet the appropriate written specifications for identity, strength, quality, and purity.

Specifically [redacted] and [redacted] vendor lot # [redacted] was partially released for further processing, although [redacted] (refer to Table 1-1) of this lot exhibited [redacted] on routine incoming [redacted] testing. [redacted] was determined to be an [redacted] by the firm's [redacted] laboratory.

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Table 1-1 Receipts of [redacted] Lot# [redacted]

McNeil Receipt #	Vendor Lot #	McNeil Lot #	Receipt Date
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]

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[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

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[REDACTED]

In addition, the firm's investigation into this event revealed the same [REDACTED] was recovered by the manufacturer of [REDACTED], vendor lot [REDACTED], during their routine [REDACTED] testing. This lot of [REDACTED] was used to manufacture approximately [REDACTED] of Infant's and Children's Tylenol Suspension formulations (refer to Table 1-2) that were released for commercial distribution in [REDACTED]. According to the firm's investigation, the rationale for release of [REDACTED], vendor lot [REDACTED], and finished product lots produced from this raw material was based on satisfactory results obtained on routine testing of the raw material and finished product lots and an assessment of the physical characteristics of Infant's and Children's Tylenol Suspension formulations (i.e. [REDACTED]).

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Table 1-2 List of Product types Manufactured using [REDACTED] Lot# [REDACTED]

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Children's Tylenol Suspension 4 oz. Cherry	Children's Tylenol Plus Flu 4 oz. Bubblegum
Children's Tylenol Suspension 4 oz. Cherry, Hospital Govt.	Children's Tylenol Plus Cold/Allergy 4 oz. Bubblegum
Children's Tylenol Suspension 4 oz. Grape	Infant's Tylenol Suspension 1/4 oz. Grape
Children's Tylenol Suspension 4 oz. Bubblegum	Infant's Tylenol Suspension 1/2 oz. Grape
Children's Tylenol Suspension 4 oz. Strawberry	Infant's Tylenol Suspension 1 oz. Grape
Children's Tylenol Dye Free Suspension 4 oz. Cherry	Infant's Tylenol Suspension 1/2 oz. Cherry
Children's Tylenol Suspension 4 oz. Cherry	Infant's Tylenol Suspension 1 oz. Cherry
Children's Tylenol Plus Cough and Runny Nose 4 oz. Cherry	Infant's Tylenol Suspension 1 oz. Grape
Children's Tylenol Plus Cold MS Suspension 4 oz. Grape	Infant's Tylenol Suspension Drops H/G 1/2 oz. Grape
Children's Tylenol Plus Cold Suspension	Infant's Tylenol Dye Fee Suspension 1

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4 oz. Grape	oz. Cherry
Children's Tylenol Plus Cough/ST Suspension 4 oz. Cherry	Tylenol Pediatric Suspension 1 oz. Suspension Cherry

Reference: 21 CFR 211.84(e)

Supporting Evidence and Relevance and Discussion with Management:

*This portion of the report was written by Investigator Whetstone.*

Summary of [redacted] vendor lot [redacted] Receipts:

Exhibit HLJW-10 represents the investigation report for Quality Notification (QN) [redacted] initiated on [redacted] into the [redacted] result for [redacted] vendor lot # [redacted]

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Exhibit HLJW-11, pages 1-21 represents the Executive Summary of [redacted] provided by Jerome Hayes. The QN was initiated in response to an [redacted] result [redacted] performed for [redacted] and [redacted] vendor lot# [redacted] and McNeil Lot# [redacted] on [redacted]. The [redacted] identified was [redacted]. According to [redacted]

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[redacted] The [redacted] was recovered in the [redacted] of raw material, [redacted]

Table 1-1 Receipts of Avicel Lot# DN08819021

McNeil Receipt #	Vendor Lot #	McNeil Lot #	Receipt Date	Date Block Initiated	Date Block Removed
[redacted]	[redacted]	[redacted]	[redacted]	NA	NA
[redacted]	[redacted]	[redacted]	[redacted]	NA	NA
[redacted]	[redacted]	[redacted]	[redacted]	NA	NA
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	NA

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The [redacted] receipt of [redacted] vendor lot # [redacted] was received by McNeil on [redacted] under [redacted] McNeil lot [redacted] this lot was tested using routine testing procedures established by the firm [redacted]

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and released for use in the manufacturing process. The [redacted] receipt of [redacted] vendor lot [redacted] under McNeil Lot# [redacted] was received on [redacted] and [redacted] at incoming receipt due to [redacted]. The [redacted] and [redacted] receipts of [redacted] vendor lot # [redacted] was received by McNeil on [redacted] and [redacted] respectively under McNeil lot # [redacted] and [redacted]. Both lots were tested using routine testing procedures established by the firm and released for use in the manufacturing process. The [redacted] receipt of [redacted] vendor lot # [redacted] was received by McNeil on [redacted] under McNeil lot # [redacted] was tested using routine testing procedures established by the firm and [redacted] due to the [redacted] [redacted] on [redacted] as documented on the [redacted] (Exhibit HLJW- 12, pg. 5). Following the [redacted] the firm's [redacted] (located at the Fort Washington Site or the Satellite Warehouse) that used [redacted] vendor lot [redacted]. On 4/17/08, the firm decided to release all batches associated with the [redacted] and [redacted] receipts (McNeil lot #'s [redacted] and [redacted] based on the fact that all incoming raw material and finished goods acceptance criteria had been met upon receipt and release. Finished goods manufactured from the [redacted] receipt [redacted], raw material from the [redacted] receipt of [redacted] was released for production use, but subsequent [redacted].

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Microbiological Testing

Analytical and Microbiological testing is performed on each receipt of [redacted] as required per specification [redacted] (Exhibit HLJW-13, pgs. 82-88). According to SOP [redacted] effective [redacted] (Exhibit HLJW-13, pgs. 54-67) [redacted] effective [redacted] (Exhibit HLJW-13, pgs. 68-81). According to Mr. Bonilla, QA Manager, Microbiology, [redacted] is received by warehouse personnel and delivered to the Sampling and Inspection(S/I) group. The S/I group is responsible for cleaning of the sampling room according to SOP [redacted] effective date [redacted] (Exhibit HLJW-13, pgs. 31-35) and sampling the components according to SOP [redacted] effective [redacted] (Exhibit HLJW-13, pgs. 12-22) According to Mr. Monk, a typical lot of [redacted] contains approximately [redacted] of material. As described in Exhibit HLJW-16, pg 2 [redacted]

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The sample container is then transferred to the Microbiology Lab and logged in for testing per SOP [redacted] effective [redacted] Microbial Limits testing of the component is performed according to SOP [redacted] Per SOP [redacted]

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SOP [redacted] effective date

[redacted] SOP [redacted]  
The SOP also [redacted]

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Please refer to Exhibit HLJW-13, pgs. 1-7 for a summary of Microbiological Testing of [redacted]  
Upon completion of the testing the laboratory identified [redacted]

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Summary of [redacted] Supplier Audit

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As part of the investigation representatives from McNeil's Quality Assurance conducted a vendor audit of [redacted] the supplier of [redacted] located in [redacted] (Exhibit HLJW-10, pgs. 30-32). The audit included a review of the manufacturing and packaging process and equipment cleaning procedures. The audit did not identify any root cause for the [redacted] and determined that the processing steps are adequate and in a state of control to minimize the introduction of [redacted] during processing and packaging. During the investigation, McNeil did learn that [redacted] was recovered from [redacted] from the same lot of [redacted] vendor lot [redacted] but this was not communicated to McNeil at the time of discovery (Exhibit HLJW-10, pgs. 25-26). As a precautionary measure [redacted] According to Mr. Hayes, the [redacted] of [redacted] in [redacted] with the [redacted] As a result of that [redacted] of [redacted] for the presence of [redacted] Based on that established requirements, [redacted] According to Mr. Hayes, as a result of this incident, McNeil updated their customer agreement with [redacted] on [redacted] to test [redacted] for the presence of any [redacted] (Exhibit HLJW-10, pg. 27).

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Microbiology Laboratory Investigation

McNeil's internal laboratory investigation into the source of the [redacted]  
The Microbiology lab determined that the presence of [redacted] as defined by SOP [redacted] and investigated accordingly. The laboratory made the decision to [redacted] vendor lot # [redacted] McNeil Lot [redacted] on [redacted] The lab also deemed this [redacted] (Exhibit HLJW-10, pg 2).

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Additional Studies Performed

An evaluation of the affected formulations in the [redacted] was performed by the Microbiology Laboratory (Exhibit HLJW-10 pgs. 43-44) to determine their ability to [redacted] The study concluded the following: [redacted]

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vendor lot [REDACTED]

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On 4/23/08 a [REDACTED] (Exhibit HLJW-10 pgs. 35-42) was conducted under Protocol by the firms [REDACTED] to support the firm's [REDACTED] manufactured with [REDACTED] vendor lot # [REDACTED]. According to Mr. Bonilla, the study was [REDACTED]

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During this inspection, on 5/27/09, Mr. Hayes provided me with a Medical Assessment (HLJW-Exhibit 30) performed by Andre Mann, MD, Medical Safety Officer. [REDACTED] but references in literature did not reveal a single reference to a potential risk of contamination due to pharmaceutical product for ingestion in general, post-marketing safety data and scientific literature does not confirm a hypothetical risk of B.cepacia infection consequent to the use of Tylenol drops and liquid produced from [REDACTED] lot# [REDACTED] and [REDACTED] and the risk of serious adverse health consequences due to B.cepacia infection as a result of the use-as-directed of infants and children's Tylenol from [REDACTED] lot# [REDACTED] and [REDACTED] is remote. On 5/29/09 Mr. Bonilla presented me with data from a [REDACTED] entitled [REDACTED] (Exhibit HLJW-14, pgs. 1-2) conducted during the inspection which [REDACTED]

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Summary of Lot Disposition

Exhibit HLJW-15 documents the disposition of the affected [REDACTED] vendor lot # [REDACTED]. According to Mr. Wilkerson and Mr. Bauer, the following lot codes documented on the [REDACTED] Printout are as follows: [REDACTED]. As a result of the investigation the firm determined that finished goods manufactured using [REDACTED] vendor lot # [REDACTED], McNeil lot #'s [REDACTED] and [REDACTED] should remain released and available for sale. Finished goods manufactured using [REDACTED] vendor lot [REDACTED], McNeil lot # [REDACTED] met acceptance criteria for both incoming raw material testing and finished product testing and was therefore released for sale.

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The last receipt of [redacted] vendor lot # [redacted], McNeil lot # [redacted] was [redacted] due to the presence of [redacted] as described above.

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Exhibit HLJW-11 pages 6-21 represents a list of finished product lots of Children's and Infant's Tylenol.

List of products manufactured using [redacted]

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Children's Tylenol Suspension 4 oz. Cherry	Children's Tylenol Plus Flu 4 oz. Bubblegum
Children's Tylenol Suspension 4 oz. Cherry, Hospital Govt.	Children's Tylenol Plus Cold/Allergy 4 oz. Bubblegum
Children's Tylenol Suspension 4 oz. Grape	Infant's Tylenol Suspension 1/4 oz. Grape
Children's Tylenol Suspension 4 oz. Bubblegum	Infant's Tylenol Suspension 1/2 oz. Grape
Children's Tylenol Suspension 4 oz. Strawberry	Infant's Tylenol Suspension 1 oz. Grape
Children's Tylenol Dye Free Suspension 4 oz. Cherry	Infant's Tylenol Suspension 1/2 oz. Cherry
Children's Tylenol Suspension 4 oz. Cherry	Infant's Tylenol Suspension 1 oz. Cherry
Children's Tylenol Plus Cough and Runny Nose 4 oz. Cherry	Infant's Tylenol Suspension 1 oz. Grape
Children's Tylenol Plus Cold MS Suspension 4 oz. Grape	Infant's Tylenol Suspension Drops H/G 1/2 oz. Grape
Children's Tylenol Plus Cold Suspension 4 oz. Grape	Infant's Tylenol Dye Free Suspension 1 oz. Cherry
Children's Tylenol Plus Cough/ST Suspension 4 oz. Cherry	Tylenol Pediatric Suspension 1 oz. Suspension Cherry

According to this Exhibit, there were approximately [redacted] manufactured from [redacted] receipt #'s [redacted] and [redacted] that were released by QA for further commercial distribution. In addition to the corresponding [redacted] receipt number used in production of these Tylenol lots, the Exhibit documents the manufacturing and release dates for each finished product lot. According to Mr. Hayes all product lots met the release specifications for microbiological quality. Exhibit HLJW-29 represents select pages from batch production record for Infant's Tylenol Suspension, bulk lot [redacted] which was used to manufacture finished product lot [redacted] which was manufactured using [redacted] receiving lot # [redacted]. Manufacturing of the bulk was performed on [redacted] packaging activities began on [redacted] and ended [redacted] the final product was released on [redacted].

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The firm informed us that they will perform additional testing on the retain samples of the products that were manufactured using [redacted] vendor lot [redacted]. Mr. Bonilla provided me with a copy of Protocol No. [redacted].

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[REDACTED] (Exhibit HLJW-28). The protocol was collected but not reviewed. b4

End Investigator Whetstone.

LABORATORY CONTROL SYSTEM

OBSERVATION 2

Laboratory controls do not include the establishment of scientifically sound and appropriate sampling plans designed to assure that components conform to appropriate standards of identity, strength, quality and purity.

Specifically, there is no documented justification to support the [REDACTED] sampling technique used in the sampling of [REDACTED] to ensure it is representative of the lot. The firm's SOP [REDACTED] entitled [REDACTED] [REDACTED] to allow for mixing (inversion of a container 10 times). Each receipt of [REDACTED] is comprised of approximately [REDACTED]. b4  
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Please note that this observation relates to Observation # 1.

Reference: 21 CFR 211.160(b)

Supporting Evidence and Relevance and Discussion with Management:

*This portion of the report was written by Investigator Whetstone.*

Exhibit HLJW-16, [REDACTED] describes the McNeil Incoming Component Receipt Process. According to Mr. Scott Monks, QA Team leader upon receipt, incoming [REDACTED] is logged into the [REDACTED] system. Warehouse personnel deliver documents associated with the [REDACTED] to Sampling b4  
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and inspection and place them in the designated incoming receipt bin. The S/I inspectors verify the paperwork and material identification and manufacturer and number of containers. According to Mr. Monks, typical lot of [REDACTED] will contain approximately [REDACTED] of material. Once the material has been verified, the sample will be logged into the [REDACTED] system which then triggers the generation of a sampling worksheet. The [REDACTED] system assigns [REDACTED] numbers for both analytical and microbiological samples. S/I Inspectors obtain appropriate sampling equipment and personal protective equipment (PPE). The container lids are wiped and/or vacuumed to remove any dust present. Tamper evident seals are removed and the pallets are moved into the sampling booths. Prior to sampling, the magnehelic gauge reading is verified that it reads [REDACTED]. The inspector dons the appropriate PPE, inspects the drum for damage to the inner drum liner. The inspector using a [REDACTED] followed by [REDACTED]. The lid is securely tightened and rotated from top to bottom. The samples are then delivered to the laboratory for analysis.

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Exhibit HLJW-17 SOP [REDACTED] effective [REDACTED] (Exhibit HLJW-16) describes the procedure for component sampling utilized by the firm during the time period when the [REDACTED] was identified. According to [REDACTED] the SOP states that [REDACTED]. I asked Mr. Monks whether the [REDACTED] sampling technique was evaluated to ensure that it is representative of the lot. According to Mr. Monks and Mr. Hayes, [REDACTED] sampling technique has not been evaluated.

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There were no comments related to this observation.

*End Investigator Whetstone.*

**OBSERVATION 3**

Written specifications for laboratory controls do not include a description of the sampling procedures used.

Specifically, SOP [REDACTED] entitled [REDACTED], does not specify the amount of product to be removed from each final product sample to ensure a representative sample is collected. The SOP states [REDACTED]. The informal practice utilized by the [REDACTED] laboratory staff is to [REDACTED].

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[REDACTED] In addition, the SOP does not describe the directions/requirements for mixing the sample to ensure a homogenous mixture is consistently obtained prior to analysis. [REDACTED]

Please note that this observation relates to Observation # 1.

Reference: 21 CFR 211.160(b)(1)

Supporting Evidence and Relevance and Discussion with Management:

*This portion of the report was written by Investigator Whetstone.*

According to Mr. Bonilla, final product packages intended for [REDACTED] testing are removed as follows: [REDACTED]

[REDACTED] reference Exhibit HLJW-18 SOP [REDACTED] effective [REDACTED] According to Mr. Bonilla [REDACTED] Later

Mr. Bonilla corrected his previous statement regarding the amount of sample that is taken from each container after discussion with the laboratory staff, and confirmed that [REDACTED]

[REDACTED] I pointed out to Mr. Bonilla that the SOP does not specify the required volume to be removed from each container or instructions for mixing of the sample to ensure a homogeneous mixture is achieved prior to analysis. According to Mr. Bonilla the staff indicated that the sample requirements are verbally communicated during training.

Mr. Bonilla indicated that the SOP would be revised.

*End Investigator Whetstone.*

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#### OBSERVATION 4

The written stability testing program is not followed.

Specifically, the firm failed to test Tylenol Allergy Complete Multisymptom Geltabs, lot # [REDACTED] at the [REDACTED] in accordance with study [REDACTED] This lot [REDACTED]

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represented the annual stability testing to support batches manufactured during production year 2005.

Reference: 21 CFR 211.166(a)

Supporting Evidence and Relevance:

*This portion of the report was written by Chemist Pyramides.*

This observation originated through a review of Out Of Specification (OOS) Laboratory Investigation number [REDACTED]. This batch of product, Tylenol Allergy Complete Multisymptom Geltabs, Lot # [REDACTED] has an expiry of 36 months. This finished dosage form lot was the only batch put on stability for this production year and represents [REDACTED] batches of the same dosage form manufactured during [REDACTED]. The batch numbers are: [REDACTED]

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The firm set up the stability program [REDACTED] for this product for [REDACTED] instead of [REDACTED]

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The firm's Quality Assurance group first became aware of the error during the compilation of stability results for their annual product review for this dosage form. The annual product review required the 36 month stability data to support the expiry for this batch and the other twenty batches.

The firm went to the [REDACTED]

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[REDACTED] would meet specifications at expiry. The firm also considered a batch of product with similar, but not the same, granulation which had a different coating and made statements that the other batch met specifications at expiry and batch [REDACTED] which is subject of this 483 observation would meet specifications. Exhibit GP#1 is a copy of the investigation and associated data, statistical models and summaries of analysis.

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There were no systems in place at that time to prevent the firm's Quality Assurance Unit or the firm's Quality Control Laboratory from catching this error. The firm's Quality Control Laboratory is directly under the Quality Assurance Unit.



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The firm put in place procedural corrective measures that are expected to prevent this type of error from recurring. The corrective measures have been in place for approximately one year.

*End Chemist Pyramides.*

## QUALITY SYSTEM

### OBSERVATION 5

Procedures describing the handling of all written and oral complaints regarding a drug product are not followed.

Specifically, no batch review for Quality Notifications (QN) was performed as part of the investigation in response to the [REDACTED] complaint (Complaint Issue Report # [REDACTED] received on [REDACTED] into Children's Tylenol Plus Cold and Cough Dye-Free Grape 4 oz. as required by SOP [REDACTED] entitled [REDACTED] due to the fact that Complaint [REDACTED] was classified as an Adverse Event only. In addition, during the inspection, a review of the complaint database revealed additional instances of [REDACTED] complaints that had been closed without complete investigation performed [REDACTED] complaints were closed without performing batch QN reviews and [REDACTED] complaints were closed without performing trend data analysis).

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Reference: 21 CFR 211.198(a)

Supporting Evidence and Relevance and Discussion with Management:

*This portion of the report was written by Investigator Whestone.*

According to Tracy Cooper and Christine Wysocki, complaints, inquiries and adverse events are received via 800 numbers, e-mail and white mail at the [REDACTED] located at [REDACTED] contracted to handle these types of issues. Complaints, Inquiries and Adverse Events are captured in an electronic database at the [REDACTED] called the [REDACTED]. The [REDACTED].

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[REDACTED] Quality Investigators at the McNeil sites use [REDACTED] to document investigations of PQC's and evaluations of Adverse Events. All Adverse Events are evaluated by Quality to ensure there is no potential quality or design issue associated with the reported event. Adverse Events are also forwarded from the [REDACTED] to the Benefit Risk Management (BRM). BRM is a J&J Company with a local office in Horsham, PA, who is responsible for the medical review, follow-up and filing of Adverse Events with FDA. BRM physicians determine the seriousness of an Adverse Event and file [REDACTED] reports to FDA in cases deemed serious. BRM is also responsible for safety surveillance of McNeil products. BRM will refer Adverse Events to QA at McNeil FW or respective sites if the review of the case determines there is a need for a quality investigation. QA forwards the results of quality investigations requested by BRM back to BRM for closure of the file at BRM. For McNeil sites, follow-up to the consumer regarding the results of a quality investigation is handled by QA. Follow-up regarding an Adverse Event is handled by McNeil Medical Affairs and/or BRM.

During my review of complaints from [REDACTED] it was noted that Complaint Issue Report [REDACTED] (Exhibit HLJW-19) received on [REDACTED] into Children's Tylenol Plus Cold and Cough Dye-Free Grape 4 oz. was classified as a [REDACTED] complaint by McNeil Quality Investigators. The complaint was closed without performing the batch review and trend data analysis as required per SOP [REDACTED] effective [REDACTED], pgs.9-11(Exhibit HLJW-20). At the request of Investigator Matusovsky, all [REDACTED] complaints were reviewed to identify additional instances of incomplete "lack of effect" complaint investigations under [REDACTED] (Exhibit HLJW-21). The investigation revealed that out of [REDACTED] that had been closed with out complete investigation performed [REDACTED] complaints were closed without performing batch QN reviews and [REDACTED] complaints were closed without performing trend data analysis).

*End Investigator Whetstone.*

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**OBSERVATION 6**

**There is a failure to thoroughly review the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.**

**Specifically, the firm did not perform a thorough investigation or any additional analytical testing of associated lots related to the Diphenhydramine Content Uniformity failure in Benadryl Children's Fastmelt Tablets - Grape, lot # [REDACTED]. The associated lots: [REDACTED] and [REDACTED] were made during the same two-day campaign as the failed lot. The investigation did not extend beyond a document review of the batch records and**

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associated records and interviews of the operators.

Reference: 21 CFR 211.192

Supporting Evidence and Relevance and Discussion with Management:

*This portion of the report was written by Chemist Pyramides.*

This observation originated through a review of Out Of Specification (OOS) Laboratory Investigation number [REDACTED]. This investigation involved the Diphenhydramine [REDACTED] [REDACTED] Benadryl Children's Fastmelt Tablets – Grape, Lot # [REDACTED]. Exhibit GP#2 is a copy of the Quality Control Laboratory Investigation [REDACTED]

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The firm manufactured [REDACTED] batches of product during a [REDACTED] campaign using the same ingredients, equipment and operators. [REDACTED] batches in that campaign failed for [REDACTED] chemical analysis. The firm did not conduct a thorough review of batches associated with the failed batch. The investigation consisted of a paperwork review of the batch records and interviews of the operators. All the operators interviewed stated that there was no difference between the batches that [REDACTED]. The investigation could not determine an [REDACTED]. Exhibit GP#2 10 of 14 describes the batches made during this campaign.

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I requested a list of all batches that failed [REDACTED] testing in the previous [REDACTED] [REDACTED] and a total number of batches of solids dosage forms created during the same time period. This information was provided by the firm. Exhibit GP#3 is a listing of the [REDACTED] from [REDACTED]. There were [REDACTED] failures in [REDACTED] and between [REDACTED] and [REDACTED] batches made during that time interval. I discussed with the firm's management that [REDACTED] are rare in products that are formulated correctly and using validated robust manufacturing processes/equipment. This represents a [REDACTED]

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The firm did not perform any additional analytical testing or put the other [REDACTED] batches in question on a stability program to monitor their behavior through direct analytical testing.

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During discussions with the firm, I indicated that an expanded investigation to perform a close examination of the other [REDACTED] products made during the same campaign should have been conducted. During the 483 close-out meeting the firm presented additional analytical results of Content

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Uniformity measurements for lot # [REDACTED] that met specification. The firm took an additional [REDACTED] finished dosage units and tested each unit individually. The individual and pooled results were presented in a summary. The results of this expanded testing met Content Uniformity for lot # [REDACTED]. Exhibit GP#4 is a copy of the Content Uniformity summary results for lot [REDACTED].

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*End Chemist Pyramides.*

## REFUSALS

*This section of the report was written by Investigator Hoover.*

There were no refusals encountered during this inspection.

*End Investigator Hoover.*

## GENERAL DISCUSSION WITH MANAGEMENT

*This section of the report was written by Investigator Whetstone.*

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

The current process of assigning temporary holds for products associated with [REDACTED] activities assigns the responsibility to the Manufacturing Team Leaders. In one instance, QN [REDACTED] (Exhibit HLJW-22), [REDACTED] associated with [REDACTED] [REDACTED] (Exhibit HLJW-23), were released prior to close-out of study on [REDACTED] and change control [REDACTED] was closed on [REDACTED] (Exhibit HLJW-24). On 5/27/09, Mr. Hayes and Mr. Gringhold agreed to update the validation and verification protocols to include a notification to scheduling of the last validation batch as well as the implementation of the tracking form.

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During a review of [REDACTED] (Exhibit HLJW-25), which involved the addition of the wrong batch of [REDACTED], it was noted that the corrective action identified in the investigation did not include updating the batch record to add an additional check of the [REDACTED] batch information prior to charging. Mrs. Bond initiated a Change Control [REDACTED] (Exhibit HLJW-26) to update the batch record to add a requirement to ensure the correct [REDACTED] has been added to the mix tank prior to charging.

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During the inspection, it was noted that the firm does not perform a visual verification of the mix tanks prior to charging of components. The cleaning verification is performed at the control system. A corrective action was initiated by Mrs. Bond and provided to me on 5/27/09. A draft version of SOP [REDACTED] (Exhibit HLJW-26, pg 2) [REDACTED] components.

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*End Investigator Whetstone.*

**SAMPLES COLLECTED**

*This section of the report was written by Investigator Whetstone.*

Documentation sample # 536243 was collected to document the interstate movement of Tylenol Infants' Drop Dye Free Cherry Suspension, Lot # [REDACTED]

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*End Investigator Whetstone.*

**VOLUNTARY CORRECTIONS**

*This portion of the report was written by Investigator Hoover.*

Corrections implemented by the firm in response to the deficiencies documented on the FDA Form-483, Investigational Observations and verbally discussed during the previous 2/2008 inspection were evaluated during the current inspection. My review of these corrective actions was unremarkable in that there were no apparent deficiencies observed.

*End Investigator Hoover.*

**EXHIBITS COLLECTED**

LMH Exhibits

1. Fort Washington Plant Headcount (1 page);
2. Drug Firm Annual Registration Status printout (1 page);
3. List of Johnson & Johnson Corporate and Consumer Sector Office Locations (1 page);

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- 4. List of addresses of McNeil Companies (1 page);
- 5. List of Johnson & Johnson Subsidiaries (9 pages);
- 6. List of countries where McNeil Consumer Healthcare does business (1 page);
- 7. List of addresses of Distribution Centers and Warehouse (1 page);
- 8. List of the products manufactured and / or packaged at the FW plant, (a.k.a. Product Matrix), (3 pages);
- 9. List of NDA/ANDA that tie in Fort Washington (1 page);
- 10. List of "New Product Launches" (1 page);
- 11. Representative labeling for Children's Motrin, Oral Suspension, 100 mg per 5 ml, 4 Fl. Oz., Berry Flavor (3 pages);
- 12. Representative labeling for Benadryl, Severe Allergy Plus, Sinus Headache, 20 caplets (3 pages);
- 13. Representative labeling for Children's Zyrtec Allergy, 1 mg / ml oral solution, 4 Fl. Oz., Bubble Gum Syrup (3 pages);
- 14. Organizational Charts (10 pages);
- 15. List of Management Changes (1 page);
- 16. List of FW plant employees interviewed during this inspection and the corresponding topic discussed (6 pages);
- 17. List of Major Equipment (4 pages);
- 18. Manufacturing Building, First Floor, Facility Floor Plan (1 page);
- 19. Microbiology Laboratory Floor Plan (1 page);
- 20. Analytical Laboratory Floor Plan (1 page);
- 21. Production Schedule of Solid Dose products for 5/17/09 - 5/24/09 (1 page);
- 22. Table for cross-referencing granulation, bulk code, type, count, form, strength, Material description, and finished goods codes for Solid dose. (3 pages);
- 23. SOP [REDACTED] effective date [REDACTED] (16 pages); b4
- 24. Production Schedule of packaging of Liquid products for [REDACTED] (1 page); b4
- 25. Table for cross-referencing material number, description, and form for Liquids (2 pages);
- 26. SOP 20 [REDACTED] effective date [REDACTED] (15 pages); b4  
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- 27. SOP [REDACTED] effective date [REDACTED] (7 pages). b4  
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HLJW Exhibits

- 1. Children's Motrin Suspension Family Process Review (1 page);
- 2. Process Description for [REDACTED] Children's Motrin Berry Suspension (3 pages); b4
- 3. Manufacturing Process Flow Diagram Zyrtec Sugar Free Syrup-Bubblegum Flavor [REDACTED] (1 page); b4  
b4
- 4. Process Description for [REDACTED] Zyrtec Sugar Free Syrup-Bubblegum flavor (5 pages); b4

5. Benadryl Allergy and Cold KapGels Process Review (2 pages);
6. Benadryl Allergy and Cold KapGels Process Flow Diagram (2 pages);
7. Work Order for repair of mezzanine in [REDACTED] (1 page); b4
8. SOP [REDACTED] (33 pages); b4  
b4
9. FDA DQRS and Complaint Investigation Status spreadsheet (pages 3);
10. [REDACTED] (50 pages); b4  
b4
11. [REDACTED] Executive Summary (23 pages);
12. Official Microbiological Record: Test Worksheet [REDACTED] pages); b4
13. Microbiological Testing of Chemical Components and Finished Products and [REDACTED] (103 pages); b4
14. Water Activity determination for Products made with [REDACTED] part number [REDACTED] (13 pages); b4  
b4
15. [REDACTED] Transaction Printouts for [REDACTED] lots: [REDACTED] and [REDACTED] (6 pages); b4  
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16. [REDACTED] (2 pages); b4  
b4
17. SOP [REDACTED] effective [REDACTED] (11 pages); b4
18. SOP [REDACTED] effective [REDACTED] (9 pages); b4  
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19. Compliant Issue Report [REDACTED] (4 pages); b4
20. SOP [REDACTED] effective [REDACTED] (25 pages.); b4  
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21. [REDACTED] (53 pages); b4
22. [REDACTED] (21 pages); b4
23. List of Batches Associated by [REDACTED] (49 pages)0; b4
24. Change Control [REDACTED] (48 pages); b4
25. [REDACTED] (8 pages); b4
26. Change Control [REDACTED] (4 pages); b4
27. SOP [REDACTED] (3 pages); b4
28. [REDACTED] (20 pages); b4  
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29. Select pages from the manufacturing and packaging batch record for Tylenol Infants DYE-FREE Tylenol Suspension Drops-Cherry Flavor [REDACTED] (7 pages). b4

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GP Exhibits

1. Copy of the investigation and associated data, statistical models and summaries of analysis, 11 pages.
2. Copy of the Quality Control Laboratory Investigation [REDACTED] 14 pages. b4
3. Listing of the [REDACTED] failures from [REDACTED] 1 page. b4
4. Copy of the [REDACTED] summary results for lot [REDACTED] 2 pages. b4
5. Organizational charts for the Chemistry Laboratory, 1 page.
6. Schematic diagram of the purified generation room and the systems that are inside this room, 1 page.
7. Large schematic diagram of the entire building where the manufacturing operations, 1 page.
8. Copies of the R & D summaries of the studies and results, 5 pages.

ATTACHMENTS

- DORS #'s [REDACTED] b4  
[REDACTED] that were covered during this inspection; b4
- Form FDA-482, Notice of Inspection, dated 5/19/09;
- Form FDA-483, Inspectional Observations, dated 6/4/09.



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*Vlada Matusovsky*  
Vlada Matusovsky, Investigator

*George Pyramides*  
George Pyramides, Chemist

*Hala L. J. Whetstone*, Investigator  
Hala L. J. Whetstone, Investigator

*Linda M. Hoover*  
Linda M. Hoover, Investigator