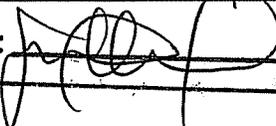


Establishment Inspection Report
McNeil PPC, Inc.
Lititz, PA 17543-8701

(GEN)	SPEC
RELEASE	EI Start: 05/12/2008
F# _____	EI End: 05/16/2008
DATE 5/17/2010	
Reviewed by: 	

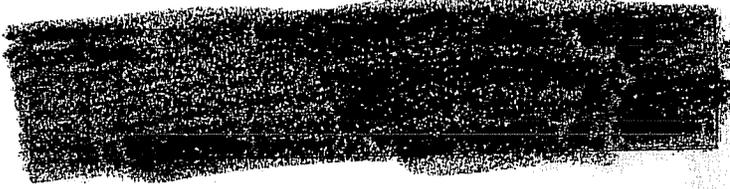
2510770
05/12/2008
05/16/2008

SUMMARY

This comprehensive GMP inspection of a finished pharmaceutical and cosmetic manufacturer was conducted per FACTS Assignment ID 857335 and Operation ID 3368316 and in accordance with Compliance Program 7356.002 titled Drug Manufacturing Inspection and in accordance with Compliance Program 7329.001 titled Cosmetics Program; Import and Domestic for PHI-DO FY-08 work plan. The inspection also covered Consumer Complaint [REDACTED] for the product Listerine Fresh Burst; coverage of this complaint was instructed in the FACTS assignment listed above. b4

Previous GMP inspection was conducted 03/06, 08, 09/08 and covered a complaint into [REDACTED]. The previous GMP inspection covered quality system, packaging and production systems. No significant cGMP deficiencies were noted and no FDA-483 was issued. The inspection was classified [REDACTED]. Previous Directed Inspection was conducted 04/16,17/07 and focused specifically on the recall of Listerine Agent Cool Blue (LACB) flavors Bubble Blast and Glacier Mint; this was not a complete GMP inspection. There were no discussion items addressed with management and no FDA 483 was issued during the Directed Inspection and was classified [REDACTED]. b4 b4 b2

Current inspection covered Quality Systems; Facilities and Equipment Systems; Material Systems; Production Systems; Packaging and Labeling Systems and Lab Systems. The products evaluated were chosen using a risk based inspectional approach and included the following: [REDACTED] and the Listerine Product Line for OTC. The inspection covered the firm's complaint system for all products; Adverse Event Reports; Annual Product Reviews; stability; validation studies; and laboratory confirmed and non confirmed OOS. Also evaluated during the inspection was the firm's investigations for manufacturing and packaging lines. Various SOP were reviewed. Batch records were reviewed for [REDACTED]. The micro-lab and analytical lab were inspected. Training records were reviewed. On 04/11/07 the firm initiated a voluntary nation wide consumer recall of all lots of GLACIER MINT™ and Bubble Blast™ flavors of Listerine® Agent Cool Blue Plaque-Detecting Rinse. The voluntary recall was initiated by the firm because of the preservative system was not adequate against microorganisms. The firm stopped manufacturing the product. The firm contacted the PHI-DO on 04/25/08 to notify the FDA they will be initiating compounding and filling Listerine Agent Cool Blue. According to Ms Williams the firm will be compounding on 05/18/08 and filling on 05/19/08. Also reviewed during the inspection was the reformulated, new preservative system and re-labeled Listerine Agent Cool Blue (LACB) flavors Bubble Blast and Glacier Mint. Management informed that Listerine Agent Cool Blue is now a cosmetic and no longer considered an OTC or device. No Form FDA 483 was issued to management during this inspection. However there were 2 discussion items addressed with management for the following: 1. During the inspection of the analytical lab I observed [REDACTED] being stored in the same area as the [REDACTED]. Specifically, the expired standards were in a clear case adjacent to the [REDACTED]. I requested to see the procedure where it explains that unapproved products being tested are in an [REDACTED] via the [REDACTED] and therefore are prevented from being used to [REDACTED]. b4 b4 b4 b4 b4



Establishment Inspection Report

McNeil PPC, Inc.
Lititz, PA 17543-8701

FEI: 2510770
EI Start: 05/12/2008
EI End: 05/16/2008

manufacture products or released. A procedure explaining this could not be provided. Corrective actions to these discussion items were reviewed and verified during the inspection.

ADMINISTRATIVE DATA

On 05/12/08 I (Anita R. Michael, Investigator) and Prabhu P. Raju, Investigator presented our Credentials and issued the Form FDA 482 Notice of Inspection (**attachment-1**) and attachment Resources for Regulated Businesses to David A. Burton, Site Leader Lititz who identified himself as the most responsible person at the firm at that time and authorized to accept the forms. Prabu P. Raju, Investigator was present specifically to conduct my Level II Certification Audit only. I also presented Mr. Burton with a copy of the order/ Consent Decree of Permanent Injunction (number 93-3525) dated 08/16/93. The site continues to operate under Consent Decree of Permanent Injunction (number 93-3525) dated 08/16/93. The Form FDA 482 was modified per the IOM Follow-Up Inspections by Court Order. The following statement was read to Mr. Burton. "This inspection is being conducted under the authority of injunction (number 93-3525) granted by the United States District Court against this firm on 08/16/93. The inspection will cover all items specified in the court decree, I am issuing you a Notice of Inspection under the authority of Section 704 of the FD&C Act which authorizes inspections of firm's subject to that Act". Mr. Burton accepted the forms.

I (Anita R. Michael, Investigator) wrote the entire EIR.

Please address all correspondence to the attention of David Burton, Site Leader at the address below.

Inspected firm: McNeil PPC, Inc.
Location: 400 W Lincoln Ave
Lititz, PA 17543-8701
Phone: 717-626-2011
FAX:
Mailing address: 400 W Lincoln Ave
Lititz, PA 17543-8701

Dates of inspection: 5/12/2008, 5/13/2008, 5/14/2008, 5/15/2008, 5/16/2008
Days in the facility: 5
Participants: Anita R. Michael, Investigator

HISTORY

According to Ms Williams the firm's legal name is McNeil PPC, Inc. The site was purchased by McNeil in December 2006. The firm's corporate headquarters remains located at McNeil Consumer Healthcare, 7050 Camp Hill Road, Fort Washington PA.

Establishment Inspection Report

McNeil PPC, Inc.
Lititz, PA 17543-8701

FEI: 2510770
EI Start: 05/12/2008
EI End: 05/16/2008

The firm remains under Consent Degree of Permanent Injunction from 1993 (number 93-3525). This site continues to produce the product [REDACTED] which is listed in the 1993 Consent Degree. According to Ms Williams, the firm is going to transfer the manufacturing of [REDACTED]. In addition, she explained [REDACTED] will be transferred to the [REDACTED] on or about [REDACTED]. The firm has discontinued manufacturing [REDACTED] the last batch was manufactured on [REDACTED] lot number [REDACTED] expiration date [REDACTED]. Lot [REDACTED] was released to market [REDACTED] is the last remaining product at this site that is identified within the Consent Decree. [REDACTED] Batch records for [REDACTED] continue to be reviewed and certified by an outside consulting firm. The batch certification is conducted by [REDACTED] Analysis involved in the analysis of [REDACTED] continue to be certified by [REDACTED]

b4

On 04/11/07 the firm initiated a voluntary nation wide consumer recall of all lots of GLACIER MINT™ and Bubble Blast™ flavors of Listerine® Agent Cool Blue Plaque-Detecting Rinse. Please see section of the EIR titled Recall for details concerning this product.

The firm has a current FDA drug registration, registration date 02/07.

According to Ms Williams the firm's operates [REDACTED] hours a day, five days per week. The firm's hours of operation can also extend into the weekends as needed. According to Ms Williams the firm employs [REDACTED] employees of which [REDACTED] of them are part of the Quality Unit.

b4
b4

INTERSTATE COMMERCE AND JURISDICTION

According to Ms Williams the firm receives [REDACTED] of their incoming raw materials interstate and [REDACTED] intrastate. [REDACTED] Of the firm's finished products are shipped interstate and [REDACTED] intrastate. Ms Williams provided a list of the firm's currently marketed products packaged and manufactured at this location. Please see exhibit-1 for details. Ms Williams informed that the firm has discontinued manufacturing the product [REDACTED]

b4
b4
b4

The firm manufactures various cosmetics such as

- Listerine Stay White
- Corn Huskers Lotion
- Lubriderm Lotions
- Listerine Agent Cool Blue (Glacier Mint and Bubble Blast)

The firm manufactures the following Rx pharmaceuticals

[REDACTED]

b4

Zyrtec D Tablets 5mg/120 mg Packaged only at this location

Establishment Inspection Report

McNeil PPC, Inc.
Lititz, PA 17543-8701

FEI: 2510770
EI Start: 05/12/2008
EI End: 05/16/2008

The firm manufactures the following OTC

Benedryl Cream 1% and 2%

Listerine (Antiseptic; Citrus; CoolMint; Freshburst; Smart Rinse Cool Berry Citrus and Jungle Mint; Tartar Control; Tarter Control Advanced; Total Care; Vanilla Mint; Whitening Mouthwash; Whiting Pre-Brush Treatment; Listerine Citrus 100% Natural)

Neosporin (Lip Treatment; Original Ointment; Plus Ointment; Plus Cream)

Polysporin Ointment

According to Ms Williams McNeil PPC, Inc is contracted by [REDACTED] to manufacture [REDACTED] and contract packages Zyrtec D Tablets 100 mg. She provided the document titled [REDACTED] for my review. Please see exhibit-2 for details.

b4
b4
b4

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

Ms Williams explained the firm's organizational structure and individual responsibilities for all of the individuals described below except for Tom Himmelsbach, Manager of the Quality Assurance Laboratory.

David Burton, Site Leader remains the most responsible person at this location. Mr. Burton continues to be the most responsible individual at this site in charge of overseeing Materials Management, Human Resources, Production Operations and the Lean Lead Organization. He oversees the production operations involving OTC, RX and Cosmetics manufactured at this location. The individuals responsible for the manufacturing of oral care and personnel care products report to Mr. Burton. Mr. Burton reports to Paul Lefebvre, VP of Global Supply Chain. Mr. Burton's office is located at this address. Mr. Lefebvre's office is located at 199 Grandview in Skillman, New Jersey 08558. Please see exhibit-3 pg 1 for details.

Bobette Williams, Director of Quality Assurance is responsible for quality control which oversees the analytical laboratories and micro laboratories, quality assurance. She is ultimately responsible for the release of product. She explained the quality assurance is involved with product release as well as assuring that materials or components of known accepted or controlled disposition are used for the manufacturing of products. Ms Williams explained she is the most responsible person at this site that has the authority to prevent, detect and correct possible violation. Ms Williams reports to Teresa Gorecki, VP QA Northern America. Ms Gorecki's office is located at 199 Grandview in Skillman, New Jersey 08558. Ms. Williams office is at this location. Please see exhibit-3 pg 2 and 3 for details.

According to Tom Himmelsbach, Manager of the Quality Assurance Laboratory he is responsible for overseeing the analytical laboratory and micro laboratory. He is responsible for assuring the laboratories are operating in compliance with current GMP's. Mr. Himmelsbach is also involved

Establishment Inspection Report

McNeil PPC, Inc.

Lititz, PA 17543-8701

FEI: 2510770

EI Start: 05/12/2008

EI End: 05/16/2008

with investigations involving the laboratories. He can hire and fire. He reports to Ms. Williams. His office is at this location. **Please see exhibit-4 for details.**

The following individuals provided the majority of records, answered the majority of the questions and accompanied me throughout the inspection of the facility: Bobette Williams, Director Quality Assurance; Tom Himmelsbach, Manager Quality Assurance Laboratory; Scott Weeks, Manager Quality Assurance; and Judy Case, Manager Quality Assurance.

The following individuals also provided information during the inspection: Ron Wood, QA Team Leader Product Release; Jeff Jenner, Staff QA Scientist; Lynn Hostetler, Team Leader Oral Care Packaging; Bob Courtot, Staff Quality Engineer Investigations; and Greg Littrell Facilities Maintenance Manager.

On 05/12/08 I conducted a general inspection of the plant. The following individuals were present:

Dave Engwall, Manage Oral Care

Tyran Welch, Manager Personal Care

Dennis McLaughlin, Team Leader Personal Care

Ralph Greenawalt, QC Technician II

Lynn Hostetler, Team Leader Oral Care Packaging

Tammy Pugliese, Team Leader, Microbiology

On 05/14/08 I conducted an inspection of the Mouthwash Packaging Line 2001. The following individuals were present:

Todd Danforth, Team Leader Oral Care Packaging

Tim Gragg, Packaging Line Mechanic

On 05/15/08 I conducted an inspection of the Dilantin® 125mg Suspension manufacturing area. The following individuals were present:

Ty Welch, Manager Personal Care

Drew Bradley, Business Unit Leader

Aris Nicholas, Manager Process Technology

Dennis McLaughlin, Team Leader Personal Care

Sammy Soto, Personal Care

On 05/15/08 I conducted an inspection of the micro lab. The following individuals were present:

Tammy Pugliese, Team Leader Microbiology

Steve Witmer, QA Team Leader

Establishment Inspection Report

McNeil PPC, Inc.
Lititz, PA 17543-8701

FEI: 2510770
EI Start: 05/12/2008
EI End: 05/16/2008

On 05/15/08 I conducted an inspection of the analytical lab. The following individual was present:
Sue Butler, QA Team Leader

On 05/16/08 I conducted an inspection of [REDACTED] The following individuals were present:
Ty Welch, Manger Personal Care
Drew Bradley, Business Unit Leader, Personal Care
Aris Nicholas, Manager Process Technology

b4

On 05/16/08 I conducted an inspection of the packaging lines [REDACTED] and [REDACTED] for [REDACTED] and LACB. The following individuals were present:
Drew Bradley, Business Unit Leader, Personal Care
Cindy Grill, Team Leader Personal Care

b4
b4

FIRM'S TRAINING PROGRAM

I requested to see the training records for the employee involved with the manufacturing [REDACTED] and [REDACTED] involved the downline inventory of [REDACTED] of Freshburst bulk lot [REDACTED] manufactured on [REDACTED] prior to startup on [REDACTED]. The [REDACTED] again involved the downline inventory of [REDACTED] of Listerine bulk lot [REDACTED] manufactured on [REDACTED] prior to production startup on [REDACTED]. Ms Williams provided the records as requested. I reviewed the employee training records for [REDACTED] in detail. [REDACTED] last GMP training was [REDACTED]. The training records appeared complete except for documenting in [REDACTED] training records that the issues involved with [REDACTED] and [REDACTED] had been reviewed and discussed with this employee. Ms Williams explained she understood and agreed to include the re-training or counseling in the [REDACTED] in the future for employees identified as involved in multiple [REDACTED].

b4
b4
b4
b4
b4
b4
b4
b4
b4

I requested to see the training records for the QA Scientist involved with laboratory investigation reports. As requested Mr. Himmelsbach provided the GMP training records for [REDACTED] and [REDACTED]. The 2007 GMP training for quality topics microbiology; manufacturing and the [REDACTED] were reviewed for these employees. No deviations were revealed.

b4
b4
b4

As requested Ms Williams provided the training records for Mr. Weeks from the Quality Assurance group. I reviewed his recent training records for specific knowledge and skills in areas such as product recalls; field alerts; consumer complaint vigilance; stability protocols and quality assurance. During the inspection he answered various questions regarding quality assurance procedures, complaint procedures, trending of complaints and manufacturing processes. No deviations were revealed.

MANUFACTURING/DESIGN OPERATIONS

Manufacturing process for [REDACTED]

b4

Establishment Inspection Report
McNeil PPC, Inc.
Lititz, PA 17543-8701

FEI: 2510770
EI Start: 05/12/2008
EI End: 05/16/2008

I observed the manufacturing of [REDACTED] during the inspection. I inspected [REDACTED] My inspection revealed no deviations.

b4
b4

According to Mr. Weeks the following manufacturing process is employed to produce [REDACTED] Mr Weeks provided the flow diagram for [REDACTED] please see exhibit-5 for details:

b4
b4

[REDACTED]

b4

[REDACTED]

b4

[REDACTED]

b4

[REDACTED]

b4

Quality Systems and Production Systems

I requested Ms Williams provide the firm's most recent annual product review for [REDACTED] and FreshBurst Listerine. I reviewed the annual product review provided by Ms Williams for [REDACTED] dated [REDACTED] through [REDACTED]. I reviewed the specific sections Product Change Request; Validation; [REDACTED] and [REDACTED]. I reviewed the document to determine if any trends were identified and addressed in this report. There was one possible trend identified by the firm for [REDACTED] results resulting in [REDACTED] being generated. I requested Mr. Himmelsbach explain the details concerning these dissolution results. Mr. Himmelsbach informed the firm identified a possible trend for out of alert limits for the dissolution results. However the dissolution test results were within compliance specifications. I evaluated the assessment the firm had conducted into the impact of quality for the dissolution out of alert limits described in [REDACTED] and [REDACTED]. The firm evaluated the products stability history, expiration period and overall impact on product quality. My review of the records concerning [REDACTED] and [REDACTED] revealed no deviations. As requested Ms Williams provide the most recent [REDACTED] annual product review dated [REDACTED] through [REDACTED]. I reviewed this document. The records indicated that the firm conducted an evaluation of a possible trend for viscosity. I requested Mr. Himmelsbach explain in further detail the viscosity results for investigations [REDACTED] and [REDACTED]. He explained that the results were outside the alert limits but were within the compliance specifications. In addition, for [REDACTED] and [REDACTED] the low out of alert limit viscosity results were evaluated. As indicated in these [REDACTED] the firm investigated the impact of these results on product quality. In addition, the firm evaluated their stability program and concluded that based on the amount of stability data that currently exists for [REDACTED] the alert limits should be eliminated as a requirement of [REDACTED] analytical procedure. I also reviewed the firm's Annual Product review for Fresh Burst Listerine dated 02/01/06 through 01/31/07 provided by Ms Williams. I reviewed the sections Validation; [REDACTED] Reports; and stability. My review revealed no deviations.

b4

Ms Williams explained the Benefits Risk Management Center (BRMC) which office is located at Johnson & Johnson Pharmaceutical Research and Development 100 Tournament Drive Horsham PA 19044 receives all complaints via the call center and processes all consumer complaints for products manufactured and packaged at this location except for [REDACTED]. She explained the calls come into the complaint center and adverse events are reviewed by the (BRMC) and are then referred to this site for further investigation if warranted. Complaints concerning product quality are also forwarded to this location from the call center for further investigation. She provided the procedure titled [REDACTED] Investigating Consumer Complaints for J&J Consumer Healthcare Products using the Product Quality Management System (PQMS). I requested to see a list of complaints for all products since the previous inspection excluding [REDACTED] product complaints

b4

b4

b4

Establishment Inspection Report

McNeil PPC, Inc.

Lititz, PA 17543-8701

FEI: 2510770

EI Start: 05/12/2008

EI End: 05/16/2008

were evaluated separately during this inspection (see below). Mr. Weeks provided multiple spreadsheets which trended complaints concerning consistency texture; damaged containers; difficult to open and foreign materials for the Benadryl; Listerine; Lubriderm and Neosporin product lines. I reviewed the summary complaint reports with Mr. Weeks. He explained how the complaints for [REDACTED] complaints were trended in the reports and evaluated at monthly meeting with management. I reviewed the data for possible trends in any of the areas specified above. My review of the reports indicated there were [REDACTED] complaints for [REDACTED] for the product line Listerine Original Packaged during April 2007. I requested to see the complaint report [REDACTED] addressing [REDACTED]. I reviewed this complaint. The root cause was identified as [REDACTED]. Samples were received for [REDACTED] complaints for product line Listerine Original Packaged April 2007. Mr. Weeks and I reviewed the reports that indicated that for [REDACTED] complaint for which samples were received the firm's investigations revealed that the root cause was also identified as backwash. My review of these complaints and supporting documentation revealed no deviations.

b4
b4
b4
b4

Ms Williams explained complaints for [REDACTED] products are received at the [REDACTED]. She provided the procedure titled [REDACTED]. I reviewed this document. I requested to see a list of all of the [REDACTED] Complaints since the previous inspection and the current prescribing information. I reviewed this document. Ms Case provided a spread sheet titled [REDACTED] Complaints. Since [REDACTED] which listed [REDACTED] complaints which were investigated at this location. I reviewed this list for possible complaint trends. I observed that [REDACTED] complaints were for efficacy. Complaint [REDACTED] was in progress and Complaint [REDACTED] indicated the lot number was unknown. I requested to see the detailed investigational reports for complaint [REDACTED]. I reviewed Complaint [REDACTED] (investigation) to determine if the history of the lot was evaluated or if there had been any other lots of this product manufactured with similar efficacy complaints. The report indicated there was one related complaint [REDACTED] that was investigated and found not to be processed related. I reviewed the complaint [REDACTED] report to determine if the product testing had been evaluated for this lot and if all specifications were met. The firm evaluated the testing data and reported the results in the complaint report. The stability data generated for this lot was reviewed by the firm and reported in the complaint report. My review of the complaints revealed no deviations.

b4
b4
b4
b4
b4
b4
b4
b4

In addition, I requested to see a list of all complaints for [REDACTED] product complaints associated with adverse events received from the previous inspection to date and the current prescribing information. Ms Case provided a spread sheet that included this information and the prescribing information. I reviewed this list for possible complaint trends. I requested to see the detailed complaint investigation reports [REDACTED] for a color complaint and [REDACTED] related to an efficacy complaint. I reviewed [REDACTED] for whether the history of the lot was evaluated; product history evaluated; batch record review; stability data review; and retains examined. No deviations were revealed. I reviewed complaint [REDACTED]. Ms Case explained for this complaint a sample or lot number was provided therefore the history of the lot could not be evaluated. The firm evaluated the product history. The product complaint history;

b4
b4
b4

Establishment Inspection Report
McNeil PPC, Inc.
Lititz, PA 17543-8701

FEI: 2510770
EI Start: 05/12/2008
EI End: 05/16/2008

stability history for released lots was evaluated by the firm. I reviewed the report to see if the firm had identified a trend of efficacy issues for this product. The firm's evaluation of the products history revealed no trends concerning efficacy. I requested to see the adverse event reports; Medwatch Form FDA 3500A for Adverse Event Reports [REDACTED]. I reviewed these Medwatch reports for description of the event; type of report 15 day or periodic and the reported time frames. My review revealed no deviations.

b4
b4

I requested to see the firm's complaint investigation for review. Ms Case provided the Issue Report Tracking Consumer Complaint [REDACTED] 6 for my review. I reviewed this document. No field sample was obtained for this lot [REDACTED]. The complaint history was evaluated for adverse events. I also reviewed the investigational findings. The firm reviewed and evaluated the lab test results for this lot. Retains were evaluated. My review of this investigational report revealed no deviations.

b4
b4

I requested to see a list of manufacturing deviations sorted by product since the previous inspection for all products manufactured at this location. Ms Williams provide a spreadsheet listing the deviations for the specific products as requested. I reviewed this list for possible trends related to product risk for the various products manufactured. I requested to see the [REDACTED]. Ms Williams provided the procedure titled [REDACTED] for my review. I reviewed this document. My review revealed no deviations.

b4
b4
b4
b4

According to Ms Williams the firm had not filed any Field Alerts since the previous GMP inspection. In addition, she explained the firm has not reworked or reprocessed any products since the previous GMP inspection. She further explained the firm has had no validation failures since the previous GMP inspection.

I requested Ms Williams provide a list of all rejected materials including batches since the previous GMP inspection. She provided me with a list describing all of the rejected materials. I reviewed this list for possible trends within the specific products and or problem descriptions. I reviewed this list in detail and observed an [REDACTED] was initiated for lot [REDACTED]. The records indicated that a [REDACTED] was introduced into the batch. I requested to see the detailed investigation conducted into this [REDACTED]. According to the records the root cause was a piece of [REDACTED] and was introduced into the [REDACTED]. The impact on product quality was evaluated and the lot was destroyed. I requested Ms Williams provide the firm's procedure used to destroy unusable materials. She provided the procedure titled [REDACTED] for my review. I reviewed this procedure and the associated documentation for [REDACTED]. My review of the rejected materials list revealed no trends specific to other products or [REDACTED]. My review of these records revealed no deviations.

b4
b4
b4
b4
b4
b4
b4

Ms Williams as requested provided a list of all their returned products and materials since the previous GMP inspection. I reviewed this list for possible trends identified with specific products or

Establishment Inspection Report

McNeil PPC, Inc.

Lititz, PA 17543-8701

FEI: 2510770

EI Start: 05/12/2008

EI End: 05/16/2008

lots of products. Ms Hostetler was also interviewed during the inspection and she explained the process implemented for returned goods as well as rejected materials. My review of the records and interview revealed no possible trends or deviations.

According to Mr. Himmelsbach the firm has had no stability failures for [REDACTED] of [REDACTED] since the previous GMP inspection.

b4
b4

I requested Ms Williams provide a comprehensive list of all of the firm's changes made to all areas of manufacturing since the previous GMP inspection. She provided this list for my review. I reviewed this list and requested to see the [REDACTED] and [REDACTED] including all associated documentation. [REDACTED] was initiated for the [REDACTED] modification for the [REDACTED] was initiated for [REDACTED]. According to Mr. Littrell dissolved [REDACTED]. I reviewed the [REDACTED] in detail and observed the impact on validation was evaluated in the [REDACTED]. I also requested to see the procedures associated with Change Control. The procedure titled [REDACTED] was provided for my review. I reviewed this document and evaluated the [REDACTED] provided accordingly. No deviations were revealed.

b4
b4
b4
b4
b4
b4
b4

I requested to see the most recent validation protocol, final report and associated raw data for the validation performed for [REDACTED]. Ms Williams provided the documents for the process validation regarding [REDACTED] for my review. She explained the objective of the validation was to monitor a batch of [REDACTED] using the [REDACTED] with a [REDACTED]. I reviewed the documents provided. All major equipment was identified; description of the manufacturing process and detailed steps in manufacturing were described. I requested to see where the critical process steps were outlined in the records. I observed these steps were identified. The acceptance criteria were identified and specifications outlined for all tests to be performed were explained. All analytical results met the specifications. The lots to be placed on stability were also identified. There were no deviations observed for the validation documents provided for my review.

b4
b4
b4
b4

Mr. Jenner and I discussed the [REDACTED] cleaning validation. I requested to see the cleaning validation final report, protocol and all associated data. He provided these documents for my review. Mr. Jenner and I discussed the validation of soiled equipment and the allowed time intervals prior to cleaning. I explained to Mr. Jenner that this product is a [REDACTED] and may become more difficult to clean over time if not cleaned in a timely fashion. He explained that the [REDACTED]. He pointed this out in the cleaning validation documents provided for my review. We also reviewed the microbial swab and rinse samples testing and corresponding data. In addition, he explained the preliminary alert limits for samples. I requested Mr. Weeks provide the cleaning logs for [REDACTED]. I reviewed the cleaning logs for the following areas: [REDACTED].

b4
b4
b4
b4
b4
b4
b4
b4

The validation study was

Establishment Inspection Report

McNeil PPC, Inc.

Lititz, PA 17543-8701

FEI:

2510770

EI Start:

05/12/2008

EI End:

05/16/2008

reviewed approved by Quality Operations. My review of these cleaning logs and validation records revealed no deviations.

I requested Mr. Himmelsbach provide a list of all of the lots of [redacted] and Listerine Freshburst manufactured since the previous GMP inspection. The list indicated that [redacted] were manufactured; [redacted] were manufactured and [redacted] of Freshburst Listerine since the previous GMP inspection. The focus of the batch record review was on the [redacted]. As requested Mr. Himmelsbach provided the master batch records for [redacted] for my review.

b4
b4
b4
b4
b4
b4

I requested to see the batch record (Bulk Manufacturing Orders) for [redacted] mg Lots [redacted] and [redacted]. According to Ms Williams the equipment used to manufacturer [redacted] products are dedicated including the packaging lines. I reviewed each of the manufacturing orders. Each piece of equipment was identified in the batch records. The phases of the manufacturing process were also identified. For example the [redacted] and [redacted]. A list of the raw materials and theoretical quantity were identified. Ranges were also included for different phases of the process. The recorded data was documented and batch records were complete. Mr. Wood explained how the Theoretical yields; % usable yields; and accountable yields are calculated. I reviewed the calculations in the manufacturing orders with Mr. Wood. The sample analysis reports and raw data were reviewed for the in process dissolution testing. My review revealed no deviations.

b4
b4
b4
b4

I requested Mr. Woods provide the complete batch records for [redacted] lots [redacted] and [redacted] for review. He explained the batch records and how the pertinent steps are documented in the batch and reviewed. I reviewed each of these batch records and the master batch provided for consistency. The quantity required of raw materials was listed in each batch and amount used. The equipment used in the manufacturing process was listed in the batch record. The time limits for manufacturing steps such as [redacted] were specified. The start times and completion times were documented in the Bulk Manufacturing Orders. Mr. Wood explained the yield calculations such as actual yield, losses in manufacturing, % theoretical yields and the specified limits [redacted]. The batch records were reviewed for these calculations and specified limits. I also reviewed the raw data, and Sample Analysis Reports for bulk testing and finished product testing. I reviewed the [redacted] for the bulk and specific gravity, [redacted] impurity degradation testing and dissolution raw data and results for the finished product testing. My review of these documents revealed no deviations.

b4
b4
b4
b4
b4

Facilities and Equipment Systems and Material Systems

I explained to Ms Williams on the first day of the inspection that I would like to inspect the raw material receiving area of the facility. During the inspection of the raw material receiving area Mr. Himmelsbach explained the firm's procedure for receiving raw materials. I observed the area where incoming raw materials are received. Mr. Himmelsbach explained how packaging components are

Establishment Inspection Report

McNeil PPC, Inc.
Lititz, PA 17543-8701

FEI: 2510770
EI Start: 05/12/2008
EI End: 05/16/2008

sampled, inspected and approved by QC prior to being used in manufacturing. He explained that the Bill of Ladings received are verified, reviewed and compared to what is received in the shipments. The firm inspects the raw material pallets for damage. Tickets are attached on pallets. Information is documented on the [REDACTED]. A computerized receiving report is generated and sampling plan initiated. Ms Williams accompanied me to the rejected caged area in the firm's warehouse. She explained all rejected items are stored in the locked caged area separated from other products. I requested to see the firm's [REDACTED] which documents and accounts for rejected materials. Ms Williams provided the forms requested. I reviewed [REDACTED] of these forms. All products that were observed in the rejected cage had been documented on the forms accordingly. My review revealed no deviations.

b4
b4
b4

I requested Mr. Himmelsbach explain how raw materials and container closures are sampled and inspected upon receipt. He explained about visual exams of container closures. He explained pallets are checked before they are taken into the sampling booth. COA received with each shipment of a lot and are reviewed. Employees verify the cleaning has been documented and environmental conditions and pressures are correct of the sampling booth. The raw materials intended to be sampled are moved into the sampling booth. The bulk description is checked against what is in the containers. Samples are obtained using specific sampling instructions. Sampling reports are initiated. Mr. Himmelsbach provided the procedure titled [REDACTED] for my review. Mr. Himmelsbach explained that samples are logged and approved in the firm's automated [REDACTED] with quality assurance oversight. Also raw materials are in quarantined status [REDACTED] and in [REDACTED] in the firm's automated [REDACTED]. Please see Section of the EIR titled **Objectionable Conditions and Managements Response** for details.

b4
b4
b4
b4

I also requested to see the [REDACTED] for the ID test performed on the [REDACTED] to verify their testing procedures were followed. He provided these records as well as the re-assay associated laboratory data for my review. The firm employs a FIFO system. No deviations were revealed.

b4
b4

According to Mr. Himmelsbach the [REDACTED] used in [REDACTED] is manufactured at the [REDACTED]. Internal annual audits are conducted at that location. The active is ID tested using and IR method and description of the active is verified at this location. No deviations were revealed.

b4
b4

Mr. Littrell accompanied me during the inspection of the USP Purified Water System. USP Purified Water is used to manufacture the products at this facility. Mr. Littrell explained the diagrams of the USP Purified Water System. I inspected the [REDACTED]. I compared the updated diagrams with the actual equipment used to process the USP Purified Water. I requested to see the Sample Analysis Reports for the Purified Water, USP since the previous GMP inspection. Mr. Himmelsbach provided these records. I selectively reviewed [REDACTED] of these reports. I reviewed the microbial limit-total aerobic count data. I requested to see the firm's most recent annual report for the Purified Water System.

b4
b4
b4

were deviations; the deviations were documented and evaluated accordingly. I requested to see the most recent semi annual inspectional reports for [redacted] and calibration records for the [redacted]. Mr. Himmelsbach provided the Work Orders and calibration records requested. I reviewed the following Work Orders: [redacted]. I also reviewed the most recent Instrument Calibration Data Sheet for the [redacted]. No deviations were revealed.

b4
b4
b4
b4
b4

According to Ms Williams all areas in the facility are non-classified. The manufacturing areas employ an HEPA air handling system.

Laboratory Control System and Packaging and Labeling System

I requested to see all of the confirmed and non confirmed OOS investigations for [redacted] and the Listerine Freshburst since the previous GMP inspection. Mr. Himmelsbach explained that the only product that had confirmed and non confirmed OOS investigations was the Listerine Freshburst. He provided a list of the [redacted] which consisted of [redacted]. I requested to see all [redacted] which were provided by Mr. Himmelsbach. For the Listerine Freshburst the firm had [redacted] for the [redacted] and could be a possible trend. I reviewed each of the [redacted] provided in detail. I reviewed each of the [redacted] for an assignable cause. In each of the [redacted] the assignable cause was documented as a [redacted]. Mr. Himmelsbach explained that the [redacted] results are consistent with the stability history trends and the assignable cause is [redacted]. The reports were reviewed and approved by a QA reviewer. My review revealed no deviations. He also provided the procedure the firm uses to investigate laboratory OOS. My review of these documents revealed no deviations.

b4
b4
b4
b4
b4
b4
b4
b4
b4

The analytical records for [redacted] and [redacted] were reviewed during the batch record review described above in the section of the *EIR Quality Systems and Production Systems*. These records were reviewed for analytical and micro testing performed for the batches. The [redacted] method for performing the Description test and ID (IR) were reviewed. Mr. Himmelsbach provided the records and explained the IR infrared spectrum of a potassium bromide dispersion of the test substance exhibits maxima or minima only at the same wavelengths as that of a similar prep of [redacted] Reference Standards. The description is a white powder. Mr. Himmelsbach also provided as requested the methods used to test [redacted]. I reviewed the specifications which included the assay; impurity / degradation test; and microbial limits.

b4
b4
b4
b4
b4

I requested to see a list of the laboratory equipment used to analyze [redacted] lots [redacted] and [redacted]. Mr. Himmelsbach provided this list. From this list I requested to see the LC used specifically in the testing for lot [redacted]. I reviewed the Installation Qualification Protocol and Annual Operation Qualification dated [redacted]. In addition I reviewed the analytical testing data for [redacted] for the system suitability checks. My review revealed no deviations. I requested to see the Installation Qualification for the dissolution bath [redacted] and Operational

b4
b4
b4
b4
b4

Establishment Inspection Report

McNeil PPC, Inc.
Lititz, PA 17543-8701

FEI: 2510770
EI Start: 05/12/2008
EI End: 05/16/2008

Qualification. This dissolution batch was used in the testing of lot [REDACTED] I reviewed the reports and results. My review revealed no deviations. I requested Mr. Himmelsbach provide all of the investigations conducted for equipment failures in the laboratories since the previous GMP inspection. He provided the investigations as requested. I selected [REDACTED] to review. This investigation documented a deviation of the alarm system while the equipment was being calibrated. The impact on quality of the products was addressed in this investigation. My review did not reveal any deviations. I requested to see the investigation [REDACTED] concerning the [REDACTED] which was found to be out of tolerance. I reviewed the investigation to determine if the firm had evaluated the data obtained using this instrument and if there was any impact on the data due to the out of tolerance reading. The firm had reviewed the data and determined that the data obtained was not effected by the out of tolerance reading. My review of the investigation reviewed no deviations.

b4
b4
b4

According to Mr. Himmelsbach for [REDACTED] receives the stability samples and is responsible for testing the samples and has all the associated documentation and records. No [REDACTED] stability studies are conducted at this location. I requested to see the stability protocol for Benadryl Cream 1% (non aloe) that is tested and evaluated at this location. I reviewed the specific tests conducted and the corresponding specifications. I reviewed the test data for Lot [REDACTED] at pull dates months 00; 03; 06 and 09. My review of these records revealed no deviations. Mr. Courtot explained the stability chamber alarm system. Specifically he explained that the small stability chambers have [REDACTED] sensor and the large stability chambers have [REDACTED] sensors that monitor the temperature and humidity. The stability chambers are monitored by an [REDACTED] alarm system. The firm utilizes [REDACTED] system. When an alarm is initiated notice are sent via email to designated individuals and is followed up by automatic phone calls. The system keeps calling individuals until someone is reached and the stability system returns to specifications. Emails are always sent out automatically to inform designated individuals of the stability alarms. As requested Mr. Courtot provided the document titled [REDACTED] I reviewed this document for the validation of the [REDACTED] and computer system for the stability chambers. My review of these documents revealed no deviations.

b4
b4
b4
b4
b4
b4
b4
b4

An inspection was conducted of the micro-laboratory and analytical laboratory. Ms Pugliese and Mr. Witmer accompanied me during the inspection of the micro-lab. Ms Butler accompanied me during the inspection of the analytical lab. Mr. Himmelsbach was present for the inspection of both labs. During the inspection of the micro-lab I inspected and evaluated the firm's procedures; records of receipt; preparation and labeling including storage for the microbial media. I also evaluated the testing of the media. I inspected and evaluated the procedures, storage, receipt and testing for the firm's biological indicators. My inspection of the micro-lab revealed no deviations. An inspection of the firm's analytical lab was conducted. Mr. Himmelsbach explained how samples are processed in [REDACTED] I inspected various pieces of equipment, lab note books and sample reports during the inspection. Mr. Himmelsbach explained how receipt, labeling, storage of analytical reference standards are processed. During the inspection of the analytical lab I observed some [REDACTED]

b4
b4

Ms Williams provided the procedure titled [REDACTED] for my review. My review of the records revealed no deviations. b4

RECALL

On 04/11/07 the firm initiated a voluntary nation wide consumer recall of all lots of GLACIER MINT™ and Bubble Blast™ flavors of Listerine® Agent Cool Blue Plaque-Detecting Rinse. The voluntary recall was initiated by the firm because of the preservative system was not adequate against microorganisms. The firm stopped manufacturing the product. Please see [REDACTED] b4

[REDACTED] The firm contacted the PHI-DO on 04/25/08 to notify the FDA they will be initiating compounding and filling Listerine Agent Cool Blue. The firm will be compounding on [REDACTED] and filling on [REDACTED]. During the inspection Ms Williams informed the firm has been corresponding with Think Nguyen, Director of Combination Products (FDA Center Contact Person). According to Ms Williams the firm has revised the label which previously read Listerine Agent Cool Blue Plaque-Detecting Rinse (Glacier Mint) and now reads Listerine Agent Cool Blue Tinting Rinse (Glacier Mint). The label Listerine Agent Cool Blue Bubble Blast also now reads Tinting Rinse. Please see exhibit-6 for the new labels for Listerine Agent Cool Blue (Glacier Mint and Bubble Blast). According to Ms Williams the product is now considered a cosmetic and not an OTC Drug or Device. As requested she provided the new formulation data sheets titled [REDACTED] b4

[REDACTED] Please see exhibit-7 for details. She also provided the [REDACTED] b4

[REDACTED] Please see exhibit-8 for details. As requested she provided the documents related to the new preservative system for this product. Specifically, the list of ingredients which includes [REDACTED] b4

[REDACTED] Please see exhibit-9 for details. She also provided a memo dated 05/16/08 describing the rational for Agent Cool Blue rational for selection of [REDACTED] b4

[REDACTED] Please see exhibit-10 for details. I requested she provide the following documents for the reformulated Listerine Agent Cool Blue (Bubble Blast and Glacier Mint): Research and Development Batches: R & D Preservative Effectiveness Testing Summary Data Results; Pilot Scale Preservative Effectiveness Testing Data Results; and the Full Manufacturing Scale Preservative Effectiveness Test Data Results. These documents were collected and submitted as exhibit-11. I reviewed these documents. I also reviewed the document titled [REDACTED] b4

[REDACTED] Please see exhibit-12 for details. I requested to see a list of the Adverse Event Complaints for the recalled Listerine Agent Cool Blue (Bubble Blast and Glacier Mint) investigated at this location since the previous inspection. Ms Case provided this list. I requested to see the investigations for the following Adverse Event Complaints: Tracking # [REDACTED] b4

[REDACTED] and [REDACTED] I reviewed each one of these documents in detail. My review revealed no deviations. b4

I inspected the manufacturing, packaging and labeling line for Listerine Agent Cool Blue Bubble Blast and Glacier Mint. Ms Williams was present during the inspection of these areas. I inspected the equipment Bulk Manufacturing Orders for both products. My inspection revealed no deviations. I

requested to see the Product Recall Procedure QSP1036. Ms Williams provided this procedure. My review revealed no deviations.

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

No Form FDA 483 Inspectional Observations was issued to the firm. However the were discussion items addressed with management for the following: b4

During the inspection of the analytical lab I observed [redacted] being stored in the same area as the [redacted]. Specifically, the [redacted] were in a clear case adjacent to the [redacted]. Mr. Himmelsbach explained that an [redacted] is an in-house standard utilized by Lititz Analytical Services. [redacted] will in the future indicate for [redacted]. He provided a draft Procedure titled [redacted] as corrective action. I reviewed this document. No deviations were revealed. Please see exhibit-13 for details. b4 b4 b4 b4

During the review and inspection of raw material receiving and testing Mr. Weeks explained that raw materials are in quarantined status [redacted] and in [redacted] in the firm's automated [redacted]. I requested to see the procedure where it explains that unapproved products being tested are in an [redacted] via the [redacted] and therefore are prevented from being used to manufacture products or released. Mr. Weeks explained they did not have such a procedure specifying that for my review. As corrective action he provided the document explaining how materials will be received in a Quality stock status (designated by Q). Please see exhibit-14 for details. I reviewed this document. My review revealed no deviations. He explained the firm is changing over from the [redacted] to the [redacted]. b4 b4 b4 b4

REFUSALS

There were no refusals during this inspection.

CLOSING DISCUSSION WITH MANAGEMENT

On 05/16/08 closing discussions were held with management. The following individuals were present: Bobette Williams, Director, Quality Assurance; Tom Himmelsbach, Manager Quality Assurance Laboratory; David Burton, Site Leader Lititz; Jake Harding, Oral Care; Michael Streb, PE Lean; Drew Bradley, Business Unit Leader Personal Care; Scott Weeks, Manager Quality Assurance; and Judy Case, Manger Quality Assurance. Prabhu P. Raju, Investigator and I were also present. I explained the systems evaluated during the inspection and reviewed the two discussion items; please see section Objectionable Conditions and Managements Responses for details. There were no questions so I concluded the inspection.

SAMPLES COLLECTED

There were no samples collected during the inspection.

Establishment Inspection Report

McNeil PPC, Inc.
Lititz, PA 17543-8701

FEI: 2510770
EI Start: 05/12/2008
EI End: 05/16/2008

EXHIBITS COLLECTED

1. Copy of a list of Product Currently Manufactured / Packaged at the Lititz Facility 2 pages.
2. Copy of the [REDACTED] (13 pages). b4
3. Copy of the Lititz Organization Chart (3 pages).
4. Copy of the Lititz Microbiology Laboratory Organizational Chart (1 page).
5. Copy of the Process Flow Diagram for [REDACTED] (2 pages). b4
7. Copy of the Formula Data Sheet for Agent Cool Blue Bubble Blast with [REDACTED] (4 pages). b4
8. Copy of the Formula Data Sheet for Agent Cool Blue Cool Merrimint with [REDACTED] (4 pages). b4
9. Copy of the list of ingredients which includes [REDACTED] (1 page). b4
10. Copy of memo dated 05/16/08 describing the rationale for Agent Cool Blue rationale for selection of [REDACTED] (1 page). b4
11. Copy of documents for the reformulated Listerine Agent Cool Blue (Bubble Blast and Glacier Mint): Research and Development Batches: R & D Preservative Effectiveness Testing Summary Data Results; Pilot Scale Preservative Effectiveness Testing Data Results; and the Full Manufacturing Scale Preservative Effectiveness Test Data Results (20 pages).
12. Copy of the document titled [REDACTED] (5 pages). b4
13. Copy of provided a draft Procedure titled [REDACTED] submitted as corrective action (17 pages). b4
14. Copy of the document explaining how materials will be received in a Quality stock status (designated by Q) submitted as corrective action (1 page).

ATTACHMENTS

1. Copy of the Form FDA 482 Notice of Inspection dated 05/12/08.

Establishment Inspection Report

McNeil PPC, Inc.

Lititz, PA 17543-8701

FEI:

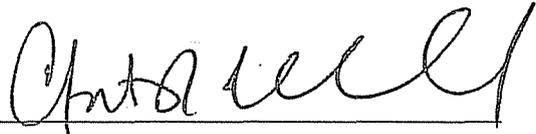
2510770

EI Start:

05/12/2008

EI End:

05/16/2008



Anita R. Michael, Investigator