DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Customhouse, Rm 900 2nd & Chestnut St Philadelphia, PA 19106 (215) 597-4390 Fax:(215) 597-0875 Industry Information: www.fda.gov/oc/industry	10/27/2010 - 12/09/2010* FEI NUMBER 2510184

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Hakan Erdemir, Vice President of Operations

FIRM NAME	STREET ADDRESS
McNeil Consumer Healthcare, Div Of McNeil-PPC, Inc.	7050 Camp Hill Road
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Fort Washington, PA 19034	OTC Pharmaceutical Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

QUALITY SYSTEMS

OBSERVATION 1

Procedures describing the handling of written and oral complaints related to drug products are deficiently written or followed.

A. Specifically, written complaint procedures that were in effect during November 6, 2009 Tylenol Arthritis Relief product recall require the complaint category assigned to a complaint file be an accurate description of the event as transcribed from the reporter of the event. A review of 136 complaints in PQMS that were received from 1/1/2010 and 1/14/2010 against recalled Tylenol lots revealed the following information:

- The total number of complaints containing reports of stomach pain, diarrhea and/or vomiting in the Complaint Investigation Event Description and were placed into the category "Uncategorized Adverse Event" was 131 (96.3% of 136 complaints). In contrast, two gastrointestinal illness complaints (1.5% of 136 complaints) were placed into the "Digestive / Gastrointestinal" category.
- The criterion being used by QA in trending for TBA-related complaints is the report of the presence of "musty / moldy" smell in the product container. The total number of complaints containing reports of "musty / moldy" smell associated with reports of gastrointestinal illness from the same set of data was 8 (5.9% of 136 complaints). One complaint of "musty / moldy" smell was categorized as "Uncategorized Adverse Event".

The lots and 136 complaint tracking numbers are as follows: AHM422 – 10000334169; 09GMC101 – 10000331628, 10000332424, 10000332425, 10000333529, 10000333699, 10000334335; 09EMC073 – 10000332717, 10000332897, 10000333559, 10000333866; AEA180 – 10000331888, 10000333031;

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AHA077 – 10000332609, 10000333043, 10000333026, 10000332985, 10000333738; AJA116 – 10000333044, 10000333018, 10000332968, 10000333733, 10000334947; AJA117 – 10000331142, 10000334619; 08KMC123 – 10000334354; 09DMC066 – 10000331976, 10000333519, 10000333558; ALM345 – 10000331720, 10000331721; 09BMC024 – 10000333827, 10000333465; 09XMC114 – 10000331178, 10000331056, 10000330277, 10000330446, 10000331106, 10000331440, 10000331288, 10000332434, 10000332308, 10000332310, 10000332313, 10000332316, 10000332739, 10000332447, 10000332463, 10000331750, 10000332435, 10000332437, 10000332438, 10000332440, 10000332441, 10000332318, 10000332319, 10000332304, 10000332479, 10000332742, 10000333320, 10000333623, 10000333666, 10000333727, 10000333857, 10000334287, 10000334360, 10000334364, 10000334268, 10000334269, 0000334529, 10000334530, 10000334414, 10000334727; 09XMC116 – 10000330712, 10000331179, 10000330422, 10000330752, 10000330760, 10000331291, 10000330757, 10000332465, 10000332466, 10000332467, 10000332471, 10000332475, 10000332477, 10000332482, 10000332483, 10000332478, 10000332190, 10000332192, 10000332195, 10000332196, 10000332469, 10000332202, 10000332203, 10000332206, 10000332207, 10000332402, 10000332847, 10000332744, 10000332746, 10000332748, 10000333169, 10000333237, 10000333240, 10000333112, 10000333123, 10000333717, 10000333747, 10000333636, 10000333646, 10000333657, 10000333531, 10000333703, 10000333729, 10000334288, 10000334289, 10000334358, 10000334361, 10000334245, 10000334038, 10000334532, 10000334533, 10000335250, 10000335289; 09BMC024 – 10000333827, 10000333465; ALM345 – 10000331720, 10000331721; APM305 – 10000332936, 10000334813; ASM357 – 10000334586; 09FMC082 – 10000332999; and AHA082 – 10000333001.

B. Reported symptoms in the "Event Description" were not always completely captured in a complaint category. From the 136 complaints reviewed, as described above, the following instances were observed:

- Tracking # 10000333717 –report of faint smell was not captured in complaint in any category.
- Tracking # 10000332195 – report of rash was not captured in complaint in any category.
- Tracking # 10000331178 – report of rash was not captured in complaint in any category.

C) A review of the complaints received against lots of Benadryl Children's Fastmelt Tablets (Cherry and Grape flavors) showed there were a number of "Does not Dissolve" complaints. The following table contains information from each complaint:

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Tracking Number	Alert Date	Flavor / Lot #	Event Description
10000285565	9/29/2008	Cherry / SFC005	Consumer said had on tongue for 18 minutes and still did not dissolve.
10000285569	10/14/2008	Grape / SFC003	The product does not dissolve – my children still need to chew it.
10000286563	10/30/2008	Cherry / SFC052	This product did not dissolve.
10000304268	4/17/2009	Grape / No Lot	Please reconsider taking grape chewable children's Benadryl. The strips burn the children's mouths and the fast-melts don't melt that fast and choke them.
10000299144	3/5/2009	Grape / SPC154	Mother had given the product to her 7 year old daughter, they are not melting. She has had it in her mouth for 3 minutes and it is still not melted. At another time the child ended up chewing it. The product is not melting in the child's mouth.
10000357268	3/16/2010	Grape / ACC041	Says product caused 3 year old to gag and spit up product. Didn't melt fast on child's tongue.

None of the complaint investigations addressed the quality information found in Out of Specification Investigations 805200114 and 905200020 for content uniformity. (See related observation under Observation 3).

D) Complaint investigations did not always include all relevant quality information that was available in the (b) (4) nvestigation system. The following instances are examples:

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- Quality Notification (QN) # 1004200011 ("Temp Hold 11"), dated 1/12/2010 (TBA-related activity), blocked usage of all bottles and caps received from component supplier (b) (4) (b) (4) along with all finished goods within control that have used these components. A review of 20 gastrointestinal and/or off-odor complaint investigations that were received against 9 finished products that were manufactured from components identified in Temp Hold 11 revealed that 5 of the complaint investigation reports included information from this QN, whereas 15 of the complaint investigation reports did not reference the quality information found in Temp Hold 11. The lots and complaint tracking numbers for complaints that referenced Temp Hold 11 in the complaint investigations are as follows: AEM034 – 10000360582; ALM332 – 10000356185, 10000361392, 10000361374, and 10000338198. The lots and complaint tracking numbers for complaints that did not reference Temp Hold 11 in the complaint investigations are as follows: BCM134 – 10000379500; BDM237 – 10000381836; BAM284 – 10000394124; ASM462 – 10000357359; AEM034 – 10000361453, 10000385605; ASM384 – 10000362350, 10000358046; BCM152 – 10000396250, 10000397422; ASM455 – 10000384819, 10000386555; BCM155 – 10000392069, 10000397973, and 10000398100. The current status of these lots is they were distributed to commercial market and have not been recalled.
- QN # 1004200058 ("Temp Hold 58"), dated 2/25/2010 (TBA-related activity), described detection of haloanisole taint odor in the McNeil Fort Washington warehouse by McNeil staff, qualitative detection of the odor by an outside contractor specializing in detection of haloanisole taint odors and remediation activity. Seventeen gastrointestinal and/or off-odor complaints were received against 5 lots (4 products) that were manufactured from components previously blocked by Temp Hold 58. None of the 17 complaint investigations reference the quality information found in Temp Hold 58. The lots and complaint tracking numbers are as follows: ADM033 – 10000398473, 10000335989, 10000344160, 10000344529, 10000376016; ADM014 – 10000362614, 10000341262, 10000355972; AEM034 – 10000361453, 10000385605, 10000360582; ADM074 – 10000343603; and AMM354 – 10000353745, 10000335651, 10000336064, 10000336800, 10000341777. The current status of these lots is they were distributed to commercial market and have not been recalled.

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OBSERVATION 2

Control procedures are not established which monitor the output and validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product.

Specifically,
Benadryl Allergy Fast Melts Process Validation Report 20-VAL-RPT-0166

A) The firm's SOP titled Site Validation Requirements Procedure indicates that the Process Validation Protocol regarding the Critical Process Parameters (CPP) must provide a detailed description of the Critical Process Parameters including the set points and ranges, how they are monitored according to the batch records, and the equipment controls. The protocol did not include a detailed explanation for the chosen CPP as required by the firm's procedures.

Validation Protocol Report No.: VAL-PRO-0166 explained that the (b) (4) Critical Process Parameters (CPP) are (b) (4) For examples:

1a) Validation protocol indicates that the CPPs were established and justified based on developmental batches. The protocol did not have a detailed description for the scientific rational for choosing these CPPs. The protocol did not discuss the assessment conducted regarding the developmental batches.

2a) (b) (4) was identified as (b) (4) of the (b) (4) CPPs. The protocol report indicated that (b) (4) duration would be (b) (4) as specified in the VMR. The protocol did not explain the scientific rational used to determine (b) (4) Additionally, the protocol did not describe in detail how the (b) (4) would be monitored. For example machine and product settings that could impact end product quality. There was no discussion for the CPP regarding the VMR in the protocol.

3a) (b) (4) was identified as the (b) (4) CPP in the protocol. The target speed is identified to be (b) (4) specified as listed in the VMR. The protocol did not explain the scientific rational for identifying the target speed. Additionally, the protocol did not describe in detail how the target speed would be monitored. For example machine and product settings that could impact end product quality. There was no discussion concerning the VMR as it related to the CPP in the protocol.

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B) The firm has (b) (4) for (b) (4) The (b) (4) is then (b) (4) Concerning the validation, there were no hold time studies discussed in the process validation report to assure that the final blend (in-process material) maintains uniformity and does not exhibit segregation during storage or transfer to the second (b) (4) which is (b) (4) Additionally, there were no hold time studies discussed in the process validation for the Coated Granulated Diphenhydramine HCL to assure that segregation does not occur and it maintains uniformity over time.

C) Per the Process Validation Protocol 20-VAL-PRO-0166 and Validation Report the initial batch matrix consists of (b) (4) batches of formula (b) (4) Grape Flavor and (b) (4) batches (b) (4) Cherry Flavor. Additionally, the report specifies batches (b) (4) (for Grape Flavor) and batches (b) (4) (for Cherry Flavor). Validation Batches (b) (4) and (b) (4) were destroyed because they did not meet the product specifications. (b) (4) additional Grape Flavor batches were produced in replacement, batches (b) (4) to meet the requirements of the validation matrix. A portion of the replacement validation batch (b) (4) was rejected because the in-process tablet weight variability was greater relative to the other process validation batches. This portion of the batch was rejected without being fully tested and evaluated to see if the weight variations had any effects on the tablet content uniformity results, DPH assay or dissolution.

D) During process validation materials that did not meet their predetermined specifications were used in the process validation batches. Specifically, the Coated Diphenhydramine (b) (4) did not meet the specification requirements of white to off white granules because dark specks were found in the materials. This material was placed on blocked status, not approved for use. However, the materials were released from the blocked status in order to allow them to be used in the process validation batches prior to the investigation being completed.

Comprehensive Action Plan Process Validation Quality Indicator Assessment Report
St. Joseph Enteric Coated Aspirin Tablets 81 mg Formula (b) (4)

A) According to the section Data Thresholds in your Comprehensive Action Plan (CAP) it indicates for Batch Rejection Rates, at minimum, products with greater than a (b) (4) rejection rate will be further analyzed. For the St. Joseph Enteric Coated Aspirin Tablets 81 mg only full batch rejects were

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considered in the calculations to determine the rejection rate. The calculated rejection rates were 1% (for review period 2/1/07-1/31/08), 0% (for review period 2/1/08 - 1/31/09) and 1% (for review period 2/1/09-1/31/10). In each of these cases the conclusion was that the results were below the (b) (4) threshold therefore no further action was deemed necessary. However, review of the data revealed that partial rejects were not included in the calculated rejection rates and were excluded. For example, when partial rejections are included in the calculated rejection rates the following results are obtained: 2.54% (for review period 2/1/07-1/31/08), 3.70% (for review period 2/1/08 - 1/31/09) and 3.61% (for review period 2/1/09-1/31/10).

B) The discussion in the PV/QIA for the St. Joseph Enteric Coated Aspirin Tablets was incomplete. The PV/QIA did not thoroughly explain if there were similar trends indentified across the review periods (2/1/07-1/31/08, 2/1/08 - 1/31/09 and 2/1/09-1/31/10) concerning the partial and full batch rejections. Additionally, there was no discussion regarding the rational for excluding the partial rejected batches from the calculated rejection rates.

OBSERVATION 3

There is a failure to thoroughly review any unexplained discrepancy and 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,
Per the firm's Quality Assurance Procedure 20-QA-QA-009 Subject Deviation Investigation Procedure section 6.1 requires that a thorough investigation of the deviation will be performed. The results of the investigations into the deviations are documented in Notification Reports.

Benadryl Allergy Fast Melts

A) Approximately (b) (4) lots of Benadryl Fast Melts tablets were produced for Grape (formula C-1210-1) and Cherry flavor (formula C-1211-1) between 05/2008 and 03/2010 and released to market. For the Grape Flavor there were multiple confirmed OOS and confirmed OOT results observed throughout the manufacturing of the (b) (4) batches. For the batches listed below the firm continued to manufacture batches and release the batches to market before and after obtaining OOS and OOT results without conducting complete investigations from 08/2008 through 03/2010.

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1. On or about 06/2008 OOS results for the active ingredient Diphenhydramine HCL Content Uniformity was observed for batch SEM0000537 and described in Investigation 805200114.

2. On or about 01/2009 three OOT's for the active ingredient Diphenhydramine HCL Assay was observed for batches SSM0000575, SSM0000576, and SSM0000577 and described in Investigation 905200007.

3. On or about 02/2009 OOS results for the active ingredient Diphenhydramine HCL Content Uniformity was observed for batch AAM0000787; and described in Investigation 905200020.

4. On or about 05/2009 OOT results for the active ingredient Diphenhydramine HCL Assay was observed for batch ADM0000185 and described in Investigation 905200047.

B) Investigations 805200114, 905200007, 905200020 and 905200047 did not include a review complaints, adverse events or lack of effect reports for consumer complaints received for Fast Melts. Additionally, a CAPA was not initiated in a timely fashion to include an evaluation of the firm's complaints related to Fast Melts or how complaints were reviewed and evaluated. For example CAPA-01961 was initiated on April 8, 2010. CAPA-01961 section titled Investigation of Root Cause (Measure & Analyze) did not describe or cross reference an investigation of the complaints to determine if a root cause and corrective actions could have been identified and initiated earlier.

C) For each of the investigations conducted for the OOS and OOT listed in above 1-4, there were no discussions regarding an evaluation of the stability data.

D) Per the firm's procedure 20-QA-QA-084 a Preventive Action is defined as steps taken to eliminate the cause of the existing non-conformity to prevent its recurrence. Without assessing the Process Validation reports approved 06/17/08 or the Research and Development Reports that supported the manufacturing process. The investigations 805200114, 905200007, 905200020 and 905200047 conducted for the multiple OOS and OOT (described above) determined that no root cause was identifiable. The firm determined that no Preventive Action was warranted since no assignable or definite root causes could be determined for each of the OOS and OOT listed above.

E) For the investigations for the batches described in 1-4 the Notifications did not address or discuss the stability results for the Fast Melts. Specifically, a review of the stability data and whether or not it

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was trending towards failure was not documented as conducted or evaluated in the notifications.

F) A risk assessment was not initiated and completed prior to this the inspection concerning Benadryl Allergy Fast Melts.

Sudafed PE Non-Drying Sinus Caplets

A) Specifically, the firm's laboratory investigations into Out of Specification and/or Atypical results are not always complete or accurate. For example,
Laboratory Investigation QN 805200160 was initiated 9/22/08 to investigate the initial Stability Out-Of-Specification values for an Unspecified Individual Chromatographic Impurity found in Sudafed PE Non-Drying Sinus Caplets, batches (b) (4) Sudafed PE Non-Drying Sinus Caplets contain two Active Pharmaceutical Ingredients, Phenylephrine HCl and Guaifenesin. The Investigation's concluded root cause is that the unspecified impurity's results were originally quantitated relative to Phenylephrine and therefore is not correct. However, the Research Report presented as part of the Investigation stated that the unknown peak was Guaifenesin related and therefore should be calculated relative to Guaifenesin which yields results within specification. The Laboratory Investigation did not accurately identify the source of the unknown impurity or extend to other batches to accurately isolate the impurity to the product.

OBSERVATION 4

Records are not maintained so that data therein can be reviewed at least annually to evaluate the quality standards of each drug product to determine the need for changes in specifications or manufacturing or control procedures.

Specifically,

Sudafed PE Cold and Cough Caplets Formula Number C-1145-1

Your APR dated 04/01/09 - 03/31/10 for Sudafed PE Cold and Cough Caplets Formula Number C-1145-1 indicates there were no OOS or OOT investigations for this period. However review of the data revealed the following OOT results exceeding the established Upper Control Limits or falling below the Lower Control Limits for the listed analytical tests:

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For Acetaminophen Assay UCL =(b) (4) and LCL =(b) (4)
For Batch AJM0003350 the Acetaminophen Assay was (b) (4)nd below the LCL
For Batch AJM0003113 the Acetaminophen Assay was above the UCL

For Guaifenesin Assay the UCL =(b) (4) and LCL =(b) (4)
For Batch AJM0003350 the Guaifenesin Assay was (b) (4) and above the UCL

For Dextromethorphan HBr Assay the UCL = (b) (4) and LCL =(b) (4)
For Batch AJM0003350 the Dextromethorphan HBr Assay was (b) (4) and above the UCL.

For Phenylephrine HCL Assay the UCL = (b) (4) and the LCL =(b) (4)
For Batch AJM0003350 the Phenylephrine HCL Assay was(b) (4)and above the UCL.

For Acetaminophen Content Uniformity the UCL =(b) (4) and the LCL=(b) (4)
For Batch AJM0003350 the Acetaminophen Content Uniformity was (b) (4) and below the LCL.

For Guaifenesin Content Uniformity the UCL =(b) (4) and the LCL = (b) (4)
For Batch AJM0003350 the Guaifenesin Content Uniformity was (b) (4) and above the UCL.

For Dextromethorphan Hbr the Content Uniformity UCL = (b) (4) and the LCL = (b) (4)
For Batch AJM0003349 the Dextromethorphan Hbr the Content Uniformity was(b) (4) and above the UCL.

For Phenylephrine HCL the Content Uniformity UCL =(b) (4) and the LCL = (b) (4) For Batch AJM0003350 the Phenylephrine HCL the Content Uniformity was (b) (4) and above the UCL.

For Acetaminophen Dissolution average the UCL =(b) (4) and LCL =(b) (4)
For Batch APM0003178 the Acetaminophen Dissolution was(b) (4)and below the LCL.

For Guaifenesin Dissolution average the UCL =(b) (4)nd the LCL = (b) (4)
For Batch AFM0000548 the Guaifenesin Dissolution was (b) (4)and below the LCL.
For Batch AJM0003350 the Guaifenesin Dissolution was and above the UCL.

For Dextromethorphan HBr Dissolution average the UCL =(b) (4) and LCL =(b) (4)

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For Batch AJM0003350 the Dextromethorphan HBr Dissolution was (b) (4) and above the UCL. For Batch APM0003178 the Dextromethorphan HBr Dissolution was (b) (4) and below the LCL.

For Phenylephrine HCL Dissolution the average UCL =(b) (4) and LCL =(b) (4)
For Batch AJM0003350 the Phenylephrine HCL Dissolution was (b) (4) and above the UCL.

Additionally, per the SOP 02-QA-NCR-003 a lab investigation is required upon identification of suspect OOT or OOS result. The investigation is to be thoroughly documented as an event according to site event procedures. Also, the procedures require confirmed OOS and OOT to be forwarded to appropriate departments for a full scale investigation. The QCU did not initiate OOT investigations for the test results listed above. The APR should include have included an evaluation of these values and corrective actions should have been initiated to account for the shifts and trends in the process.

Additionally, the third party review conducted and documented in the PV/QIA for formula C-1145-1 indicates that for two Annual Product Reviews covering batches produced between dated 04/01/09 - 03/31/10 there were no OOT results for C-1145-1. Additionally the PV/QIA review did not reveal that investigations should have been conducted for the OOTs listed above.

OBSERVATION 5

Investigations of an unexplained discrepancy and a failure of a batch or any of its components to meet any of its specifications did not extend to other batches of the same drug product and other drug products that may have been associated with the specific failure or discrepancy.

Specifically, for the following:

Benadryl Allergy Fast Melts

A) Per the SOP 02-QA-NCR-003 a lab investigation is required upon identification of suspect OOT or OOS result. The investigation is to be thoroughly documented as an event according to site event procedures. Also, the procedure requires confirmed OOS and OOT to be forwarded to appropriate departments for a full scale investigation. Investigation report 905200007 initiated 01/2009 for 3

confirmed OOTs for Diphenhydramine HCL assay regarding batches SSM0000575, SSM0000576 and SSM0000577 did not extend to evaluate the previous OOS for content uniformity that resulted in 06/2009. The electronic review in (b) (4) was incomplete and did not reveal the previous OOS for Batch SEM0000537 that was rejected for not meeting the predefined specifications for content uniformity on 06/2009.

B) Investigation 905200047 documented a confirmed OOT result for assay for ADM0000185 dated 05/2009. This investigation did not extend to previous batches that had similar OOT results for the Assay or previous batches that had OOS results for content uniformity. For example a (b) (4) search was conducted for the API used and did not extend to evaluate 3 previous and similar OOT for assay identified for batches SSM0000575, SSM0000576 and SSM0000577 (described in Investigation report 905200007) that was initiated 01/2009. Also the (b) (4) search conducted for Investigation 905200047 did not reveal the OOS results for Batch SEM0000537 reported under investigation 805200114 which is dated 06/2008.

C) Investigation 10052003 1intiated 02/24/2010 documented an additional confirmed OOS for content uniformity regarding batch (b) (4) . This investigation did not extend to previous batches that had multiple OOT results recorded in Investigation 905200047 for batch ADM0000185 and 3 OOT confirmed assay results for batches SSM0000575, SSM0000576 and SSM0000577 (described in Investigation report 905200007) that was initiated 01/2009. The (b) (4) search conducted for Investigation 10052003 did not reveal the previous OOT results for other batches.

OBSERVATION 6

Written records are not always made of investigations into unexplained discrepancies.

Specifically,

A) QN # 1004200058 ("Temp Hold 58"), dated 2/25/2010 (TBA-related activity), described detection of haloanisole taint odor in the McNeil Fort Washington warehouse by McNeil staff, qualitative detection of the odor by an outside contractor specializing in detection of haloanisole taint odors and remediation activity. The TBA specialist advised in two summary reports titled Sensory Assessments of McNeil Warehouse, Fort Washington, PA for Haloanisole Taint (dated 3/3/2010 and 3/9/2010) that

quantitative sampling be conducted of environment (i.e., atmosphere and water) and certain materials (i.e., wood, paint, insulation and cardboard). Each summary report contains the following statement: "Under most circumstances, analytical testing can detect haloanisole taint below the sensory threshold of individuals." Such quantitative testing was not performed and materials within the warehouse that was blocked by Temp Hold 58 were approved for use and released. However, the Investigation Findings section of Temp Hold 58, written by the Quality Control Unit, contains the following statement: "Dr. S*** performed a follow-up sensory assessment on 3/5/2010 after the ventilation was stoppend [sic] and the warehouse was allowed to stabilize for (b) (4) Dr. S***'s conclusion at the end of his assessment was that the presence of perceived haloanisole taint was not identified in any location within the Fort Washington warehouse. During the walkthrough, no haloanisole odors were detected from a sensorial perspective and that analytical testing is capable of detecting at lower levels. Based on the absence of haloanisole odors, Dr. S*** was not recommending any remediation for the facility." On 3/1/2010, caps and bottles manufactured by the (b) (4) facility were removed from the Fort Washington Warehouse before remediation because they may have been exposed to haloanisole in the (b) (4) facility (remediation action was aeration of the warehouse on 2 occasions). However, bottles received into the warehouse on 3/30/2009 that were manufactured by (b) (4) (McNeil Material # 5426800 and Lot # 9M10297) were not removed from the Fort Washington Warehouse and remained in the warehouse during remediation. There was no investigation initiated describing where the bottles were stored in the warehouse and on what pallets, when the bottles were received and if any portions were released for use in products. A review conducted during the inspection revealed that a portion of Lot 9M10297 was used to package Tylenol 8 hour caplets (b) (4) finished lots AEM034 and ADM074 that were released to market and have not been recalled. There was no investigation initiated that describes the impact on these products or the health hazard to consumers. A review of PQMS complaint records showed there were complaints received against lots AEM034 (10000361453, 10000385605, 10000360582) and ADM074 (10000343603) for gastrointestinal symptoms.

B) Quality Notification # 1004200056 (dated 2/24/2010) placed certain components and finished goods lots in blocked status ("Temp Hold 56") because they may have been exposed to haloanisole in the (b) (4) facility that could possibly impact components in the Fort Washington manufacturing facility. A review of the finished goods lots showed that lots AEM034 and ADM074 were placed on hold even though these two lots were released for commercial distribution the previous year (AEM034 was released in May 2009 and ADM074 was released in June 2009). There was no investigation initiated to determine how this situation could occur.

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Customhouse, Rm 900 2nd & Chestnut St Philadelphia, PA 19106 (215) 597-4390 Fax:(215) 597-0875 Industry Information: www.fda.gov/oc/industry	10/27/2010 - 12/09/2010* FEI NUMBER 2510184

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Hakan Erdemir, Vice President of Operations

FIRM NAME	STREET ADDRESS
McNeil Consumer Healthcare, Div Of McNeil-PPC, Inc.	7050 Camp Hill Road
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Fort Washington, PA 19034	OTC Pharmaceutical Manufacturer

C) On January 15, 2010 a recall was initiated that included Lots that were within the expiration dates from January 1, 2007 through January 15, 2010. This recall included lots that were packaged using any packaging components sources from (b) (4) and received on non-heat treated pallets. Regarding the Fort Washington facility on January 12, 2010 all materials received from (b) (4) were required to be placed into blocked status and moved into trailers. However five containers of (b) (4) Materials were received back into the facility after the Jan 12, 2010 notification. There was no investigation initiated describing the events concerning these five containers of materials. For examples, the containers disposition, additional searches in (b) (4) to assure that no other containers were received and implemented corrective actions to prevent additional containers from coming in the facility. No written investigation was available describing what materials were in the containers that were received from (b) (4) The TBA Fort Washington investigation was initiated during the inspection.

D) On 01/14/2010 a sensory assessment revealed presence of perceived haloanisole taint in the following areas: A pallet that had (b) (4) bottles stacked ((b) (4) part number) on top location at position 601. Also a pallet located in position 609 had (b) (4) bottles ((b) (4) part number) stacked on top revealed presence of perceived haloanisole taint. The was no investigation initiated on 01/21/10 documenting the quantity of bottles on each pallet, the Lot number , whether or not any of the bottles were released and used in products, and if there were any other materials that were impacted by these bottles.

OBSERVATION 7

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

Specifically,

A) There was no CAPA initiated for the Fort Washington PA facility regarding TBA and identifying the actions taken to minimize the risks. 87 Lots of various products were recalled as of Jan 2010

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Anita R. Michael, Investigator Joseph L. Despins, Investigator Temar Q. Williams, Chemist Linda M. Hoover, Investigator	12/09/2010

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manufactured and released from this facility related to TBA. There was no site specific CAPA initiated per the Fort Washington CAPA procedure 20-QA-QA-084. There was no CAPA initiated that identified trends associated with TBA, deviations and assessing the evaluation conducted consumer complaints associated with TBA. There was no CAPA initiated documenting and preventative measures for the January 2010 recall. An existing CAPA initially initiated for a recent recall for Lot BCM155 related to TBA was retrospectively updated during the inspection to capture the missing information.

B) The Quality Control Unit instructed warehouse personnel to remove multiple lots of products associated with the corrective actions related to the TBA recall. The were no deviation reports available describing what materials were associated with the Lots destroyed. For example, the suppliers or material descriptions. Additionally, there was no deviation report initiated by Quality to determine if there were portions of the Lots used in products that were released to market. The Lots removed from the warehouse included Lots (b) (4) (b) (4)

C) Regarding the Field Alert Report (FAR) for product 01-9872, initial and 2 follow-up reports, dated 09/20/2010, 09/27/2010 and 10/24/2010, the FAR report indicates that all information related to (b) (4) components were reviewed previously and did not meet the criteria for being shipped in chemically treated pallets. However, review of your records during the inspection revealed that approximately 6 months prior to the Field Alert Report your Quality Control Unit previously segregated and destroyed portions of (b) (4) Components both bottles and caps. Lots (b) (4) identified with TBA. Also, finished Lots (b) (4) associated with these (b) (4) bottles and caps were also segregated.

D) There was no testing performed on the retain samples for the additional lots of St. Joseph's Aspirin Lot SSM112 and Lot ABM024 using (b) (4) bottle Lot (b) (4) The same Vendor Lot was used for Lot BCM155 which was recalled 10/14/10 for TBA detected in the field samples and retain samples.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

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Fort Washington, PA 19034	OTC Pharmaceutical Manufacturer

*** DATES OF INSPECTION:**
10/27/2010(Wed), 10/28/2010(Thu), 10/29/2010(Fri), 11/01/2010(Mon), 11/02/2010(Tue), 11/03/2010(Wed), 11/05/2010(Fri), 11/08/2010(Mon), 11/09/2010(Tue), 11/10/2010(Wed), 11/12/2010(Fri), 11/15/2010(Mon), 11/16/2010(Tue), 11/17/2010(Wed), 11/18/2010(Thu), 11/22/2010(Mon), 11/23/2010(Tue), 11/29/2010(Mon), 11/30/2010(Tue), 12/01/2010(Wed), 12/02/2010(Thu), 12/03/2010(Fri), 12/06/2010(Mon), 12/07/2010(Tue), 12/09/2010(Thu)

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE

Anita R. Michael, Investigator
Joseph L. Despins, Investigator
Temar Q. Williams, Chemist
Linda M. Hoover, Investigator

DATE ISSUED

12/09/2010