

**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 466 Fernandez Juncos Ave. San Juan, PR 00901-3223 (787)-474-9500 Fax:(787) 729-6809 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 10/22/2009 - 01/08/2010*
	FEI NUMBER 2650141

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED  
**TO: Nuria Ramirez Ordoñez, General Manager**

FIRM NAME McNeil Healthcare, LLC	STREET ADDRESS Road #183, km 19.8 Bo. Montones
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CITY, STATE, ZIP CODE, COUNTRY Las Piedras, PR 00771	TYPE ESTABLISHMENT INSPECTED Drug Manufacturer
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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 System**

**OBSERVATION 1**

An NDA-Field Alert Report was not submitted within three working days of receipt of information concerning bacteriological contamination and significant chemical, physical, or other change or deterioration in a distributed drug product.

Specifically,

On 2008, your firm received a heightened number of uncharacteristic musty odor consumer complaints for Tylenol Arthritis Relief Caplets (TAR) lots 08BMC013 (approximately 27 complaints) and 08BMC020 (approximately 49 complaints). However, no formal investigation was conducted even though your firm received over eight (8) complaints associated to gastrointestinal adverse events reports. Although organoleptic examination confirmed the presence of the odor in September 2008, your firm concluded that based on macroscopic and microscopic examination the odor does not originate from the presence of microorganisms in the product or container closure. Your quality unit failed to conduct additional testing to evaluate the possibility of chemical contamination or other change or deterioration in the distributed drug product. No field alert was generated in 2008 for the distributed drug product.

Afterward, your firm received atypical trends of uncharacteristic odor complaints and associated adverse event reports for lots 09BMC034, 09CNC036, and 09CMC040 since April, June, and August 2009 respectively, but the trend was not discovered until 08/03/2009. A Contract Operations Quality Management (COQM) Investigation Report (CIR# (b) (4)) was generated on 09/17/2009. A field alert was not initiated until 09/18/09, and a recall was initiated on 12/04/09 during the current inspection.

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**OBSERVATION 2**

Investigations of an unexplained discrepancy 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,

- A. Since April 2009, your firm has received an increasing trend of uncharacteristic smell consumer complaints for Tylenol Arthritis Caplets (TAR). According to Investigation CIR # (b) (4) initiated on 09/17/09, the trend was discovered on 08/03/09. Interim reports for investigation CIR # (b) (4), approved on 10/28/09 and 12/11/09 concluded that the most probable root cause for the uncharacteristic odor complaints is the proximity of chemically treated wood from pallets and empty bottles transported from the bottle manufacturer to the product packager. However, since the date of the discovery, your firm did not extend the assessment of the event to other products that received packaging components from the same supplier, such as Roloids, which received over ten (10) musty-moldy odor consumer complaints. Your firm neither extended the assessment to other products that received similar complaints such as Tylenol Extra Strength (ESK), which received over thirty-nine (39) musty-moldy odor consumer complaints including three (3) adverse event reports. Even though the investigation has not identified a root cause for the event, your Quality Unit did not conduct an evaluation of other possible sources of contamination at your site, external contractors, and suppliers.
- B. Your firm did not take an action with the distributed finished product, Motrin IB Caplet 24 count bottle, lot SDA149 which was manufactured using granulation lot SDA0001017 that was involved in the manufacture of two (2) recalled lots, SHC003 and SHC004 (Motrin IB Caplet, 8 caplet vial).

On 11/20/08 your laboratory detected a failure in the stability dissolution results (stages 1-3 (S1/S2/S3)) of the three (3) months time point stability samples of lot SHC003. Investigation # (b) (4) initiated on 11/20/08 included additional testing of retain compression samples of associated granulation batches. On 12/16/08 your laboratory obtained out of specification dissolution results for retain samples of the bulk compression lot SDA0000807 used in the manufacture of finished product lot SHC004. The investigation # (b) (4) revealed an extended downtime of (b) (4) and (b) (4) due to electrical failure and for ten (10) additional minutes due to a broken bag situation during the manufacturing drying process of granulation lot SDA0001017. This granulation lot was used for the manufacture of finished product lots SHC003, SHC004, and SDA149. Investigation # (b) (4) did not find a root cause for the dissolution failures.

On 03/10/09, your technical services department generated the Development Report No (b) (4) 77 to simulate the extended downtimes during the granulation drying and coating processes and to document the impact on the dissolution of Motrin IB Caplet. The development study concluded that the extended downtimes in granulation and coating have no impact on Motrin IB Caplet Dissolution. However, the actual conditions such as electrical failures, temperature and sensor problems, computer and instrument problems that may affect the process critical parameters during extended downtimes were not considered during the study.

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Your Quality Unit documented an amendment to investigation # (b) (4) through investigation (b) (4) initiated on 09/18/09 to include additional assessment and testing findings. On 09/22/09, an atypical value of 57% (minimum limit 55%) with a dissolution range of 57%-103% and an average of 96% were obtained in stage 3 for additional testing of compression bulk lot SDA0000808, which was manufactured using the granulation lot SDA0001017 (subsequently used for packaging lot SDA149). Even though the investigation did not identify a root cause for the atypical behavior of lots SHC003, SHC004 and SDA149, corrective actions were isolated to lots SHC003 and SHC004 and not to the distributed drug product lot SDA149. There is no assurance that the causes affecting these lots whether or not they are associated to a failure or discrepancy have been identified and corrected.

**OBSERVATION 3**

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

Specifically,

- A. On September 2008, your firm initiated a "Notification to Management Form" according to procedure (b) (4) "Notification to Management" to notify uncharacteristic musty smell/odor complaints observed since May 2008 for Tylenol Arthritis Caplets (TAR). Nevertheless, your Quality Unit failed to complete the form according to procedure requirements and include a summary of the investigation steps taken, results obtained, corrective and preventive actions taken, conclusions, and site quality recommendation regarding the proposed disposition of the product. The Notification to Management form was not routed to the Quality Site Leader or QA designee for approval.

No other record such as an event investigation or COQM Investigation Report (CIR) was generated as required in procedure (b) (4) "Contractor Investigation Procedure" to document the conclusions of the investigation until 09/17/09, one year later.

- B. Procedures describing the handling of written and oral consumer complaints related to drug products are deficiently written and followed.
- Complaint procedures (b) (4) "Requirements for Complaint Handling" and (b) (4) (b) "Handling Complaint Investigations for Third Party Contractors" were not followed to monitor complaint data for the identification of possible trends. For example, trends for numerous atypical complaints of uncharacteristic musty smell/odor for Tylenol Arthritis Relief Caplets (over 200 complaints) and Tylenol Extra Strength (over 39 complaints) were not detected nor investigated in a reasonable time period. For example, your firm received multiple uncharacteristic smell consumer complaint reports since May 2008, but the trend was not detected until August 2008. The criteria for the identification, notification, and documentation of trends have not been clearly defined in the procedures.
  - Procedure (b) (4) "Requirements for Complaint Handling", defines a "confirmed complaint"

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as one which cannot exclude the manufacturing or packaging process as a potential source of the complaint issue. However, even though your firm received one hundred and twenty-three (123) mix-up related complaints, from which you received over fifty (50) consumer complaint samples for evaluation, none of them have been confirmed. Your Quality Unit considered all complaints as isolated occurrences of unknown origin. Most of the complaint investigations conclude that there is insufficient evidence to absolutely determine that the reported condition occurred at McNeil, even though your firm has reported over twelve (12) mix-up event investigations. In addition, at least seventeen (17) event investigations, four (4) In-Process Assessment Forms (minor events) and four (4) manufacturing "clearance incidences" (detected during verification) have been reported, all of them associated to cleaning deviations.

**OBSERVATION 4**

There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed.

Specifically,

A. Your firm did not investigate extended downtimes observed during the manufacturing process (granulation and coating) of Motrin to determine the impact of the event in the product even when critical parameters of the process may be impacted. Your procedure (b) (4) "Extraordinary Events during the Granulation Process" does not require the operator to notify the supervisor and generate an investigation for events that may impact the critical process parameters and the drug product. Investigation (b) (4), issued on 11/20/09, identified twenty-three (23) extended downtime events of Motrin granulation batches for year 2008 ranging from approximately (b) (4). For example,

1) On 04/16/08, during the Motrin IB granulation drying process of lot SDA0001017 (used in the manufacture of lot SDA149 and recalled lots SHC003 and SHC004), the manufacturing operator recorded in the batch record two electrical failures and a broken bag event for a total granulation downtime of (b) (4). Your firm did not initiate an event investigation at the time of occurrence to determine the impact of the (b) (4) interruptions in the product. Afterward, on 11/20/08 your laboratory detected a failure in the stability dissolution results of the three (3) months time point stability samples of lot SHC003. Out of specification dissolution results were also obtained for lot SHC003 and atypical results for lot SDA149, which were impacted by this event.

2) On 04/06/08, during the Motrin IB granulation (b) (4) of lot SCA0002400, the manufacturing operator recorded a problem with the (b) (4) in the batch record resulting in a downtime of (b) (4). The operator notified the event to the mechanics and technicians which replaced the temperature recorder (RTD). However, there is insufficient information to determine if the (b) (4) exceeded the critical parameter limits of (b) established in the batch record. The last inlet temperature reading recorded in the batch record was (b). Your firm did not investigate the event at the time of occurrence.

B. Your firm failed to conduct a thorough investigation during the evaluation of the presence of unknown peaks observed during the Assay test for Motrin IB product in 2008. The presence of these unknown peaks continues to the present.

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The unknown peaks affected the results for the analysis of Total Chromatographic Impurities (TCI%). As per Methods # (b) (4) and (b) (4), the acceptance limit for TCI % is (b) (4). The root cause was attributed to laboratory contamination, specifically the use of disposable pipettes. The preventive actions taken were not effective in that your firm continues to encounter contamination incidents. The following are events related to the extraneous peaks:

1) The laboratory investigations # (b) (4) (date initiated: 8/5/08), (b) (4) (date initiated: 10/30/08), (b) (4) (date initiated: 1/21/09), 905220113 (date initiated: 5/29/09), and # (b) (4) (date initiated: 9/25/09) were initiated because the out of specification of TCI % was observed (b) (4) respectively) for Motrin IB Caplet, Lots #: SHA0001798, SMA0001698, AAA0000394-IP, AEA0001306-F and SLA016. The investigations concluded that the most probable root cause for the events was a laboratory external contamination during the vial filling, identified as acetaminophen.

2) The event # (b) (4) was initiated on November 11, 2008 because the out of specification of TCI % was observed (b) (4) for Motrin IB Tablet Lot # SMA0002592-IP. The root cause for this event was a laboratory external contamination during the vial filling, identified as acetaminophen. The most probable sources of contamination were the disposable transfer pipettes or HPLC vials.

**Production System**

**OBSERVATION 5**

Written procedures are not followed for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product.

Specifically,

The established procedures and controls for cleaning and maintenance may not be sufficient to prevent mix-ups and/or contamination during the manufacturing and packaging process as evidenced by the received mix-up consumer complaints, deviations, and incidents involving manufacturing and packaging operations. There is no assurance that operators and quality personnel follow the established procedures for the cleaning and verification of manufacturing and packaging areas and equipment. Since August 2008 your firm has reported twelve (12) mix-up events from which ten (10) are related to human error. For example,

- A. On 10/01/09, during the set up process of the packaging line No. 2 for ES TYLENOL PM GELTAB 24, the filler operator and the packaging area mechanic detected thirteen (13) TYLENOL PM RAPID RELEASE (b) (4) at the filler machine. Investigation (b) (4), dated 10/01/09, concluded that the most probable cause for the cleaning failure was human error.

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- B. On 09/26/09, during the set up process of the packaging line No. (b) (4) for ES Tylenol Caplet 150, the filler operator detected one (1) Tylenol PM Geltab (PMJ) at the filler machine. Investigation (b) (4), dated 09/27/09, concluded that the most probable root cause was ineffective cleaning by the operators.
- C. On 06/02/09, during the set up process of the packaging Line No. (b) (4) for Motrin IB Caplet 100, the filler operator detected two (2) Tylenol PM Caplets (PMK) at the filler machine. Investigation (b) (4), dated 06/02/09, found that the major cleaning performance and verification was inadequate since the packaging operators forgot to remove and install a (b) (4) to the filler machine prior to initiating the packaging process of Motrin IB Caplet.
- D. On 05/29/09, the QA Manager of your packaging contractor site notified you that during the packaging process of Tylenol Arthritis (TAR) bulk transfer lot ADA212 (b) (4) the filler operator observed one round white tablet of Tylenol PM (PMK). Your investigation (b) (4), dated 06/10/09, concluded that the most probable cause is that during the (b) (4) testing of TAR the manufacturing operator involuntarily mixed at least one core tablet of PMK with TAR during product handling.
- E. On 04/16/09 during the rework activities of Children's Tylenol Meltaway 30 Grape lot ADA072 in packaging Line No. (b) (4) the packaging operator found a bottle containing Tylenol PM Geltab (PMJ) units at the Reject Station of the induction sealer. Investigation (b) (4), dated 04/18/09, concluded that the event is associated to an inadequate cleaning performance and verification.
- F. On 09/27/08, during the packaging process of Motrin IB Caplet 300's in Line No. (b) (4) the operator detected a white Tylenol (ESK325) caplet. Your investigation (b) (4), dated 09/29/08, found as the most probable root cause the ineffective cleaning by the packaging operators and verification of QA technician.
- G. ...

In addition, since August 2008 your firm has generated approximately seventeen (17) event investigations, four (4) In-Process Assessment Forms (minor events) and four (4) manufacturing "clearance incidences" (detected during verification) all of them associated to cleaning deviations.

Moreover, a total of one hundred and twenty-three (123) mix-up related consumer complaints have been received by your firm for the same period. Your Quality Unit classified all the referenced mix-up complaints as isolated occurrences based on the fact that no prior complaints were reported for the specific lot number investigated, and that no quality-related issue could be identified. (Refer to observation # 3 for additional deficiencies related to complaint management system).

There is no assurance that the preventive and corrective actions taken are adequate to prevent recurrence.

The potential for product mix-up at your facility is a recurrent observation.

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**Laboratory Control System**

**OBSERVATION 6**

Laboratory controls do not include the establishment of scientifically sound and appropriate specifications, standards, and test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically,

- A. Your firm established a limit of (b) (4) for investigation of extraneous peaks on section (b) (4) of the SOP (b) (4), Version (b) (4), Effective date: (b) (4). Title: Extraneous Peaks. However, this limit was established without scientific data and rationale to support the established specifications.
- B. No analytical method for stability test has been established to monitor the impurities and degradants in Tylenol Arthritis Caplets (TAR) product. Your firm currently monitors the impurities and degradants for other finished products containing the same active ingredient, acetaminophen.

**OBSERVATION 7**

Laboratory records do not include complete data derived from all tests, examinations and assay necessary to assure compliance with established specifications and standards.

Specifically,

- A. Laboratory records do not include the initials or signature of a second person showing that the original records have been reviewed for accuracy, completeness, and compliance with established standards. (b) (4) (Contract Laboratory) performed the test for the identification of the uncharacteristic odor of Tylenol Arthritis Caplets (TAR) related with investigation CIR # (b) (4) that was initiated on 09/17/2009 by COQM (Contract Operations Quality Management). The chromatograms, spectra and records were not reviewed by a second person to assure that the records comply with the specifications. Additionally, your Quality Unit failed to review the data for errors. For example, some of the chromatograms showed the acquisition date as May 2003. However, the actual analysis was performed in September 2009. There is no assurance that the data provided is accurate and reliable.
- B. Laboratory records related to the (b) (4) reports of 09/11/09, 09/25/09, 10/30/09, and 12/03/09 for uncharacteristic odor of Tylenol Arthritis Caplets, were not readily available during the inspection. Your Quality Unit failed to provide all spectra and raw data associated to the (b) (4) reports. The laboratory records do not include raw data to support the evidence of sample preparation, standards preparation and did not include a statement of the weight or measure of the samples used for each test.

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C. The test method used by (b) (4) for the identification of the uncharacteristic odor for Tylenol Arthritis Caplets (investigation CIR # (b) (4) is not validated.

**\* DATES OF INSPECTION:**

10/22/2009(Thu), 10/23/2009(Fri), 10/28/2009(Wed), 10/29/2009(Thu), 11/02/2009(Mon), 11/05/2009(Thu), 11/06/2009(Fri), 11/09/2009(Mon), 11/10/2009(Tue), 11/12/2009(Thu), 11/17/2009(Tue), 11/18/2009(Wed), 12/07/2009(Mon), 12/15/2009(Tue), 12/16/2009(Wed), 12/17/2009(Thu), 12/23/2009(Wed), 12/30/2009(Wed), 01/08/2010(Fri)

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