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	05/19/2009 - 06/04/2009* FEI NUMBER 2510184

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Peter B. Luther, President

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	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.

GEN. SPEC.
RELEASE
F# _____ DATE 5/12/2010
Reviewed by:

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

MATERIALS SYSTEM

OBSERVATION 1

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

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

Table 1-1 Receipts o[redacted]

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

[redacted]

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

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	H. Jamillah for Hala L. J. Whetstone, Investigator Hala Jwhetstone Vlada Matusovsky, Investigator Vlada Matusovsky George Pyramides, Chemist George Pyramides 06/04/09 LINDA M. HOOVER, INVESTIGATOR Linda M. Hoover	06/04/2009

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characteristics of Infant's and Children's Tylenol Suspension formulations (i.e. [redacted]

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

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

LABORATORY CONTROL SYSTEM

OBSERVATION 2

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

Specifically, there is no documented justification to support the [redacted] sampling technique used in the sampling of [redacted] to ensure it is representative of the lot. The firm's SOP [redacted], entitled [redacted] to allow for mixing (inversion of a container 10 times). Each receipt of [redacted] is comprised of approximately [redacted]

Please note that this observation relates to Observation # 1.

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OBSERVATION 3

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

Specifically, SOP [redacted], entitled [redacted], does not specify the amount of product to be removed from each final product sample to ensure a representative sample is collected. The SOP states [redacted]. The informal practice utilized by the [redacted] laboratory staff is to [redacted] In addition, the SOP does not describe the directions/requirements for mixing the sample to ensure a homogenous mixture is consistently obtained prior to analysis.

Please note that this observation relates to Observation # 1.

OBSERVATION 4

The written stability testing program is not followed.

Specifically, the firm failed to test Tylenol Allergy Complete Multisymptom Geltabs, lot [redacted], at the [redacted] in accordance with study [redacted]. This lot represented the annual stability testing to support batches manufactured during production year 2005.

QUALITY SYSTEM

OBSERVATION 5

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

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

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Hala L.J. Wheeler, Investigator HJW Vlada Matusovsky, Investigator VM George Pyramides, Chemist GP 06/04/09 LINDA MCHOOKEN, INVESTIGATOR LMH	06/04/2009

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OBSERVATION 6

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

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

* DATES OF INSPECTION:
05/19/2009(Tue), 05/20/2009(Wed), 05/21/2009(Thu), 05/22/2009(Fri), 05/26/2009(Tue), 05/27/2009(Wed), 05/28/2009(Thu), 05/29/2009(Fri), 06/04/2009(Thu)

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SEE REVERSE OF THIS PAGE	Hala L. J. Whetstone, Investigator, Hala J. Whetstone Vlada Matusovsky, Investigator Vlada Matusovsky George Pyramides, Chemist George Pyramides 06/04/09 LINDA M. HEAVNER, INVESTIGATOR Linda M. Heavner	06/04/2009