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	04/19/2010 - 04/30/2010
	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 System

OBSERVATION 1

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

Specifically,

a. The Quality Control Unit (QA) authorities most responsible for overseeing daily operations at the Fort Washington facility did not ensure that the responsibilities of the Analytical, Microbiological, Compliance, and Quality Assurance departments were enforced for rejection and withholding from approval any raw material component that contained "known" contamination of gram negative organisms. Raw material (b) (4) (4), lots (b) (4) had known contamination with gram negative organisms and were approved for use to manufacture several finished lots of Children's and Infant's Tylenol drug products, which remain within expiration date(s) on the market. Responsible firm officials did not adhere to GMP regulations per (b) (4) for (b) (4) (b) (4) in that no Quality Notification was implemented regarding the rejection of contaminated lots of (b) (4) (4)

b. QA and Compliance Department overall responsibilities per the firm's (b) (4) is deficient as follows: It does not maintain adequate laboratory facilities for the testing and approval (or rejection) of components and drug products; it neglects review and approval of validation protocols regarding changes in product processes and equipment to determine when revalidation is or should be warranted; it is default in investigations, tracking, trending and maintenance of consumer complaint follow-up; and it lacks trending of products, components (i.e., water), and complaints to demonstrate a broad perspective to assure plant conformance with CGMPs.

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	Anita R. Michael, Investigator Matthew R. Noonan, Investigator Sharon K. Thoma, Investigator Hala L. Whetstone, Investigator Selby 5/20/10	04/30/2010

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OBSERVATION 2

There are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess.

Specifically,
Lack of process validation for the manufacture of Infant's Dye-Free Tylenol Suspension Drops, Cherry, Formula (b)(4) 80 mg/0.8 mL. The compounding and transfer of the (b)(4) batch size suspension to the (b)(4) hold tank is not in a "state of control". The firm did not effectively evaluate the change in the manufacturing process (agitation and tank level time to shut off of agitator) when the batch size was increased from (b)(4) into a (b)(4) hold tank; and/or when the hold tank size used for a (b)(4) batch was decreased from a (b)(4) to a (b)(4) (b)(4) hold tank.

OBSERVATION 3

Control procedures fail to include adequacy of mixing to assure uniformity and homogeneity.

OBSERVATION 4

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,

Control procedures used did not validate the manufacturing processes that caused variability in the characteristics of the drug product. For examples, the agitation speeds and time to reach (b)(4) in the hold tank during processing of the (b)(4) super potent batches that failed APAP (end of run) assays, (b)(4) released batches, and the demonstration batch. The firm did not demonstrate the adequacy of mixing to assure uniformity and homogeneity for Infant's Dye-Free Tylenol Suspension Drops, Formula (b)(4) using a (b)(4) batch in a (b)(4) hold tank. Agitation and tank levels with (b)(4) the amount of liquid) in a (b)(4) hold tank were evaluated with one demonstration bulk batch, lot

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(b)(4) packaged as lot (b)(4). The (b)(4) batches into (b)(4) hold tanks used (b)(4) and the agitator was shut off at (b)(4) using the weight of (b)(4) for the (b)(4) batch in a (b)(4) hold tank. With the (b)(4) super potent batches, APAP concentrated at the end of run when the agitator was shut off at (b)(4) in the tank).

Critical process parameters established during the original process validation for a (b)(4) batch in a (b)(4) hold tank for agitation speed used (b)(4) and for a (b)(4) batch in a (b)(4) hold tank used (b)(4). Original validation for the (b)(4) batch in a (b)(4) tank used weights from (b)(4) to weights of (b)(4), whereas the (b)(4) batch in a (b)(4) (b)(4) hold tank used weights from (b)(4) to (b)(4).

OBSERVATION 5

Written production and process control procedures are not followed in the execution of production and process control functions.

Specifically,

a. (b)(4) requires a CAPA (Corrective Action Preventive Action) to be initiated when systemic GMP issues or significant trends have been identified associated with nonconformance events, consumer complaints, manufacturing events and significant trends. The procedure defines a CAPA as a process for ensuring that identified corrective and preventive actions are verified for effectiveness. No CAPA was initiated for the following batches from May 2009 to April 2010 where foreign material, particulate matter and/or contamination were observed:

- (b)(4)
-
-
-
-
-
-
-
-
-
-

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- (b) (4) [redacted]

b. No CAPA was initiated for ~46 consumer complaints regarding foreign materials, black or dark specks from June 2009 to April 2010.

c. (b) (4) [redacted] section (b) (4) requires a (b) (4) metrics review of all new CAPAs, closed CAPAs, CAPAs open for more than (b) (4), and CAPAs exceeding the due date for review. No (b) (4) Metrics for CAPAs was completed.

d. No CAPA was completed for QN (b) (4) for OOS on (b) (4) [redacted]

OBSERVATION 6

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

Specifically,

1. A thorough investigation or any additional analytical testing was not conducted for Infants Dye-Free Tylenol Suspension Drops, Cherry, 80 mg/0.8 mL, Formula (b) (4) for the following:
   a. (b) (4) lots that were super potent and confirmed to fail release specification of (b) (4) [redacted] Acetaminophen (APAP) assay. For example(s) on End of Run Sample lot #s (b) (4) [redacted] (b) (4) [redacted] and (b) (4) [redacted] (b) (4) is the [redacted] batch manufactured

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of the (b)(4) batch campaign following manufacture of the demonstration batch, (b)(4) is the (b)(4) batch of the campaign, and (b)(4) is the (b)(4) batch manufactured. Quality Notification/Investigations (b)(4) rejected these (b)(4) batches based on release testing of end of run samples that failed assay.

b. The firm's investigations did not extend to the (b)(4) other batches and the demonstration batch of the same drug product associated with the manufacturing change. These (b)(4) batches and demonstration batch passed release specs for APAP assay and were distributed to the market. For examples: Lots (b)(4) (b)(4)

c. As of 04/23/10, no trending was completed to include the (b)(4) batches of the total (b)(4) batch campaign manufactured including: (b)(4)

2. The firm's investigation into recalls for various Tylenol products containing (b)(4)(b)(4) did not include review of all lots of (b)(4)(b)(4) received from the contract manufacturer between the lot used in manufacture of recalled products (i.e., (b)(4) to the first full lot of (b)(4)(b)(4) received from one entire vendor lot (i.e. (b)(4) McNeil lot (b)(4). For examples: Vendor lots (b)(4) (b)(4) Review of these vendor lots found that (b)(4) contained drums contaminated with gram negative organisms. Vendor lot (b)(4) was received on 12/04/08 as receiving lot (b)(4) and on 12/23/08 as receiving lot (b)(4) (b)(4)(b)(4) lots (b)(4) and (b)(4) were used to manufacture the following Tylenol Infant and Children's products which were marketed/distributed and remain within expiration dating as follows:

a. Lot (b)(4)(b)(4)(b)(4) was manufactured into the following bulk / finished product lots:
   - (b)(4) for Tylenol Infant's Drops, 80 mg/0.8mL, expiration date 11/10.
   - (b)(4) for Children's Tylenol Oral Suspension, expiration date 11/10.
   - (b)(4) for Children's Tylenol Oral Suspension, expiration date 11/10.
   - (b)(4) for Children's Tylenol Oral Suspension, expiration date 11/10.
   - (b)(4) for Children's Tylenol Plus Cold, expiration date 11/10.

- (b) (4) for Children's Tylenol Plus Multi-Symptom Cold, expiration date 11/10.
- (b) (4) for Children's Tylenol Plus Cold, expiration date 11/10.
- (b) (4) for Children's Tylenol Plus Multi-symptom Cold, expiration date 12/10.
- (b) (4) for Children's Tylenol Oral Suspension, expiration date 11/10.
- (b) (4) for Children's Tylenol Plus Multi-Symptom Cold, expiration date 11/10.
- (b) (4) for Children's Tylenol Oral Suspension, expiration date 12/10.
- (b) (4) for Children's Tylenol Plus Multi-Symptom Cold, expiration date 11/10.
- (b) (4) for Children's Tylenol Plus Cold & Cough, expiration date 12/10.
- (b) (4) for Infant's Tylenol Drops, expiration date 12/10.
- (b) (4) for Children's Tylenol Oral Suspension, expiration date 12/10.
- (b) (4) for Infant's Tylenol Drops, expiration date 12/10.
- (b) (4) for Infant's Tylenol Drops, expiration date 12/10.
- (b) (4) for Children's Tylenol Oral Suspension, expiration date 11/10.

b. Lot (b) (4)

- (b) (4) for Children's Tylenol Plus Cold & Cough, expiration date 12/10.
- (b) (4) for Children's Tylenol Oral Suspension, expiration date 12/10.
- (b) (4) for Children's Tylenol Oral Suspension, expiration date 12/10.
- (b) (4) for Children's Tylenol Plus Cold & Cough, expiration date 12/10.
- (b) (4) for Children's Tylenol Oral Suspension, expiration date 12/10.

- (b)(4) for Children's Tylenol Oral Suspension, expiration date 12/10.
- (b)(4) for Children's Tylenol Oral Suspension, expiration date 12/10.
- (b)(4) for Tylenol Infant's Drops, expiration date 12/10.
- (b)(4) for Children's Tylenol Plus Cold & Cough, expiration date 12/10.

OBSERVATION 7

GMP training is not conducted with sufficient frequency to assure that employees remain familiar with CGMP requirements applicable to them.

Specifically, employees are not given training in current good manufacturing practices and written procedures required by current good manufacturing practice regulations as follows:

a. As of 04/23/10, (b)(4) Compliance Specialist, and (b)(4) Granulation Operator, did not attend new employee cGMP classroom training which is conducted (b)(4) (b)(4) version (b)(4) (b)(4) effective 3/29/10, (b)(4), requires initial cGMP training before departmental training.
   - (b)(4) started working for the firm as a contract employee on 02/24/10, and started departmental training on 02/25/10.
   - (b)(4) was temporarily transferred from the company's Lancaster, PA plant from 02/01/10 to 04/18/10, and started departmental training on 02/01/10. According to (b)(4) version (b)(4) transfer employees must receive the same initial training as new employees.

b. As of 04/23/10, there was no documented training in (b)(4) for (b)(4) of (b)(4) granulation SOPs required to be reviewed by (b)(4) Granulation Operator, during his transfer from 02/01/10 to 04/18/10. The firm uses (b)(4) learning management system to electronically document training activities.

c. As of 04/20/10, (b)(4) Change Parts Coordinator, did not receive training on (b)(4) (b)(4) (b)(4) effective 04/02/10. (b)(4) is responsible for cleaning and maintaining tooling in the Compression tool room.

Production Systems

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OBSERVATION 8

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

Specifically,
No review of the batch production and packaging records was conducted for "lack of effect" regarding Infant's Dye Free Tylenol Suspension Drops, Cherry, Lot (b)(4)

Quality Assurance evaluation of complaints documented in Quality Notifications (QNs) (b)(4) (b)(4) determined that no quality issues were warranted and hence, no manufacturing or packaging investigation was conducted. QN (b)(4) regarding the recall of Microcrystalline Cellulose and Carboxymethycellulose Sodium NF McNeil, lot# (b)(4) was associated with this finished product lot (b)(4) Approximately (b)(4) QN reports regarding lot (b)(4) were forwarded from the Corporate Benefits Risk Management group to this manufacturing site for investigation from August to November 2009.

OBSERVATION 9

Each container of component dispensed to manufacturing is not examined by a second person to assure that the weight or measure is correct as stated in the batch records.

Specifically, Infant's Tylenol Suspension Drops, Cherry, batch (b)(4)

Acetaminophen (APAP) Assay results for beginning, middle and end samples were OOS and sub potent as follows (release spec is (b)(4)

(b)(4) Beg = (b)(4)
Mid =
End =

Retest (i.e., re-measure) results were also OOS and confirmed the original OOS results.

Manufacturing batch records indicate that (b)(4) of the active APAP was weighed as required by the formulation. The batch record also states that the correct amount was weighed as (b)(4) drums at

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(b)(4) each) and (b)(4) drum of APAP at (b)(4). The batch record indicates that the correct amount of APAP was weighed by operator 1 and verified by operator 2. Investigation states the likely cause of sub-potency is caused by not charging in the correct amount of APAP. A mix up occurred and a partial drum weighing less than the required amount was used instead of the correct drum. Operator 1 and Operator 2 weights checks did not prevent the use of the wrong amount of APAP.

Labeling & Packaging Systems

OBSERVATION 10

Strict control is not exercised over labeling issued for use in drug product labeling operations.

Specifically, on 04/20/10, labeling was observed to be stored throughout the warehouse accessible to all warehouse operators and personnel that have access to the raw material/component storage warehouse. Labeling was not stored in a locked cage with limited access. For examples:

a. (b)(4) immediate container labels for Concentrated Motrin Infants' Drops, Oral Suspension, 50 mg ibuprofen per 1.25 mL, 1 fl. oz., Original Berry Flavor, part (b)(4) label lot (b)(4) were stored in warehouse location (b)(4)
b. (b)(4) immediate container labels for Children's Tylenol Plus Multi-Symptom Cold, Oral Suspension, 160 mg acetaminophen per 5 mL, 4 fl. oz., Grape, part # (b)(4) label lot (b)(4) were stored in warehouse location (b)(4)
c. Several others.

Laboratory Operations

OBSERVATION 11

There is no written testing program designed to assess the stability characteristics of drug products.

Specifically,

a. Lack of stability data to support the (b)(4) expiration date assigned to lots produced following the

manufacturing change for Infants Dye-Free Tylenol Suspension Drops, Cherry, 80 mg/0.8 mL, Formula (b) (4) using a (b) (4) batch size in a (b) (4) hold tank. For examples, (b) (4) released/marketed batches: (b) (4) (demonstration batch), (b) (4) (b) (4)

b. Stability samples collected off of the packaging line for lots (b) (4) were pulled from the beginning of the packaging run only. Per (b) (4) for (b) (4) (b) (4) all stability samples are pulled from the beginning of the packaging run. Stability samples are not representative samples from the beginning, middle and end of the fill run specifically for the three batches with super potent end sample fills. For example, (b) (4)

OBSERVATION 12

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

Specifically,

Scientific justification does not identify the reason(s) why the firm does not test TSA, a non-selective general microbial growth medium, lot (b) (4) during growth promotion tests for microorganisms to include for example, molds, yeasts and other potential known environmental contaminants found in the manufacturing facility and/or raw materials. This media was used for testing raw materials and finished products for microbial limits testing from 03/01/09 to 08/03/09. (b) (4) was isolated from raw material lot (b) (4) (vendor lot (b) (4) however, TSA was challenged with (b) (4) *and* (b) (4) only. (b) (4) was not isolated from raw material lot #s (b) (4) (vendor lot (b) (4)

OBSERVATION 13

Adequate lab facilities for testing and approval or rejection of components and drug products are not available to the quality control unit.

Specifically,

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1. Lack of investigation, review and follow-up of (b)(4) as follows:
   a. Calibration on 03/09/10 per Test Report No (b)(4) demonstrates that certification of the (b)(4) was outside the (b)(4) tolerance criteria and the leak test for the (b)(4) filter failed the specification of penetration (b)(4) of the upstream concentration in two areas on the (b)(4) filter at (b)(4) in addition to leakage at the frame.
   b. Test Report No. (b)(4) demonstrates airflow into the (b)(4) back room where microbiological testing of finished products and raw materials is conducted in Hoods (b)(4) in relation to the general microbiological room outside of the (b)(4) airflow is not positive to the general microbiological room (i.e., Walk-In Chambers, refrigerator and freezer room).
   c. The aerosol challenge installation leak test and air velocity results per Test Report No. (b)(4) (b)(4) was not evaluated by the microbiological laboratory until requested during the current inspection. This report is typically sent from the contract service to the maintenance department and filed with no evaluation or follow-up by the microbiological laboratory personnel concerning failing results.
   d. No procedure regarding the allowable percentage of leakage across the (b)(4) filter and no specifications concerning the width and height areas for total allowable repairs.

2. Lack of investigation, review and follow-up of (b)(4) as follows:
   a. Calibration on 03/09/10 per Test Report No. (b)(4) demonstrates that certification of the (b)(4) velocity was outside the (b)(4) tolerance criteria and the leak test for the (b)(4) filter failed the specification of penetration (b)(4) of the upstream concentration in two areas on the (b)(4) filter at (b)(4) in addition to leakage at the frame.
   b. Calibration on 09/16/09 per Test Report No. (b)(4) demonstrates that certification of the (b)(4) air velocity was outside the (b)(4) tolerance criteria.
   c. The aerosol challenge installation leak test and air velocity results per Test Report No. (b)(4) (b)(4) was not evaluated by the microbiological laboratory. This report is typically sent from the contract service to the maintenance department and filed with no evaluation or follow-up on failing results.
   d. No procedure regarding the allowable percentage of leakage across the (b)(4) filter and no specifications concerning the width and height areas for total allowable repairs.

3. On 04/19/10, during the walk through of the Microbiological Laboratory, the following deviations were observed:

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a. No cleaning/use log for the (b)(4) used for raw material weighing.
b. Thick dust covering the grill inside the (b)(4) filtered cabinet.
c. No identification of the temperature probes in (b)(4).
d. Duct Tape wrapping the copper piping insulation inside the (b)(4) where the firm stores water samples and refrigerated media.
e. Incubator (b)(4) had a large amount of visible grey and brown dust/debri observed on the bottom of the chamber under the shelves where media filled containers and media hold time studies were located.
f. There was a large exposed hole (gap) in the ceiling above incubator (b)(4) and next to the air vent in the ceiling.
g. No inventory of (b)(4) containing (b)(4) organisms.
h. Various microbiological rooms containing laboratory equipment "not in-use" that contained dust/debri. "Out of Service" equipment cluttered laboratory areas. For examples, equipment "out of service" dates are as follows:
   - water sample refrigerator (b)(4) (dated 07/2007);
   - pH meter (09/30/09);
   - Shaker incubator (12/16/08);
   - Culture incubator (May 2007); Etc.

4. On 04/22/10, the following deviations were observed during microbiological testing of Children's Zyrtec Sugar Free Syrup, lot (b)(4) formula (b)(4) in the (b)(4) Back Testing Room in Hood (b)(4)
   a. Hood (b)(4) had about a 6 inch silicon plug located on the right side upper (b)(4) filter.
   b. The left side of the (b)(4) had a very large spider- like crack on the left side of the hood plexiglass where the gas vacuum hose was located. This vacuum hose is not used.
   c. The microbiologist was observed to pour media into the negative control (i.e. small bottle) placed in front of the larger 250 mL bottle, which blocked/disrupted the (b)(4) air flow.
   d. The microbiologist was observed to open media (i.e. (b)(4) close to the outside of the hood rather than inside the hood with (b)(4) filtered horizontal airflow.
   e. The microbiologist was observed to spray hands and items in the hood with (b)(4) Disinfectant Scented Spray directed into the (b)(4) filter.
   f. The microbiologist was observed to spray the outside wrapped items placed in the hood, which

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were opened outside of the hood rather than inside the hood. For example, pipettes used to transfer product with (b) (4) to the plates.

g. Grills in front of the entire face of the (b) (4) filters in Hood #s (b) (4) were plastic with ~one inch diameter squares and not easily sanitized/cleaned. Hood (b) (4) grill was dirty with grime in each square and missed pieces of plastic in several locations on the plastic grill.

OBSERVATION 14

Laboratory records do not include complete records of the periodic calibration of laboratory instruments, gauges, and recording devices.

Specifically,

Laboratory refrigerators (i.e., (b) (4) were not calibrated adequately in that they were not calibrated to the probes inside the units or to a national standard until 04/22/10.

OBSERVATION 15

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

SOP deficiencies:

a. (b) (4) for (b) (4) does not include the dilution to use under Section (b) (4) for Results/Levels. The number of colonies observed is not to exceed more than (b) (4) merely references section (b) (4) for (b) (4) regarding microbiological swabbing.

b. (b) (4) does not identify the microbiological swab used for swabbing equipment after cleaning for Bioburden samples. The micro swab used is (b) (4) Applicators (Cotton), Catalog (b) (4). This SOP identifies the (b) (4) which is used for analytical cleaning procedures (e.g. (b) (4) (b) (4) (b) (4)

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US Customhouse, Rm 900 2nd & Chestnut St Philadelphia, PA 19106 (215) 597-4390 Fax:(215) 597-0875 Industry Information: www.fda.gov/oc/industry	04/19/2010 - 04/30/2010
	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

Material System

OBSERVATION 16

Samples taken of in-process materials for determination of conformance to specifications are not representative.

Specifically,

Raw material (tail gait) samples pulled by the manufacturer at the request of the firm for (b)(4) (b)(4) (4) is not a statistically significant (e.g. (b)(4) = the number of containers) representative sample of the total (b)(4) per pallet). The sample includes only (b)(4) bag from each of (b)(4) pallets or (b)(4) samples.

OBSERVATION 17

Each lot of components was not appropriately identified as to its status in terms of being quarantined, approved or rejected.

Specifically,

Separate or defined areas to prevent contamination or mix-ups are deficient regarding operations related to the storage of released components and labeling. ~~211.42(c)(3)~~ AR 4/30/10 MRN 4/30/10 HLS 4/30/10 ARM 4/30/10

a. On 4/20/10, drug components and labeling in unrestricted status were observed stored in the open incoming inspection area in the warehouse, along with materials in quarantined and blocked status. Materials were stored in two lanes of pallets on the floor, and included:
   - (b)(4) immediate container labels for Children's Non-Drowsy Reactine, Cetirizine Hydrochloride Syrup, 5 mg/5 mL, 118 mL, Dye Free Grape, part (b)(4) label lot (b)(4) unrestricted in (b)(4)
   - (b)(4) of Artificial Bubblegum Flavor, part (b)(4) component lot (b)(4) quarantined in (b)(4) but lacking a status sticker.
   - (b)(4) of Corn Starch NF, part (b)(4), component lot (b)(4), blocked in (b)(4) bearing a status sticker, leaking powder from one bag

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Anita R. Michael, Investigator ARM Matthew R. Noonan, Investigator MRN Sharon K. Thoma, Investigator Hala L. ~~Whetstone~~, Investigator HLS Selby HLS 4/30/10	04/30/2010

The status of the materials could not be determined via visual examination, with the exception of the Corn Starch NF.

b. On 04/20/10, (b)(4) cartons for Concentrated Tylenol Infants' Drops, 80 mg acetaminophen per .8 mL, 1 fl. oz., Dye Free Cherry, part (b)(4) label lot (b)(4), were observed stored in cardboard boxes on a pallet in the incoming inspection area. "Bad cartons" had been handwritten in black ink on the cardboard boxes. The cartons were in unrestricted status in SAP.

c. Stock Room (b)(4) Restricted Storage Room located in the microbiological laboratory had excess media in boxes and special projects stored in the room with no designated areas of storage for approved, quarantine, or rejected status. The room was cluttered with boxes of media, special projects that had bins with various containers of chemicals, special projects with boxed finished OTC products, boxes of computer items, out of service equipment, etc. Until 04/23/10, the firm had no inventory of the room contents.

OBSERVATION 18

Components are not microscopically examined when appropriate.

Specifically,

There are no monthly trend reports written for the microbial water test results per (b)(4) for (b)(4) since on or before 05/01/09. Pages 18 and 19 of 25 reads in part: "9.0 DOCUMENTATION 9.1 The monthly/weekly samples are automatically logged into the computerized data system (b)(4) ***9.2 Results are documented in the assigned laboratory logbook and are entered into the computerized data system (b)(4) *** 9.3 A monthly report of microbial water testing results shall be performed and documented. 9.3.1 The monthly trending of the purified and potable water systems is done *** throughout the facility. *** 9.3.2 The report will consist of the current month and at least the summarized data from the previous month. 9.3.3 The following must be part of the full report: *** Sanitization dates of the system ***Quantity of samples *** Quantity of samples within limits *** Action/Alert levels *** Investigations ***9.3.4 The report will be initiated by a Team Leader or designee and will be signed by the Microbiology Manager ***The Team Leader will have the responsibility of collecting and compiling the information from (b)(4) or the testing logbooks and verify its accuracy. The Microbiology Manager will review the report for completion and determination of any abnormal trends of the water system. *** 9.3.5 The report will be completed

within sixty days from the end of the month. ***". No (b)(4) data was entered from 02/09/10 to 04/24/10. No trend reports of microbial water testing results was conducted and documented since on or after 05/01/09.

Facilities & Equipment

OBSERVATION 19

Records are not kept for the maintenance and inspection of equipment.

Specifically,

a. On 04/20/10, hoses on the (b)(4) were said to not be dedicated to products processed on these two fluid bed dryers by an operator and team leader. Cleaning validation of the equipment did not evaluate cleaning of the 2.5 foot hose on (b)(4) (b)(4) ecause the cleaning validation followed (b)(4) Cleaning of equipment lacks documentation that (b)(4) was followed and/or a statement that the 2.5 foot hose was removed and replaced after the campaign was completed for each drug product processed in the (b)(4) (b)(4) For example, cleaning on 04/17/10 by operator (b)(4) and verified by operator TE. In addition, the person verifying that cleaning was performed (b)(4) on 04/17/10 was a temporary person from a different McNeil site and lacked training on (b)(4) (b)(4)
b. Seals on the (b)(4) were observed to be in disrepair and not maintained with several cracks.
c. Inlet air insulation was wrapped with peeling masking-like tape.
d. No documentation on cleaning and maintenance of the Microbiological Laboratory (b)(4) (b)(4) ondenser filter and gasket as required. On 04/19/10, the (b)(4) was observed to contain a large amount of visible grey and brown material on the filter behind the grill. Review of the manufactures' maintenance manual indicates to clean the condenser at least every (b)(4) or more often if the laboratory area is dust prone. The filter should be removed, fan checks performed, filters replaced, and condenser vacuumed.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

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OBSERVATION 20

The persons double-checking the cleaning and maintenance are not dating and signing or initialing the equipment cleaning and use log.

Specifically,

No second signature verifying that maintenance was completed. The second signature in the system is a sign off that the maintenance was entered into the system and not verification of the adequacy of maintenance conducted. For examples, Maintenance (b)(4) ated 12/11/09; Maintenance (b)(4))417/10; etc.

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