DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax:(313) 393-8139 Industry Information: www.fda.gov/oc/industry	06/11/2014 - 07/08/2014* FEI NUMBER 3004971302

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mr. Ekramul Ameen, President/CEO

FIRM NAME	STREET ADDRESS
American Family Pharmacy, LLC	3250 N. Post Rd. Suite 285
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Indianapolis, IN 46226	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 I OBSERVED:

PRODUCTION SYSTEM

OBSERVATION 1

Batch production and control records do not include complete information relating to the production and control of each batch.

Specifically,

Batch production records completed between [redacted] (b) (4) [redacted] for the manufacturing and packaging of acetaminophen 500mg and aspirin 81mg were deficient as follows:

1) The batch record numbering system, which utilizes the (b) (4) [redacted] does not allow for your firm to distinguish between lots manufactured and packaged on different days within the same month. For example acetaminophen 500mg lot number ~~011514A415~~ 011414A415 with expiry date of 02/2016 manufactured and packaged on 2/14/14 had the same lot number and expiry as a finished product lot manufactured and packaged on 2/24/14, from the (b) (4) [redacted].

2) Batch records do not include reconciliation of actual and theoretical yield values for components, bulk drug product, container closures and labeling at the conclusion of dispensing, compression, and packaging process stages.

3) Batch production records do not include significant steps involved in the manufacturing and packaging process such as dispensing, compression, packaging line setup and line clearance activities.

4) Batch production records do not include a description and lot number for each unique lot of containers and closures used in the manufacture and packaging process.

5) Batch production records do not include results of review of packaged and labeled product.

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6) Batch production records ~~do~~ do not include a list of all major equipment used in the manufacturing and packaging process.

7) Batch production records do not include in-process or laboratory control test results.

8) Batch production records do not include results of inspection of the manufacturing, packaging and labeling areas. Also there are no line clearance activities performed either prior to or after manufacturing and packaging operations are performed and documented.

9) Batch production records ~~do~~ do not include labeling and control specimens for each lot of finished drug products packaged.

10) Batch production records do not include the weights and measures of components used in the manufacturing process.

11) Your firm did not complete a batch record for the manufacture and packaging of acetaminophen 500mg lot number 011414B488.

Acetaminophen 500mg lots and Aspirin 81mg lots manufactured between (b) (4) [redacted] are listed in Table 3 of Observation 4.

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,

a) Your firm has not established appropriate in-process specifications nor has your firm demonstrated through validation that manufacturing processes are performed in a manner which can control and minimize variability in drug product characteristics for the manufacture of acetaminophen 500mg and aspirin 81mg. Additionally, blend uniformity for the acetaminophen blend and aspirin blend has not been verified after receipt from the material suppliers prior to compression. Acetaminophen 500mg and aspirin 81mg lots manufactured between (b) (4) [redacted] are listed in Table 3 of observation 4.

b) Your firm has not established appropriate in-process specifications nor has your firm demonstrated through validation that the packaging processes are performed in a manner which can control and minimize variability in drug product characteristics for the packaging of acetaminophen 500mg, aspirin 81mg, ibuprofen 200mg, naproxen 220mg, diphenhydramine 25mg, acetaminophen PM, aspirin 325mg, loperamide 2mg, and ranitidine 150mg. Acetaminophen 500mg and aspirin 81mg lots packaged between (b) (4) [redacted] are listed in Table 3 of observation 4. The lots listed below in Table 1 of this

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records or packaging validation having been completed.

Table 1:

Product	Lot number
ibuprofen 200mg	P84401
aspirin 325mg	3946
diphenhydramine 25mg	P77719
loperamide 2mg	3DE1777
naproxen 220mg	BU1005
acetaminophen 500mg	39564
acetaminophen PM	40103
ranitidine 150mg	HB39812

OBSERVATION 3

Employees are not given training in the particular operations they perform as part of their function, current good manufacturing practices, and written procedures required by current good manufacturing practice regulations.

Specifically,

There are no records of training for production operators, initials [redacted] (b) (6) which detail the training received for performing material receipt, tablet compression, packaging and shipping operations conducted by your firm. I observed the names of these operators on Acetaminophen 500mg and Aspirin 81mg lots manufactured between (b) (4) [redacted] as follows:

Table 2:

Operator Initials	Batch Number and date
(b) (6) [redacted]	130788 (1/23/14), 011414A357 (2/6/14), 011414A357 (2/3/14), 12084 (1/8/14), 12084 (1/21/14), 12084 (1/22/14), 12084 (1/27/14), 12084 (1/28/14), 12084

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	(1/29/14), 12084 (1/30/14), 12084 (2/4/14), 12084 (2/6/14)
(b) (6)	011414A415 (2/14/14), 011414B443 (4/18/14), 12084 (1/20/14), 12084 (1/21/14), 12084 (1/23/14), 12084 (2/7/14), 12084 (2/24/14), 12084 (3/5/14), 12084 (4/1/14), 12084 (4/8/14)
(b) (6)	130788 (1/10/14), 011414A415 (2/24/14), 011414B443 (3/7/14), 12084 (1/24/14), 12084 (2/25/14), 12084 (2/28/14), 12084 (3/4/14), 12084 (4/4/14), 12084 (5/5/14)
(b) (6)	011414B443 (3/7/14), 011414A415 (2/13/14)
(b) (6)	12084 (2/7/14), 12084 (1/8/14), 12084 (1/20/14), 011414A415 (2/13/14)

QUALITY SYSTEM

OBSERVATION 4

Drug product production and control records, are not reviewed and approved by the quality control unit to determine compliance with all established, approved written procedures before a batch is released or distributed.

Specifically,

The procedure titled *Responsibilities of the Quality and Production Units* states in part 1 of section VIII the specific responsibilities of the Quality Unit include but are not limited to release or reject of raw materials, intermediates, packaging, labeling materials and finished product.

The following finished product lots were manufactured and distributed from your facility between (b) (4) (b) (4) without written record of release from your firm's quality unit:

Table 3:

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Product	Lot #	Date of Manufacture
Acetaminophen 500mg	011414B488	(b) (4)
Acetaminophen 500mg	011414B443	
Acetaminophen 500mg	011414B443	
Acetaminophen 500mg	011414A357	
Acetaminophen 500mg	011414A357	
Acetaminophen 500mg	011414A357	
Acetaminophen 500mg	011414A415	
Acetaminophen 500mg	011414A415	
Acetaminophen 500mg	011414A415	
Acetaminophen 500mg	011414A415	
Acetaminophen 500mg	130788	
Acetaminophen 500mg	130788	
~~Aspirin 81mg~~	~~12084~~	
Aspirin 81mg	12084	
Aspirin 81mg	12084	
Aspirin 81mg	12084	
Aspirin 81mg	12084	
Aspirin 81mg	12084	
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Aspirin 81mg	12084	

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OBSERVATION 5

Complaint records are deficient in that they do not include the findings of the investigation and follow-up.

Specifically,

During my review of your complaint file the following deficiencies were noted:
1) on 1/27/13, 1/29/14, and 2/28/14 three separate customers contacted your firm regarding discoloration among aspirin 81mg tablets. However your firm did not complete an internal investigation including a review of aspirin 81mg lots produced nor were any attempts to contact the customer and retrieve product lot numbers recorded.

2) On 4/1/14 your firm received a complaint regarding 81mg aspirin being stuck or clumped together. Your firm did not perform an internal investigation including a review of 81mg lots produced nor were any attempts to contact the customer and retrieve product lot numbers recorded.

MATERIALS SYSTEM

OBSERVATION 6

Representative samples are not taken of each shipment of each lot of components, drug product containers, and closures for testing or examination.

Specifically,

Your firm did not retain representative samples of the following materials used between (b) (4) in the manufacture of finished drug product:

Table 4:

Product	Lot #	Dates used in manufacturing
(b) (4) Acetaminophen	(b) (4)	Unknown
(b) (4) Acetaminophen	(b) (4)	(b) (4)
(b) (4)	(b) (4)	(b) (4) (b) (4)

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Acetaminophen		
(b) (4)	(b) (4)	(b) (4)
Acetaminophen		
Acetaminophen(b) (4)	(b) (4)	
Aspirin(b) (4)	(b) (4)	

OBSERVATION 7

Written procedures are not followed for the receipt, identification, storage, handling, sampling, testing, and approval of components, drug product containers, and closures.

Specifically,

The procedure titled *Material Receipt and Control* is not followed in the following manner:

1) Material Receipt and Use Records, described in section 6 of this procedure, are not maintained for each lot of material received. Per this procedure the material receipt and use record shall include the date, quantity used, quantity remaining, and product lot number for all material used in the manufacture of drug product. For example Material Receipt and Use Records were not maintained for Acetaminophen(b) (4) (b) (4) which was compressed and packaged on(b) (4)

2) The use of colored status labels to indicate quarantine, released, and reject status is not being employed. During my walkthrough of your facility only a single box of 81mg aspirin lot C13001 was labeled with a red colored status tag. No other material staged in the warehouse area (including materials staged in the quarantine and reject areas) was observed to be tagged as to its current status. For example during my walkthrough of the warehouse I observed an opened box of Ibuprofen cartons staged outside of the reject area with no status labeling present.

This procedure was also observed to be insufficient in the following manner:

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1) There is no requirement for the recording of incoming visual inspection of containers by either quality or receiving personnel. Additionally, the confirmation performed by Quality Assurance that the material received is of the same name, part number, model number, size, and/or quantity as that ordered is also not recorded. For example there is no requirement to record the incoming visual inspection and subsequent review of the receipt of (b) (4) of Acetaminophen (b) (4) lot (b) (4) which was compressed and packaged on (b) (4)

2) There is no requirement for the recording of the verification performed by quality that the supplier's CofA for all materials and cartons received match the lot number present on each material or carton and that the CofA meets the material specification. For example there is no requirement to record the CofA verification for the receipt of (b) (4) of Acetaminophen (b) (4) lot (b) (4) which was compressed and packaged on (b) (4)

3) There is no requirement for recording and tracking of rejected material outside of the (b) (4) (b) (4) system. During my walkthrough of your facility I observed rejected untagged material both inside and outside of the designated reject area however the reason this material had been rejected was not documented nor were any (b) (4) reports made for these observed materials. For example during my walkthrough of the warehouse I observed an opened box of Ibuprofen cartons staged outside of the reject area. Though you stated the Ibuprofen cartons were rejected material, the box in which they were contained was not identified as to its status nor was there a (b) (4) report associated with this material.

OBSERVATION 8

Drug products are not stored under appropriate conditions of temperature so that their identity, strength, quality, and purity are not affected.

Specifically,

Your firm's warehouse is not equipped to maintain controlled room temperature conditions for storage of components and finished pharmaceutical product. During this inspection the temperature of your warehouse was observed to reach and maintain temperatures above 80°C as observed during this inspection. Finished products stored in the warehouse include acetaminophen 500mg lot number 011414B488 and aspirin lot number 12084.

FACILITIES & EQUIPMENT SYSTEM

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OBSERVATION 9

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

Specifically,
Though there was no notation of the equipment used in manufacturing, there are no records of the usage, cleaning, maintenance, and calibration of the following pieces of equipment observed in your facility:

Table 5:

Manufacturing/Compression
(b) (4)
(b) (4)
Packaging
(b) (4)
Warehouse
(b) (4)
Laboratory

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(b) (4)

Acetaminophen 500mg and Aspirin 81mg finished product lots manufactured in your facility between (b) (4) are listed in Table 3 of Observation 4.

PACKAGING & LABELING SYSTEM

OBSERVATION 10

Procedures designed to assure that correct labels, labeling, and packaging materials are used for drug products are not written and followed.

Specifically,

Your firm has no specifications regarding the approval and release of labeling materials including container labels and cartons for products manufactured between (b) (4) listed Table 3 of Observation 4. Additionally, lots listed in Table 1 of Observation 2 were also observed to have no specifications regarding the approval and release of labeling materials including container labels and cartons.

LABORATORY SYSTEM

OBSERVATION 11

Laboratory controls do not include determination of conformance to appropriate written specifications for the acceptance of each lot within each shipment of components, drug product containers, closures, in-process materials, labeling, and drug products used in the manufacture, processing, packing, or holding of drug products.

Specifically,

Your firm does not have specifications for the acceptance of each shipment of components (including acetaminophen and

aspirin blends), containers and closures (including bottles and caps), and labeling (including bottle labels and cartons). Also, your firm has not performed any confirmatory testing (including identity testing) or periodic reevaluation of supplier CofA for lots of components, containers and closures and labeling received at your firm between (b) (4) . For example, your firm has no specifications for (b) (4) acetaminophen and aspirin (b) (4) components which were used in the manufacture of acetaminophen 500mg lot 011414B488 and aspirin 81mg lot 12084 respectively. Also no incoming samples were collected and tested for these components prior to use in the manufacture of the aforementioned lots.

Finished product lots manufactured and packaged by your firm between (b) (4) are listed in Table 3 of Observation 4. Components received by your firm between (b) (4) are listed in Table 4 of Observation 6.

OBSERVATION 12

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications and identity and strength of each active ingredient prior to release.

Specifically,

Acetaminophen 500mg and aspirin 81mg lots manufactured from (b) (4) were not evaluated/tested to ensure that finished drug products conform to specifications prior to finished product release. Finished product lots manufactured, released and distributed without any evidence of release testing between (b) (4) are listed in Table 3 of Observation 4.

OBSERVATION 13

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

Specifically,

Your firm has not established a stability testing program, including stability specifications, for finished drug products manufactured and or packaged at your firm between (b) (4) . Products manufactured and or packaged during this time period include acetaminophen 500mg and aspirin 81mg finished product lots listed in Table 3 of Observation 4.

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