DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Ave. Jamaica, NY 11433 (718) 340-7000 Fax:(718) 662-5661 Industry Information: www.fda.gov/oc/industry	01/09/2014 - 02/07/2014* FEI NUMBER 2434153

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: David Miller, Senior Vice President, Quality Management

FIRM NAME	STREET ADDRESS
Amneal Pharmaceuticals of New York, LLC.	85 Adams Avenue
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Hauppauge, NY 11788	Prescription Drug 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:

OBSERVATION 1

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, the following investigations were not conducted *as* per *SOP P_CQCM_0271, Ver. 4.0 (effective 10/14/13)* titled "*Investigation System*", in that root causes & corrective actions were not defined and there is a lack of an adequate investigation conducted by Quality Assurance:

i. **Investigation No:** (b) (4) Gabapentin Capsules, USP 100mg, Batch #HJ30713, did not meet the specification of Not More Than (NMT) (b) (4)% of any other unknown impurity during the related substance testing conducted on 11/16/13 (actual result (b) (4) %). The initial Out of Specification (OOS) result for single largest unknown impurity was confirmed on 11/22/13 and the impurity was identified as Naproxen also manufactured in your facility.

However, at the time of this inspection Quality Assurance had failed to initiate an investigation as per *SOP P_CQCM_0271, Ver 4.0 (effective 10/14/13)* titled "*Investigation System*" and did not disposition the batch as either quarantined or rejected. Additionally, a root cause and corrective actions have not been defined.

ii. **Investigation No** (b) (4) : Stability testing results for Impurity D at (b) (4) -mos. interval for Amlodipine Besylate 5mg Tablets, Lot #HA27712 (Exp. 1/14) were greater than the specification of NMT (b) (4) %. Actual OOS results were (b) (4) %. This was the (b) (4) lot of a (b) (4) batch campaign. The Quality Control Lab investigation concluded the initial result as an analytically valid result on 5/24/13. The manufacturing investigation concluded that the result could not be attributed to raw materials or the manufacturing process.

However, there is a lack of justification by Quality Assurance per *SOP P_CQCM_0271* to support their final disposition on 6/11/13 stating that "*this result in context with the other results generated as*

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Demitria J. Xiradakis, Investigator	02/07/2014

part of this investigation and the stability history of the product. Therefore, Amneal will not take any market action at this time". Additionally, the Field Alert submitted on 6/3/13 concluded that "i*t is unlikely that any bottles remain on the market at this time*"…"*therefore we will not take any market action at this time*" even though the product was still within expiration (Exp 1/14).

iii. **Investigation No** (b) (4) : On 1/2/13, during the related substances testing of Stability samples of Amlodipine Besylate Tablets 5mg, USP, Batches #HG10112 and #HD36612), <blister package>, the test result did not meet the impurity-D specification of NMT (b) (4) % or the specification for total impurities of NMT (b) (4) %. The investigation record did not extend the testing to retention samples for the 90ct bottles packaged for the two lots involved (HD36612 and HG10112). For example: Batch #HD36612 had a total # of tablets produced of (b) (4) of which only (b) (4) were blister packaged and (b) (4) tablets were packed into 90ct bottles. A root cause and corrective actions has not been defined and these lots have not been placed on stability. (Distributed Lots).

iv. **Investigation No** (b) (4) : On 11/11/13, OOS Dissolution results were obtained during testing of the CRT (b) (4) -month stability testing interval for Extended Phenytoin Na Sodium Capsules, USP 100mg, Batch #HL17811 (Exp 11/13)(100's and 1000 counts). The investigation concluded "*because the batch is expiring at the end of this month, we are taking no further action*" even though the OOS result was confirmed on 11/14/13. (Distributed Lot).

Furthermore, the firm has established a correlation between the failing test results for this and at least (b) other batches since 2011 to low humidity during the encapsulation process as explained in *Investigation No.* (b) (4) and Field Alert dated 11/14/13. *Investigation No* (b) (4) concluded that as corrective action, humidity controls will be installed in the encapsulation room, however corrective action has yet to be initiated.

OBSERVATION 2

Not all adverse drug experiences that are both serious and unexpected have been reported to FDA within 15 calendar days of initial receipt of the information.

Specifically, the following records reporting both serious and unexpected adverse events were not submitted as 15-Day Alerts:

i. (b) (4) : (Oxycodone and Acetaminophen Tablets, USP 10mg/325mg) The ADE final medical assessment on 1/9/13 concluded the report was serious since the patient had been hospitalized and contained unexpected adverse events; however the "*Product Complaint Summary Report*" (dated 2/6/13) assessed the report as non-serious without a documented justification. As a

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result, a 15-Day Alert Report was not submitted to the Agency.

ii. (b) (4) (Metformin HCl ER Tablets, USP 500mg) The ADE final medical assessment on 12/30/13 concluded the report contained unexpected adverse events; however the report was classified as non-serious even though the patient required treatment in an emergency room, making it a serious event. As a result, a 15-Day Alert Report was not submitted to the Agency.

*** DATES OF INSPECTION:**
01/09/2014(Thu), 01/10/2014(Fri), 01/27/2014(Mon), 01/28/2014(Tue), 02/04/2014(Tue), 02/07/2014(Fri)