DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
60 Eighth Street NE Atlanta, GA 30309 (404) 253-1161 Fax:(404) 253-1202 Industry Information: www.fda.gov/oc/industry	07/06/2015 - 07/10/2015
	FEI NUMBER 1046838

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Omaira Shelor, Aiken Site Director

FIRM NAME	STREET ADDRESS
GlaxoSmithKline Consumer Healthcare; dba-GlaxoSmithKline	65 Windham Blvd
CITY, STATE, ZIP CODE, COUNTRY Aiken, SC 29805-9384	TYPE ESTABLISHMENT INSPECTED 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 WE OBSERVED:

OBSERVATION 1

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

Specifically, the Quality Assurance unit has failed to follow:

a) Your firm has failed to follow your procedure "Deviation Investigation Handling" SOP #GOP-004.11 dated 3/11/15, in that Packaging Investigation #PR108774, regarding a dissolution failure for Panadol Extra Strength Tablets 500mg, opened on 6/19/14 and closed on 8/21/14 exceeded the (b) (4) required timeframe indicated in the procedure. In addition, the investigation lacked a written justification for the delayed completion.

b) Your firm has failed to follow your procedure "Investigations of Out-of-Specification and Atypical Results" SOP #QLG-015.8 dated 6/12/13, in Laboratory OOS Investigation #PR107752, referencing an OOS nicotine assay result for Nicorette Spearmint Lozenges 2mg, opened on 1/8/14 and closed on 3/11/14 exceeded the (b) (4) completion timeframe and lacked the interim report in (b) (4) as required in the SOP.

c) The Quality Laboratory Lead or trained designee failed to perform a material classification (b) (4) transaction for the rejection of Panadol Extra Strength Tablets 500 mg, batch R1400212 per Aiken Site SOP WH-001 "Removal of Rejected Material From the (b) (4) System and Destruction of Rejected and Waste Material" which lead to the generation of a reject label outside of (b) (4) with the incorrect reject date. In addition, the deviation from SOP WH-001 did not initiate a Notice of Event or investigation to justify the incorrect labeling of the rejected batch.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Tamara J. Henderson, Investigator Reba A. Gates, Investigator Adam R. Cooke, Investigator	07/10/2015

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OBSERVATION 2

Procedures describing the warehousing of drug products are not followed.

Specifically, during a tour of the facility a rejected batch of Panadol Extra Strength Tablets lot R1400212 was found stored in the warehouse near the incoming receiving area instead of in the rejection cage or in a trailer as per Aiken Site SOP WH-001 "Removal of Rejected Material From the (b) (4) System and Destruction of Rejected and Waste Material". In addition, the deviation from SOP WH-001 did not initiate an NOE or investigation to justify improper storage of the rejected batch.

OBSERVATION 3

Written records of investigation of a drug complaint do not include the follow-up.

Specifically, your complaint investigations are not thoroughly investigated and lack an adequate follow-up and conclusion.

a) Complaint #5288423 dated 2/16/15, regarding different size capsules in a bottle of Alli 60mg 120ct, concluded that tampering occurred outside the facility's internal operation. During the review of this investigation, it was determined that the complainant product is related to the March 2014 Voluntary Recall of Alli 60mg Capsules. In addition, the investigation lacked any written documentation of follow-up with the consumer and the firm's internal Recall Coordinator to ensure that all recalled products have been removed from the market and that an effective recall has been completed.

b) Complaint #PR13-0037279 dated 2/7/14, regarding a brown substance in a bottle of Beano Tablets 100ct, concluded that the source of contamination did not occur during the manufacturing process. However, the investigation did not evaluate whether the source of contamination could have occurred during the packaging process.

OBSERVATION 4

Written procedures for sanitation are not followed.

Specifically, the Facilities Services (FS) group has failed to follow your "Aiken Pest Control Program" SOP #ENE-001.14 dated 12/18/14, which states that "Insecticutors are serviced by the FS Designee every (b) (4) ' According to records reviewed, the time interval between checks performed in January, March, April, and May of 2015 failed to adhere to the above SOP in that those intervals were not within the (b) (4) time frame.

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