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	12/10/2018-12/13/2018
	FEI NUMBER 1000110770

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Darren D. Timmons, Director of Operations

FIRM NAME	STREET ADDRESS
Wellman Advanced Materials, LLC	520 Kingsburg Hwy
CITY, STATE, ZIP CODE, COUNTRY Johnsonville, SC 29555-8011	TYPE ESTABLISHMENT INSPECTED 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:

Quality System

OBSERVATION 1

The responsibilities and procedures applicable to the quality control unit are not in writing.

OBSERVATION 2

Acceptance criteria for the sampling and testing conducted by the quality control unit is not adequate to assure that batches of drug products meet each appropriate specification as a condition for their approval and release.

Specifically, reagents for performing tests and measuring compliance to product specifications were found to be expired. Within the chemical cabinet, the following bottles were observed: a bottle of (b) (4) with an expiration date in 2016, a bottle of (b) (4) listing a 9/2017 expiration, and a bottle of (b) (4) listing a 11/2017 expiration.

OBSERVATION 3

Written procedures are not established for evaluations conducted at least annually to review records associated with a representative number of batches, whether approved or rejected.

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Jared P Stevens, Investigator

X Jared P Stevens
Investigator
Signed By: Jared P. Stevens -S
Date Signed: 12-13-2018 10:26:57

DATE ISSUED
12/13/2018

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
60 Eighth Street NE Atlanta, GA 30309 (404)253-1161 Fax:(404)253-1202	12/10/2018-12/13/2018
	FEI NUMBER 1000110770

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Darren D. Timmons, Director of Operations	
FIRM NAME Wellman Advanced Materials, LLC	STREET ADDRESS 520 Kingsburg Hwy
CITY, STATE, ZIP CODE, COUNTRY Johnsonville, SC 29555-8011	TYPE ESTABLISHMENT INSPECTED Manufacturer

Specifically, there are no annual product reviews procedures written nor are annual reviews being conducted of FDA regulated products.

OBSERVATION 4

The batch production and control records are deficient in that they do not include identification of persons supervising and checking each significant step in the operation.

OBSERVATION 5

GMP training is not conducted on a continuing basis and with sufficient frequency to assure that employees remain familiar with CGMP requirements applicable to them.

Specifically, according to Mr. Harrelson, GMP training has not been conducted for several years. During a review of training documents, the most recent cGMP training occurred on 10/2/2014.

In addition, training for laboratory personnel responsible for testing FDA regulated products to determine conformance to specifications has not been documented.

Facilities and Equipment System

OBSERVATION 6

Buildings used in the manufacturing, processing, packing and holding of a drug product are not maintained in a good state of repair.

Specifically, the building used for the processing and holding of the API ingredient lanolin was seen leaking rainwater in the warehouse area during the inspection, contained multiple puddles of water on

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jared P Stevens, Investigator	X Jared P Stevens Investigator Signed By Jared P. Stevens -S Date Signed 12-13-2018 10:26:57	12/13/2018

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
60 Eighth Street NE Atlanta, GA 30309 (404)253-1161 Fax:(404)253-1202	12/10/2018-12/13/2018
	FEI NUMBER 1000110770

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Darren D. Timmons, Director of Operations	
FIRM NAME Wellman Advanced Materials, LLC	STREET ADDRESS 520 Kingsburg Hwy
CITY, STATE, ZIP CODE, COUNTRY Johnsonville, SC 29555-8011	TYPE ESTABLISHMENT INSPECTED Manufacturer

the floor, had gaps under the loading doors when in a closed position and a large hole, approximately 12 inches by 12 inches, through the southeastern loading door.

Production System

OBSERVATION 7

The master production and control records are deficient in that they do not include complete manufacturing, instructions, sampling, testing, procedures and specifications.

Laboratory Control System

OBSERVATION 8

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

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Jared P Stevens, Investigator X Jared P Stevens Investigator Signed By: Jared P. Stevens -S Date Signed: 12-13-2018 10:26:57	12/13/2018