DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Ave,Bldg 51,Rm 4225 Silver Springs, MD 20993 (301)796-3334 Fax:(301)847-8738	9/11/2017-9/15/2017 FEI NUMBER 3006323509

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Thomas Guebeli, Ph.D. , Executive Director, Global Internal Manufacturing Quality

FIRM NAME	STREET ADDRESS
Celgene International Sarl	Route de Perreux 1
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Boudry, 2017 Switzerland	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

Control procedures are not established which monitor the output of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product.

Specifically, the performance of start-up and/or in-process checks was deficient to detect potential variability in capsule and tablet manufacture:

a. A (b) (4) tablet press (b) (4) is utilized for the compression of (b) (4) (b) (4) mg Tablets, but representative tablets from (b) (4) are not evaluated either during start-up or routine in-process checks. Although there are (b) (4), only (b) (4) tablets are taken at start-up from (b) (4) to measure tablet weight, thickness, and hardness, as well as appearance. In-process checks performed approximately (b) (4) collec (b) (4) tablets from (b) (4) for the same parameters, as well as periodic checks for friability. Inspection of tablet pu es and dies for appearance/damage is not specifically recorded between each batch/campaign.

b. Start-up checks during (b) (4) on the (b) (4) include weight and length; however, data from weight measurements is not recorded, and printouts are discarded. Following acceptable start-up checks, a capsule checkweigher is (b) (4), and subsequent in-process inspections do not include capsule weight. Although the (b) (4) of the checkweigher are individually verified and an operational check of the (b) (4) is performed (b) (4) at the start of each operation, suitable performance of the rejection mechanism for capsules outside the acceptable limits has not been challenged since 2007. (b) (4) g are all (b) (4) on this equipment.

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Nicholas A Violand, Investigator

X Nicholas A Violand
Investigator
Signed By: Nicholas A. Violand -S
Date Signed: 9/15/2017

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