DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Office of Surveillance, Inspection Assessment Branch Food and Drug Administration-CDER/OC/DMPQ/ICT 10903 New Hampshire Avenue, Bldg 51, Room 4225 Silver Spring, MD 20993 Phone: 001-301-796-3334 Fax: 001-301-847-8738 Industry Information: www.fda.gov/oc/industry	June 18 - 22, 2018
	FEI NUMBER 3006305265

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Carlos Villalobos, Global Head & Vice President Internal Manufacturing

FIRM NAME	STREET ADDRESS
Celgene Chemical GmbH	Untere Bruhlstrasse 4
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
4800 Zofingen, Switzerland	Non-sterile API 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) (WE) OBSERVED:

Observation 1
The main responsibilities (i.e. the release and retesting of raw materials) are delegated to a third party contractor. The procedures and specifications shared between the third party contractor and Celgene Chemicals are not specified in the Quality Agreement.

Observation 2
The validation associated with the cleaning of the equipment used in the campaign manufacturing of (b) (4) (b) (4) does not address potential build-up and carry-over of contaminants. Campaign lengths can last from (b) (4)

Observation 3
System suitability is not required to be performed prior to running IPC checks during the production of (b) (4) (b) (4) APIs.

Observation 4
The stability program designed to assess the stability characteristics of drug stubstance is deficient. Specifically,
A. The written stability program for (b) (4) do not include specific test methods in that the impurity methods have not been proven to be stability indicating.
B. Stability data is not reviewed when new data becomes available.

Observation 5
Temporary employees are not given training in current good manufacturing practices. Specifically, temporary employees are not trained in TRN-000865 GMP Training (b) (4) Refresher.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Sandra A Hughes	Sandra A. Hughes, Investigator	June 22, 2018