DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Ave, Bldg71, Rm 5054 Silver Spring, MD 20993-0002 (240)402-9160	11/14/2024-11/22/2024* FEI NUMBER 3002806503

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Valerie De Schutter, Site Quality Head

FIRM NAME	STREET ADDRESS
Baxalta Belgium Manufacturing SA	Boulevard Rene Branquart 80
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Lessines, Hainaut, 7860 Belgium	Plasma Derivative 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 batch production and control records are deficient in that they do not include the identity of major equipment used.

Specifically,

A. Your firm manufactured and released GAMMAGARD Liquid ® and Cuvitru ® in the (b) (4) filling line(b) (4). Filling parameters are embedded in "(b) (4)" and executed by (b) (4) . The "(b) (4)" which controls (b) (4) parameters such as fill (b) (4) and (b) (4) filling), are not documented in the batch records. For example, "(b) (4)" used to manufacture GAMMAGARD Liquid ®, lot no. (b) (4) , manufacture date 7 October 2024 is not documented in the batch record.

B. Your firm manufactured and released Glassia ®, used to treat lung problems (emphysema). (b) (4) alarms, such as fill (b) (4) or (b) (4) , generated during filling in (b) (4) filling line(b) (4) are not always reviewed/addressed/evaluated during batch record review. For example, (b) (4) alarms such as fill (b) (4) and (b) (4) captured by the (b) (4) filling line, during the filling process of Glassia manufacturing batch record no. BE23E022, release date, 4 July 2024, was not evaluated and reviewed.

***DATES OF INSPECTION**

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Alan L Truong, Investigator Malgorzata G Norton, FDA Center Employee Shafiq Ahadi, Investigator	X Alan L Truong Investigator Signed By: 2002619229 Date Signed: 11-22-2024 05:03:15	11/22/2024

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11/14/2024(Thu), 11/15/2024(Fri), 11/18/2024(Mon), 11/19/2024(Tue), 11/20/2024(Wed), 11/21/2024(Thu), 11/22/2024(Fri)

X Shafiq Ahadi
Investigator
Signed By: 2000594974
Date Signed: 11-22-2024 05:03:53

X Malgorzata G Norton
FDA Center Employee
Signed By: Malgorzata G. Norton -S
Date Signed: 11-22-2024 05:04:39

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Alan L Truong, Investigator
Malgorzata G Norton, FDA Center Employee
Shafiq Ahadi, Investigator

X Alan L Truong
Investigator
Signed By: 2002619229
Date Signed: 11-22-2024
05:03:15

DATE ISSUED
11/22/2024

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."