DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	9/10/2025-9/18/2025*
	FEI NUMBER 1000519965

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Stephen B. Hatke, Vice President of Operations/Site Head

FIRM NAME	STREET ADDRESS
Baxalta US Inc.	1700 Rancho Conejo Blvd
CITY, STATE, ZIP CODE, COUNTRY Thousand Oaks, CA 91320-1424	TYPE ESTABLISHMENT INSPECTED 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

An MDR report was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Specifically, your firm has not reported apparent malfunctions for the device constituent part of your firm's combination drug and medical device product (Vonvendi). The combination product's primary mode of action relates to the biologic drug product (recombinant von Willebrand factor). The medical device constituent part (Mix2Vial) is used for reconstituting the lyophilized drug product. Medical Device Reports (MDRs) were not submitted for the following complaints regarding "Incomplete Diluent Transfer" (i.e., incomplete transfer of diluent via the device): (b) (4) (product code (b) (4) ;(b) (4) (b) (4) (product code (b) (4) (b) (4) (product code (b) (4) ; (b) (4) (product code (b) (4) ; (b) (4) (product code (b) (4)) and (b) (4) (product code (b) (4) . In addition, an MDR was not submitted for the following complaint regarding a "Defective Device": (b) (4) (product code (b) (4) .

OBSERVATION 2

The batch production and control records are deficient in that they do not include the identity of major equipment and lines used.

Specifically, there was no identification of critical equipment throughout batch production records. For example, the batch production records for ADVATE®, Drug Product Batch (b) (4) and its corresponding BAXJECT III®, Finished Drug Product (FDP) Batch (b) (4) failed to include

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Alan L Truong, Investigator Gene D Arcy, Investigator	X Gene D Arcy Investigator Signed By: 1300159963 Date Signed: 09-18-2025 15:06:52	DATE ISSUED 9/18/2025

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	9/10/2025-9/18/2025*
	FEI NUMBER 1000519965

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Stephen B. Hatke, Vice President of Operations/Site Head

FIRM NAME	STREET ADDRESS
Baxalta US Inc.	1700 Rancho Conejo Blvd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Thousand Oaks, CA 91320-1424	Plasma Derivative Manufacturer

identification of:

A.
B.
C. (b) (4)

***DATES OF INSPECTION**

9/10/2025(Wed), 9/11/2025(Thu), 9/12/2025(Fri), 9/15/2025(Mon), 9/16/2025(Tue), 9/17/2025(Wed), 9/18/2025(Thu)

X Alan L Truong
Investigator
Signed By: 2002619229
Date Signed: 09-18-2025 15:07:27

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE

Alan L Truong, Investigator
Gene D Arcy, Investigator

X Gene D Arcy
Investigator
Signed By: 1300159963
Date Signed: 09-18-2025 15:06:52

DATE ISSUED
9/18/2025

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	9/10/2025-9/18/2025*
	FEI NUMBER 1000519965

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Stephen B. Hatke, Vice President of Operations/Site Head	
FIRM NAME Baxalta US Inc.	STREET ADDRESS 1700 Rancho Conejo Blvd
CITY, STATE, ZIP CODE, COUNTRY Thousand Oaks, CA 91320-1424	TYPE ESTABLISHMENT INSPECTED Plasma Derivative Manufacturer

Annotations to Observations

Observation 1:

Observation 2:

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Alan L Truong, Investigator Gene D Arcy, Investigator	X Gene D Arcy Investigator Signed By: 1300159963 Date Signed: 09-18-2025 15:06:52	9/18/2025

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."