

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER 10903 New Hampshire Ave, Bldg71, Rm 5054 Silver Spring, MD 20993-0002 (240) 402-9160		DATE(S) OF INSPECTION 11/4/2024-11/8/2024 FEI NUMBER 3008923644	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Thoralf Petzold , General Manager			
FIRM NAME Octapharma Dessau GmbH		STREET ADDRESS Otto-Reuter-Str. 3	
CITY, STATE, ZIP CODE, COUNTRY Dessau-Roslau, Saxony-Anhalt, 06847 Germany		TYPE ESTABLISHMENT INSPECTED Packaging and Labeling	
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 Failure to submit biological deviation reports. Specifically, your current standard operating procedures 0170-SOP-00084 (ver. 2.0) titled "Assessment and process for issuing BPDRs," 0170-SOP-00068 (ver. 2.0) titled "Handling of Product Quality Complaints," and SOP6006/13 (ver. 13) titled "Deviation Control" are not aligned to support Biological Product Deviation Reporting (BPDR) requirements. On 07NOV2024, your Qualified Person (QP) stated that your current process for managing potential BPDRs relating to complaints follows complaint procedure 0170-SOP-00068 and (b) (4) contacting the (b) (4) (b) (4), who is responsible for classifying the event as reportable or non-reportable. This practice does not follow current BPDR and Deviation procedures 0170-SOP-00084 and SOP6006/13 which identify that your (b) (4) has responsibility for classifying potential reportable events related to complaints and deviations. From 2021 to the present, the following events were observed: • On 08NOV2023, you received complaint #R/US/2023/017 pertaining to a missing vial label from one package of (b) (4) from the U.S. Market. This complaint was investigated and assessed by your (b) (4) and not identified as a reportable event (b) (4) to assure compliance with reporting BPDRs to the Agency. This batch was identified to still be within expiration (b) (4). • On 15JUL2021, you received complaint #R/US/2021/010 pertaining to a missing vial label from one package of (b) (4) from the U.S. Market. This			
SEE REVERSE OF THIS PAGE		EMPLOYEE(S) SIGNATURE Lewis K Antwi, Investigator Travis S Bradley, Investigator DATE ISSUED 11/8/2024 Lewis K Antwi Investigator Signed By: 2001796124 Date Signed: 11-08-2024 04:33:44 X _____	

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER 10903 New Hampshire Ave, Bldg71, Rm 5054 Silver Spring, MD 20993-0002 (240) 402-9160		DATE(S) OF INSPECTION 11/4/2024-11/8/2024 FEI NUMBER 3008923644	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Thoralf Petzold , General Manager			
FIRM NAME Octapharma Dessau GmbH		STREET ADDRESS Otto-Reuter-Str. 3	
CITY, STATE, ZIP CODE, COUNTRY Dessau-Roslau, Saxony-Anhalt, 06847 Germany		TYPE ESTABLISHMENT INSPECTED Packaging and Labeling	
complaint was investigated by your (b) (4) and not identified as a reportable event as required to assure compliance with reporting BPDRs to the Agency. This batch was identified as currently expired (b) (4) (b) (4).			
OBSERVATION 2 Written records of investigations into unexplained discrepancies do not include the conclusions and follow-up. Specifically, the following was observed: CAPA #204728 was initiated on 14MAY2024 in response to deviation #201944 pertaining to rework of batch (b) (4) to (b) (4) (b) (4) involving the identification of two product vials with missing labels from (b) (4) total packages during repackaging on 28MAR2024 (identified as major deviation). As a corrective action, procedure 0170-SOP-00004 (ver. 1.0) titled "Tasks of (b) (4) packaging during manufacturing" was implemented (17SEP2024) (b) (4). (b) (4). No effectiveness check was assigned within the CAPA to verify effectiveness of the corrective action and to prevent future reoccurrence of the deviation. No justification was documented as required per procedure SOP6006/13 (ver. 13) titled "Deviation Control." CAPAs #157434 and 157435 were initiated on 12DEC2021 in response to deviation 156341 (critical deviation) pertaining to the wrong (b) (4) content printed on a label and folding carton of (b) (4) for the U.S. market (b) (4) units distributed to U.S. customers and returned/destroyed). This deviation was reported to the agency as a BPDR on 24NOV2021 (b) (4). As corrective actions, CAPA #157434 implemented the			
SEE REVERSE OF THIS PAGE		EMPLOYEE(S) SIGNATURE Lewis K Antwi, Investigator Travis S Bradley, Investigator Lewis K Antwi Investigator Signed By: 2001796124 Date Signed: 11-08-2024 04:33:44 X	
		DATE ISSUED 11/8/2024	

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER 10903 New Hampshire Ave, Bldg71, Rm 5054 Silver Spring, MD 20993-0002 (240) 402-9160		DATE(S) OF INSPECTION 11/4/2024-11/8/2024 FEI NUMBER 3008923644	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Thoralf Petzold , General Manager			
FIRM NAME Octapharma Dessau GmbH		STREET ADDRESS Otto-Reuter-Str. 3	
CITY, STATE, ZIP CODE, COUNTRY Dessau-Roslau, Saxony-Anhalt, 06847 Germany		TYPE ESTABLISHMENT INSPECTED Packaging and Labeling	
(b) (4) and CAPA #157435 implemented the (b) (4) . No effectiveness check was assigned within both CAPAs to verify effectiveness of the corrective actions and to prevent future reoccurrence of the deviation. No justifications were documented within the CAPAs as required per procedure SOP6006/13 (ver. 13) titled "Deviation Control." Your firm initiated deviations between 2021 through 2024 to address a known problem regarding the (b) (4) which resulted in wrong expiration date applied to finished drug product labels. You initiated deviations 141664 and 161611 for products intended to be shipped to the U.S Market. Due to similar deviations in 2019 a change request ((b) (4)) for (b) (4) was initiated on 08 August 2019 to address the discrepancies and was closed on 29 May 2020 without any corrections. Due to reoccurrence of the error, a new change request ((b) (4)) was initiated on 12 September 2022. However, at the time of the inspection, the request has not been completed to address the repeated deviation or error. Your firm continues to document in your deviation investigation reports that the repeated deviations is attributed to human error without appropriate corrective actions.			
OBSERVATION 3 The batch production and control records are deficient in that they do not include documentation of the accomplishment of each significant step in manufacturing and packing. Specifically, your current process for handling in-process, rejected unlabeled vials from the (b) (4) (b) (4) for all licensed biological products ((b) (4)) you package for distribution to the U.S. market, is to (b) (4) procedure 0170-SOP-00004 (ver. 3.0) titled "Tasks of (b) (4) packaging during manufacturing". This process was implemented as a corrective action (CAPA 204728) in response to deviation #201944 pertaining to rework of (b) (4) (b) (4) when two vials from (b) (4) packages were found with missing labels identified			
SEE REVERSE OF THIS PAGE		EMPLOYEE(S) SIGNATURE Lewis K Antwi, Investigator Travis S Bradley, Investigator Lewis K Antwi Investigator Signed By: 2001796124 Date Signed: 11-08-2024 04:33:44 X	
		DATE ISSUED 11/8/2024	

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		
DISTRICT ADDRESS AND PHONE NUMBER 10903 New Hampshire Ave, Bldg71, Rm 5054 Silver Spring, MD 20993-0002 (240) 402-9160		DATE(S) OF INSPECTION 11/4/2024-11/8/2024 FEI NUMBER 3008923644
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Thoralf Petzold , General Manager		
FIRM NAME Octapharma Dessau GmbH	STREET ADDRESS Otto-Reuter-Str. 3	
CITY, STATE, ZIP CODE, COUNTRY Dessau-Roslau, Saxony-Anhalt, 06847 Germany	TYPE ESTABLISHMENT INSPECTED Packaging and Labeling	
during repackaging on 28MAR2024. Additionally, it was observed that (b) (4) total (b) (4) and (b) (4) product complaints (b) (4)) were observed from 2021 to the present for the same critical deviation. Your process (implemented on 17SEP2024) for (b) (4)) is a critical packaging step and is not documented within your batch records for all licensed biological products. OBSERVATION 4 The quality control unit lacks responsibility to approve and reject all procedures or specifications impacting on the quality of drug products. Specifically, you failed to include the (b) (4) (b) (4) for your (b) (4) visual inspection (b) (4) during the initial qualification or re-qualification of your (b) (4) visual inspection (b) (4) . Your Quality Control unit approved parameters in your procedure (b) (4)) for various (b) (4) were not included in the initial qualification or re-qualification of the s (b) (4) visual inspection (b) (4) . Your (b) (6), (b) (7)(C) confirmed that the (b) (4) of your (b) (4) visual inspection (b) (4) are critical parameters that helps in detecting defective (b) (4) and that the (b) (4) should have been included in the initial qualification and re-qualification. (b) (4) visual inspection (b) (4) have been in use for over (b) (4) years and have been utilized to perform visual inspections of licensed biological drug products shipped to the U.S market.		
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Lewis K Antwi, Investigator Travis S Bradley, Investigator	DATE ISSUED 11/8/2024 Lewis K Antwi Investigator Signed By: 2001796124 Date Signed: 11-08-2024 04:33:44 X

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER 10903 New Hampshire Ave, Bldg71, Rm 5054 Silver Spring, MD 20993-0002 (240) 402-9160		DATE(S) OF INSPECTION 11/4/2024-11/8/2024	
		FEI NUMBER 3008923644	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Thoralf Petzold , General Manager			
FIRM NAME Octapharma Dessau GmbH		STREET ADDRESS Otto-Reuter-Str. 3	
CITY, STATE, ZIP CODE, COUNTRY Dessau-Roslau, Saxony-Anhalt, 06847 Germany		TYPE ESTABLISHMENT INSPECTED Packaging and Labeling	
Travis S Bradley Investigator Signed By: Travis S. Bradley-S Date Signed: 11-08-2024 04:34:21 X			
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Lewis K Antwi, Investigator Travis S Bradley, Investigator		DATE ISSUED 11/8/2024
	Lewis K Antwi Investigator Signed By: 2001796124 Date Signed: 11-08-2024 04:33:44 X		
FORM FDA 483 (09/08)		PREVIOUS EDITION OBSOLETE	INSPECTIONAL OBSERVATIONS
PAGE 5 of 5 PAGES			

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."