DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	9/9/2024-9/12/2024
	FEI NUMBER 3004094142

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Alexandre Rogee, Plant Quality Manager

FIRM NAME	STREET ADDRESS
Laboratoires Anios	3330 rue de Lille
CITY, STATE, ZIP CODE, COUNTRY Sainghin-en-Melantois, Nord, 59260 France	TYPE ESTABLISHMENT INSPECTED 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

Laboratory controls do not include the establishment of scientifically sound and appropriate specifications, standards, sampling plans and test procedures designed to assure that components, in-process materials and drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically,

A) Your firm failed to establish specifications requiring testing of raw material (b) (4) with the respective USP Monographs for Identification (b) (4) Limit of (b) (4) (b) (4) This raw material is received and approved for release without testing for impurity limits. (b) (4) is used in your drug product (b) (4)

B) Your firm has not established specifications requiring testing of the incoming raw material (b) (4) within the respective USP Monographs for Identification of (b) (4) These raw materials are received and approved for release without testing for impurity limits. (b) (4) is used in your drug product (b) (4)

Since 01/01/2022, approximately (b) (4) batches of drug product have been manufactured and shipped to the U.S.

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EMPLOYEE(S) SIGNATURE
Joohi Castelvetere, Investigator - Dedicated Drug Cadre

X Joohi Castelvetere
Investigator - Dedicated Drug Cadre
Signed By: Joohi Castelvetere -S
Date Signed: 09-12-2024
13:42:58

DATE ISSUED
9/12/2024

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OBSERVATION 2

There is no written testing program designed to assess the stability characteristics of drug products.

Specifically,

Your firm has not established a stability testing program for your drug product (b) (4) to confirm and ensure that these products maintain their efficacy and quality attributes throughout the established shelf life (b) (4) In addition, your stability program is deficient in that:

Your most current stability study, study number 16/275ANA, was completed in 2018 and signed off in 2020. This study was performed under the requirements of the European Good Laboratory Practices (GLPs), and not the U.S. Current Good Manufacturing Practices (CGMPs). There have been no ongoing stability studies performed since, and stability samples included in your 2018 study did not include microbiological testing, and/or testing for impurities. Additionally, stability chambers used in the study for accelerated and real-time conditions were not controlled for relative humidity.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Joohi Castelvetere, Investigator - Dedicated Drug Cadre X Joohi Castelvetere Investigator - Dedicated Drug Cadre Signed By: Joohi Castelvetere -S Date Signed: 09-12-2024 13:42:58	9/12/2024