DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Division of Biotechnology Manufacturing 10903 New Hampshire Avenue; White Oak Building 51, Room 2269, Silver Spring, MD 20993 Email: OPMABLAInspection483Responses@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	06/08/2023 - 06/16/2023
	FEI NUMBER 1819470

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Matt Edwards, Sr. Vice President - Indianapolis Parenteral Operations

FIRM NAME	STREET ADDRESS
Eli Lilly and Company	Lilly Corporate Center
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Indianapolis, Indiana 46285	Drug Product 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:

A written procedure is not followed or is deficient for production and process controls designed to assure that the drug products you manufacture have the identity, strength, quality, and purity that they purport or are represented to possess. Specifically,

On 12 June 2023, I (WS) observed a (b) (4) table sanitized, with only the top equipment contact surface sanitized in Grade B space for the building (b) (4) Line. Post sanitization, a portion of the (b) (4) table was moved into the critical adjacent Grade A space. Procedure PRD-96285, "(b) (4) and Filler", v33.0, Effective 25 May 2023 indicates under additional information: a. Sanitize & position (b) (4) tables; h. Sanitize (b) (4) table up to the (b) (4) The procedure was not followed as the complete portion of the (b) (4) table moved into Grade A space was not sanitized.

Furthermore, observed was the transition of an environmental monitoring (b) (4) from Grade B space into the critical adjacent Grade A space without sanitization. The sanitization requirement for the (b) (4) was not conducted.

Observation 2:

A laboratory procedure, practice is deficient in support of test sample traceability.

Samples for test are acquired from manufacturing according to a sample plan, where extra samples may be acquired. According to procedure PRD-95676, "Sample Handling and Chain of Custody", 001-004011, v20.0, Effective date 22 May 2023, Section 5.11.1 indicates: Following second person verification and/or release of results by the consultant, samples should be disposed of in a timely manner. Although you may have a robust system in assuring test sample control, you fail to reconcile the extra test samples to the batch, with the sample destruction process not documented.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Wayne Seifert Debara Reese	Wayne Seifert, Consumer Safety Officer Debara Reese, Consumer Safety Officer Melina Rodriguez Upton, Consumer Safety Officer	06/16/2023

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Observation 3:

An equipment validation is inadequate in support of manufacture. Specifically,

(b) (4) 2607A and (b) (4) 2607B support the (b) (4) sterilization of equipment used in manufacture. The (b) (4) unit are inadequately validated and (b) (4) revalidated, where a biological indicator and (b) (4) is not placed inside the (b) (4) to assure the (b) (4) sterilization process is to specification.

LA 06/16/23

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