

EIR COVERSHEET

02/17/2023

Firm Information**FEI**

(b) (4)

Firm Name

(b) (4)

Firm Physical Address

(b) (4)

Phone

(b) (4)

Profile Required

Yes

Firm Mailing Address

(b) (4)

Number of Employees**Establishment Size**

(Unknown)

Responsible FDA Org

Baltimore District Office

Inspection Details**eNSpect Operation ID**

(b) (4)

Inspection Start Date

(b) (4)

Inspection End Date

(b) (4)

Inspection Basis

Compliance

Pre-Announced / Unannounced to Firm

Pre-Announced

Days at the Facility

5

Endorsement

Bioverativ Therapeutics Inc BLA STN 125771/0 ALTUVIIIIO (efanesoctocog alfa) Pre-License Inspection (PLI) of (b) (4)

PURPOSE: CBER conducted a PLI of (b) (4) facility (b) (4) in (b) (4) from (b) (4) under eNSpect OP ID (b) (4). The (b) (4) facility is intended to be used for the contract manufacture of ALTUVIIIIO lyophilized finished drug product. ALTUVIIIIO is a recombinant factor VIII replacement product used in the treatment of Hemophilia A. The scope of the current PLI was in support of review of the BLA STN 125771/0 from (b) (4) for ALTUVIIIIO (efanesoctocog alfa).

HISTORY: (b) (4) has an acceptable FDA inspection history. Two previous back-to-back inspections of (b) (4) facility were conducted in (b) (4). One was a pre-approval inspection (PAI) (b) (4) and the other was a PLI (b) (4). Both inspections were classified as voluntary action indicated (VAI).

CURRENT FINDINGS: At the conclusion of the inspection, a four-item Form FDA 483 Inspectional Observations was issued to (b) (4) management with the following observations:

- (1) Written production and process control procedures are not followed in the execution of production and process control functions.
- (2) Procedures are not established to prevent contamination.
- (3) There is insufficient document control by the Quality Unit.
- (4) Failure to establish adequate written procedures for production and process controls designed to assure that the drug products have the identity, strength, purity, and quality that they are purported or represented to possess.

EIR COVERSHEET

02/17/2023

ACTION:

Recommend approval of BLA STN 125771/0 based on (b) (4) adequate responses to Form FDA 483 observations and

EIR COVERSHEET

02/17/2023

commitment to make timely corrections. Confirm corrective actions to the Form FDA 483 during the next routine inspection.

Products Covered

Product Code	Establishment Type	Description	Additional Product Description
(b) (4)	Manufacturer	Hematological Agent, NEC	Recombinant Human Factor VIII

Inspected Processes & District Decisions

PAC	Establishment Type	Process Code	Inspection Conclusions
(b) (4)	Manufacturer	(b) (4)	Correction Indicated

Final Decision	District Decision Made By	District Decision Date/Time	Decision Type	Follow-Up
N	Price, Gregory	02/17/2023 12:54 PM	Voluntary Action Indicated	

Remarks

PAC	Establishment Type	Process Code	Inspection Conclusions
(b) (4)	Manufacturer	(b) (4)	Correction Indicated

Final Decision	District Decision Made By	District Decision Date/Time	Decision Type	Follow-Up
Y	Ertel, Donald	02/17/2023 01:53 PM	Voluntary Action Indicated	

Remarks

Refusals

No refusal

Related Operations

FDA 483 Issued? Yes

Samples Collected	Recall Numbers	Related Consumer Complaints
-------------------	----------------	-----------------------------

Assignees Accomplishment Hours

Employee Name	Position Class	Hours Credited To	PAC	Establishment Type	Process	Hours
---------------	----------------	-------------------	-----	--------------------	---------	-------

EIR COVERSHEET

02/17/2023

Varadkar, Prajakta	FDA Center Employee	CBER	(b) (4)	Manufacturer	(b) (4)	120
Price, Gregory	FDA Center Employee	CBER	(b) (4)	Manufacturer	(b) (4)	120
Ghadiali, Alifiya	FDA Center Employee	CBER	(b) (4)	Manufacturer	(b) (4)	120
Lagasse, Daniel	FDA Center Employee	CBER	(b) (4)	Manufacturer	(b) (4)	120

Total Hours 480**Endorsement Details****Endorsing Supervisor Name**

Ertel, Donald

Date and Time of Signature

02/17/2023, 14:08:10 EST

Investigator Name

Price, Gregory

Date and Time of Signature

02/17/2023, 10:42:08 EST