DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
17901 Fairchild Ave Irvine, CA 92612 949-608-2900 orabioinspectionalcorrespondence@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	06/18/2018 - 06/22/2018
	FEI NUMBER 3013306140

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Edwin N. Pines, President

FIRM NAME	STREET ADDRESS
Genetech, Inc.	3030 Bunker Hill Suite 308
CITY, STATE AND ZIP CODE San Diego, CA 92109	TYPE OF ESTABLISHMENT INSPECTED Umbilical Cord Blood

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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

ITEM 1

The eligibility of an HCT/P donor was not determined and documented by a responsible person, based on results of donor screening and donor testing.

A. Since operations began in mid-2017, there has been no documentation on whether donors of umbilical cord blood stem cells are eligible or not and there are no donor eligibility determination statements made by Genetech, Inc.

B. Relevant medical records, including the medical/social history interview and physical exams, are not consistently received from the umbilical cord blood recovery hospitals (suppliers). When these records are received from the supplier, they are not reviewed. The only records reviewed by Genetech, Inc. to determine whether to process the cord blood are communicable disease test results and sterility results. One supplier only provides a certificate of analysis. This supplier does not perform and/or does not provide relevant medical records which are needed to evaluate the donor for risk factors for and clinical evidence of communicable disease agents and diseases.

C. For all products distributed since mid-2017, there is no completed summary of records and accompanying records provided by Genetech, Inc. The only information provided to the distributor is the communicable disease test results and sterility test results.

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ITEM 2

Communicable disease agent tests were not FDA-licensed, approved or cleared donor screening tests.

A. All umbilical cord blood collections received by one of the suppliers (recovery hospital) only comes with a certificate of analysis. This certificate states FDA licensed or approved test kits were used for communicable diseases, testing was performed in a "CLIA Lab", and results were negative, but the laboratory performing this testing, the test kit manufacturers, and actual test kits used are not known.

B. Umbilical cord blood collected from donor (b) (6) recovered and processed on 8/31/17, did not have appropriate test kits used. The test results received specifically state on the report provided that the HBV, HCV, and HIV (b) (4) or (b) (4) assay should not be used for screening donors of HCT/Ps. The CMV test results show a total CMV test was not performed as is required; the results show IgG and IgM results separately. There are no HTLV I/II and WNV test results included. Additionally, this supplier did not perform and/or did not provide relevant medical records.

ITEM 3

Procedures for all steps performed in the determining of donor eligibility of HCT/Ps were not established, implemented, followed and reviewed.

Specifically, there are no donor eligibility determination procedures.

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ITEM 4

There is no quality control unit.

A. Umbilical cord blood stem cell Lot # (b) (4) showed growth (failed sterility) and was discarded. Speciation was not performed. No investigation was conducted and/or documented, including but not limited to, reviewing environmental monitoring, equipment review, and review of production activities.

B. There are no written procedures that establish a quality unit.
C. There is no documented final review/approval of products before release to the distributor.
D. Procedure GEN-SOP-004, (Purification of Hematopoietic Progenitor Stem Cells from Human Umbilical Cord Blood), does not provide any incoming acceptance criteria for receipt of umbilical cord blood.

E. The following procedures in use were prepared but not approved. For example:
1) GEN-SOP-001, Laboratory Safety and Security, prepared 3/24/18
2) GEN-SOP-002, Cord Blood Receipt and Handling Protocol, prepared 3/28/18
3) GEN-SOP-003, Clean Room Operating and Maintenance Protocol, prepared 3/28/18
4) GEN-SOP-004, Purification of Hematopoietic Progenitor Stem Cells from Human Umbilical Cord Blood, prepared 4/2/18.
5) SOP: Product Recall/Adverse Events, prepared 5/24/18

F. Incoming supplies used during aseptic processing of umbilical cord blood are not verified by certificate of analysis or other acceptance criteria before use. For example, the sterile (b) (4) with (b) (4), sterile (b) (4) spray bottles, ISO CLASS 5 Nitrile Clean Room Gloves, and sterile (b) (4) used during aseptic processing within the (b) (4).

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ITEM 5

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

A. There are no written environmental monitoring procedures. Environmental monitoring has been done once (May 2018), since operations began in mid-2017. And there is no documented rationale for determining that monitoring will begin being performed once every 2 months.

B. There is no gowning procedure. And there has been no personnel monitoring.

ITEM 6

The batch production and control records are deficient in that they do not include documentation of the accomplishment of each significant step in processing.

Specifically, the aseptic processing steps described in GEN-SOP-004 (Purification of Hematopoietic Progenitor Stem Cells from Human Umbilical Cord Blood) are not documented to assure all steps were performed as directed. For example: that the proper amount of (b) (4) was added, proper centrifuge parameters were performed, proper amount of (b) (4) were added, proper incubation times and temperatures were performed, and proper controlled rate freezing was performed.

On 6/20/18, I observed aseptic processing of donor (b) (6). The calculation performed did not follow step (b) (4) and labeling of the vials as instructed in step (b) (4) of GEN-SOP-004 was not done.

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ITEM 7

Control procedures are not established which validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product.

Specifically, the aseptic process used to manufacture umbilical cord blood stem cells was not validated, does not have an established incoming bioburden of collected umbilical cord blood, and was not revalidated after changing the cryopreserving agent.

ITEM 8

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

Specifically, a 1 year expiration date is assigned to products shipped to the distributor without supporting data. Additionally, the potency or cell concentration (total nucleated cells) stated on the label is determined by a calculation prior to adding the cryopreserving agent and freezing.

ITEM 9
Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.

Specifically, the cleaning process has not been validated.

A. There was no data or rationale provided to determine the selection of cleaning agents and rotation being used to clean the room and (b) (4) used in aseptic processing. Cleaning agents include (b) (4).
B. There was no information on whether the cleaning agents require dilutions and contact times. Cleaning records do not document whether dilutions or contact times occurred.

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ITEM 10
Distribution records do not contain the name and address of consignee and date and quantity shipped.

Specifically, there are no distribution records.

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