Our STN: BL 125660/0

BLA APPROVAL
May 3, 2018

OCTAPHARMA Pharmazeutika Produktionsges.m.b.H.
Attention: Mr. Stanley Ammons
Octapharma USA, Inc.
121 River Street, Suite 1201
Hoboken, NJ 07030

Dear Mr. Ammons:

Please refer to your Biologics License Application (BLA) for Plasma Cryoprecipitate (For Further Manufacturing Use) dated July 31, 2017, received July 31, 2017, submitted under section 351(a) of the Public Health Service Act (PHS Act).

We have approved your BLA for Plasma Cryoprecipitate (For Further Manufacturing Use) effective this date. You are hereby authorized to introduce or deliver for introduction into interstate commerce, Plasma Cryoprecipitate (For Further Manufacturing Use) under your existing Department of Health and Human Services U.S. License No. 1646. Plasma Cryoprecipitate (For Further Manufacturing Use) is used as a starting material for the manufacture of (b) (4) trade name (b) (4) manufactured by (b) (4)

Under this license, you are approved to manufacture Plasma Cryoprecipitate (For Further Manufacturing Use) at your facility located at Oberlaaer Strasse 235, Vienna, Austria.

We did not refer your application to the Blood Product Advisory Committee because our review of information submitted in your BLA did not raise concerns or controversial issues that would have benefited from an advisory committee discussion.

DATING PERIOD

The dating period for Plasma Cryoprecipitate (For Further Manufacturing Use) shall be (b) (4) from the date of manufacture when stored at (b) (4)

FDA LOT RELEASE

You are not currently required to submit samples or protocols of future lots of Plasma Cryoprecipitate (For Further Manufacturing Use) to the Center for Biologics Evaluation and Research (CBER) for release by the Director, CBER, under 21 CFR 610.2(a). We will continue to monitor compliance with 21 CFR 610.1 requiring completion of tests for conformity with standards applicable to each product prior to release of each lot.

BIOLOGICAL PRODUCT DEVIATIONS

You must submit reports of biological product deviations under 21 CFR 600.14. You should identify and investigate all manufacturing deviations promptly, including those associated with processing, testing, packaging, labeling, storage, holding and distribution. If the deviation involves a distributed product, may affect the safety, purity, or potency of the product, and meets the other criteria in the regulation, you must submit a report on Form FDA 3486 to the Director, Office of Compliance and Biologics Quality, at the following address:

Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Ave.
WO71-G112
Silver Spring, MD 20993-0002

MANUFACTURING CHANGES

You must submit information to your BLA for our review and written approval under 21 CFR 601.12 for any changes in, including but not limited to, the manufacturing, testing, packaging or labeling of Plasma Cryoprecipitate (For Further Manufacturing Use), or in the manufacturing facilities.

Sincerely,

Wilson W. Bryan, MD
Director
Office of Tissues and Advanced Therapies
Center for Biologics Evaluation and Research