File No. X-11026/81/2018-BD
Government of India
Director General of Health Services
Central Drugs Standard Control Organization
(Biological Division)

FDA Bhawan, New Delhi-110002
Dated: 22 JAN 2020

ORDER

Subject: Non-Compliance of labeling requirements as per the provisions of Drugs and Cosmetics Act 1940 and Rules1945 there under for Anti-Hemophilic Factor-VIII (Human) method M, monoclonal purified nano-filtered (Brand name-HEMOPHIL-M)-regarding

WHEREAS, M/s Baxalta Bioscience India Pvt.Ltd, 1st floor, Plot 70, A-26, Rama Road, Industrial Area, New Delhi, Motinagar-110015 is the registered Indian agent with Registration Certificate No. BP-60 in Form 41 and Import license no. BP-60-203 for import and marketing of Anti hemophilic factor (Human), Method M, Monoclonal purified, Nanofiltered (HEMOFIL M)-10ml bottle from manufacturer M/s. Baxalta US Inc., 1700 Rancho Conejo Boulevard, Thousand Oaks, California, 91320, USA.

WHEREAS, It has come to the notice of this office that during an investigation by the O/o the Director (Drugs), Ranchi, Jharkhand that yow were involved in falsification of information and stickering, labeling for product Anti-Hemophilic Factor-VIII 500 IU (HEMOPHIL-M) Lot No. THA16205AA Expiry Date: July 24 2018 and Human Coagulation factor VIII 250 IU (IMMUNATE) lot No. VNC3R014 Exp. Date: 01/ 2018.

WHEREAS, you were asked to clarify the reason vide letter dated 31.07.2019 for supply of Anti-Hemophilic factor-VIII 500 IU and 250 IU at M/s Central Medicine Store, RIMS, Bariatu, Ranchi on 31.07.2018.

WHEREAS, the response submitted by you dated 06.08.2018 w.r.t the query letter issued by this Directorate dated 31.07.2018 was not satisfactory as you have not submitted specific response and not in compliance with the provisions of Drugs and Cosmetics Act & Rules.

WHEREAS, a show cause notice was issued to you dated 08.10.2018 regarding supply of Anti-Hemophilic Factor-VIII (Human) method M, monoclonal purified nano-filtered 500 IU (Brand name - HEMOPHIL-M) and Purified freeze dried Human Coagulation Factor VIII virus inactivated 250 IU (Brand name -IMMUNATE) imported by M/s Baxalta Bioscience India Pvt. Ltd. to M/s Central Medicine Store, RIMS, Bariatu, Ranchi.

WHEREAS, response to the show-cause notice was submitted by you to this office dated 16.10.2019 has informed that consignment of Anti-Hemophilic Factor-VIII, Batch no. THA16205AA was imported from the manufacturing site with the actual potency of 555 IU under a valid Import License no. BP-60-203 issued to you and also informed that you did not put the sticker of 500 IU on the secondary package of the subject batch and it appears that such a stickering of 500 IU was done after the batch was supplied to the customer as such the delivery of the batch was complete and beyond the control of Baxalta Bioscience India Pvt. Limited. Further, you have also informed that information with respect to the full composition (active & inactive ingredients) has always been included on the secondary

component package of HEMOFIL M in accordance with Rule 96 (1) (iii) of the Drug Rules and the primary component package of the Batch also contains information on the composition (except active ingredient and actual potency).

WHEREAS, you have again submitted a revised response on 18.06.2019 to the show-cause notice vide letter dated 08.10.2019 issued by this office, informing that the primary component package of product HEMOFIL M, Batch no. THA16205AA also contains information on the composition (includes active ingredient and actual potency) along with copy of HemoFil-M primary vial label of the batch THA16205AA which was also enclosed in import documents for ADC clearance.

WHEREAS, you were asked to furnish the requested to clarify the reason for non-compliances and what corrective and preventive action has been taken by you for such non-compliances as a part of Good distribution practices and SOP thereof vide letter dated 11.09.2019.

WHEREAS, with reference to your letter dated 22.11.19 submitted to this office wherein you had intimated about the reason for non-compliance and corrective and preventive action taken by you for Non-Compliance of labeling requirements as per the provisions of Drugs and Cosmetics Act 1940 and Rules1945 there under for Anti-Hemophilic Factor-VIII (Human) method M, monoclonal purified nano-filtered (Brand name-HEMOPHIL-M) Batch no. THA16205AA (Exp. Dt. July 24, 2018) imported by M/s Baxalta Bioscience India Pvt. Ltd. New Delhi.

WHEREAS, you have submitted SOP'S for Good Warehousing Practices, Packaging and Dispatch Process, Transporters used, Local release of imported products and Global Field Corrective Action procedure as a part of corrective and preventive actions.

AND THEREFORE, after perusal of the documents submitted by you and as per the provision of Drugs and Cosmetics Act, 1940 and Rules made there under, it was observed that you had not fulfilled Registration Certificate (BP-60) condition No. 2 and 6, Rule 96 (iii), Rule 96 (5,6,7) of the Drugs and Cosmetic Rules 1945 for the subject product.

In view of the above, the product permission of Anti-Hemophilic Factor-VIII (Human) method M, monoclonal purified nano-filtrated (Brand name-HEMOPHIL-M) in Registration Certificate vide RC No. BP-60 and its corresponding import license (BP-60-203) are hereby suspended for 15 days from the date of issuance of this letter as per the provisions of Drugs and Cosmetics Rules, 1945.

Yours faithfully,

(Dr. V. G. Somani)
Drugs Controller General (India)

To,

M/s Baxalta Bioscience India Pvt.Ltd, 6th floor, Tower C, Building No. 8, DLF cyber city, DLF Phase-II, Gurgaon, India.

Copy to:

a. **All CDSCO Zonal/Sub Zonal/Port offices**
b. **M/s. Baxalta US Inc., 1700 Rancho Conejo Boulevard, Thousand Oaks, California, 91320, USA.**