File No. X-11026/98/2018-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: Contravention of Drugs & Cosmetics Rules 1945 for imported products Albumin (Human) Solution, 20% (100ml), Tetanus Gamma 250 IU, Rho GAM 300 mcg, Immuno HBs 180 IU & EMOCLOT 250 IU by M/s Kedrion Biopharma India Private Limited, TFC-04D, 3rd Floor, JMD Reagent Plaza, Main M.G.Road, Gurgaon-122001, Haryana, India.-regarding

This is with reference to your letter dated 25.11.19 submitted to this office wherein you had submitted the response to show cause notice issued by this office vide letter dated 05.08.2019.

WHEREAS, a complaint was received in this Directorate alleging M/s Kedrion Biopharma India Pvt. Ltd, was carrying out fallacious activities which are in contravention to Drugs and Cosmetics Act 1940 and Rules there under. The complaint has stated that innermost container of Human Albumin 20%, 100ml, Tetanus Gamma 250 IU, RhoGAM 300 mcg, ImmunoHBs 180IU & Emoclot 250 IU does not have any label, violating section 96 of Drugs and Cosmetic Rules and the sale of the blood product Human Albumin 20% bearing batch no. 200807171B was suspended from marketing due to quality defect and M/s Kedrion Biopharma Pvt. Ltd has sold the drug inspite of its quality defect.

WHEREAS, in view of the contents and nature of the complaint and based on the investigation report dated 30.08.2018 received from DDC (I), CDSCO, North zone, clarification was sought from you, for contravention of Drugs & Cosmetics Rules 1945 for imported products Albumin (Human) Solution, 20% (100ml), Tetanus Gamma 250 IU, Rho GAM 300 mcg, Immuno HBs 180 IU & EMOCLOT 250 IU by M/s Kedrion Biopharma India Private Limited, Gurgaon, India vide letter dated 15.01.2019.

WHEREAS, clarification submitted by you vide letter dated 1.04.2019 w.r.t the query letter dated 15.01.2019 issued by this Directorate was not found satisfactory and hence forth, a show cause notice vide letter dated 05.08.2019 was issued to you regarding contravention of Drugs & Cosmetics Rules 1945 for imported products Albumin (Human) Solution, 20% (100ml), Tetanus Gamma 250 IU, Rho GAM 300 mcg, Immuno HBs 180 IU & EMOCLOT 250 IU by M/s Kedrion Biopharma India Private Limited, TFC-04D, 3rd Floor, JMD Reagent Plaza, Main M.G.Road, Gurgaon-122001, Haryana, India.

WHEREAS, response submitted by you vide letter dated 26.08.2019 to show cause notice issued by this office was not specific to the various points asked in the show cause notice and not supported by any documents.

WHEREAS, you were again directed to submit specific reply to each point of the show-cause notice dated 05.08.2019 along with supportive documents vide letter dated 17.09.2019.

WHEREAS, response submitted by you vide letter dated 25.11.2019 has furnished information that the products namely, Tetanus Gamma 250 IU, RhoGAM 300 MCG, ImmunoHBs 180 IU and Emoclot 250 IU, which have purported to have violated Rule 96 of the Drugs and Cosmetics Rules, 1945 are well within the exception given in Rule 96(1) (iii) (b) provision, which expressly states that, "if the preparation is contained in an ampoule, it will be enough if the composition is shown on the label or wrapper affixed to any package in which such ampoule is issued for sale. Further, you have also informed that an wholesale license was issued to M/s Kedrion Biopharma India Pvt. Ltd, B4 Basement A B Block, Shankar Garden Vikaspuri, New Delhi and there is no prohibition in any law declaring that a product cannot be transferred from one licensed place to another licensed place, it is merely a matter of common business custom and a matter of logistics and shipping.

WHEREAS, it was also observed that revised primary labels submitted by you for the blood product Human Albumin 200g/l, manufactured in Nov. 2018 included manufacturer name address and marketed by address as per the Provision of Drugs and Cosmetics Act 1940 and Rules there under.

WHEREAS, you have also attached the bill of entry, relevant import documents, stock transfer Note along with logistic Challan regarding transfer of the said products from Gurgaon to Vikaspuri. Further, with respect to the observation of generating sale invoice from a different premise, which was not the premise of receiving the product, you have stated that they are in complete compliance as per Central Goods and Services Act, 2017.

AND THEREFORE, after perusal of the documents submitted by you, it was observed that you had contravened conditions of Registration Certificate, Import License and Rule 96 (xii) of Drugs & Cosmetic Rules of the Drugs and Cosmetic Rules 1945 for the imported blood product Human Albumin 200g/l.

In view of the above, the product Human Albumin 200g/l permission in Registration Certificate vide RC No. BP-38 and corresponding import license BP-38-148 is hereby suspended for 7 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 Kedrion Biopharma India Private Limited, TFC-04D, 3rd Floor, JMD Reagent Plaza, Main M.G.Road, Gurgaon-122001, Haryana, India

Copy to:

1. All CDSCO zonal/sub zonal/port offices
2. M/s Human Bioplazma. Manufacturing & Trading limited Liability company, H-2100, Godollo, Tancsics Minaly ut. 82 Hungary.