

F. No X-11026/24/2018-BD
Directorate General of Health Services
Office of Drugs Controller General (India)
(Biological Division)

FDA Bhawan, Kotla Road,
New Delhi 110002
Dated: 07-02-18

Office Memorandum

This office has received representation from Organisation of Pharmaceutical Producers of India (OPPI) wherein it has been stated that several consignments of Insulin formulations are pending for release at various port offices due to delay in ongoing analytical testing at NIB, Noida. It has been also stated that these Insulin formulations are life-saving products and may lead to shortage in the market due to delay in testing. It is understood from the representation that each and every batch of the imported Insulin formulation are forwarded to NIB for the testing purpose.


It is informed by NIB that during last 3 years, there has been no case of failure of imported Insulin formulations in respect of the quality parameters.

In view of above and in public interest, you are directed to release all the consignments of imported Insulin formulations including consignments released on letter of guarantee, subjected to the condition that:

- 1) The product shall comply with all the provisions of Drugs & Cosmetics Act 1940 and Rules, 1945 thereunder.
- 2) You may take a written undertaking from the Indian agent stating that in case the product is declared as not of standard quality by the NIB, the same shall be recalled from the market.

Further, in this connection it is also directed to draw samples of r-DNA derived drugs in future, as per the risk-based criteria communicated to port offices vide this office letter no. Import/Misc/89/2015-DC.

The action taken in this regard shall be communicated to this Directorate.


(Dr. G. N. Singh)
Drugs Controller General (I)

To:-

All port offices of CDSCO

Copy for information to:

1. PPS to DGHS, Ministry of Health and Family Welfare, Nirman Bhawan, New Delhi-110001
2. The Director, NIB Noida
3. PS to JS (R), Ministry of Health and Family Welfare, Nirman Bhawan, New Delhi-110001
4. All DDC (I)/ADC (I) of Zonal and sub-zonal offices of CDSCO.
5. OPPI, Mumbai