GOVERNMENT OF INDIA
MINISTRY OF COMMERCE & INDUSTRY
DEPARTMENT OF COMMERCE
DIRECTORATE GENERAL OF FOREIGN TRADE
UDYOG BHAVAN, NEW DELHI-110011

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POLICY CIRCULAR NO. 9(RE-2003)/2002-2007 Dated :30 .6.2003

To

All Licensing Authorities
All Commissioners of Customs

Sub : Imports of approved & unapproved drugs under the Advance Licensing Scheme – Exemption from Registration procedure.

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Attention is invited to Notification No.2(RE-2003)/2002-2007 dated 31.3.2003 vide which certain types of drugs & pharmaceuticals have been placed under free category and their imports have been subjected to the registration and other requirements administered by the Drugs Controller General of India under the provisions of Drugs & Cosmetics Act.

2. Subsequent to the above Notification, representations have been received from various Drug Manufacturers Associations requesting for exemption from registration requirements of the Drugs & Cosmetics Act for imports under the Advance Licensing Scheme. The requests have been considered and It has been decided that import of approved & unapproved drugs under the Advance Licensing Scheme will not be subjected to the Registration procedure and the imports will be permitted subject to the following conditions:

i) Import licence will only be given against an existing valid export order and to the extent raw material is required as per that order.
ii) The Drug Controller would be a member of the Advance Licensing Committee. A copy of the licence would be endorsed to the Drug Controller and the concerned State Drug Controller.
iii) Drug Controller along with the State Drug Controller would make random checks.
iv) Any violation is punishable under the Foreign Trade Development and Regulation Act and the Customs Act. The Drug Controller could also make provisions for penalizing the Drug Manufacturing Units in terms of suspension or canceling of his licence.
v) Pre import condition will have to fulfilled.
vi) Export obligation will be fulfilled within a period of six months from the date of issuance of the licence.

3. Similarly, 100% EOU/EPZs & SEZs would also be exempted from the condition of registration. However, if they make supplies to the domestic market, they will have to follow the formalities of registration as under the Drugs & Cosmetics Act.

4. Representations have also been received regarding issuance of Form-10 under the Drugs & Cosmetics Act for manufacturers. It is clarified that Form -9 issued by the registered manufacturers should also be accepted for the purpose of issuing Form-10 licence under the Drugs & Cosmetics Act.

5. In addition as far as imports of drugs/raw materials for purposes of (i) clinical trials & (ii) for formulation development is concerned, it is clarified that exemption in such cases will be permitted on case to case basis.

This issues with the approval of the DGFT.

(DR. PRATIMA DIKSHIT)
JT.DIRECTOR GENERAL OF FOREIGN TRADE