Circular No. 21/2003-CUS.
28th March, 2003

F.NO.450/25/2003-CUS.IV
Government of India
Ministry of Finance
Department of Revenue
Central Board of Excise & Customs

Subject: Requirement of registration of manufacturing premises of foreign drugs manufacturer prior to their import in the country under Drugs and Cosmetics Rules - reg.

I am directed to invite your attention to the above mentioned subject and state that Ministry of Commerce is contemplating to remove certain drugs from the restricted list in the new Exim Policy. Notwithstanding this, certain conditions imposed by the Ministry of Health & Family welfare will continue to apply.

2. Attention in this regard is also invited to the Notification GSR No. 604(E) , dated 24.8.2001 issued by the Ministry of Health and Family Welfare, amending various provisions of the Drugs and Cosmetics Rules, whereby a new provision for the registration, in India, of foreign manufacturers of bulk drugs and formulations, has been introduced. This condition has to be satisfied before imports are effected from any foreign manufacturer of bulk drugs or formulations. A provision has also been introduced for obtaining import permission from the Drug Controller of India, prior to import. The other conditions can be seen from the above notification dated 24.8.2001 read with the guidelines issued by the Ministry of Health & Family Welfare (copy enclosed) . In case of doubt the local Assistant/Deputy Drug Controller may be consulted.

3. The new provisions will apply to all consignments of drugs & formulation imported from 1.4.2003 onwards (The provisions were to come into effect initially from 1.1.2003, but were subsequently extended by 3 months).

4. You are, therefore, requested to bring to the notice of all concerned by issuance of suitable instruction/public notice.

5. Hindi version will follow.

6. Kindly acknowledge the receipt.

D.S.Garbyal
Under Secretary to the Government of India

Guidelines

Government of India, Ministry of Health and Family Welfare has published a Gazette Notification GSR. No.604(E) dated 24.08.2001 amending the various provisions of the Drugs & Cosmetics Rules, thereby introducing a new provision for the registration of the manufacturing premises of foreign drug manufacturer and the individual drugs prior to their import into the country. The notification has also introduced few other provisions viz. enhanced import licence fees, increased validity period of licence, deletion of exemption from requirement of import licence for bulk drugs for actual users, requirement of minimum 60% of retained shelf life for imported drugs and provisions for import of small quantities of new drugs by Govt. hospitals for treatment of their own patients etc.

2 Under the new dispensation, foreign manufacturers have to apply for registration certificate for their manufacturing premises and the individual drugs to be imported. The applications can be made by authorized agents of foreign firms in India. The documents required for registration certificates have been clearly specified in the amendments. The

validity of registration certificates will be 3 years from the date on which these are issued. A fee of 150 USD is to be charged for the registration of overseas manufacturer's premises and fee of 1000 USD will be charged for every individual drug. The rules provide now for inspection of the premises of a foreign manufacturer by Indian Drug Authorities, whenever so required. In such cases, an additional fee of 5000 USD is to be charged. The rules also provided for payment of testing charges by registration holders. The foreign manufacturer or his authorized agent in India shall be liable to report any change in the manufacturing and testing process of a drug. However, no registration certificate shall be insisted in respect of an inactive bulk substance to be used as pharmaceutical aid for manufacture of drug formulation. The registration may be suspended or cancelled in the event any violation of the conditions for registration comes to notice. The new registration and import licence scheme shall also cover diagnostic kits viz. HIV I & II, HbsAg and blood group reagents.

3 According to new rules, import licence will be required for all types of drugs instead of existing import licence requirements for Schedule C & C (1) and Schedule X drugs only. Import licence in Form 10 would be granted after completing the registration of overseas manufacturers and their specific drugs to be imported. The import licence for specific drugs will be valid for 3 years from the date on which these are granted. The import licence fee has been kept Rs.1000/- for a single drug and at the rate of Rs. 100/- for additional drug. The fee of import licences for test and analysis of a drug has been kept Rs. 100/- for a single drug and at the rate of Rs. 50/- for each additional drug. The exemption from import licences for the import of bulk drugs by the formulations for actual use under Schedule D has been deleted. A provision has been made that only drugs with minimum 60% of retained shelf life shall be allowed to be imported in the country.

4 A separate provision has been made to enable the Govt. hospitals to import small quantities of essential new drugs for the treatment of their own patients. The fee for such import licences has been kept Rs. 100/- for a single drug and the rate of Rs. 50/- for each additional drug.