

File No.JDC (I)/Misc/10/2016
Directorate General of Health Services
Central Drugs Standard Control Organization
(O/o Drugs Controller General India)

FDA Bhawan, Kotla Road
New Delhi-110002
Dated: - 30/12/2016

CIRCULAR

Subject: First time import/ manufacture in the country of an Active Pharmaceutical Ingredient (API) of a drug which has earlier been approved as New Drug in finished formulation for import and marketing and / or allowed for import under import registration and licensing.

For import and marketing of any New Drug in finished formulation, the applicant is required to obtain permission in Form 45 under Rule 122A and import Registration Certificate in Form 41 under Rule 27A as well as import license in Form 10 or 10A, as the case may be, under Rules 23 and 27 of the Drugs and Cosmetics Rules, 1945.

The issue regarding requirements of data / information for grant of import Registration Certificate and License in case of application for first time import in the country of an API of a drug which has earlier been approved as New Drug under Rule 122A as finished formulation for import or allowed for import under import registration and licensing, have been under consideration for quite sometimes now.

The issue has been examined by CDSCO keeping in view the requirements and guidelines prescribed in the said Rules and it has been decided that in such cases the applicants are required to submit application to CDSCO in Form 44 under Rule 122A for grant of New Drug permission in Form 45A accompanied with the requisite fee and information like the product specification with limits of impurities (as per IP) and published literature, before obtaining import Registration Certificate and License from CDSCO.

Same procedure will be applicable for obtaining form 46A for manufacture of such bulk drugs also, if it is not approved as New Drug (bulk) at any point of time in India, though formulation containing same are approved.


(Dr. G. N. Singh)

Drugs Controller General (India)

To,

1. All State Drugs Controllers/ Zonal Offices/ Sub-Zonal Offices/ Port Offices.
2. All stakeholders through CDSCO website.