Import/Misc/49/2020-DC
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(Import and Registration Division)

FDA Bhawan, Kotla Road
New Delhi
Dated 26th February, 2020.

NOTICE

Subject: Submission and processing of application for Registration Certificate and Import License in parallel with New Drug application-Regarding.

Import of drugs is regulated under Chapter III of the Drugs and Cosmetics Act, 1940 and Part IV of the Drugs and Cosmetics Rules, 1945. For import of drugs, the overseas manufacturing sites and the drugs are required to be registered with CDSCO as per the requirements of Rule 24 (A) and 24 of Drugs and Cosmetics Rules 1945. However, for New Drug, permission is required to be obtained under the New Drugs and Clinical Trials Rules, 2019 before obtaining the Registration Certificate and Import License.

Concerns have been raised from time to time seeking a system of simultaneous submission and processing of such applications to avoid undue delay.

In this regard, it has been decided that the applicant can submit its application for obtaining Registration Certificate and Import License simultaneously, while submitting the application for permission for import of any New Drug in the country. These applications shall be processed simultaneously and Registration Certificate & Import License shall be granted subject to condition of issuance of the New Drug permission under New Drugs and Clinical Trials Rules, 2019.

V.G.S.
26/2/2020

(Dr. V. G. Somani)
Drugs Controller General (India)

Copy to:

1. All Stakeholders.