

File No. Import/Misc./89/2015-DC
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Import & Registration Division)

FDA Bhawan, Kotla Road
New Delhi-110002
Dated: 17/9/2020

Notice

Subject: Documents required for the import -Reg.

The imported Drugs and Cosmetics are regulated as per the Chapter III of Drugs and Cosmetics Act, 1940 and Rules there under wherein mandatory requirements are mentioned. Each importer is required to comply with the conditions of the import license or the NOCs issued under the said Act.

At the time of import, all importers are required to furnish label of respective consignment, Certificate of Analysis (COA) of release of batch and import license/permission along with bill of entry and other documents as per Drugs and Cosmetics Rules, 1945 at the port office.

This is for information and necessary action for utilizing ICEGATE.

N.G.

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

To

All the stakeholders through website of CDSCO

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In light of ease of doing business and for utilizing fast track system of Risk Management System, with ICEGATE integration for online clearance of imported Drugs and Cosmetics, it is proposed that the human interface may be reduced by devising method, while ensuring that the integrity of drug/cosmetic, its packages and seal is intact before the release and out of charge. Therefore, it is responsibility of the importer to ensure the same and furnish the undertaking with each Integrated Declaration or Bill of entry that the packaging is not damaged/broken/destroyed and the content of drug/cosmetic has not deteriorated in the following prescribed format:

FORMAT FOR UNDERTAKING

I (Name & Address of Importer) -----hereby undertake with respect to the consignment imported vide Bill of Entry No. -----Dated----- that the drug/cosmetic packages seal is intact, the packaging is not damaged/ broken/destroyed and the content of drug has not deteriorated.

Importer

Name and signature with Stamp & Date
(Authorized person)

This is for information and necessary action for utilizing ICEGATE and integration with RMS.



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

To

All the stakeholders through website of CDSCO