



Import - Export

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[Conference](#) "Focus on CGMPs and FDA Inspections" July 15-16, 2015

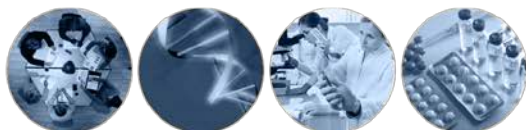
When it comes to drug import-export, the last outcome a firm wants is to end up with a detained product. Drug products, and drug components such as active pharmaceutical ingredients (APIs), imported or offered for import into the U.S. must comply with all the applicable requirements and regulations under the [Food Drug & Cosmetic Act](#) (FDCA) and Title 21 of the Code of Federal Regulations ([21 CFR](#)). Let's review the general import requirements for different types of drugs and drug products.

Imports

Finished Drug Products: Drug products imported or offered for import into the United States must comply with all of the applicable requirements related to drug approval – i.e. through submission of a new drug application (NDA), Biologics Licensed Application (BLA) regulated by CDER, abbreviated new drug application (ANDA); or conformance with an OTC monograph, proper labeling, establishment registration and drug listing, and manufacturing in accordance with current Good Manufacturing Practices (cGMPs).

- **Labeling:** All drug labels must be in English and be understandable. All drugs and drug products labeling must comply with the labeling requirements under FDCA Section 502 and 21 CFR 201.
- **Registration and Drug Listing:** Foreign manufacturers whose drugs are imported or offered for import into the U.S. are required to [register and list](#) every drug in commercial distribution in the U.S. as required by Section 510 of the Act and 21 CFR 207. These requirements apply to all manufacturers, repackers, relabelers, and control laboratories involved in the manufacture, preparation, propagation, compounding, processing or testing of human or veterinary drugs and human biological products, including the manufacturer of APIs.
- **CGMPs:** APIs are subject to the adulteration provisions of Section 501(a)(2)(B) of the FD&C Act, which require all drugs (APIs and finished pharmaceuticals) to be manufactured in conformance with CGMP. FDA inspects manufacturing facilities for compliance with [cGMP requirements](#). As discussed in the [Q7A Guidance for Industry](#), firms should establish appropriate controls at all stages of manufacturing to ensure intermediate and/or API quality.

APIs: An API is any substance or mixture of substances intended to be used in the manufacture of a drug (medicinal) product and that, when used in the production of a drug, becomes an active ingredient of the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure and function of the body. In general, APIs must comply with all the applicable requirements discussed above. An API is inherently misbranded under section 502(f)(1) of the Act [21 U.S.C. § 352(f)(1)] because its labeling will not bear adequate directions for its use. However, an API can only be imported under an exemption to 502(f)(1) of the FDCA. Section 502(f)(1) provides that an API or bulk chemical that can be used as an API must have labeling that lists adequate directions for its use, unless the API is subject to exemptions from labeling such as those found in 21 CFR parts [201.122](#), and [312.160](#). Please refer to [21 CFR 201.128](#) - Meaning of "intended uses".



Investigational new drugs: Any investigational drug imported for use in clinical studies must be covered by an investigational new drug application (IND), unless exempt per [21 CFR 312.2](#). The firm should submit the IND before importing the drug product. It must comply with [21 CFR 312.110\(a\)](#), including that it is subject to an IND under [21 CFR 312.40](#). In addition, the labeling must comply with [21 CFR 312.6](#).

Finished drug products for laboratory/animal use: Persons interested in importing investigational finished drug products for non-clinical use (such as in laboratory animals and/or in-vitro tests) must meet the requirement of [21 CFR 312.160](#). Among other requirements, the drug should be labeled "CAUTION: Contains a new drug for investigational use only in laboratory research animals, or for tests in vitro. Not for use in humans." Any product shipped under 21 CFR 312.160 cannot be diverted to human use.

Finished drug products for educational purposes: Persons interested in importing drug products for the use in teaching, law enforcement, research, and analysis must meet the requirement of [21 CFR 201.125](#). This applies only to drugs subject to [21 CFR 201.100](#) (prescription drugs for human use) or [21 CFR 201.105](#) (veterinary drugs). This does not apply to OTC drugs. This regulation applies to the shipment of Rx drugs (finished dosage form drug products only) to persons regularly and lawfully engaged in instruction in pharmacy, chemistry, medicine not involving clinical use, chemical analysis, or physical testing.

In order to import, you will also likely need to build your own product codes (different from the DRLS National Drug Code (NDC) numbers) via the [Product Code Builder](#).

Exports

In order to legally export drugs, products must meet the following criteria, in accordance with-

[FDCA 801\(e\)\(1\)](#):

- meet the specifications of the foreign purchaser
- not be in conflict with the laws of the country to which they are intended for export
- be labeled on the outside of the shipping package that they are intended for export
- not be sold or offered for sale in U.S. domestic commerce, and

[FDCA 801\(e\), 802](#):

- Legally marketed articles of drug in the U.S. have no exportation restrictions
- Articles manufactured specifically for export only may be exported & cannot be marketed in the U.S. [801(e)(1)(D)]
- Articles manufactured specifically for U.S. found to be adulterated, misbranded, or unapproved cannot be exported
- Must keep records ([21 CFR 1.101](#))

CDER issues drug [export certificates](#) per FDCA [801\(e\)\(4\)](#). For information on export certificates, please contact cderexportcertificateprogram@fda.hhs.gov.

Additional information on [imports and exports](#) is located on the FDA website. You may also contact our Import-Export Office at cderimportexports@fda.hhs.gov for further information.

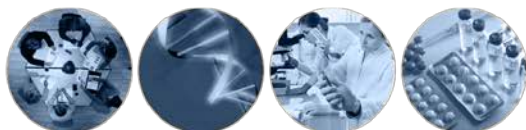
Cheers,

Renu Lal, Pharm.D.

CDER Small Business and Industry Assistance

Issues of this newsletter are archived at <http://www.fda.gov/cdersmallbusinesschronicles>

This communication is consistent with 21CFR10.85(k) and constitutes an informal communication that represents our best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of the FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.



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