CDER Office of Compliance

Office of Drug Security, Integrity & Recalls

Division of Import Operations & Recalls

Imports Exports Compliance Branch (IECB)

FDA compliance focal point for imports & exports of CDER regulated drugs

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IECB Mission: To promote and protect the public health by ensuring drug importation and exportation adhere to FDA standards of compliance.

Exports 1906

Drugs compliant with the Federal Food Drug and Cosmetic Act (FFDCA, FDCA, the Act)

– No export restrictions

Drugs which are non-compliant with the Act

– It is prohibited to introduce an adulterated or misbranded drug into interstate commerce

– Criminal and Civil Penalties

– When intended for export drug is not misbranded/adulterated

- prepared/packed to specifications/directions of the foreign purchaser
- substances not conflict with the laws of the foreign country
- drug is not offered for sale in the United States

Exports

1938

Defined “drug” and “new drug” and codified 1906 into FFDCA 801(d), [21 USC 381(d)], may not export new drugs

1986

Free markets and the start of globalization leads to reduced regulation through export applications:

- Export to the “First World” (Modernized Europe, Japan, Australia & New Zealand); or
- Drugs to treat tropical diseases; or
- Partially processed biologics

Export Globalization 1996

The Era of Market Globalization starts with

"FDA Export Reform and Enhancement Act (EREA)"

- No need for FDA export applications or prior export approval; instead created a simple notification process
- Export of unapproved drugs possible
- Export unapproved drugs and biologicals intended for investigational use to certain "listed" countries
- May apply to export unapproved drugs intended to treat diseases of low prevalence in U.S.

Exports in 2014

Misbranded or adulterated drug which do not require an approved New Drug Application

- FDCA Section 801(e), (f) [21 USC 381(e), (f)]

Unapproved New Drug

(subject to FFDCA 505, OTC monograph, or licensing)

- FDCA Sections 802 and 801(e)(1) or
- 21 CFR 312.110(b) the IND Exports Regulations

Exports Requirements

Intended to allow drugs to be introduced into interstate commerce (for export) without violating FDCA Section 301(a)

FFDCA 801(e)(1) A drug intended for export shall not be deemed adulterated or misbranded under this Act if it—

(A) accords to the specifications of the foreign purchaser

(B) is not in conflict with laws of the country to which it is intended for export

(C) is labeled on the outside of the shipping package that it is intended for export, and

(D) is not sold or offered for sale in domestic commerce

Additional Export Labels

801(f) Labeling of exported misbranded or adulterated drugs with additional label requirements:

- Both the FDA and the required foreign labeling must be on/with the product
- Must declare any indications which diverge from the FDA approval are not FDA approved

Exports under FDCA 802

Unapproved new human drug can be exported when:

- It complies with the laws of the importing country and
- It has marketing authorization in Australia, Canada, Israel, Japan, New Zealand, South Africa, or a country in the European Union, European Free Trade Association, or authorized to be marketed in the European Economic Area

Approved human drugs exported for unapproved uses

- Investigational use in listed country (see above)
- Further processing with a pending market authorization (licensing, listing)

Provision to allow shipping of drugs for tropical diseases or not of significant prevalence in the U.S.

Exports under FDCA 802

Issues to consider when planning to export a drug that requires approval and does not have such approval:

- Which section of 802 applies?
- Compliance with 801(e)(1)?
- Strength, purity, quality
- GMPs
- Other Adulteration Issues
- Injurious to health
- Imminent domestic public health hazard?
- Imminent foreign public health hazard?

Export Notification

Export Notification for Approved Drugs and Drugs distributed in compliance with the Act not required

Export Notification for other drugs per FDCA 802(g)

21CFR1.101(d) and 21CFR312.110(b)

Export Notification under FDCA Section 802(b)(1)(A)

- Provide CDER Office of Compliance initial notification identifying the drug exported to any country listed at 802(b)(1)(A)(i) or (ii)
- Provide CDER Office of Compliance initial notification identifying drug and country when country is not included in list at 802(b)(1)(A)(i) or (ii)
- Export Notification for certain INDs per the 312 Program go to the Office of International Programs

802(b) Exports Records

Exporter must maintain records including:

- Drug trade name, abbreviated or proper name
- Strength and dosage form
- Name of importing country
- Drug lot or control number
- Consignee name and address
- Date product was exported
- Quantity of drug exported
- Product meets foreign purchaser specifications
- Product does not conflict with laws of importing country
- Shipping label of exported product states for export only
- Documentation that product is not sold/offered for sale in U.S.

Prêt-à-exPorter

- Legally marketed drugs
- Drugs not marketed in the U.S.
- Drugs manufactured for foreign markets
- Country of import requires FDA certification

FDA Export Certification

- Certificate of Pharmaceutical Product (CPP)

What is a CPP?

Certificate of Pharmaceutical Product *(CPG 7150.01)*

- Certificate to export human drug products (including biological drugs)
- Conforms to the World Health Organization (WHO) certification requirements
- Contains information about the pharmaceutical regulatory or marketing status in the U.S.

Certificate May Be Issued

- Drugs that are legally marketable in the U.S.
- Drugs not authorized for sale in the U.S. which may be legally exported to a foreign country
- For a foreign manufactured drug (i.e. made outside the U.S. and exported from the U.S.)

CPPs Commonly Issued

1. Approved drug product
2. Over the counter drug (OTC) product
3. Unapproved drug product
4. Homeopathic drug
5. Drug in a bulk package (e.g. active pharmaceutical ingredient or API)

Who can apply for CPP?

- Anyone who exports a drug may submit a complete application for export certification

- Certification is intended for a drug which
  - meets the requirements of 801(e)(1) of the Food Drug and Cosmetic Act [21 U.S.C. 381(e)(1)]

    or

  - meets the applicable requirements of the Act

Process to apply for a CPP

- Submit Form 3613b*
- FDA currently allows exporters to submit the CPP application in a letter format
- FDA will be transitioning to accept CPP application solely using Form 3613b

*http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM052388.pdf

Required CPP Application Information

- Authorization to Release Information
- Billing contact
- Certification Statement
- Name of Applicant
- Applicant Contact Information
- Country of Destination
- Federal Tax Identification Number (TIN)
- FDA Marketing Authority
- Marketing Status in the Exporting Country (U.S.)
- Status of Applicant
- Complete Manufacturing Facility Address
- Facility Registration Number
- Number of certificates requested
- U.S. Trade name (the drug product's brand name)
- Bulk Substance Generic Name

Additional Required Information

- **Approved Drug Products**
  - NDA, ANDA, or AADA Approval Letter
  - Container Label(s)
  - Package Container (Immediate)
  - Package Insert
  - Status of Product-license Holder
- **Over-the-Counter (OTC) Drug Products**
  - Title of the applicable monograph
  - Product Label(s)
  - Immediate Package Container Label
- **Unapproved Drug Products**
  - Product Identification Statement
  - Product composition
- **Active Pharmaceutical Ingredients (API)**
  - Original sample of the current bulk container label
- **For Export Only**
  - Formulation page
- **Foreign Manufactured Drug**
  - Certification of Exportation from the U.S. for Foreign Manufacturing Sites

Attachments to CPP

- An application for one country requires two sets of attachments
  - set to attach to the certificate package
  - set for FDA files
- Attachments not to exceed five pages per CPP
- Consulting importing country to determine what type of information is required on CPP

Process Time

CPPs are normally issued within twenty (20) government working days of application receipt

Certification may not be issued

- Returned with a letter requesting additional information or missing information required in the CPP application
- Rejected: manufacturing facility status concerns (e.g. a violative facility inspectional status in FDA systems)
- Denied: drug is not in compliance with applicable regulation (e.g. misbranding not covered by an exemption)

Ribbons on CPPs

Colored ribbons designate the type of CPP*

- **Red** for approved drug product, API, OTC marketed per monograph, and export only drugs.
- **Blue** for unapproved drug product not marketed in the U.S.
- **Yellow** for drug manufactured outside of the U.S.

*http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/ImportsandExportsCompliance/ucm348825.htm

CPP Fee Schedule

- First Certificate (original) - **$175.00**
- Second Certificate - **$90.00**
- Third and subsequent certificates - **$40.00**

Expiration of CPP

- CPP expires twenty four (24) months from the date issued
- A new CPP application must be submitted for all certifications
- FDA no longer notarizes CPPs

Summary

- Obtaining a CPP
  - Know the requirements of the importing country prior to submitting an application
  - Complete application using FDA Form 3613b
  - Ensure that you submit the required documentation
- Form 3613b includes instructions, please review the instructions before completing and submitting the application

End

- Thank you!
- Email Exports Questions to:

  cderexportcertificateprogram@fda.hhs.gov