



Imports For Exports



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Import for Export



➤ What is Import for Export?

- ✓ IFE is an FDA thing, not a CBP thing
- ✓ IFE is a statutory exemption from refusal of admission for violative imported articles
 - ✓ Presupposes articles in violation of FFD&CA
- ✓ Does not apply to all importations that will eventually be exported
 - ✓ If there is no violation, IFE does not apply
- ✓ Compare to other exemptions
 - ✓ 801(e) indicates articles are not adulterated/misbranded



Import for Export



➤ What is Import for Export?

- ✓ Limited types of articles are allowed this exemption
 - ✓ Not foods; not cosmetics

- ✓ Exemption is only for further processing
 - ✓ Not for storage

- ✓ All conditions must be met
 - ✓ Statements
 - ✓ Bond
 - ✓ Accounting



➤ Section 801(d)(3) states:

“...no component of a drug, no component part or accessory of a device, or other article of device requiring further processing, which is ready or suitable for use for health-related purposes, and no article of a food additive, color additive, or dietary supplement, including a product in bulk form, shall be excluded from importation into the United States under subsection (a) of this section if each of the following conditions is met:”



Import for Export (IFE) - 801(d)(3)



- i. The importer of such article submits to the Secretary, at the time of initial importation, a statement in accordance with the following:
 - I. Article is intended to be further processed by the initial owner or consignee, or incorporated into a drug, biological product, device, food, food additive, color additive, or dietary supplement that will be exported from the United States in accordance with applicable laws.
 - II. The statement identifies the manufacturer and each processor, packer, distributor, or other entity that had possession of the article in the chain of possession from the manufacturer to importer.
 - III. The statement is accompanied by such certificates of analysis as are necessary to identify such article, unless the article is a device or is an article described in paragraph (4).



Import for Export (IFE) - 801(d)(3)



- ii. At the time of initial importation and before the delivery of such article a good and sufficient bond providing for the payment of such liquidated damages in the event of default as may be required pursuant to regulations of the Secretary of the Treasury.
- iii. Article is used and exported by the initial owner or consignee in accordance with the intent described under clause (i)(I), except for any portions of the article that are destroyed.
- iv. The initial owner or consignee maintains records on the use or destruction of such article or portions thereof, as the case may be, and submits to the Secretary any such records requested by the Secretary.
- v. Upon request of the Secretary, submit a report that provides an account of the exportation or destruction of such article or portions thereof, and the manner in which the owner or consignee complied with the requirements.



➤ Important Points

- ✓ 801(d)(3)(A)(i): “...at the time of initial importation...”
 - ✓ IFE should be declared up front
 - ✓ Articles intended for further processing & exportation
 - ✓ Not acceptable to claim after a violation is discovered

- ✓ 801(d)(3)(A)(ii): “...good and sufficient bond...”
 - ✓ Bond needs to be maintained while articles are in US
 - ✓ Entry type determines bond type which determines process



➤ Important Points

- ✓ 801(d)(3)(A)(iii):“...used and exported by the initial owner or consignee ...” AND
- ✓ 801(d)(3)(iv):“...initial owner or consignee maintains records...”
 - ✓ Exemption does not allow for processing by third parties
- ✓ 801(d)(3)(A)(v):“...report that provides an account...”
 - ✓ Importer/consignee must maintain records and provide to FDA upon request

Failure to meet all conditions will void the exemption from refusal of admission.



➤ Declaration of IFE & Required Statements

- ✓ Affirmation of Compliance code = IFE
- ✓ District should request entry documents & required statements
- ✓ Importer should provide entry/shipping documentation and statements required by 801(d)(3)(A)(i):
 - ✓ Articles are intended for further processing
 - ✓ Chain of custody for the articles
 - ✓ Certificates of analysis for the articles (unless a device)
- ✓ Also include the basis for claiming the IFE exemption
- ✓ District should detain the entry



➤ Detention

- ✓ IFE is an exemption from refusal of admission
- ✓ A detention is not a refusal
 - ✓ For FDA, detention refers to an administrative process
 - ✓ Detention indicates articles are subject to refusal
 - ✓ As violative, IFE articles are subject to refusal
- ✓ While detained the articles can be moved and processed
 - ✓ Outlined in the required statements
- ✓ Detention keeps the entry 'open'; and maintains the bond



➤ Bonds and Entry Type

- ✓ 801(d)(3)(A)(ii) requires a bond be in place:
 - “...good and sufficient bond providing for the payment of such liquidated damages in the event of default as may be required pursuant to regulations of the Secretary of the Treasury...”
- ✓ Failure to have a bond in place voids the exemption from refusal
 - ✓ The bond needs to be maintained
- ✓ This is why FDA does not issue a release for all IFE entries



➤ Temporary Importation Under Bond Entry Type

- ✓ TIB includes a special bond with CBP
 - ✓ 1 year duration; option for 2 – 1 year extensions
 - ✓ Bond stays in effect no matter what FDA does
- ✓ IFE with a TIB Entry Type = FDA release of the entry
 - ✓ “Release with Comment” indicating violative articles are IFE
- ✓ FDA will arrange for follow up at the ‘home District’
 - ✓ Will verify the articles were exported/destroyed, or still in possession of importer/consignee
 - ✓ Will arrange appropriate regulatory action if not



➤ Consumption or Warehouse Entry Types

- ✓ Not all activities qualify for TIB, but may qualify for IFE
 - ✓ Labeling is one

- ✓ Conditional Release Period affects the bond
 - ✓ Bond goes away if FDA issues a release
 - ✓ If the bond goes away, so does the exemption from refusal

- ✓ IFE with a Consumption or Warehouse Entry Type =
FDA maintains detention of the entry
 - ✓ While detained the articles can be moved and processed



➤ Consumption or Warehouse Entry Types

- ✓ Liquidation:
 - ✓ Bond goes away
 - ✓ Consumption entry: ~314 days
 - ✓ Warehouse entry: 5 years
 - ✓ If the bond goes away, so does the exemption from refusal

- ✓ Therefore, there is a time limit on the IFE process

- ✓ FDA does not choose or direct the Entry Type
 - ✓ FDA adjusts its process based upon Entry Type



➤ Consumption or Warehouse Entry Types

- ✓ District should request updates and accounting
 - ✓ 801(d)(3)(A)(iv) and (v)
 - ✓ Importer should provide them
- ✓ Importer lets District know when exported/destroyed
 - ✓ District verifies
 - ✓ “Release with Comment” indicating violative articles have finished processing IFE



➤ Consumption or Warehouse Entry Types

- ✓ Exemption criteria must be maintained by the importer
- ✓ Articles can be refused admission:
 - ✓ Failure to maintain records
 - ✓ Failure to provide accounting upon request
 - ✓ Failure to otherwise comply
 - ✓ When liquidation is imminent



Import for Export



- **801(d)(3)(B):** Articles may be refused admission if FDA determines there is credible evidence or information that the articles will not be further processed and exported/destroyed

- **301(w): Prohibited Acts**
 - Knowingly making false statements related to IFE
 - Failure to submit certificate of analysis
 - Failure to maintain & submit records upon request
 - Release into interstate commerce of any IFE-entered articles



Frequently Asked Questions



- ✓ Does labeling of finished drugs/devices fall under IFE “further processing”?
 - ✓ Yes

- ✓ Does sterilization of finished drugs/devices fall under IFE “further processing”?
 - ✓ Yes

- ✓ Can I bring IFE articles into compliance and then distribute on the US market?
 - ✓ No, this is a Prohibited Act under 301(w)



Frequently Asked Questions



- ✓ Can you ask CBP to allow me a TIB Entry Type?
 - ✓ No. There are specific requirements for a TIB entry over which FDA has no control.

- ✓ What are the time limits for IFE?
 - ✓ None specified; dependent upon entry type and the bond

- ✓ Can I get an extension to the liquidation period for a consumption entry?
 - ✓ Not an FDA function, you must ask CBP

- ✓ Will FDA ask CBP for me?
 - ✓ No, nor will we recommend to CBP that they grant your request.