International Issues and Imports

Introduction to U.S. Device Law and Regulation

Kristin Kaplan

Shook Hardy & Bacon

FDLI

This is Me

Kristin Kaplan

I am a regulatory attorney with a passion for Food and Drug Law, and how the history of those laws impacts the current regulatory environment.

I counsel clients about their regulatory obligations and represent them before FDA, Customs, and other government agencies.

I work at Shook Hardy & Bacon

My favorite thing to do in my free time is exercise… I'm currently on an OrangeTheory kick.

I drive my family crazy by telling them how tv shows and movies get FDA-regulated products wrong.

FDLI

What's so special about imports anyways …

- Foreign Device Facility Inspections
  - Foreign device facility registrations: 13,857 (CY 2019)**
  - Number of FDA Foreign Inspections: 520 (FY 2019)**
- Device Imports: 22,967,758 (FY 2019)*

**From* FDA, Fiscal Year 2021 Justifications
***From* FDA, Annual Report on Inspection of Establishments in CY 2019

FDLI

Telling Stories

Q: Where's My Stuff?

"I'm waiting for a shipment of examination gloves, but they're on FDA hold. Something about 'exam/sample?' I just want my gloves."

FDLI

A: Where's My Stuff?

FDA can hold and examine any import shipment for compliance with the Act.

FDLI

Section 801(a)

The Secretary of the Treasury shall deliver to the Secretary of Health and Human Services, upon his request, samples of food, drugs, devices, tobacco products, and cosmetics which are being imported or offered for import into the United States, giving notice thereof to the owner or consignee, who may appear before the Secretary of Health and Human Services and have the right to introduce testimony. The Secretary of Health and Human Services shall furnish to the Secretary of the Treasury a list of establishments registered pursuant to subsection (i) of section 360 or section 387e(h) of this title and shall request that if any drugs, devices, or tobacco products manufactured, prepared, propagated, compounded, or processed in an establishment not so registered are imported or offered for import into the United States, samples of such drugs, devices, or tobacco products be delivered to the Secretary of Health and Human Services, with notice of such delivery to the owner or consignee, who may appear before the Secretary of Health and Human Services and have the right to introduce testimony. If it appears from the examination of such samples or otherwise that (1) such article has been manufactured, processed, or packed under insanitary conditions or, in the case of a device, the methods used in, or the facilities or controls used for, the manufacture, packing, storage, or installation of the device do not conform to the requirements of section 360j(f) of this title, or (2) such article is forbidden or restricted in sale in the country in which it was produced or from which it was exported, or (3) such article is adulterated, misbranded, or in violation of section 355 of this title or the importer (as defined in section 384a of this title) is in violation of such section 384a of this title, or prohibited from introduction or delivery for introduction into interstate commerce under section 331(ll) of this title, or is a controlled substance subject to an order under section 360bbb–8d of this title, or (4) the recordkeeping requirements under section 2223 of this title (other than the requirements under subsection (f) of such section) have not been complied with regarding such article or (5) such article is being imported or offered for import in violation of section 331(cc) of this title, then any such article described in any of clauses (1) through (5) shall be refused admission, except as provided in subsection (b) of this section. If it appears from the examination of such samples or otherwise that the article is a counterfeit drug or counterfeit device, such article shall be refused admission. With respect to an article of food, if importation of such food is subject to, but not compliant with, the requirement under subsection (q) that such food be accompanied by a certification or other assurance that the food meets applicable requirements of this chapter, then such article shall be refused admission. If such article is subject to a requirement under section 379aa or 379aa–1 of this title and if the Secretary has credible evidence or information indicating that the responsible person (as defined in such section 379aa or 379aa–1 of this title) has not complied with a requirement of such section 379aa or 379aa–1 of this title with respect to any such article, or has not allowed access to records described in such section 379aa or 379aa–1 of this title, then such article shall be refused admission, except as provided in subsection (b) of this section. The Secretary of the Treasury shall cause the destruction of any such article refused admission unless such article is exported, under regulations prescribed by the Secretary of the Treasury, within 90 days of the date of notice of such refusal or within such additional time as may be permitted pursuant to such regulations, except that the Secretary of Health and Human Services may destroy, without the opportunity for export, any drug or device refused admission under this section, if such drug or device is valued at an amount that is $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation pursuant to section 1498(a)(1) of title 19 and was not brought into compliance as described under subsection (b). The Secretary of Health and Human Services shall issue regulations providing for notice and an opportunity to appear before the Secretary of Health and Human Services and introduce testimony, as described in the first sentence of this subsection, on destruction of a drug or device under the seventh sentence of this subsection. The regulations shall provide that prior to destruction, appropriate due process is available to the owner or consignee seeking to challenge the decision to destroy the drug or device. Where the Secretary of Health and Human Services provides notice and an opportunity to appear and introduce testimony on the destruction of a drug or device, the Secretary of Health and Human Services shall store and, as applicable, dispose of the drug or device after the issuance of the notice, except that the owner and consignee shall remain liable for costs pursuant to subsection (c). Such process may be combined with the notice and opportunity to appear before the Secretary and introduce testimony, as described in the first sentence of this subsection, as long as appropriate notice is provided to the owner or consignee. Neither clause (2) nor clause (5) of the third sentence of this subsection shall be construed to prohibit the admission of narcotic drugs, the importation of which is permitted under the Controlled Substances Import and Export Act [21 U.S.C. 951 et seq.].

FDLI

That's Ugly

- 1 paragraph with 11 sentences totally over 900 words
- Practically speaking:
  - FDA can examine any device shipment
  - Owner and consignee has the right to introduce testimony as to compliance
  - Based on FDA's examination *or otherwise* the product ***appears*** to violate the Act, then FDA shall refuse it
- This is an *in rem* action

FDLI

Q: Holes in the Gloves

"So those gloves are FDA 'detained.' I got some notice saying:

> The article is subject to refusal of admission pursuant to section 801(a)(3) in that it appears to contain defects/holes [Adulteration, section 501(c)].

What happens when FDA detains an imported product?

1. FDA seized and placed the product in a government warehouse
2. FDA labeled the product as “detained,” but the product is in the importer’s selected warehouse
3. FDA marked the product “detained” in its system, but has not done anything to the product itself

FDLI

A: Holes in the Gloves

- Notice and informal hearing if an article appears subject to import refusal (“detention”)
- If article appears non-compliant after hearing, import refusal

Detention

- Importer/consignee given notice that it appears the article is subject to refusal (appears that it appears non-compliant…)
- At this stage, FDA refers to the product being "detained," a word that does not appear in FDCA or CFR
- Informal hearing where importer can submit testing as to compliance
  - Failure to respond will result in a default judgment of sorts

FDLI

Release, Recondition, or Refusal

- Release: Detention an error, or issues resolved (like registration/listing)
- Recondition: Fixed the problem
  - Parallels Section 304 of the Act, authority comes from 801(b)
- Refusal: Continues to appear violative
  - Must be exported or destroyed with appropriate government supervision within 90 days

FDLI

Enforcement – Customs Bond

- To import, the importer must file a bond with Customs, which should be of a value to cover 3x the value of the goods
- Failure to redelivery or do it appropriately, FDA will instruct Customs to collect “liquidated damages”

FDLI

Q: Future Glove Shipments

“I have 10 more containers of gloves on the water about to be imported; what will happen to them.”

A: Future Glove Shipments

- Future shipments will be automatically detained under an “Import Alert”
- Opportunity to provide evidence (product testing) to prove product complies, otherwise import refusal
- Continues until petitioned to be removed

FDLI

Bans and Restrictions: Import Alerts

- "or otherwise" strikes back – import alerts
- Burden shifts essentially: product subject to refusal unless the importer can provide testimony as to compliance (usually testing)
- There are *per se* bans where no testimony will persuade FDA (a failed FDA facility inspection)
  - APA problem?

FDLI

Q: Product Listing … I'll Get There

"We airfreighting these crutches because they need to be there tomorrow. No we don't have time to have the manufacturer list them!"

A: Product Listing … I'll Get There

Not being listed makes the device misbranded and subject to import detention and possible refusal

Q: Uncleared Device for Packaging and Sterilization

“We need to take an EU cleared device, but bring it to the US to be packaged and sterilized before sending it back to the EU. The device lacks a 510(k).”

FDLI

A: Uncleared Device for Packaging and Sterilization

Let’s use the Import-for-Export Regime

Import-for-Export: Importing (801(d)(3))

- Basic: can import a violative device, component, or accessory for further processing and exporting if the importer
  - Submits a statement to FDA with a chain of custody [***and COA***]*
  - Obtains a "good and sufficient" bond
  - Performs the further processing and exportation
  - Maintains records of use and/or destruction
- Article can be refused admission if there is credible evidence that it is not intended to be further processed

FDLI

*not required for a device

Import-for-Export (or Just Export): Exporting (801(e))

- Also applies to domestic manufactured product intended for export
- Basic Requirements
  - Meets foreign purchaser's specifications
  - Not illegal in foreign market
  - Labeled that intended for export
  - Not sold or offered for sale in the United States
- Maintain records supporting this
- Don't forgot about 801(e)(2) carve-out

FDLI

Import-for-Export (or Just Export): Exporting (801(e))

- 801(e) alone does not apply for
  - PMA devices (Class III)
  - Class II devices subject to performance standards
  - Investigational devices requiring PMA
  - Banned devices
- To export:
  - FDA concludes that it is not contrary to public health and safety, and has approval in other country, or
  - Complies with Section 802

FDLI

Q: Manufacturing and Exporting Hair Fibers

“Prosthetic hair fiber taken from llamas are the wave of the future in nonUS.”

FDLI

A: Manufacturing and Exporting Hair Extension

- It's a banned device (21 CFR 895.101), but still could be made here under the right circumstances …

FDLI

Import-for-Export (or Just Export): Exporting (802)

- Comply with 801(e)(1)
- Manufactured under conditions that substantially meet QSRs (or an international quality standard recognized by FDA (there are none)
- Not be adulterated for various reasons
- No subjected to notice that re-importation poses an imminent hazard, or the country intended for
- Appropriately labelled for foreign market in several aspects
- Comply with the laws of the receiving country, and
- Marketing authorization from a Tier 1 Country*

FDLI

*Australia, Canada, Israel, Japan, New Zealand, Switzerland, South Africa, a member of the European Union (United Kingdom, Spain, Ireland, Denmark, Greece, Belgium, Portugal, Germany, France, Italy, Luxembourg, Netherlands, Sweden, Finland, Austria, Bulgaria, Romania, Cyprus, the Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovakia, and Slovenia), or the European Economic Area (includes the European Union countries and Norway, Iceland, and Liechtenstein).

Import-for-Export (or Just Export): Exporting (802)

- Submit simple notification to FDA when first exporting
  - Trade name
  - Type of device
  - Product model
  - Country receiving the article if not a Tier 1 country
- Maintain additional records (beyond 801(e))
- Can't meet all that – must obtain an Export Permit Letter under 801(e)(2)

FDLI

Q: FDA Compliant Product

“I want to export this product that complies with every part of the FDCA; what special things do I need to do under the FDCA.”

FDLI

What do you think?

1. Submit a notification to FDA
2. Nothing
3. Obtain FDA’s blessing prior to shipping

FDLI

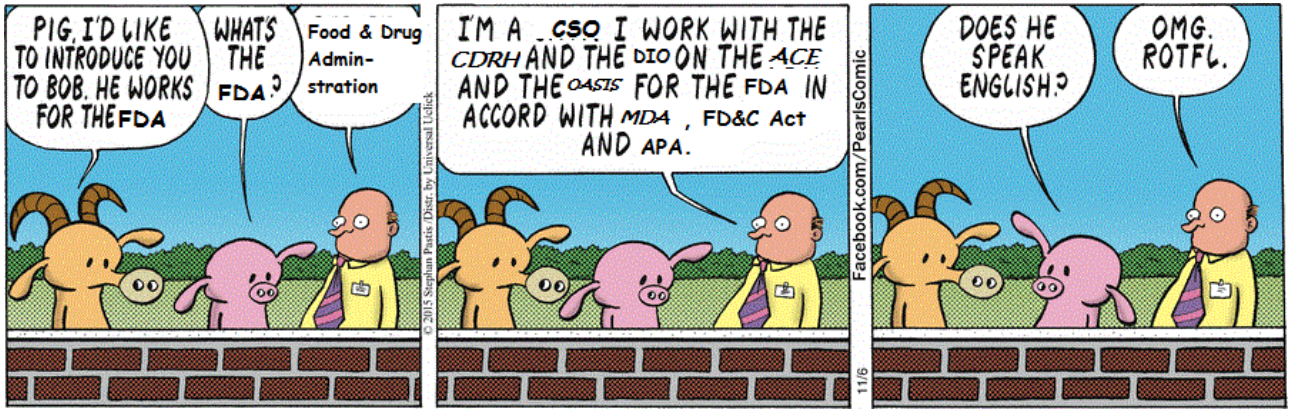
A: FDA Compliant Product

… … …

nothing

… … …

Questions?



Email: kkaplan@shb.com
Phone: 816-933-5813

FDLI

CONTENT SLIDES

FDLI

FDA Authority over Imported Devices

FDLI

Section 801(a)

The Secretary of the Treasury shall deliver to the Secretary of Health and Human Services, upon his request, samples of food, drugs, devices, tobacco products, and cosmetics which are being imported or offered for import into the United States, giving notice thereof to the owner or consignee, who may appear before the Secretary of Health and Human Services and have the right to introduce testimony. The Secretary of Health and Human Services shall furnish to the Secretary of the Treasury a list of establishments registered pursuant to subsection (i) of section 360 or section 387e(h) of this title and shall request that if any drugs, devices, or tobacco products manufactured, prepared, propagated, compounded, or processed in an establishment not so registered are imported or offered for import into the United States, samples of such drugs, devices, or tobacco products be delivered to the Secretary of Health and Human Services, with notice of such delivery to the owner or consignee, who may appear before the Secretary of Health and Human Services and have the right to introduce testimony. If it appears from the examination of such samples or otherwise that (1) such article has been manufactured, processed, or packed under insanitary conditions or, in the case of a device, the methods used in, or the facilities or controls used for, the manufacture, packing, storage, or installation of the device do not conform to the requirements of section 360j(f) of this title, or (2) such article is forbidden or restricted in sale in the country in which it was produced or from which it was exported, or (3) such article is adulterated, misbranded, or in violation of section 355 of this title or the importer (as defined in section 384a of this title) is in violation of such section 384a of this title, or prohibited from introduction or delivery for introduction into interstate commerce under section 331(*ll*) of this title, or (4) the recordkeeping requirements under section 2223 of this title (other than the requirements under subsection (f) of such section) have not been complied with regarding such article, then such article shall be refused admission, except as provided in subsection (b) of this section. With respect to an article of food, if importation of such food is subject to, but not compliant with, the requirement under subsection (q) that such food be accompanied by a certification or other assurance that the food meets applicable requirements of this chapter, then such article shall be refused admission. If such article is subject to a requirement under section 379aa or 379aa–1 of this title and if the Secretary has credible evidence or information indicating that the responsible person (as defined in such section 379aa or 379aa–1 of this title) has not complied with a requirement of such section 379aa or 379aa–1 of this title with respect to any such article, or has not allowed access to records described in such section 379aa or 379aa–1 of this title, then such article shall be refused admission, except as provided in subsection (b) of this section. The Secretary of the Treasury shall cause the destruction of any such article refused admission unless such article is exported, under regulations prescribed by the Secretary of the Treasury, within ninety days of the date of notice of such refusal or within such additional time as may be permitted pursuant to such regulations, except that the Secretary of Health and Human Services may destroy, without the opportunity for export, any drug refused admission under this section, if such drug is valued at an amount that is $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation pursuant to section 1498(a)(1) of title 19) and was not brought into compliance as described under subsection (b)..[The Secretary of Health and Human Services shall issue regulations providing for notice and an opportunity to appear before the Secretary of Health and Human Services and introduce testimony, as described in the first sentence of this subsection, on destruction of a drug under the sixth sentence of this subsection. The regulations shall provide that prior to destruction, appropriate due process is available to the owner or consignee seeking to challenge the decision to destroy the drug. Where the Secretary of Health and Human Services provides notice and an opportunity to appear and introduce testimony on the destruction of a drug, the Secretary of Health and Human Services shall store and, as applicable, dispose of the drug after the issuance of the notice, except that the owner and consignee shall remain liable for costs pursuant to subsection (c). Such process may be combined with the notice and opportunity to appear before the Secretary and introduce testimony, as described in the first sentence of this subsection, as long as appropriate notice is provided to the owner or consignee. Clause (2) of the third sentence of this paragraph shall not be construed to prohibit the admission of narcotic drugs the importation of which is permitted under the Controlled Substances Import and Export Act [21 U.S.C. 951 et seq.].

FDLI

That's Ugly

- 1 paragraph with 11 sentences using a total of ~850 words
- Practically speaking:
  - FDA can examine any device shipment
  - Owner and consignee has the right to introduce testimony as to compliance
  - Based on FDA's examination *or otherwise* the product ***appears*** to violate the Act, then FDA shall refuse it
- This is an *in rem* action

FDLI

Detention

- Importer/consignee given notice that it appears the article is subject to refusal (appears that it appears non-compliant…)
- At this stage, FDA refers to the product being "detained," a word that does not appear in FDCA or CFR
- In formal hearing where importer can submit testing as to compliance
  - Failure to respond will result in a default judgment of sorts

FDLI

Release, Recondition, or Refusal

- Release: Detention an error, or issues resolved (like registration/listing)
- Recondition: Fixed the problem
  - Parallels Section 304 of the Act, authority comes from 801(b)
- Refusal: Continues to appear violative
  - Must be exported or destroyed with appropriate government supervision within 90 days

FDLI

Enforcement – Customs Bond

- To import, the importer must file a bond with Customs, which should be of a value to cover 3x the value of the goods
- Failure to redelivery or do it appropriately, FDA will instruct Customs to collect “liquidated damages”

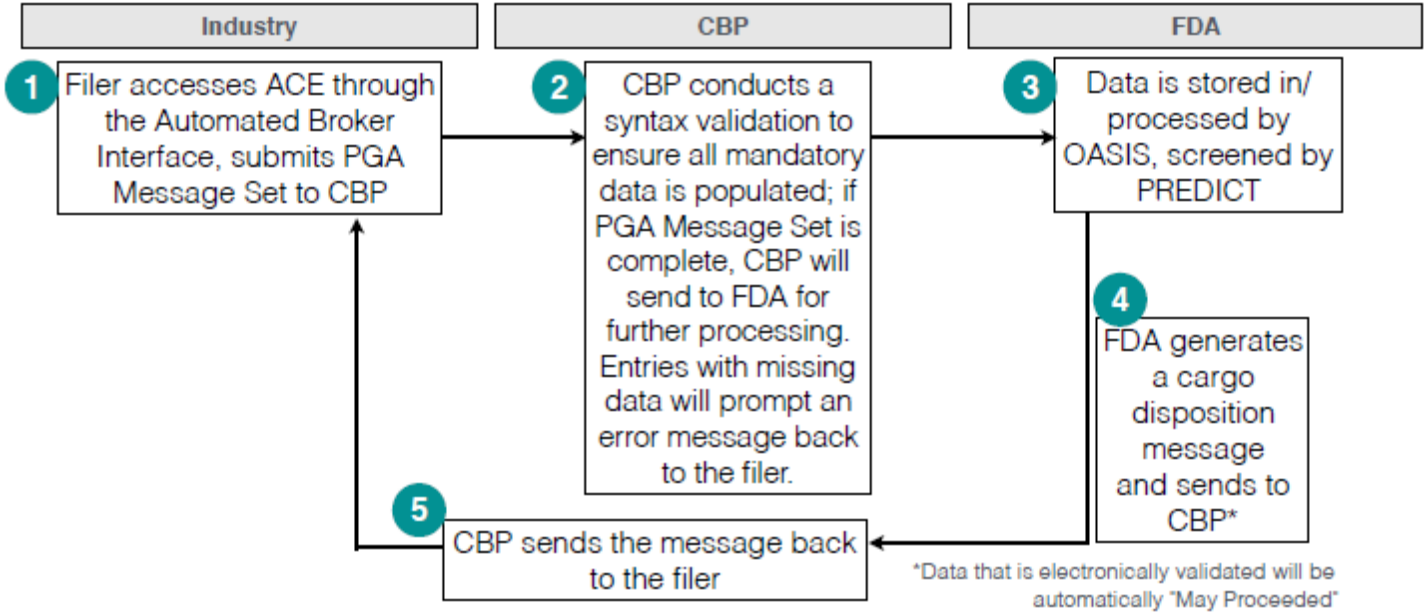
FDLI

Bans and Restrictions: Import Alerts

- "or otherwise" strikes back – import alerts
- Burden shifts essentially: product subject to refusal unless the importer can provide testimony as to compliance (usually testing)
- There are *per se* bans where no testimony will persuade FDA (a failed FDA facility inspection)
  - APA problem?

FDLI

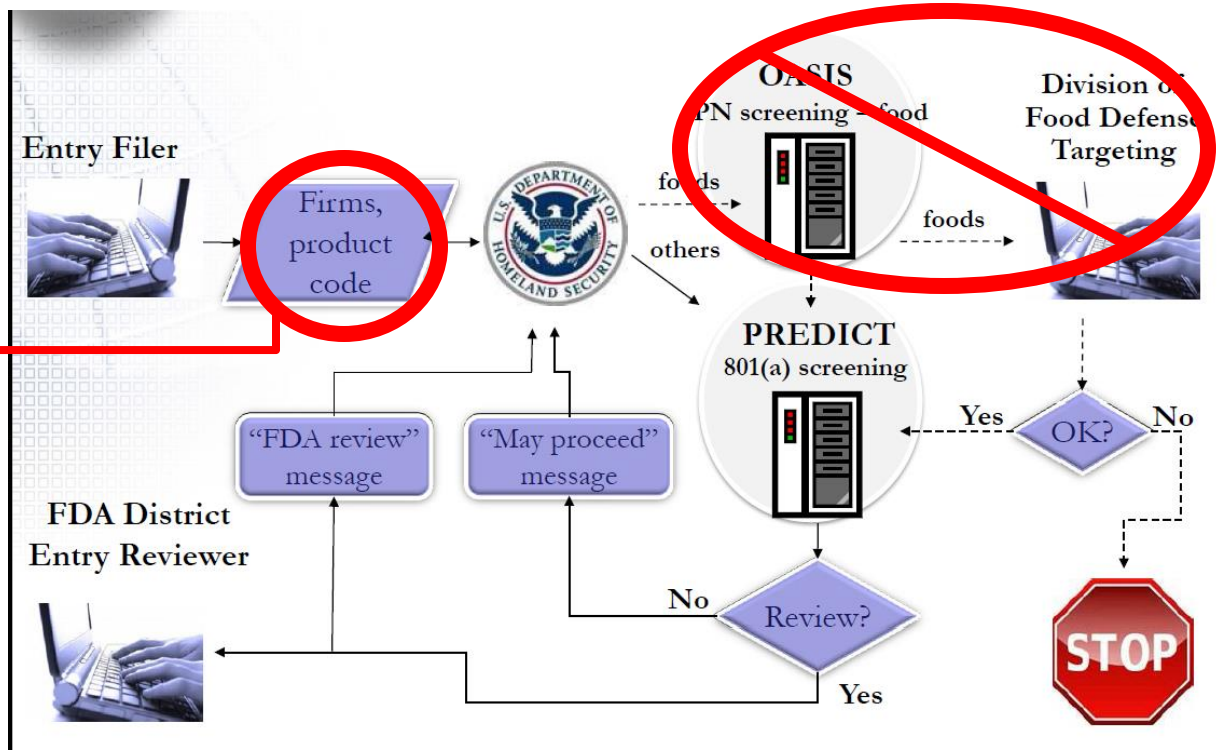
Process in Practice, Part 1



Taken from Jessica Aranda & Gayle Gehrman, Importing FDA-Regulated Products in ACE

Process in Practice, Part 2

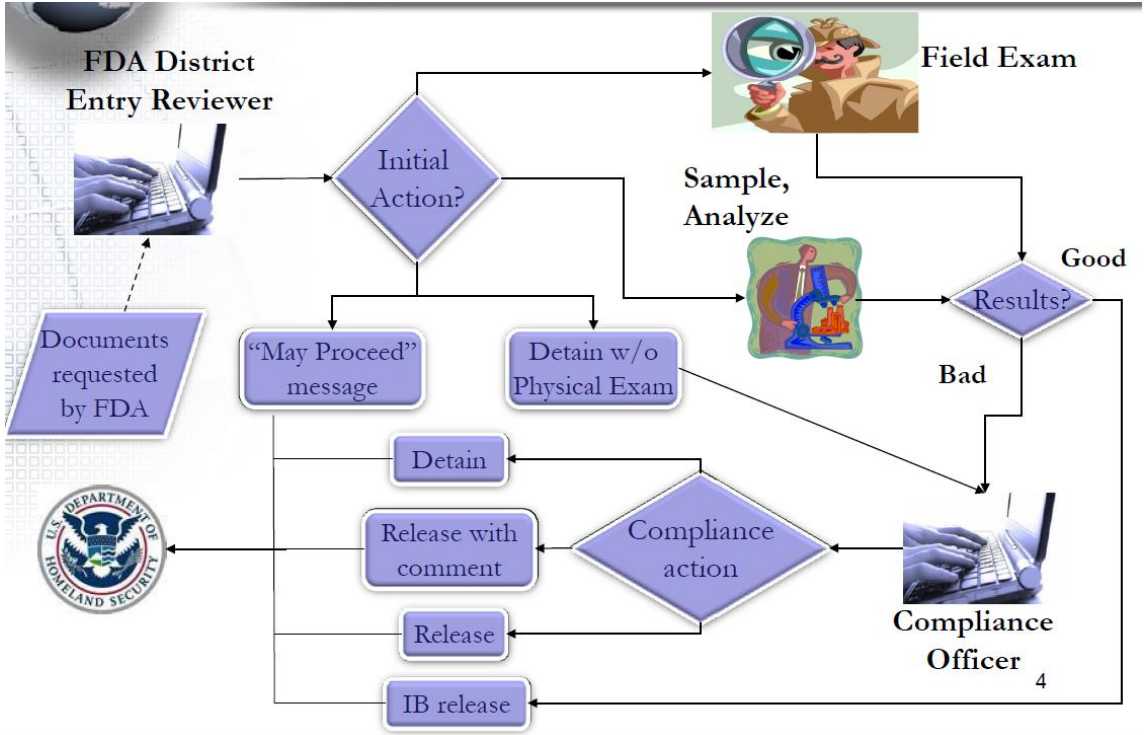
ACE changed this



Taken from FDA, Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT)

FDLI

Process in Practice, Part 3



Taken from FDA, Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT)

FDLI

What is ACE?

- Automated Commercial Environment
- With launch FDA began requiring more information to file entry

ACE

- Manufacturer & Shipper
- Product Description
- FDA Product Code
- Intended Use Code
- Facility Registration, and Device Listing Numbers
- 510(k) Number (or PMA)

*for a finished device subject to a 510(k)

FDLI

Import-for-Export: Importing (801(d)(3))

- Basic: can import a violative device, component, or accessory for further processing and exporting if the importer
  - Submits a statement to FDA with a chain of custody [***and COA***]*
  - Obtains a "good and sufficient" bond
  - Performs the further processing and exportation
  - Maintains records of use and/or destruction
- Article can be refused admission if there is credible evidence that it is not intended to be further processed

FDLI

*not required for a device

FDA Authority over Exported Devices

FDLI

Import-for-Export (or Just Export): Exporting (801(e))

- Also applies to domestic manufactured product intended for export
- Basic Requirements
  - Meets foreign purchaser's specifications
  - Not illegal in foreign market
  - Labeled that intended for export
  - Not sold or offered for sale in the United States
- Maintain records supporting this
- Don't forgot about 801(e)(2) carve-out

FDLI

Import-for-Export (or Just Export): Exporting (801(e))

- 801(e) alone does not apply for
  - PMA devices (Class III)
  - Class II devices subject to performance standards
  - Investigational devices requiring PMA
  - Banned devices
- To export:
  - FDA concludes that it is not contrary to public health and safety, and has approval in other country, or
  - Complies with Section 802

FDLI

Import-for-Export (or Just Export): Exporting (802)

- Comply with 801(e)(1)
- Manufactured under conditions that substantially meet QSRs (or an international quality standard recognized by FDA (there are none)
- Not be adulterated for various reasons
- No subjected to notice that re-importation poses an imminent hazard, or the country intended for
- Appropriately labelled for foreign market in several aspects
- Comply with the laws of the receiving country, and
- Marketing authorization from a Tier 1 Country*

FDLI

*Australia, Canada, Israel, Japan, New Zealand, Switzerland, South Africa, a member of the European Union (United Kingdom, Spain, Ireland, Denmark, Greece, Belgium, Portugal, Germany, France, Italy, Luxembourg, Netherlands, Sweden, Finland, Austria, Bulgaria, Romania, Cyprus, the Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovakia, and Slovenia), or the European Economic Area (includes the European Union countries and Norway, Iceland, and Liechtenstein).

Import-for-Export (or Just Export): Exporting (802)

- Submit simple notification to FDA when first exporting
  - Trade name
  - Type of device
  - Product model
  - Country receiving the article if not a Tier 1 country
- Maintain additional records (beyond 801(e))
- Can't meet all that – must obtain an Export Permit Letter under 801(e)(2)

FDLI

Exporting a Compliant Product

… … …

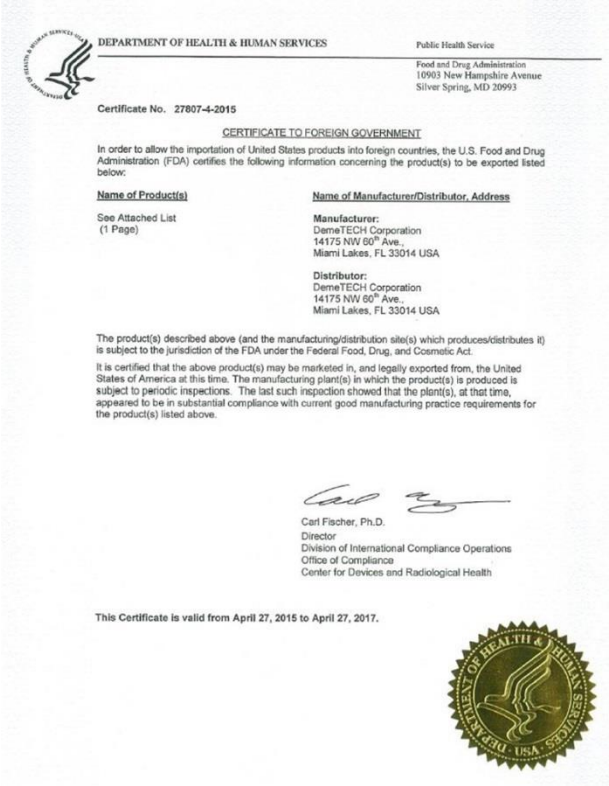
nothing

… … …

FDA Certificates

Certificate to Foreign Government: Legally marketed in the United States

Certificate of Exportability: Cannot be legally marketed in the United States, but complies with 801(e) or 802



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Certificate No. 27807-4-2015

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries, the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

Name of Product(s)

See Attached List
(1 Page)

Name of Manufacturer/Distributor, Address

Manufacturer:
DemeTECH Corporation
14175 NW 60th Ave.,
Miami Lakes, FL 33014 USA

Distributor:
DemeTECH Corporation
14175 NW 60th Ave.,
Miami Lakes, FL 33014 USA

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections. The last such inspection showed that the plant(s), at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the product(s) listed above.

Carl Fischer, Ph.D.
Director
Division of International Compliance Operations
Office of Compliance
Center for Devices and Radiological Health

This Certificate is valid from April 27, 2015 to April 27, 2017.