

Common problems with FDA Entries along the Northern/Canadian Border

**Import Seminar:
Shipment of Food from Canada to the U.S.
January 16, 2008**

Goal

**to make the process easier
& faster for all members of
the import community –
shipper, carrier, importer &
FDA**

Problems typically fall into 3 categories:

- **Electronic Entry data**
- **Crossing issues**
- **Compliance issues**

Electronic Entry Data

- Select a suitable Broker/Filer
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Electronic Entry Data

Broker/filer needs to:

- work with you on data submission
- Effectively communicate with the Import Community
- Effectively transmit data to CBP/FDA
- Be capable of participating in OASIS as a “Paperless Filer”

Electronic Entry Data

OASIS = Operational & Administrative
System for Import Support -
electronically processes:

1. Manufacturer
2. Product Code
3. Shipper
4. Country of origin
5. # lines

Electronic Entry Data

- **wrong FDA product code submitted – tutorial on www.fda.gov**

FDA Product Code Builder

Application - Product Code Builder - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Refresh Home Search Favorites Stop Check AutoLink AutoFill Options

Address <http://www.accessdata.fda.gov/scripts/ora/pcb/pcb.cfm> Go Links >>

Google Search 26 blocked ABC Check AutoLink AutoFill Options

[Help/FAQ's](#) **Product Code Builder** [Tutorial](#)

Option 1- Search Industry [Helpful Tips](#)

Alcoholic Beverage - 32
Anesthesiology - 73
Animal Devices and Diagnostic Products - 68
Animal Feed(Non-Medicated) - 70
Antibiotics (Human/Animal) - 56

[Clear](#)
[Next >](#)

Option 2- Search Partial Code [Helpful Tips](#)

[Clear](#)
[Next >](#)

Option 3- Search Product Name [Helpful Tips](#)

[Clear](#)
[Next >](#)

Option 4- Verify Product Code [Helpful Tips](#)

[Clear](#)
[Next >](#)

Done Local intranet

Electronic Data Submission

- Need correct name & address for actual manufacturer + shipper
- Affects CBP's MID (manufacturer identifier) and FDA's FEI (FDA Establishment Identifier)

Electronic Entry Data

- **failure to provide additional information requested by FDA in a timely manner**



Electronic Entry Data

- **failure to provide FDA product/firm qualifying data, if appropriate (i.e. FCE #, SID, NDA, IND, etc.)**

Electronic Entry Data

- multiple products included on a single line of entry



Electronic Entry Data

➤ "port shopping" when FDA issue arises - slows down the process – inconsistent results and data sharing required – deal straight forwardly

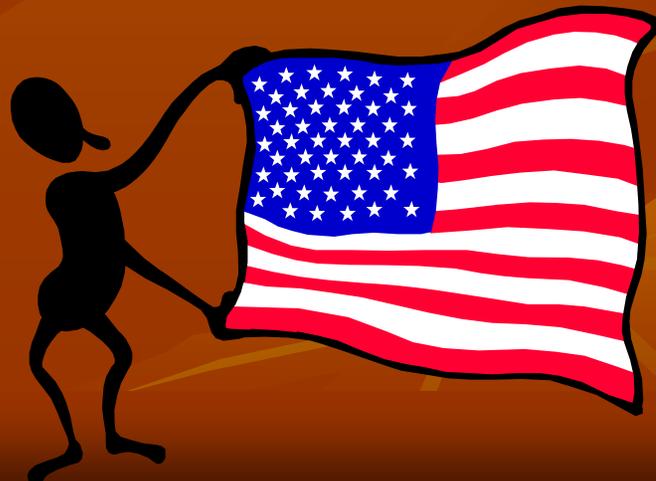


Electronic Entry Data

- **importing product on Import Alert – do homework – www.fda.gov**

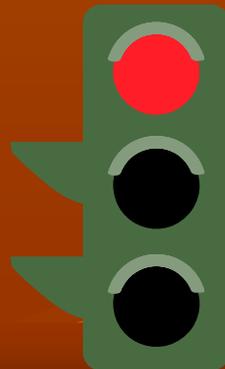
Electronic Entry Data

- **failure to provide reason for US goods returned entries**



Crossing Issues

- failure to stop at FDA when "FDA Review" displayed after receipt of CBP conditional release



Crossing Issues

- drivers unfamiliar with border procedures, including failure to check with broker upon arrival at crossing – may already be “may proceeded”



Crossing Issues

- drivers lacking paperwork/entry data when reporting to FDA



Crossing Issues

- **failure to hold entry intact prior to receiving FDA disposition on entry 21 CFR 1.90 & Bond Action**

Compliance Review

- premature calls on products sampled and undergoing analysis – COs generally not assigned a case until analysis completed



Compliance Review

- multiple calls from different parties on the same subject



Compliance Review

- **failure to respond to Detention Notice within 10 days will result in Refusal**

Compliance Review

- **repeated shipment of misbranded product, with the plan of relabeling in the US – Import Alert for non health hazards**

The End

- Organizational Chart in your packet.
Call us if you have a question.
- Work with us – working together we can speed the process and make everyone's job easier.