WHAT FDA IS LOOKING FOR WHEN REVIEWING IMPORT ENTRIES

This is not comprehensive so the FDA website or FDA should be consulted. We are not FDA experts and the Importer is responsible to confirm their requirements and compliance with agency laws. All information is advisory only and is subject to Coppersmith Terms & Conditions of Service.

General:

- Invoices should have adequate product name and/or description in English so FDA can determine if they regulate the item
- In addition to the Shipper MID (name & address) we must provide the Manufacturer or processors MID for each product
- The shipping units from largest to smallest packaging (inner packs, container or # of items per carton)
- Report if food products are being held at ambient or refrigerated or frozen conditions
- FEI code (Name & address other than importer for US location of goods after release)
- Brand Name if applicable
- Qty, Base Unit and Container Codes (FDA codes applied by broker from invoice information)
- Model Numbers
- Additional information not already accounted for in specific fields such as Fermented, Bulk for further processing, pH level, OTC etc. which provide details necessary to assist in review

For specific products FDA is also looking for the following as Affirmations of Compliance (A of C)

Medical Devices

What is a Medical Device? www.fda.gov/cdrh/devadvice/312.html

Medical Devices range from tongue depressors and bed pans to complex pacemakers, surgical devices, in vitro diagnostics, general purpose lab equipment, reagents, and test kits. Also, certain electronic radiation emitting products such as ultra sound, x-ray and lasers for medical and industrial use are medical devices.

Any product that is labeled or promotes or is used in a manner to cure, treat, mitigate or prevent disease in man or animal but is not a drug.

The DEV and PMN can be verified on the FDA website: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm

The DEV is available if the filer has a current registration, this must be renewed each year.

The DEV will list products, each product will have a product code that was applied for and should be used on the entry/FDA submission.

Product Code: IME

Device Class: 1

Regulation Number: 890.5700

Industry	Product	Code
Physical Medicine	Portion of device code / Pack, Hot Or Cold, Reuseable	89 I - - ME

WHAT FDA IS LOOKING FOR WHEN REVIEWING IMPORT ENTRIES CONT.

Here are some of the A of C (Affirmations of Compliance) that FDA is looking for on an entry with a Medical Device.

DEV – **D**evice **E**stablishment **R**egistration Number (foreign manufacturer) (Example DEV 3001234567)

DII – Device **I**nitial **I**mporter Registration Number (Importer who takes 1st title to device into the U.S.) **(NEW)**

DFE- **D**evice **F**oreign **E**xporter Registration Number (Exporter who exports or offers to export for a foreign entity in a foreign county including devices originally manufactured in the U.S. **(NEW)**

LST – **L**isting **N**umber for specific product (filed by either party and is **proprietary**) (Example LST A123456)

PMN – **P**re**M**arket **N**otification (501K) (Example PMN K950123)

PMA – **P**re**M**arket **A**pproval Number

MDL – Model Number **(NEW)**

CPT – Device Component (component of a device that requires further processing OR inclusion into a finished device. This is not used if the component is classified by FDA as a finished device such as components of wheel chairs. **(NEW)**

CFR – Exempt from 510K (example CFR 872.6855)

IRC - **I**mpact **R**esistant Lens **C**ertificate (No qualifier used) Certifies filer has on hand test result or certificate that product meets impact resistance standards.

FOOD

Bioterrorism Act (BTA) what's needed?

Under BTA "food" is defined as: Articles of food or drink used for man or other animals (human and animal food including dietary supplements); Chewing Gum; Articles used as components of any of the above, except food contact substances and pesticides. Exemptions: Meat, poultry and eggs, (USDA), homemade goods as gifts, personal food.

Registration Number of foreign facilities, **all locations of facilities not per entity** that manufacture, produce, pack, or hold food must be reported.

Low Acid and Acidified Foods (includes cans, jars, pouches etc.)

FCE – Food **C**anning **E**stablishment Registration (Example-FCE 12345)

SID – Submission **I**dentifier (Example – SID 950105001) and Container Dimensions (**DIMS** 300x 407)
SID's are the process that is filed by the foreign food processor and includes the description & container size. We recommend you ask for a copy and advise the supplier to include the information on the Commercial Invoice exactly as it is on the SID.

Seafood (Use acceptable market name or common name)

SIF – Seafood **I**mporter **F**irm (Example – SIF followed by an FEI obtained for the US importer)

Drugs

(Veterinary products have separate A of C's)

What is a Drug? FDA Drug Pathfinder http://www.fda.gov/cder/drug/default.htm

DLS – **D**rug **Li**sting Number (Example – DLS N-123456 or C-1234)

NDA- **N**ew **D**rug **A**pplication (Example – NDA 20-123)

AND – **A**bbreviate **N**ew **D**rug (Example – AND 70-123)

IND – **I**nvestigation **N**ew **D**rug (Exemption for) (Example – IND 40,123)

CFR – Statement for Investigation Non-Human Use (Example CFR 312.160)

Radiation-emitting electronic products

What is a Radiation Emitting Electronic Product? http://www.fda.gov/cdrh/radhealth/products/bytopic.html A to Z

ORIGINAL SIGNED 2877 by the Importer of Record must be in the file for all applicable entries.

ACC EPRC (**E**lectronic **P**roduct **R**adiation **C**ontrol) Accession Number

ANC EPRC Annual Report Accession Number (due annually by September 1)

RA1 EPRC Product Declaration A1 (FDA 2877)
Products that were manufactured prior to the effective date of an applicable performance standard. The qualifier needed is the date of manufacture.

RA2 EPRC Product Declaration A2 (FDA 2877)
Excluded from the applicability clause or definition in the standard or by FDA written guidance. Specific reason for exclusion is required with transmission of this code.

See the FDA form 2877 for the declarations for RA3, RA4, RA5, RA6 and RA7
As well as RB1, RB2, RC1, RC2, RD1, RD2 and RD3
FDA Form 2877 can be found at www.coppersmith.com under Customer Forms.

Here are a few other areas under FDA's purview.

Fresh and Frozen Shellfish
Soft Cheese
Food and Color Additives
Cosmetics
Biologics
Veterinary Products

Note: Other A of C's exist, but are not as common and are not listed here.