

FDA Affirmations of Compliance

Affirmations of compliance are additional pieces of information such as medical device listing, drug listing, Radiation Declaration, FCE/SIDS (canning establishment). In all, there are more than 200 different types of Affirmations of Compliance in the differing industries within FDA jurisdiction.

Requirements vary by commodity; check with your customs provider to see what applies to your product database. To help you identify what some of these codes might be, we have highlighted the most common ones, per FDA category.

Food

- FCE - Food canning establishment number
- SIDS - Schedule identifier (container dimensions are required also)
- AIN - Food additive identification number
- FAP - Food additive petition approval number
- IBP - Indian black pepper certificate number
- PFR - Manufacturer food facility registration number
- SFR - Shipper food facility registration number
- JIF - Juice HACCP importer firm number
- SIF - Seafood HACCP importer food number

Drugs

- DLS - Drug listing number
- IND - Investigational new drug number
- DA - New drug application number
- REG - Drug registration number (DUNS number)

Medical Devices

- PM# - Device premarket notification number 510k
- DEV - Device foreign manufacturer registration number
- IDE - Investigational device exemption number
- LST - Device listing number
- DFE - Device foreign exporter registration number
- PMA - Device premarket approval number
- DDM - Domestic device manufacturer
- CPT - Device component

Biologics

- PMA - Biologics device premarket approval number
- PMN - Biologics premarket notification number 510k
- HDE - Humanitarian device exemption
- HRN - Biologic cells, tissues product establishment registration

- IND - Biologic investigation new drug application number
- BLN - Biologic license number
- STN - Biologic submission tracking number

Veterinary Medicine

- VAN - Veterinary abbreviated new animal drug number
- VFL - Veterinary medicated feed license
- VIN - Veterinary investigational new animal drug number
- VNA - Veterinary new animal drug application number
- REG - Drug Registration number

Cosmetics

- COS - Cosmetic registration number (voluntary registration)

Electronics

- Multiple affirmations - Provide 2877 form for radiation-emitting products

Contact Livingston

www.livingstonintl.com



Have questions or need help with your FDA imports under ACE?

Contact your account executive,

write to us at: simplify@livingstonintl.com

or give us a call at **1-855-225-5548**