



R.L. JONES
CUSTOMHOUSE BROKERS
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FDA - ACE DATA UPDATES

To assist the industry with the transition to ACE, the FDA will **temporarily** relax the below requirements:

- Intended Use** - Impacted Commodities = Biologics; Drugs; Tobacco; **Medical Devices**; Radiation-Emitting Products – if Intended Use is not available, provide a value of “**UNK**”
- Trade/Proper/Brand Name** – Impacted Commodities = Biologics; Drugs; Animal Drugs/Devices; Tobacco; Radiation-Emitting Products – if Trade, Proper or Brand name is not available, provide a value of “**UNK**”
Medical Devices = Optional Requirement if claiming:
***NED (Non-Radiation Emitting Device)**
- Device Listing Number (LST)** - Impacted Commodities = Biologics; **Medical Devices** – if Intended Use is not available, provide a value of “**UNK**”
- API Producer** – Impacted Commodity = Drugs; if Active Ingredient Producer is unknown at time of entry, this field may be left blank.

PLEASE NOTE: It is highly recommended to transmit **ALL** Data Elements. If not available, we can submit “UNK”. However, this will make the entry subject to a manual review by FDA and may take longer to release the entry.

The changes will become effective after **April 4th 2016.**

ACE Entries will have priority over ACS Entries