Relaxation of Four Data Elements

Food and Drug Administration
Office of Regulatory Affairs
Office of Enforcement and Import Operations
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Background

- To assist industry in the transition to ACE, FDA will relax the requirement for:
  - API Producer,
  - Intended Use,
  - Brand Name, and
  - Device Listing Number
- Filers may temporarily submit a value of “UNK” (unknown)
- Once the entry gets to FDA, the Agency may request documentation related to the aforementioned data in order to make an admissibility decision

Active Ingredient Producer

- Impacted Commodities: Drugs
- If Active Ingredient Producer is unknown, entry may be transmitted without providing this entity
- Message Set Record: PG19/20 (Entity Role Code “GD”)
- This data element is becoming optional

Trade/Brand/Proper Name

- Impacted Commodities: Biologics; Drugs; Animal Drugs/Devices; Tobacco; Radiation-Emitting Products
- If Trade, Brand, or Proper name is not available, provide a value of “UNK”
- Message Set Record: PG07
- Allowed value of “UNK” is temporary

Intended Use Code

- Impacted Commodities: Biologics, Drugs, Tobacco, Medical Devices, Radiation-Emitting Products
- If Intended Use is not available, provide a value of “UNK”
- Message Set Record: PG01
- Allowed value of “UNK” is temporary

Device Listing Number (LST)

- Impacted Commodities: Medical Devices; Biologics
- Device listing is required per 21 CFR 807
- If Device Listing Number is unknown, provide Affirmation of Compliance “LST” with a description of “UNK”
- Message Set Record: PG23
- Allowed value of “UNK” is temporary

FDA's Guidance

- FDA highly encourages the submission of entries with complete and correct data, including:
  - API Producer,
  - Brand/Trade/Proper Name,
  - Intended Use, and
  - Device Listing Number.

FDA's Guidance

- Although CBP will not reject entries that have no API Producer or values of "UNK" for LST, Trade/Brand/Proper name, or Intended Use, FDA may request documentation to determine why complete data was not provided.

- Entries that include complete data will be prioritized and may receive systematic May Proceeds. Entries with missing information may result in manual review, requests for further information, and delays in processing.

Accurate, Consistent, & Complete Data

- To expedite entry processing, importers and entry filers should provide:
  - Consistent, accurate, & complete PGA Message Sets

- With this data FDA will expedite the review process