

NEWLY REQUIRED FDA DRUG DATA ELEMENTS IN ACE

Shapiro is fully programmed for all FDA filings and has been actively filing FDA through ACE for many months. So far, we have limited this to a subset of customers while FDA and CBP worked out technical and operational issues. Most of these issues have been resolved and Shapiro will be moving to full FDA filing via ACE in the next 30 to 60 days.

While a hard deadline has yet to be set to make FDA filing via ACE mandatory, it is coming and most certainly will be required before the end of the year. In regards to filings for FDA drugs, there are a few new data elements that were previously not required for filing FDA drugs. Below is a list and brief description of the new required elements for FDA drugs in ACE.

Our goal is to assure all of our customers are as prepared as possible, and that there are no delays in facilitating the release of their products. If you have any questions about these new requirements please reach out to your account coordinator for further information.

Brand Name: The brand name the drug is to be sold under

Deliver to Party: U.S. party that physically receives the goods

Agency Processing Code: Possible codes shown below

- Investigational
- Over the Counter
- Pharmaceutical Necessities
- Prescription
- Research & Development

Intended Use Code: Possible codes shown below depending on Agency Processing Code

Prescription (PRE)		
Finished Form	080.000	For Human Medical Use as a Non-Food Product under Controlled Distribution
Finished Form	970.000	Import for Export
Finished Form	100.000	Importation for Personal Use
Finished Form	155.012	Drug to be used as a constituent part in a Medical Device
Not Finished Form: Active Pharmaceutical Ingredient/Bulk Drug Substance	150.007	For processing into a pharmaceutical product.
Not Finished Form: Active Pharmaceutical Ingredient/Bulk Drug Substance	970.000	Import for Export
Not Finished Form: Active Pharmaceutical Ingredient/Bulk Drug Substance	150.017	Drug to be used as a component in a Medical Device

Over the Counter (OTC)		
Finished Form	130.000	For Consumer Use as a Non-Food Product
Finished Form	970.000	Import for Export
Finished Form	100.000	Importation for Personal Use
Finished Form	155.012	Drug to be used as a constituent part in a Medical Device
Not Finished Form: Active Pharmaceutical Ingredient/Bulk Drug Substance	150.007	For processing into a pharmaceutical product.
Not Finished Form: Active Pharmaceutical Ingredient/Bulk Drug Substance	970.000	Import for Export
Not Finished Form: Active Pharmaceutical Ingredient/Bulk Drug Substance	150.017	Drug to be used as a component in a Medical Device
Pharmaceutical Necessities & Containers (PHN)		
No intended use codes for this commodity sub-type.		
Research and Development (INV)		
180.009		Chemical for research and development in a pharmaceutical product – clinical trial or other human/animal use.
Research and Development (RND)		
180.017		Chemical for research and development in a pharmaceutical product – laboratory testing only, no human/animal use.

ABOUT SHAPIRO

Shapiro, a third generation family-owned business founded in 1915, provides creative and flexible logistics services. With six offices, over 100 employees, and worldwide strategic alliances, Shapiro is the supply chain partner that delivers customized, compliant, and reliable solutions to address your specific import and export needs. Only Shapiro has an experienced and personable staff that truly cares about your company and commits themselves to proactively achieving your business goals.

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