ACE: Specific Information for Pharmaceutical Importations

Central Atlantic States Association of Food and Drug Officials Pharmaceutical Industry Seminar

April 25, 2016

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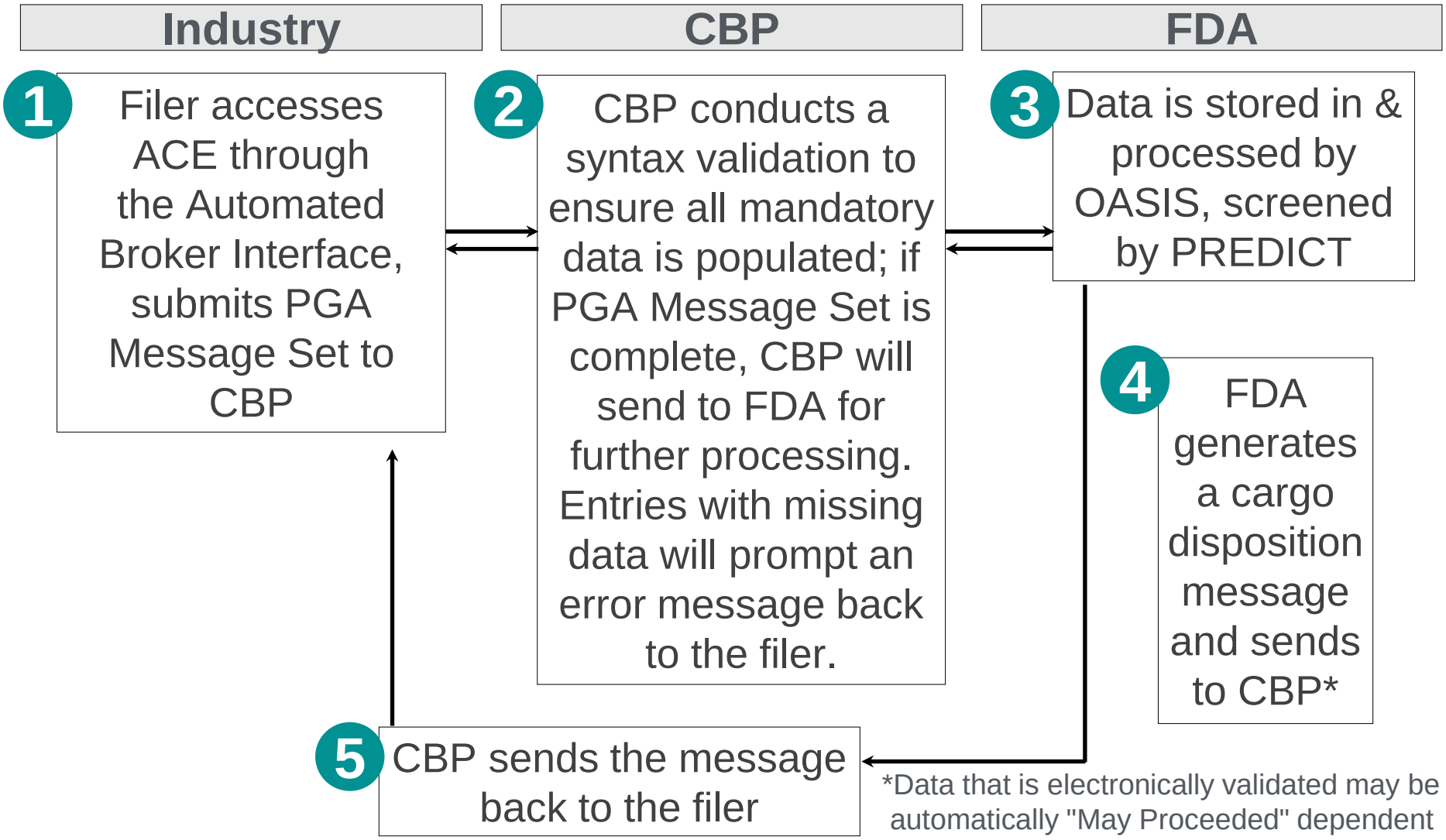
How Does ACE Change Current Business Processes?

- All entry information for all partner government agencies (PGAs) is submitted in ACE; messages from each agency are sent back to the filer
- FDA will require complete data sets at the time of transmission of the entry
- Complete and correct information will reduce the need for document requests, and improve processing times

FDA ACE Process



*Data that is electronically validated may be automatically "May Proceeded" dependent on risk ranking

Import Process

- Importer provides entry information to Entry Filer (or “Broker”)
- Entry Filer transmits entry data to Customs
- Customs forwards FDA-regulated products to FDA
- FDA uses entry data to determine admissibility

Import Process

FDA conducts Entry Review; decision to:

- **Release**
- **Detain** without exam based on--
  - *Submission of required information*
  - Import alerts
- **Request more information** through--
  - Documents
  - Examination and/or sample collection

ACE: Importing Drug Products

Expedite FDA's Processing by Providing:

- Correct FDA Product Code and Intended Use Code
- Accurate Product Description (Active Ingredient/Brand or Trade Name)
- Name, Address (and DUNS# if known) for:
  - Manufacturer, Shipper, Importer, Delivered To Party
- *Affirmations of Compliance: (required based on Intended Use)*
  - REG (Drug Registration)
  - DLS (Drug Listing)
  - DA (Drug Application Number)
  - IND (Investigational New drug)

Affirmations of Compliance

- AoCs are used to provide additional information:

  REG = Drug Registration Number

  DLS = Drug Listing Number

  NDA = New Drug Application Number*

  AND = Abbreviated New Drug Application Number*

  IND = Investigational New Drug Number

- Entry filer submits AoCs in electronic transmission

* In ACE, NDA and AND are combined into “DA”

Affirmations of Compliance

- TODAY: AoCs are not required
  - Entry reviewers verify info regardless of AofC submission
- BUT, AoCs will **speed** entry review
  - New system automates lookup but only if AoCs provided
  - Accurate info likely to receive **"Systems May Proceed"**
  - Otherwise, time-consuming manual lookup required

ACE: Affirmations of Compliance

- With ACE: AoC information will be required
  - Entries cannot be submitted to FDA without this information

  - **Prompts for necessary information** based on entry declarations
    - **Registration** numbers for declared manufacturers
    - **Listing** numbers
    - **Approval** numbers for prescription drugs
  - AoC information will be necessary to make entry
  - Builds in edits for exemptions

ACE: Affirmations of Compliance

Data prompts will help **speed** FDA entry decisions

- **Accurate** information = more **efficient** processing
- **Accurate** information = more **system-based releases**

ACE and Pharmaceutical Products

- Take-home message:
  - Know your products
  - Know the product requirements
  - Give your Entry Filers the information they need
    - They won't be able to process your entry without it
    - With the right information, your entry will process quicker

- FDA is prioritizing the transition to ACE
  - Talk to your Entry Filer about filing through ACE
  - Be ready when ACE becomes mandatory January 2017

Drug Entry Review

- Drug provisions apply (not imports)
- Entry reviewers verify information
  - **Drug Registration (§510(i))**
  - **Drug Listing (§510(j))**
  - **Drug Approval (§505)**
- Information provided in entry transmission
  - **Declared manufacturer**
  - **Declared Importer/Consignee**
  - **Product description**
  - **Affirmations of Compliance**

Drug Entry Review

- **"Drugs"** include:
  - Finished dosage form drugs
  - Active Pharmaceutical Ingredients (API)
- **APIs**
  - Same **drug requirements apply**
  - Must be **listed**
  - Must be intended for an **approved use**
  - Labeling exemption in 21 CFR 201.122

Drug Entry Review: Registration

- **Site specific**
  - Manufacturers required to register (510(i))
  - Manufacturing **facility (NOT corporate office)**
  - **Declared manufacturer** in the entry declaration

- Includes **known importer**
  - Foreign manufacturer identifies all known US importers
  - Also, **declared importer or consignee**

Drug Entry Review: Registration

Entry Information verified against FDA sources

- Information doesn't match = **appearance of violation**
- Product **detained as misbranded** per FFD&CA 502(o)

Drug Entry Review: Drug Listing

- Site Specific
  - Manufacturers submit **product list** to FDA (510(j))
  - Product declaration: **FDA Product Code and description**
  - Includes **dosage form & strength**
- Entry Information **verified** against FDA sources
  - If information doesn't match, product **appears violative**
  - **Detained as misbranded** (502(o))

Drug Entry Review: Approvals

- Approval is **product specific**
  - Must include dosage form and strength
  - Product description in entry declaration
- **Foreign source must be approved** in marketing approval
  - Manufacturing facility (NOT corporate office)
  - Declared manufacturer in entry declaration

Drug Entry Review: Approvals

- Product must go to **approved entity**
  - Either **declared importer** or **consignee** in the entry declaration
- If information in entry cannot be verified:
  - Creates **appearance of violation**
  - Product detained as unapproved (505)

Drug Entry Review: Approvals

Approval is very specific

- Product
- Dosage form and strength
- Firms involved in manufacturing process
  - Manufacturer
  - Packager
  - Testing Labs
  - Raw Materials Sources
- Labeling

Drug Entry Review: Approvals

Any information not consistent with information in approved application is an Unapproved Drug

Drug Entry Review: Investigational New Drugs

- Investigational New Drugs are **product specific**
  - Must include dosage form and strength
  - Product description in entry declaration
- **Foreign source must be identified** in the IND
- The IND must be in effect
- Imported by or consigned to the **IND sponsor, their agent, or qualified investigator**

Drug Entry Review: Exemptions

- Limited exemptions from approval requirements
  - Investigational New Drugs
  - R&D Products
  - Specific drug shortage issues
  - Personal Importations
  - Pre-Launch (PLAIR)

Drug Entry Review: Exemptions

- Limited exemptions from labeling requirements
  - Products for law enforcement use
  - R&D Products
  - Products for further manufacturing
- Not an all-inclusive list

Drug Entry Review: Exemptions

- Exemptions to be **claimed during entry**
  - FDA will not assume an exemption

- **Importer's responsibility** to claim exemption
  - Ensure declarations are correct
  - Ensure entry filer understands requirements

Drug Entry Review: Detentions

Detentions occur when:

- Declared manufacturer/product combination is not listed

OR

- Declared manufacturer/product/importer combination are not part of an approval

AND

- No exemption exists

Drug Entry Review: Detentions

Entry review process **matches** entry information with internal databases to **verify**:

- Is declared manufacturer registered?
- Does registration include declared importer as "known importer?"
- Has declared manufacturer listed product in correct dosage form and strength?

Drug Entry Review: Detentions

- Is drug approved?
- Is declared manufacturer included in approval?
- In correct dosage form and strength?
- Is declared importer/consignee listed in approval as sponsor or other entity included in approval?

Drug Entry Review: Detentions

- **Inaccuracies cause delays!**
  - Firm info matters
  - Particulars matter
  - Any “no” answer will result in delays
- FDA wants to **facilitate compliant trade**
  - Accurate declarations will avoid delays
  - Moving compliant trade is in everyone’s interest

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Thank You!