NAFTZ Annual Conference & Exposition

Brief Primer on FDA & FTZs

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PRESENTATION OVERVIEW

I. Imports into FTZs and FDA

- Section 801 of FFD&CA
- “imported or offered for import”
- Entry Admissibility

II. Weekly Entry Filing Process

- General FDA Process
- Procedure Development

FDA Import Law

- Covered by the Federal Food Drug & Cosmetic Act (section 801)
- 801(a): Allows for refusal of apparently violative FDA-regulated products which are "…being imported or offered for import"
- Focuses on the product, not the importer or their activities

FDA Import Law
"imported or offered for import"

- FDA relies on CBP definition of "import"
- Goods going into the FTZ are not considered "imported or offered for import"
  - see: Customs Territory of the US
- FDA does not make an 801(a) admissibility determination on goods entering an FTZ

See FDA Compliance Policy Guide 110.600:

http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm073833.htm

FDA Import Law
Entry Admissibility

- Articles which may otherwise be inadmissible can be brought into an FTZ

- FDA does have jurisdiction:
  - FDA can take action if there are issues
  - Other sections of law have to be used
  - Using 801(a) to refuse is not an option

- FDA does make an 801(a) admissibility determination on goods withdrawn from the FTZ for US consumption
  - Product must be compliant with laws & regulations

FDA - FTZ Activities

- Activities conducted within an FTZ do fall under FDA's jurisdiction
  - Registration requirements may apply
  - Subject to FDA Establishment Inspection

- FDA can take action if there are issues
  - Know the requirements for manufacturing products intended for export [section 801(e) & section 802]

See FDA Compliance Policy Guide 110.200:

http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm073831.htm

FDA - Export from FTZ

- Know the export requirements
  - Section 801(e)
  - Section 801(f) – Drug labeling
  - Section 802 – Drugs & Devices

- Depending on your business model:
  - May be simpler than Import for Export
  - May be an option when IFE isn't allowed
  - May be alternative to PLAIR

FDA Imports & FTZs Summary

- FDA does not determine admissibility of products going into a foreign trade zone under 801(a)
  - Other entry requirements may apply
    - Prior Notice for food and feed - 801(m)

- FDA does determine admissibility of products being withdrawn from an FTZ for US consumption:
  - Must meet all applicable product requirements

FDA Imports & FTZs Summary

- Activities within the FTZ do fall under FDA's jurisdiction
  - Facility/processing requirements may apply
    - Registration requirements – check with the appropriate FDA Center
    - Establishment Inspection
  - Products intended for Export
    - Know & Comply with Export requirements
      - 801(e)
      - 801(f)
      - 802
    - May be an alternative to Import for Export

Weekly Entry Filing

- FDA's Weekly Entry Filing Process
  - Developed ~ 1994
  - Requires firms/products have a compliant history
    - Determined by review of information provided
  - Requires products be designated "low risk"
    - "Low risk" language taken from FTZ Manual regarding WEF
    - Risk designations made by FDA Product Centers

Weekly Entry Filing - Process

- FTZ Operator provides data to FDA District
  - Firms involved
    - Foreign suppliers
    - Domestic processor
  - Products involved
    - Raw materials
    - Finished goods

Weekly Entry Filing - Process

- FDA's focus is different than CBP's
  - FDA is not concerned about how much
    - A product is admissible (or inadmissible) whether there are 10 units being entered or 10,000,000
  - FDA is concerned with admissibility
    - We ask for more information regarding who and what are involved
  - FDA will check historical data for compliance
    - Compliant history = Yes
    - Non-compliant history = No

Weekly Entry Filing - Process

- FDA allows WEF only for “low risk” products
  - FDA Product Centers make risk determinations
    - “Low risk” = Yes
    - Not “low risk” = No

- If there is a compliant history and the product is low risk, WEF will be allowed for the product
  - FDA screening criteria is adjusted to allow expedited processing

Weekly Entry Filing - Procedure

- FDA is developing a step-by step procedure for WEF
- Mirrors the 1994 process

  - Provides criteria for compliance review determinations
  - Standardizes the review flow
  - Standardizes decision making
  - Standardizes feedback to the requestor
  - Provides a format for submitting WEF applications

Weekly Entry Filing - Procedure

- We have discussed the procedure with NAFTZ
- Have provided to NAFTZ for feedback
  - We want to hear from the FTZ community
- We can make no promises on an implementation date
  - We are trying out the process in certain Districts

Thank you

Questions?