NAFTZ Annual Conference & Exposition

Brief Primer on FDA & FTZs

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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:
• 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• FDA does make an 801(a) admissibility determination on goods withdrawn from the FTZ for US consumption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:
• 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• FDA does determine admissibility of products being withdrawn from an FTZ for US consumption: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
• 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?