U.S. Department of Health and Human Services

Food and Drug Administration

Overview of Operational Components of Prior Notice

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ORA OPERATIONAL OVERVIEW

- Prior Notice is a "Reporting" requirement
  - Not an [801(a)]Admissibility Requirement

- Components of Prior Notice
  - Receipt
  - Review
  - Response

Components of Prior Notice

- **Receipt**
  - **ABI/ACS**
  - **PNSI**
  - **Email/Fax (Contingency ONLY)**
- **Review**
  - **Prior Notice review will occur in a Central Location (not local FDA Districts)**
  - **Prior Notice review will occur 24/7**
  - **Prior Notice review will be separate from, and occur prior to, [801(a)] admissibility review**

Components of Prior Notice (continued)

- **Response**

  - **PN review will determine what shipments require a response at the border**

  - **Response will be accomplished by either FDA or CBP - depending on the port and time of arrival**

Components of Prior Notice (continued)

- Response may consist of:

  - Cargo examination/verification

  - Sample collection

  - Direction of shipment to a secure facility or storage at the port of arrival or port of entry if PN is inadequate

Admissibility of Cargo

- Admissibility is determined as per Section 801(a) of the FFD&CA
- Admissibility of cargo will continue to be determined at local FDA offices
- Admissibility decisions will be made after Prior Notice requirements have been met

Screening of International Mail

International mail will be screened by CBP as follows:

- **Food mailings without a Prior Notice confirmation number on the declaration will be identified**

  - Packages with return addresses may be returned to sender

Screening of International Mail (continued)

- packages without return addresses and containing only food, may be destroyed at FDA expense

-"Mixed" packages without return addresses may have the food products removed, a form letter inserted, and sent to addressee

Enforcement of Prior Notice

- FDA plans to exercise enforcement discretion for over first several months after Prior Notice goes into effect

For Further Information . . .

- For current information on FDA's efforts under the Bioterrorism Act you may access information at the following URL:

  http://www.fda.gov/oc/bioterrorism/bioact.html