FDA Challenges of Importing Dietary Supplements into the US

FDA Product Violations Related to Dietary Supplements

- Adulteration -- contains poisonous or deleterious substance injurious to health, unsafe pesticide residue, unsafe food additive, unsafe new animal drug, filth; or is otherwise unfit for food; or was prepared, packed, or held under insanitary conditions [21 U.S.C. 342]
- Misbranding -- labeling is false or misleading, fails to declare major food allergen, or fails to meet nutrition labeling or other labeling requirements [21 U.S.C. 343]
- Unapproved New Drug – if a dietary supplement has claims that it diagnoses, treats, cures, or prevents disease, then it may be considered a drug by FDA and be charged as an unapproved new drug.

Importing Dietary Supplements - Consider these before you bring your product into the US

Import checklist:

- ❑ Check ingredient list for non-permitted ingredients, non-permitted colors or colors that require certification; check for proper ingredient declaration
- ❑ Format labels properly – Statement of Identity, Net Quantity, Supplement Facts, Ingredient List, Manufacturer/Packer/Distributor, Country of Origin
- ❑ Animal-origin ingredients requiring a permit (APHIS/USDA)
- ❑ Low-acid or acidified canned food (pH/water activity)

Importing Dietary Supplements

Import checklist (continued)

- ❑ Disease claims – use caution to avoid FDA drug regulation (see page 6)
- ❑ Follow Food Facility Registration requirements
- ❑ Obtain Customs licensed broker familiar with FDA requirements
- ❑ File Prior Notice – a notification to FDA in advance of the arrival of the food at the border. Requirement of the Bioterrorism Preparedness and Response Act of 2002

If FDA wants to examine your shipment, here is what to expect

- Information needed for FDA review
  - Invoice, packing list
  - Product code
  - Firm names and addresses
  - Statement of intended use
  - COA, MSDS, other supporting documents
  - Copies of Labels
- Information is reviewed by Entry Reviewer; release or further review/exam
- Field Investigator conducts exams, collects sample for lab analysis
- Compliance Officer reviews entry if sample collected or any appearance of violation observed – releases, detains, refuses shipment

What can halt my products?

- Common reasons for FDA detentions of dietary supplements
  - Disease claims on labeling (includes the product website, product inserts, any accompanying promotional literature, etc.) which cause the product to be deemed a drug by FDA. Dietary supplement labeling cannot bear claims that the product diagnoses, cures, mitigates, treats, or prevents any disease.
  - Labeling includes structure and function claims that are not truthful or that are misleading
  - Label violations, e.g., no English, no Supplement Facts, no Statement of Identity
  - Prohibited/undeclared ingredients, e.g., sibutramine, ED drugs, ephedrine
  - New dietary ingredient that is unsafe or not adequately evaluated for safety
  - Unapproved/undeclared colors
  - Pesticides
  - Filth

Often the things that halt shipments are tied to FDA Import Alerts

- Internal decision by FDA that future shipments of a product will appear subject to import refusal (“automatic detention” or “detention without physical examination”)
  - Typically includes information on shipper/manufacturer and specific problems found with product
  - Some are country- or region-wide
- Once the shipment is automatically detained:
  - Importer has opportunity to present evidence that this particular shipment complies
- Import Alerts for Dietary Supplements:
  - 54-13 (cGMPs)
  - 66-41 (unapproved new drugs)
  - 99-08 (pesticide residues)

How can I get off Import Alert?

- FDA wants to see evidence that
  - The problem was found and fixed
  - Future entries will be compliant - usually through entry history
  - Other evidence as necessary
- Petitions to remove a firm from an import alert are filed with the Division of Import Operations

How to avoid delays with your shipments

- Provide thorough and accurate information upfront
- If FDA requests entry documentation, submit ASAP
- If FDA requests exam/sampling, send location ASAP
- Important information on FDA notices – contact information for reviewer/compliance officer, detention due dates, charges
- Address any detentions before due date! (Propose reconditioning, challenge the detention, request extension)
- Remain in communication with appropriate FDA contact
- Anticipate possible problems in advance e.g., labels correctly formatted, no disease claims, ingredient check, etc.
- Participate in FDA's VQIP once it is finalized

Questions? Need Help?

FDAImports.com works with companies from all over the world to successfully distribute and market products in the United States that are regulated by FDA, USDA, and U.S. Customs and Border Protection.

- Registration and US Agency
- Label review and claims analysis
- FDA detentions and refusals
- Import alert assistance
- FDA inspections
- New product evaluation

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