US FDA Published Brand New Import Alert Category Relating to FDA Facility Inspection Refusals

The United States Food and Drug Administration ("FDA") published an entirely new category for Import Alert relating to Facility Establishment Inspections. This new Import Alert #99-32, "Detention Without Physical Examination of Products From Firms Refusing FDA Foreign Establishment Inspection" ("IA 99-32"), entitles FDA with the enforcement right to refuse any and all products entering United States Commerce from a firm which refuses FDA of the right to inspect their manufacturing facility. Benjamin England, founder of FDAImports.com, LLC and former FDA employee of 20 years, notes that, "Although allowing FDA to inspect your foreign facility may result in undesirable comments on your Form 483, it is far more detrimental to be automatically detained for denying the inspection in the first place."

All manufacturing facilities, of all FDA regulated products, are subject to intense FDA inspection for current Good Manufacturing Practices ("cGMP"), safety, and sanitary conditions. Following each facility inspection, FDA issues a Form 483, which outlines any objectionable conditions observed during the inspection. Any facility which does not comply with the strict FDA guidelines and regulations may receive enforcement FDA Notices of Action such as Warning Letters of Untitled Letters. "It is far simpler to correct an objectionable Form 483 from FDA," says Mr. England, "than it is to petition to be removed from an FDA Import Alert."

Any firm placed on IA 99-32 is charged under Section 801(a)(1) of the Federal Food, Drug and Cosmetic Act (the "Act"), stating that the Article(s) is refused entry for reason of appearing to have been manufactured, processed, or packed under insanitary conditions. Although this may not be the case, it is FDA's right to assume by proof of refusal to inspect the facility conditions.

"The FDA Guidance for IA 99-32 clearly outlines the leaps and hurdles which will be necessary to be removed from the Alert," says Mr. Benjamin England. All FDA Import Alerts contain a Guidance section which define the actions necessarily required in order to be removed from the Alert. "Although these are only Guidelines, meaning 'tips and suggestions'," adds Mr. England, "FDA tends to treat them more like regulations and requirements."

The Guidance for IA 99-32 states that "FDA considers submission of analytical results to be insufficient to overcome the appearance of the product having been prepared, packed, or held under insanitary conditions." It also states that a third party facility inspection is not sufficient to offer as evidence of FDA compliant manufacturing practices. Only FDA may inspect the facility, and if found to comply with cGMP's, may they consider removing the firm from the Import Alert.

If you refuse to allow FDA the right to inspect your facility, expect to be placed on this new Import Alert for the appearance if manufacturing, processing, and packaging under insanitary conditions. FDAImports.com, LLC, a Food and Drug Law consulting firm, can assist you with all necessary actions which may be required to be removed from the Import Alert. If, on the

other hand, you allow FDA to inspect your foreign facility and receive objectionable results on your Form 483, FDA expects a written response to answer any objections. These responses must address the agency's concerns and should include manufacturing, storage, processing or operating procedural changes undertaken based upon the inspection. FDAImports.com is able to assist you in the complexity of responding to such Form 483s, Warning Letters, and Untitled Letters. Let FDAImports.com show you 'the way through'. Don't allow a facility inspection keep your product out of the United States market.