



PHARMACEUTICALS EXPORT PROMOTION COUNCIL

(Set up by Ministry of Commerce, Govt. of India)

COPY

Date : 15-05-2010

News / Story reproduced with thanks:- **Pharmabiz**

US FDA adds 25 firms to Red List in Import Alert for promotion of unapproved drug, say experts

Saturday, May 15, 2010 11:00 IST Maryland

Direct link to the News/Story:-

<http://www.pharmabiz.com/article/detnews.asp?articleid=55475>

The US Food and Drug Administration (FDA) has added 25 more firms to the Red List in the first five months of this year, as it has republished its Import Alert for detention without physical examination of unapproved new drugs promoted in the country, on May 11, 2010, reveals a regulatory consulting firm in US.

Over 300 foreign manufacturers have been placed on the Import Alert #66-41 Red List, charged with promoting unapproved drugs to people in the US. The regulator enforces laws and regulations related to new drug approvals and now, FDA often applies these laws to dietary supplements, dietary ingredients and even to cosmetics, according to experts from FDAImports.com, LLC, the regulatory consultant firm in US.

According to Benjamin L England, of FDAImports.com, LLC, "Generally, US FDA won't allow unapproved drugs into the US at all. US FDA may exercise some discretion for personal use in certain circumstances but they are not required to do so. In this alert they are trying to stem the tide of the marketing of unapproved drugs targeting US citizens companies are trying to exploit the existence of the exception. But US FDA is also starting to enforce against products that the importer or shipper thinks are dietary supplements or cosmetics."

A company is placed on IA 66-41 when US FDA believes it is marketing an unapproved drug by mail order, when US FDA field agents determine that the product represents a health fraud, or when the product represents a direct or indirect health risk. Shipments sent by companies on IA 66-41 will be detained by Customs at the Port of Entry without inspection. US FDA considers promotion of unapproved drugs by mail order solicitations, press releases, advertising materials and other public announcements to be evidence of a violation.

"If the public knows anything about US FDA, they know that it is the agency that approves drugs" stated Mr. England, "US FDA's ability to enforce in this area is key to their legitimacy in the public eye and political arena. Companies that try to circumvent their [FDA's] authority over drugs can face the strongest penalties."

The US FDA surveillance and enforcement over imported products has been increasing for two consecutive years. Even though the economy is weak and tax revenues are down, Congress increased FDA's budget appropriation by 20 per cent this year and the current administration has proposed an additional 19 per cent for 2011. A significant portion of US FDA's budget is being devoted to drug safety enforcement. This is evidenced by US FDA's addition of 25 companies to this IA 66-41 in the first five months of 2010.

FDAImports.com, LLC is a consulting firm that can help you avoid violating US FDA regulations, as well as help the pharma firms correct violations that have put the companies in the Import Alert #66-41.