U.S. FDA Issues Import Alert for Medical Glove Manufacturing Defects, Many Non-U.S. Companies are Affected, According to FDAImports.com, LLC

With the growing number of product and tainted food recalls in recent years, American consumers are becoming more and more concerned with protecting their health from unsafe products. However, many Americans are unaware of the large number of companies the U.S. Food and Drug Administration (FDA) has singled out for having sold unsafe products in the U.S. market; products such as medical gloves with dangerous defects or holes. The FDA has placed a total of 15 shippers and/or manufacturers on Import Alert #80-04 since the beginning of the year for exporting and distributing subpar medical gloves in the United States.

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Benjamin L. England, of FDAImports.com, LLC stated recently that "...if you get caught shipping subpar medical gloves once, the FDA requires you to make 5 consecutive clean shipments to get off the alert." This means that if you are cited, then your next 5 shipments will be detained in port and you'll have to incur the cost of 5 separate lab tests in order to verify the safety of your product. If you are cited twice within a 24 month period, which is a Level 2 violation, then in order to get off the alert you will need to have 10 consecutive clean shipments. A third offense could result in potential charges, fines, and in all likelihood, a visit from the FDA.

In the first quarter of 2010, 15 different medical glove manufacturers were added to Import Alert #80-04. In total, over 100 companies have been placed on automatic detention, also known as the "Red List" for shipping substandard medical gloves since 1992. The FDA will place a company on IA 80-40, which will mean automatic detention of the company's products at the Customs Port of Entry, if they find even a single shipment of defective gloves.

Benjamin England has stated that this alert is very different from similar alerts that the FDA has issued. “This alert has three levels of violation, each of which progressively worsens the consequences for the foreign manufacturer.” Companies will be placed on a Level 1 violation for
a single shipment of defective gloves. The consequences of being placed on a Level 1 violation entail shipments being Detained Without Physical Examination (DWPE). Future shipments can be released after the firm provides sufficient evidence that the medical gloves in the shipment are not adulterated or defective. Companies do have the right to petition the FDA to get an alert removed after a succession of consecutive, non-defective shipments. But if a company does succeed in being taken off the alert, any subsequent violation will lead to a Level 2 violation. After being placed on a Level 2, considerably more consecutive clean shipments will be required before the Import Alert can be removed. What most companies don't realize, is that even after subsequent shipments have been proven clean, the petition process to have the alerts removed can take a substantial amount of time. This means that even more shipments will have to go through the testing process until the FDA removes the alert. Many companies are unaware that they legally have the right to petition the FDA for removal of any alerts. If a firm receives a third violation, the FDA's Center for Device and Radiological Health (CDRH) can require a company to face an FDA audit or inspection, which will necessitate a substantial amount of proof before an Import Alert will be removed.  

**FDAImport.com, LLC** can help your firm whether it is in violation of Level 1, Level 2, or even Level 3 of IA 80-04. FDAImports.com, LLC is a consulting firm that can help if your entries have been targeted for detention for possible violations. Even if you are just worried about your company's regulatory compliance, FDAImports.com, LLC can help you make sense of all the various regulations and requirements, as well as help you from receiving any future violations. You can save your company a great deal of time and expense when you're dealing with an IA 80-04 by contacting FDAImports.com, LLC. If you're a domestic or foreign manufacturer, and you find yourself in one of these situations, or you want to avoid the possibility being placed on import alert in the future, contact FDAImports.com, LLC for knowledgeable, professional help and solutions.