US FDA Enforces OTC Monograph With Seizure of Hand Sanitizer as an Unapproved New Drug

All products that are marketed as over-the-counter (OTC) drugs must comply with FDA’s OTC Monographs – which are creatures of FDA regulation and indicate only specific active ingredients, doses, formulations and labeling. If a product does not receive pre-approval through the New Drug Application (NDA) process and is marketed as an OTC, it must comply with an OTC monograph. If it does not, it is subject to FDA enforcement under the FDCA.

On July 8, 2010 the United States Food and Drug Administration (FDA) seized $230,000 worth of an over-the-counter (OTC) hand sanitizer gel product made and distributed in Puerto Rico charging the large quantity of product as unapproved New Drugs under the Food Drug and Cosmetic Act (“FDCA”). All products that are marketed as OTC drugs must comply with FDA’s OTC Monographs – which are creatures of FDA regulation and indicate only specific active ingredients, doses, formulations and labeling. If a product does not receive pre-approval through the New Drug Application (NDA) process and is marketed as an OTC, it must comply with an OTC monograph. If it does not, it is subject to FDA enforcement under the FDCA. “Once a product is recognized as noncompliant with FDA’s Monograph system,” noted Benjamin L. England, founder of FDAImports.com and Food & Drug Law expert, “it is subject to enforcement; especially those products that violate the monograph because of using unapproved, and therefore ‘unsafe’, ingredients. The surprise here is that FDA did anything at all, showing the agency to be increasing its enforcement posture and trying to make an example out of someone in the industry.”

The manufacturer and distributor in Puerto Rico is receiving harsh FDA punishment for distributing Hand Sanitizer as an Unapproved New Drug due to the use of the active ingredient benzalkonium chloride; which is not recognized as safe and effective for OTC antifungal drugs. Using this ingredient, unauthorized by the OTC Antifungal Drug Monograph, caused the product to fall into an “unapproved drug” status, violating the FDCA.

The obtaining an FDA approval through the new drug application process is time-consuming, complicated, and costly. An FDA NDA must include the results of clinical trials or tests; explanation of safety and efficacy of all ingredients; expected physical, mental and emotional reactions to the drug when used as intended; as well as how the product is manufactured, processed and packed (proving to meet the standards of current Good Manufacturing Practices (cGMPs) for drugs). “While the NDA process requires submission and review of a large volume of information, the OTC Monographs are not necessarily ‘simple’,” added Mr. England, “because there are more than 300,000 OTC drug products in the market today, which FDA has separated into over 80 classes according to the products’ intended therapeutic uses.”
While these OTC products are being seized as unapproved new drugs, there are many other requirements FDA enforces with such severity. Labeling violations are among the most common violations enforced by FDA. “Labeling is the simplest thing for FDA to spot during an inspection…” says Benjamin England, “they don’t have to run any diagnostics – the safety of the product may be perfectly clear, but if it is mislabeled, the product will present a problem for the manufacturer, distributor or importer.” While the safe use of drugs and drug ingredients is one of FDA’s primary concerns for consumers, labeling is merely a means for discovering the misuse.

If you are a drug manufacturer of distributor and don’t know if you product is compliant with FDA regulations, contact FDAImports.com today. FDAImports.com is a consulting firm that regularly assists manufacturers through the complicated process of determining whether a product can be sold over-the-counter (OTC) or whether it requires a prescription to be dispensed. Most prescription drugs are subject to FDA pre-approval and submission of an NDA. FDAImports.com can help you identify how FDA will regulate your drug product and show you ‘the way through’ the complicated NDA process or OTC Monograph compliance processes. Don’t let your products be seized for using non-monograph ingredients that render your products unapproved new drugs. Contact Benjamin England with FDAImports.com to learn “the way through.”