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On the Attack: FDA Pursues Online Retail Fulfillment House

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In an unprecedented move, the U.S. Food and Drug Administration (FDA or Agency) sent a warning letter to Amazon.com, Inc. (Amazon), a fulfillment house, with respect to distributing over-the-counter (OTC) drug products that are in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act). We have seen FDA take enforcement actions against companies who introduce violative products into interstate commerce. However, this appears to be the first time that FDA has taken action against an online retail fulfillment house. FDA's actions may be viewed as a signal that the Agency is closely reviewing and evaluating online retail houses for products that raise safety concerns and violate the FD&C Act.

On August 4, 2022, the FDA issued a warning letter to Amazon regarding its distribution of products that violate the FD&C Act. The products at issue are OTC drug products marketed for mole and skin tag removal. As the drug products have not been approved for their marketed use by the FDA, the warning letter states that Amazon is responsible for introducing and delivering into commerce products that are unapproved new drugs, and such activity is a violation of the FD&C Act. While the FDA recognized that Amazon distributed each of the products on behalf of third parties, it noted that distribution was made directly by Amazon to the consumer and that product orders are "fulfilled" by Amazon, with such fulfillment including storage, packing, and shipping.

The FDA also issued warning letters to Ariella Naturals and Justified Laboratories for selling these unapproved drug products for mole and skin tag removal.

In the letter, the FDA stated, "[t]here are no over-the-counter (OTC) drugs that can be legally sold for mole or skin tag removal, and FDA has safety concerns about drugs marketed OTC directly to consumers for these uses." The FDA further stated that moles should be evaluated by health care providers rather than using such OTC products for mole and skin tag removal, which may lead to delayed cancer diagnosis and cancer progression.

In a news release, Donald Ashley, director of the Office of Compliance in the FDA's Center for Drug

Evaluation and Research said, “[t]he Agency’s rigorous surveillance works to identify threats to public health and stop these products from reaching our communities. This includes where online retailers like Amazon are involved in the interstate sale of unapproved drug products. We will continue to work diligently to ensure that online retailers do not sell products that violate federal law.”

Amazon has 15 working days from receipt of the warning letter to respond to FDA explaining the specific steps taken to address the violations. The FDA also stated that failure to adequately address this matter may result in legal action such as seizure and injunction.

Furthermore, in the news release, FDA stated it will continue to use all tools available to protect public health and remove fraudulent or unproven drug products from the U.S. marketplace. These recently issued warning letters may signal a new trend of enforcement actions against retailers, including fulfillment operators, who sell products deemed to be unapproved new drugs by the FDA.

Online retailers should carefully review the products that they offer for sale to insure that the products comply with FDA regulatory requirements.

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