Michael Best

February 16, 2021

Update – FDA's Regulation of OTC Drug Products in 2021

Over-the-Counter Drug Products (OTC) include many of the well-known products that we use to treat or control the symptoms of occasional and moderate health conditions like the common cold, heartburn, itchiness, toothaches, and body aches . Available without a prescription and for purchase directly off-the-shelf, OTC drug products currently represent nearly 60% of all drug products sold in the United States. Examples include hand sanitizer, cough medicine, antihistamines, aspirin, lip balm, sunblock, and laxatives.

Congress has granted the U.S. Food and Drug Administration's (FDA) regulatory authority over the formulation, manufacturing, labeling, marketing and promotion, and import / export of OTC drug products into the U.S. This webinar will cover:

- An introduction to the knowledge and skills needed to develop and produce an OTC drug product for marketing and sale in the U.S.
- An understanding of the FDA's regulation of OTC drug products
- The available pathways for marketing an OTC drug product in the U.S.
- The 2020 CARES Act OTC Monograph Reform and its impact on how FDA regulates such products including administrative orders, changes to some existing monographs, market exclusivity, and user fees among others
- Strategic recommendations for mitigating the risk of enforcement action in the future.

We will apply for CLE credit in WI, CO, IL, NC, TX, UT, and VA (if applicable).

Related People

Karl Nobert
Senior Counsel

Events Details

Date:
Tuesday, February 16, 2021
Time (Eastern):
12:00 - 1:45 p.m.
Location:
Complimentary Zoom Meeting

Related Practices

FDA Regulatory
Regulatory

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