Hogan Lovells

OTC Drugs and Cosmetics

There is a myriad of issues to consider when developing, manufacturing, and marketing over the counter (OTC) drugs pursuant to the OTC Drug Review. When marketing your OTC drug, significant attention must be paid to compliance issues, including your product's labeling and marketing claims.

There is a myriad of issues to consider when developing, manufacturing, and marketing over the counter (OTC) drugs pursuant to the OTC Drug Review. When marketing your OTC drug, significant attention must be paid to compliance issues, including your product's labeling and marketing claims.

Our broad experience with drug companies has resulted in a sophisticated understanding of the legal and competitive landscape they face. When marketing OTC drugs, you are faced with both opportunities and regulatory challenges — ones that our pharmaceutical and biotechnology lawyers have decades of experience handling, with some of them having worked at FDA.

In our work, we advise OTC drug manufacturers, marketers, and large retailers on monograph compliance and product labeling, including Drug Facts. We also offer marketing strategies and counsel on the requirements for switching prescription products to OTC status. We can also assist in product advertising, Hatch Waxman exclusivity related to OTC drug products, the regulatory status of long-marketed

Contacts

Heidi Forster Gertner,
Washington, D.C.

David Horowitz,
Washington, D.C.

Practices

Pharmaceuticals and Biotechnology
Regulatory

"legacy" products, adverse event reporting, and current Good Manufacturing Practice (cGMP) standards as applied to OTC drugs.

Representative experience

Advised a client on regulatory risks associated with novel dosage forms under the OTC monograph system and anticipated changes under the OTC drug monograph reform legislation.

Advised an influenza drug product's sponsor on strategies for regulatory approval of OTC epidemic and pandemic kits.

Advised clients on applicable monograph requirements for sunscreens, including under monograph reform legislation.

Advised foreign OTC drug manufacturers regarding requirements applicable for importing OTC drugs.

Advised multiple clients on regulatory issues related to recent FDA guidance on the labeling, registration/listing and manufacture of alcohol-based hand sanitizers during the COVID-19 emergency.

Advised OTC cough/cold products marketers on potential changes to pediatric dosing information in light of safety concerns.

Analyzed and advised on OTC switch strategies for lipid-lowering and heartburn drug products for top-tier pharmaceutical companies.

Assisted an OTC drug manufacturer on developing and launching a topical analgesic and an antifungal, including reviewing product labeling, website content, and other promotional materials.

Assisted companies with limited drug manufacturing experience in achieving compliance with OTC drug monograph requirements, Drug Facts labeling requirements, and Current Good Manufacturing Practice requirements.

Assisted the developer of a new labeling format that enables the provision of weight-based pediatric dosing Information for OTC drug products within the Drug Facts labeling format.

Conducted due diligence for a client acquiring an OTC insecticide product.

Conducted due diligence for medium-size OTC drug manufacturer acquiring another medium-size OTC drug manufacturer.

Counseled companies on the law surrounding the OTC drug monograph reform, including ingredient status post reform, OMOR submissions, exclusivity, and more.

Counseled large retailers on implementing adverse event reporting requirements for OTC drug monograph products.

Evaluated the regulatory status of long-marketed "legacy" OTC drug products for purposes of price reporting and assessing the risks of continued marketing.

Prepared an in-depth analysis for a client with a significant stake in the Plan B® debate, on the FDA's authority to restrict a drug to behind-the-counter (BTC) status.

Reviewed a new advertising campaign for OTC cough/cold products.

Latest thinking and events

Insights and Analysis

Life Science Law Update – Key developments for pharma and device companies in EU and EU Big Five

News

Homeopathic drug product makers warned to follow FDA premarket and GMP rules

News

FDA expands inspection obstruction guidance to apply to device facilities

News

Modernization of U.S. cosmetics regulation will be phased in over time

News

FDA pushes OTC switch for naloxone, continuing trend toward making more drugs available without a prescription

News

FDA may permit Rx-to-OTC switch using additional conditions beyond traditional labeling