U.S. Over-The-Counter Drug Monograph Reform Enacted

When H.R. 748: Coronavirus Aid, Relief, and Economic Security (CARES) Act was enacted on March 27, 2020, the Over-the-Counter Monograph, Safety, Innovation, and Reform Act of 2019 (S. 2740) was also passed into law. Found in Subtitle F: Over-the-Counter Drugs, the over-the-counter (OTC) drug monograph reform bill will provide the U.S. Food and Drug Administration (FDA) new tools, allowing them to better regulate and review OTC drug products. The OTC drug monograph reform bill includes provisions on:

- How nonprescription drugs marketed without an approved drug application, such as OTC drugs following a tentative final monograph or proposed monograph, shall be regulated. This determination is based on the drug category – Category I (Generally Recognized as Safe and Effective – GRASE), Category II (not GRASE), or Category III (more data is needed to make a GRASE determination)
- Expedited procedures to update monographs when a hazard is identified or when labeling needs to be updated for safety reasons
- The ability for companies to request updates to monographs. Note: Depending on the type of request, the FDA may require a fee
- Exclusivity periods for new OTC drugs, within certain limitations
- Confidentiality provisions to help protect trade secrets
- Updates to the Sunscreen Innovation Act, including the addition of an exclusivity clause
- Annual fees for OTC drug facilities
- The review of cough and cold medicine for children under six

Click to view the bill, the link should take you directly to Subtitle F:
https://www.congress.gov/bill/116th-congress/house-bill/748/text#toc-H378EC548F73A4A95B3E964028BCD3C39

Background:
Most over-the-counter drug products are regulated under a monograph. A monograph being a sort of recipe, where, if the drug product follows the monograph – meaning it contains the permitted active ingredient or combination of ingredients in the proper amount(s), with all the necessary labeling, and meets additional requirements that may be required (such as SPF determination for sunscreen products) – the drug does not need to go through the New Drug Approval (NDA) process.

How Bureau Veritas Can Help
Our knowledgeable professionals can design a program to meet your specific needs - whether it be to demonstrate quality and safety control, identify which product offers the best value, which product your customers prefer, or if the product meets your quality requirements.

For over 35 years, Bureau Veritas has worked successfully with top retailers and manufacturers around the world to help them better manage risk and regulatory compliance. If you have any questions, please contact your customer service representative or email: cps.info@us.bureauveritas.com.

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