Why Marketers Should Care about FDA's OTC Drug Review

March 28, 2014

We're all familiar with the phrase "speak now or forever hold your peace." If you develop products that are in commerce pursuant to an OTC drug monograph — such as fluoride toothpastes, facial washes that also treat acne, antiperspirants, cough/cold medicines, or thousands of other products that contain a "drug" — now is the time to speak or, more specifically, comment. FDA is about to make some decisions that can greatly impact how you develop (or even modify existing) products to meet consumer preferences.

FDA's Center for Drug Evaluation and Research is seeking comment on the OTC drug review process. The process produced final monographs (in essence, pre-approved recipes) for various categories of OTC drug products which currently permit consumer health and personal care product manufacturers' to sell covered drug products without obtaining additional premarket FDA approval.

According to its Federal Register Notice, FDA "is interested in exploring ways to re-engineer the process of regulating OTC drugs that are currently regulated under the OTC Monograph Process to, among other things, create a process that is more efficient and more responsive to newly emerging information and evolving science, and to allow for more rapid product innovation where appropriate." The notice outlines several areas of interest to FDA, some of which can greatly impact marketing strategies.

For example, often companies develop new delivery systems for OTC drug ingredients to meet consumer preferences and demand (e.g., quick-dissolving tablets). But, in some cases, the advancements were not contemplated by FDA at the time the monographs were created. Future FDA action is expected to address these product innovations, including when they're covered by the monographs. Such action can have significant implications for consumer health and personal care product companies that are trying to meet consumer demands while complying with the OTC monographs so that the products do not become unapproved new drugs.

Companies involved in the development of consumer health and personal care products pursuant to OTC monographs should closely monitor FDA action in this area and also consider submitting comments to FDA, either individually or through a trade association. Notably, the March 25 and 26 public hearing regarding the OTC Drug Review included testimony from various stakeholders, including industry, the Consumer Health Products Association and the Personal Care Products Council. FDA is accepting comments until May 12, and plans to release a transcript of the hearing by April 25. More information regarding the request for comment is available here.