ALERTS AND UPDATES

# FDA Publishes Final Guidance for Industry on Applications for Nonprescription Drug Products

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> **The Guidance focuses on the time-and-extent application component of the monograph application process, which requires applicants to demonstrate that the condition has been marketed OTC to a material extent and for a material time.**

The U.S. Food and Drug Administration (FDA) recently released a guidance on "Time and Extent Applications for Nonprescription Drug Products" (the "Guidance"). The Guidance describes the FDA's latest thinking on the information applicants should provide when requesting that conditions be added to the FDA's over-the-counter (OTC) drug monograph system. Specifically, the Guidance focuses on the time-and-extent application (TEA) component of the monograph application process, which requires applicants to demonstrate that the condition has been marketed OTC to a material extent and for a material time. The Guidance applies to any OTC drug that does not have any marketing experience in the United States or that is initially marketed in the United States after May 11, 1972, when the OTC drug review started.

As the first of two steps in the OTC drug monograph system inclusion process, the TEA must include information about the OTC condition. For example, this would include:

- The intended OTC uses, strengths or dosage forms;
- A list of all countries in which the condition has been marketed; and
- Information on the marketing activities in those countries, including demographics; dosage-unit sales history; and the country's system for identifying adverse drug experiences.

The TEA applicant also needs to include English versions of the product labels from every country in which the condition is marketed. Applicants submitting a TEA for an OTC drug marketed for more than five years under an FDA-approved application are exempt from some of these requirements.

The Guidance further advises that after submission, TEA applicants can anticipate eligibility determinations within one year. If the condition is found eligible for inclusion on the OTC drug monograph system, a notice will be published in the *Federal Register* and the TEA will be publicly displayed.

Applicants found ineligible will receive a publicly displayed letter from the FDA stating why the condition was not eligible. Rejected TEAs, however, will not be publicly displayed.

**For Further Information**

If you have any questions about this *Alert*, please contact Frederick R. Ball, any member of the Pharmaceutical, Pharmacy & Food industry group or the attorney in the firm with whom you are regularly in contact.