Summary: Approved Drug Products With Therapeutic Equivalence Evaluations (the "Orange Book"); Establishment of a Public Docket; Request for Comments

Notice of Availability Publication Date: June 1, 2020

Comments Due: August 31, 2020

On June 1, 2020, the Food and Drug Administration (FDA) published "Approved Drug Products With Therapeutic Equivalence Evaluations (the "Orange Book"); Establishment of a Public Docket," soliciting comments on how stakeholders and the public use the Orange Book and whether it can be improved. The request for comments includes several questions aimed at understanding who utilizes the information contained in the Orange Book and what they use the information for as well as specific questions about the usefulness of the therapeutic equivalence information.

Comments on this public must be submitted to the FDA by August 31, 2020. You may provide feedback via email to advocacy@amcp.org on any provisions included in the request for comments by **August 14, 2020**. AMCP's final comments will be available on the AMCP website and included in the Legislative-Regulatory Briefing Newsletter that is distributed to all AMCP members.

The following is a summary of key sections in the request for comments that may be of interest to AMCP members:

A. Background on the Orange Book

a. The core function of the Orange Book is to identify drug products approved by the FDA under the Food, Drug and Cosmetic (FD&C) Act and it includes patent and exclusivity information related to these drug products. It also contains therapeutic equivalence evaluations for multisource prescription drug products.

b. The Orange Book is made up of four main parts:

i. The Prescription Drug Product List – a list of approved marketed prescription drug products with therapeutic equivalence evaluations;

ii. The OTC Drug Product List – a list of marketed over-the-counter drugs that have been approved in new drugs applications (NDAs) or abbreviated new drug applications (ANDAs);

iii. The Drug Products with Approval under section 505 of the FD&C Act administered by the Center for Biologics Evaluations and Research; and

iv. The Discontinued Drug Product List – a cumulative list of approved drug products that have never been marketed, are for exportation, are for military use, are not commercially distributed, have been discontinued for marketing and the FDA has not determined that they were withdrawn from sale for safety or effectiveness reasons, or have had their approvals withdrawn for other than safety or effectiveness reasons subsequent to being discontinued from marketing.

c. The Addendum to the Orange Book includes patent information for certain listed drugs and identifies drugs that qualify under the FD&C Act for periods of exclusivity.
    i. Under the FD&C Act, NDA holders are required to submit the patent number and the expiration date of any patent which claims the drug or a method for using such drug for which a patent infringement could reasonably be asserted.

B. Solicitation of information on how the Orange Book can be improved

a. In addition to general information about how stakeholders think the Orange Book can be approved, the FDA seeks comment on the following questions:
    i. What types of people or entities use the Orange book?
    ii. What sections of the Orange Book do different types of people and or entities use?
    iii. For what reasons do people or entities use the Orange Book? What additional information or features (e.g. additional search functions) could be incorporated to make it more useful?
    iv. Is the information included on therapeutic equivalence generally useful?
        1. How useful is the second letter of a therapeutic equivalence evaluation code?
        2. How could the therapeutic equivalence information be made more user-friendly or otherwise be tailored to meet the needs of people or entities that use the Orange Book?
        3. If you use the information regarding therapeutic equivalence, how do you use it?
        4. Does the information regarding therapeutic equivalence promote drug competition? And if so, how?
    v. Is there any other information regarding the Orange Book that would be useful for the FDA to consider?