FDA Statement

Statement from FDA Commissioner Scott Gottlieb, M.D., on the agency's efforts to enhance the utility of the Orange Book to foster drug competition

For Immediate Release

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Statement

One of our key policy priorities is encouraging the timely development and approval of generics and biosimilars. Our efforts have helped foster competition in the marketplace with the ultimate goal of improving access to high quality, affordable treatment options for Americans and improving patient care.

We've made significant progress over the past year advancing efforts that have helped to strengthen and streamline the generic drug review process – setting **record numbers (/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm625314.htm)** for generic drug approvals and tentative approvals from 2017-2018; providing scientific clarity and guidance to support the development of hard-to-develop complex generics; and calling out potential abuses of the system where companies were using tactics to delay market entry of generic competitors. We will continue to advance new efforts in the year ahead. Our aim is to enhance transparency, provide greater clarity and scientific guidance for generic drug developers, and support the availability of high-quality, safe and effective generic medicines.

One of the most fundamental and crucial tools for generic drug companies in planning their development efforts is the FDA publication Approved Drug Products with Therapeutic Equivalence Evaluations Publication (also known as the **Orange Book (https://www.accessdata.fda.gov/scripts/Cder/ob/index.cfm)**). This is a list of drug products approved by the FDA under the Federal Food, Drug, and

Cosmetic Act that includes patent and exclusivity information and identifies whether a drug is currently being marketed or has been discontinued. Maintaining an up-to-date Orange Book also serves many important public health roles. Among its many benefits, the Orange Book helps keep health care providers informed on what drugs are approved and available.

Given the important benefits of a modern, up-to-date Orange Book, today we're announcing several new steps the agency will be taking to ensure that the Orange Book provides the greatest benefit to patients and providers, and generic drug developers. We want to make sure it provides as much utility as possible to aid manufacturers as they allocate resources towards the development of new generic drug products.

The first of these actions is a new draft guidance – **Marketing Status Notifications Under Section 506I of the Federal Food, Drug, and Cosmetic Act; Content and Format (/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM630099.pdf)**. The guidance provides approved drug application holders with clarity on the specific categories and descriptions of the information they're required to share with FDA on the marketing status for their brand and generic drugs and how to provide it in a timely and consistent manner. Having timely, accurate information about what drugs are being actively marketed helps provide transparency around circumstances where generic competition is lacking. It helps us also better understand circumstances where generic medicines are being approved, but not marketed so that we can better consider any policy reasons why this may be occurring.

This guidance stems from the FDA Reauthorization Act of 2017, which imposed additional reporting requirements on new drug application and abbreviated new drug application holders regarding the marketing status of approved drug products, including: notification of a withdrawal from sale; notification of a drug not available for sale; and a one-time report on marketing status for actively marketed drugs. The guidance identifies the required content for marketing status notifications, the recommended format for submitting these notifications to the agency, and the required timelines for their submission.

In the coming year we'll be taking other actions to enhance this important resource and clarify Orange Book processes. Specifically, we intend to issue draft guidance for industry, describing how the FDA evaluates therapeutic equivalence (TE) and assigns therapeutic equivalence codes, which are published in the Orange Book. We believe this guidance will increase transparency around the FDA's policies and procedures related to evaluation and assignment of TE codes to support applicants submitting requests for therapeutic equivalence and help advance pathways for achieving pharmacy-level substitution of therapeutically equivalent drug products, including products approved under the 505(b)(2) pathway.

We believe this will be particularly beneficial for those seeking to develop generic products for harder-to-copy complex drugs that often face greater scientific and regulatory challenges and thus often have less competition. For some of these drugs, the 505(b)(2) pathway may provide a more efficient development path and the agency is developing policy for how manufacturers can acquire a therapeutic equivalence rating to allow for full substitutability for products developed by this route.

We also intend to issue a draft guidance to assist drug product applicants and approved application holders in using the Orange Book. The guidance will provide answers to commonly asked questions that we have received from these interested parties regarding the Orange Book.

Separately, we'll also be soliciting public comment on Orange Book use and potential enhancements, including a re-examination of what pharmaceutical patents should be listed in the Orange Book. For example, if a product has been approved for use in conjunction with a digital application, we plan to consider whether the drug application holder should be required to list any patents associated with this digital application. We want to hear from the public on the pros and cons of requiring patent listings in these and other circumstances. To take the case of the digital application, listing such patents could help generic developers to assess all intellectual property assertions related to the product that could potentially block generic entry and determine its approach to these patents. This could allow generic competitors to better assess which products they choose to develop and provide greater clarity as to the path to market.

Making sure companies are sharing complete and timely information with the FDA helps us keep the Orange Book updated accurately and efficiently. We want the generic drug industry to be as competitive as possible to help ensure consumer access to more affordable medicines. But this market must also be sustainable – if regulatory burdens are too cumbersome or market entry too unpredictable, industry will limit their investment in certain products, ultimately undermining our goal of enhanced competition.

This is why, in addition to taking action to enhance generic competition, the FDA must work to make generic drug development more efficient and predictable. In addition to our work to reduce approval times and to enhance the efficiency of certain aspects of the submission process for generic drug applicants, we are striving to provide the industry with increased transparency to provide greater certainty around timing of market entry and enable more informed decisions on how to prioritize their resources. The steps we're taking in relation to the Orange Book are only one component of these transparency initiatives and we look forward to continuing to provide updates on additional steps in the coming year.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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Related Information

- **Marketing Status Notifications Under Section 506I of the Federal Food, Drug, and Cosmetic Act; Content and Format Guidance for Industry (PDF - 87KB) (/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM630099.pdf)**
- **FDA Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations (https://www.accessdata.fda.gov/scripts/Cder/ob/index.cfm)**

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