Contains Nonbinding Recommendations

Determining Whether to Submit an ANDA or a 505(b)(2) Application

Guidance for Industry

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

May 2019
Generics

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I. INTRODUCTION

This guidance is intended to serve as a foundational guidance to assist applicants in determining which one of the abbreviated approval pathways under the Federal Food, Drug, and Cosmetic Act (FD&C Act) is appropriate for the submission of a marketing application to FDA. Many potential drug product developers are not familiar with the different abbreviated approval pathways for drug products under the FD&C Act — the abbreviated approval pathways described in section 505(j) and 505(b)(2) of the FD&C Act (21 U.S.C. 355(j) and 21 U.S.C. 355(b)(2), respectively) — or the types of data and information that are permitted to support approval under those pathways. In order to familiarize potential drug product developers with these abbreviated pathways, this guidance highlights criteria for submitting applications under the abbreviated approval pathways described in section 505(j) and 505(b)(2), identifies considerations to help potential applicants determine whether an application would be more appropriately submitted under section 505(j) or pursuant to section 505(b)(2) of the FD&C Act, and provides direction to potential applicants on requesting assistance from FDA in making this determination.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) (Hatch-Waxman Amendments) added section 505(b)(2) and 505(j) to the FD&C Act, which

[1] This guidance has been prepared by the Office of Generic Drugs in the Center for Drug Evaluation and Research at the Food and Drug Administration.

describes abbreviated approval pathways under the FD&C Act for drug products regulated by the Agency. The Hatch-Waxman Amendments reflect Congress's efforts to balance the need to "make available more low cost generic drugs by establishing a generic drug approval procedure" with new incentives for drug development in the form of exclusivities and patent term extensions.[2] With the passage of the Hatch-Waxman Amendments, the FD&C Act describes different routes for obtaining approval of two broad categories of drug applications: new drug applications (NDAs) and abbreviated new drug applications (ANDAs).[3]

NDAs and ANDAs can be divided into the following four categories:[4]

(1) A "stand-alone NDA" is an application submitted under section 505(b)(1) and approved under section 505(c) of the FD&C Act that contains full reports of investigations of safety and effectiveness that were conducted by or for the applicant or for which the applicant has a right of reference or use.

(2) A 505(b)(2) application is an NDA submitted under section 505(b)(1) and approved under section 505(c) of the FD&C Act that contains full reports of investigations of safety and effectiveness, where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use.[5]

(3) An ANDA is an application submitted and approved under section 505(j) of the FD&C Act for a drug product that is a duplicate[6] of a previously approved drug product. An ANDA relies on FDA's finding that the previously approved drug product, i.e., the reference listed drug (RLD),[7] is safe and effective. An ANDA generally must contain information to show that the proposed generic product (1) is the same as the RLD with respect to the active ingredient(s), conditions of use, route of administration, dosage form, strength, and labeling (with certain

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[2] See H.R. Rep. No. 98-857, pt. 1, at 14-15 (1984), reprinted in 1984 U.S.C.C.A.N. 2647-2648.

[3] See section 505(b) and 505(j) of the FD&C Act. See generally 21 CFR part 314.

[4] See letter from Janet Woodcock to Katherine M. Sanzo, Jeffrey B. Chasnow, Stephen E. Lawton, and William R. Rakoczy (October 14, 2003), Docket Nos. FDA-2001-P-0369 (original Docket No. 2001P-0323/CP1 & C5), FDA-2002-P-0390 (original Docket No. 2002P-0447/CP1), and FDA-2003-P-0274 (original Docket No. 2003P-0408/CP1). (Please note that the docket numbers were changed in January 2008 after FDA transitioned to a new docketing system (Regulations.gov).)

[5] For more information on 505(b)(2) applications, see the draft guidance for industry *Applications Covered by Section 505(b)(2)* (December 1999). When final, this guidance will represent the FDA's current thinking on this topic. For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.

[6] The term *duplicate* generally refers to a "drug product that has the same active ingredient(s), dosage form, strength, route of administration, and conditions of use as a listed drug." See 54 FR 28872 at 28877 (July 10, 1989). However, the term *duplicate*, as used in this context, does not mean identical in all aspects to the listed drug.

[7] The *RLD* "is the listed drug identified by FDA as the drug product upon which an applicant relies in seeking approval of its ANDA." 21 CFR 314.3(b). Because an ANDA applicant is relying upon FDA's finding that the RLD is safe and effective, FDA's practice is to designate as RLDs drug products that have been approved for safety and effectiveness.

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