Guidance for Industry

Applications Covered by Section 505(b)(2)

DRAFT GUIDANCE

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U. S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
October 1999

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7/20/99

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U.S. Department of Health and Human Services
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Table of Contents

GUIDANCE FOR INDUSTRY[1]

Applications Covered by Section 505(b)(2)

I. WHAT IS THE PURPOSE OF THIS GUIDANCE?

This guidance identifies the types of applications that are covered by section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (the Act). A 505(b)(2) application is a new drug application (NDA) described in section 505(b)(2) of the Act. It is submitted under section 505(b)(1) of the Act and approved under section 505(c) of the Act. This guidance also provides further information and amplification regarding FDA's regulations at 21 CFR 314.54.

Section 505 of the Act describes three types of new drug applications: (1) an application that contains full reports of investigations of safety and effectiveness (section 505(b)(1)); (2) an application that contains full reports of investigations of safety and effectiveness but 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 (section 505(b)(2)); and (3) an application that contains information to show that the proposed product is identical in active ingredient, dosage form, strength, route of administration, labeling, quality, performance characteristics, and intended use, among other things, to a previously approved product (section 505(j)). Note that a supplement to an application is a new drug application.

Section 505(b)(2) was added to the Act by the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments). This provision expressly permits FDA to rely, for approval of an NDA, on data not developed by the applicant. Sections 505(b)(2) and (j) together replaced FDA's *paper NDA policy*, which had permitted an applicant to rely on studies published in the scientific literature to demonstrate the safety and effectiveness of duplicates of certain post-1962 pioneer drug products (see 46 FR 27396, May 19, 1981). Enactment of the generic drug approval provision of the Hatch-Waxman Amendments ended the need for approvals of duplicate drugs through the paper NDA process by permitting approval under 505(j) of duplicates of approved drugs (listed

[1]This guidance has been prepared by the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration. This guidance document represents the Agency's current thinking on the types of applications that may be submitted pursuant to section 505(b)(2) of the Act. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

drugs) on the basis of chemistry and bioequivalence data, without the need for evidence from literature of effectiveness and safety. Section 505(b)(2) permits approval of applications other than those for duplicate products and permits reliance for such approvals on literature or on an Agency finding of safety and/or effectiveness for an approved drug product.

Definitions for specific terms used throughout this guidance are given in the Glossary.

II. WHAT IS A 505(B)(2) APPLICATION?

A 505(b)(2) application is one for which one or more of the investigations relied upon by the applicant for approval "were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted" (21 U.S.C. 355(b)(2)).

A. What type of information *can* an applicant rely on?

What type of information can an applicant rely on in an application that is based upon studies "not conducted by or for the applicant and for which the applicant has not obtained a right of reference?"

1. Published literature

An applicant should submit a 505(b)(2) application if approval of an application will rely to any extent on published literature (a *literature-based* 505(b)(2)). If the applicant has not obtained a right of reference to the raw data underlying the published study or studies, the application is a 505(b)(2) application; if the applicant obtains a right of reference to the raw data, the application may be a full NDA (i.e., one submitted under section 505(b)(1)). An NDA will be a 505(b)(2) application if any of the specific information necessary for approval is obtained from literature or from another source to which the applicant does not have a right of reference, even if the applicant also conducted clinical studies to support approval. Note, however, that this does not mean ***any*** reference to published general information (e.g., about disease etiology, support for particular endpoints, methods of analysis) or to general knowledge causes the application to be a 505(b)(2) application. Rather, reference should be to specific information (clinical trials, animal studies) necessary to the approval of the application.

2. The Agency's finding of safety and effectiveness for an approved drug

An applicant should submit a 505(b)(2) application for a change in a drug when approval of the application relies on the Agency's previous finding of safety and/or effectiveness for a drug. This mechanism, which is embodied in a regulation at 21 CFR 314.54, essentially makes the Agency's conclusions that would support the approval of

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