

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Certifier N. Hawkins

[Docket No. 2007D-0169]

Draft Guidance for Industry on Bioequivalence Recommendations for Specific Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “Bioequivalence Recommendations for Specific Products” that describes a new process for making available recommendations on how to design product-specific bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs). Under this process, applicants planning to carry out such studies in support of their ANDAs will be able to access BE study guidance on the FDA Web site. FDA believes that making this information available on the Internet will streamline the guidance process and will provide a meaningful opportunity for the public to consider and comment on product-specific BE study recommendations. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the first group of draft product-specific BE recommendations.

DATES: Submit written or electronic comments on the draft guidance by *[insert date 90 days after date of publication in the Federal Register]*. General comments on agency guidance documents are welcome at any time.

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ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Doan T. Nguyen, Center for Drug Evaluation and Research (HFD-600), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0495.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Bioequivalence Recommendations for Specific Products.” To receive approval for an ANDA, an applicant generally must demonstrate, among other things, that its product has the same active ingredient, dosage form, strength, route of administration and conditions of use as the listed drug, and that the proposed drug product is bioequivalent to the reference listed drug (21 U.S.C. 355(j)(2)(A); 21 CFR 314.94(a)). Bioequivalent drug products show no significant difference in the rate and extent of absorption of the therapeutic ingredient (21 U.S.C. 355(j)(8); 21 CFR 320.1(e)). BE studies are undertaken in support of ANDA submissions with the goal of demonstrating BE between a proposed generic drug product and its reference listed drug. The regulations governing BE are provided at 21 CFR in part 320.

Previously, the Office of Generic Drugs (OGD) has provided information on how to design BE studies for specific products only when asked for assistance by individual applicants. In most cases, the requested information was not available anywhere else, and, in some cases, OGD performed its own research before responding to an applicant's request for information. In many cases, FDA responded to individual applicants in letter format after specific recommendations were prepared by individuals within the Center for Drug Evaluation and Research (CDER). With the increasing number of both ANDA submissions and requests for BE information during the last few years, this approach has become inefficient and extremely time consuming for the agency.

As a result, after exploring various mechanisms that would allow us to conserve our resources while responding to the needs of industry and other interested persons, OGD has developed a new approach to making guidance available on product-specific BE studies. As before, BE recommendations will be developed by the agency based on its understanding of the characteristics of the listed drug, information derived from published literature, agency research, and consultations within different offices in CDER as needed based upon the novelty or complexity of the BE considerations. FDA proposes that, once drafted, product-specific BE recommendations will be made available through the process described in the guidance.

II. Procedures for Making BE Recommendations Available

To streamline the process for making guidance available to the public on how to design product-specific BE studies, the agency intends to use the following process:

- Product-specific BE recommendations will be developed and posted on the CDER guidance page at <http://www.fda.gov/cder/index.html> in draft to facilitate public consideration and comment.

- The recommendations can be viewed by clicking on the URL associated with this guidance on the CDER guidance page (<http://www.fda.gov/cder/index.html>) or on the OGD page (see www.fda.gov/cder/ogd/index.htm). Users can also search for a specific product BE recommendation using the search tool on the guidance page.

- Newly posted draft and final BE recommendations will be announced in the New/Revised/Withdrawn list, which is posted monthly on the CDER guidance page.

- The agency will issue a notice in the **Federal Register** announcing the availability on the FDA Web site of new product-specific draft and final BE recommendations. The notice will identify a comment period for the recommendations.

- Comments on product-specific BE recommendations will be considered in developing final BE recommendations.

- The BE recommendations will be revised as appropriate to ensure that the most up-to-date BE information is available to the public.

FDA has decided to make the first group of BE recommendations available concurrently with the issuance of this draft guidance document. A notice of availability of the first group of draft product-specific BE recommendations is also being published today. It includes a list of the drug products for which draft BE recommendations are available. Comments on the product-specific draft guidances are requested within 120 days.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on a new process for making available to sponsors FDA guidance on how to design product-specific bioequivalence studies to support ANDAs. 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 statutes and regulations.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

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May 22, 2007

Jeffrey Shuren,
Assistant Commissioner for Policy.

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Dawn P. Hawkins