

Dated: November 29, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-1464]

Draft Guidance for Industry on Bioequivalence Studies With Pharmacokinetic Endpoints for Drugs Submitted Under an Abbreviated New Drug Application; Availability

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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “Bioequivalence Studies With Pharmacokinetic Endpoints for Drugs Submitted Under an ANDA.” This guidance provides recommendations to applicants planning to include bioequivalence (BE) information in abbreviated new drug applications (ANDAs) and ANDA supplements. The guidance describes how to meet the BE requirements set forth in FDA regulations. The guidance is applicable to dosage forms intended for oral administration and to non-orally administered drug products in which reliance on systemic exposure measures is suitable for documenting BE. The guidance will be especially useful when planning BE studies intended to be conducted during the postapproval period for certain changes in an ANDA.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by March 5, 2014.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY**

INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments to <http://www.regulations.gov>. Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Teresa Ramson, Center for Drug Evaluation and Research, Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 240-402-3870.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Bioequivalence Studies With Pharmacokinetic Endpoints for Drugs Submitted Under an ANDA.” The guidance is applicable to dosage forms intended for oral administration, including tablets, capsules, solutions, suspensions, conventional/immediate release, and modified (extended, delayed) release drug products, and to non-orally administered drug products in which reliance on systemic exposure measures is suitable for documenting BE (e.g., transdermal delivery systems and certain rectal and nasal drug products).

This guidance revises parts of the guidances to industry on “Bioavailability and Bioequivalence Studies for Orally Administered Drug Products—General Considerations,” and “Food-Effect Bioavailability and Fed Bioequivalence Studies Relating to BE studies in ANDAs.” Specifically, the draft guidance revises recommendations related to (1) the use of systemic exposure measures and (2) considerations for the conduct of BE studies under fed conditions. Revisions are based primarily on experience gained with recommendations contained in prior guidances as well as on scientific information that has become available to the Agency. We believe the revisions will clarify guidance to applicants conducting BE studies for systemically bioavailable generic drug products. This draft guidance contains recommendations for submission of BE studies for ANDAs only. A separate guidance entitled “Bioavailability and Bioequivalence Studies Submitted in NDAs or INDs—General Considerations” to address investigational new drugs (INDs), new drug applications (NDAs), and NDA supplements will be published in the

near future. FDA has determined that separating guidances according to application type will be beneficial to sponsors.

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 BE studies with pharmacokinetic endpoints for drug products submitted in 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.

II. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments 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, and will be posted to the docket at <http://www.regulations.gov>.

III. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). Information submitted in an ANDA under 21 CFR 314.94(a)(7), supplemental applications submitted under 21 CFR 314.70(b), and waiver requests submitted under 21 CFR 314.90 are approved under OMB control number 0910-0001.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

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