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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D-0004]

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Dossier [Signature]

Draft Guidance for Industry on Nonclinical Safety Evaluation of Drug Combinations; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Nonclinical Safety Evaluation of Drug Combinations." The guidance provides recommendations on nonclinical approaches to support the clinical study and approval of fixed-dose combination products (FDCs), copackaged products, and adjunctive therapies.

DATES: Submit written or electronic comments on the draft guidance by *[insert date 90 days after date of publication in the Federal Register]*.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.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.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 Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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

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<http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Abby Jacobs, Center for Drug Evaluation and Research (HFD-540), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2020.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Nonclinical Safety Evaluation of Drug Combinations.” Drug combinations include FDCs, copackaged products, and adjunctive therapies. An FDC is a product in which two or more separate drug components (active pharmaceutical ingredients) are combined in a single dosage form. A copackaged product consists of two or more separate drug products in their final dosage form, packaged together with appropriate labeling to support the combination use. An adjunctive therapy refers to the situation in which a patient is maintained on a second drug product that is used together with (i.e., in adjunct to) the primary treatment, although the relative doses are not fixed and the drugs need not be given at the same time. Adjunctive therapy products may or may not be labeled for concomitant use. The guidance discusses all three types of drug combinations. However, it is only intended to describe general guiding principles. To receive more detailed advice regarding a particular drug combination development program, a sponsor should contact the appropriate review division before submitting an Investigational New Drug application. In addition, FDA is in the process of publishing more specific guidance for certain categories of drug combinations.

The guidance discusses drug combinations involving the following items: (1) Previously marketed drugs, (2) one or more new molecular entities (NMEs) and one or more previously marketed drugs, and (3) more than one NME. The nonclinical studies considered important for each type of combination may differ, depending upon the information available on each drug component (active pharmaceutical ingredient). The nonclinical studies that would be appropriate to adequately characterize the combination depend on the toxicologic and pharmacokinetic profiles of the individual drugs, the treatment indication or indications, and the intended population.

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 nonclinical safety evaluation of drug combinations. 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 to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Two copies of mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

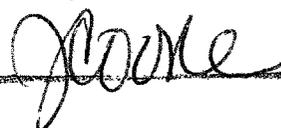
III. Electronic Access

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>.

Dated: 1/18/05
January 18, 2005.



Jeffrey Shuren,
Assistant Commissioner for Policy.

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