

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D-0570]

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Certifier

*SKee*

**Request for Comments on a Draft Guidance on the Clinical Evaluation of Weight-Control Drugs**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is requesting comments on a previously published draft guidance that has never been finalized. The draft guidance entitled "Guidance for the Clinical Evaluation of Weight-Control Drugs" was issued September 24, 1996. The draft guidance gives recommendations for the design and conduct of phase 1-3 clinical studies aimed at demonstrating the efficacy and safety of weight-loss medications. The agency would like to revise this document for republication as a draft. Before it does this, the agency would like interested persons to review and submit comments on the 1996 draft guidance document.

**DATES:** Submit written or electronic comments on the draft guidance by [*insert date 90 days after date of publication in the Federal Register*].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

**FOR FURTHER INFORMATION CONTACT:** Oluchi Elekwachi, Center for Drug Evaluation and Research (HFD–510), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6381.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

Weight-loss medications approved by FDA before the 1990s, such as phentermine and diethylpropion, are indicated for the short-term (a few weeks) treatment of obesity. The short-term indication reflects the now rejected belief that drug-induced weight loss will be maintained after the medication is stopped. In recent years, it has become clear that the successful treatment of obesity, with or without pharmacologic intervention, requires long-term, if not chronic, therapy.

In 1995, FDA's Division of Metabolic and Endocrine Drug Products convened an expert advisory panel to discuss the development of weight-loss drugs indicated for the long-term treatment of obesity. The discussions at this meeting formed the basis for a draft guidance document entitled "Guidance for the Clinical Evaluation of Weight-Control Drugs," which was made available on September 24, 1996. Two of the more important recommendations made in the draft guidance relate to the duration of the phase 3 trials and the criteria used to define efficacy.

FDA is interested in incorporating the latest scientific advances in the field of obesity and drug development into an amended obesity guidance document.

Once the draft has been revised, it will be issued again for comment before finalization. To that end, interested parties are encouraged to submit comments on the 1996 draft obesity guidance.

This request for comments on the 1996 draft guidance is being issued consistent with FDA's good guidance practices (GGPs) regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirement of the applicable statutes and regulations.

## **II. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance. 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 the brackets in the heading of this document. A copy of 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 draft guidance at either <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: 1/6/04  
January 6, 2004.

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Jeffrey Shuren,  
Assistant Commissioner for Policy.

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