

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Certifier D. Hawkins

[Docket No. 2007D-0040]

Draft Guidance for Industry on Developing Products for Weight Management; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Developing Products for Weight Management." FDA is interested in updating the September 1996 draft guidance entitled "Guidance for the Clinical Evaluation of Weight-Control Drugs" by incorporating the latest scientific and clinical advances in the drug development field of obesity, including recommendations on the development of products for weight management in pediatric patients and in patients with medication-induced weight gain, and recommendations on the development of combinations of weight-management products. This action is expected to provide clear and consistent advice to those in industry who are interested in developing weight-management products.

DATES: Submit written or electronic comments on the draft guidance by *[insert date 60 days after date of publication in the Federal Register]*.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ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD

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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 Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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: Eric Colman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 3340, Silver Spring, MD 20993-0002, 301-796-1190.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Developing Products for Weight Management," which revises the September 1996 draft guidance entitled "Guidance for the Clinical Evaluation of Weight-Control Drugs."

In 1996, following input from an expert advisory panel, FDA issued the September 1996 draft guidance. The September 1996 draft guidance provides general recommendations on the development of drugs for the long-term treatment of obesity. Important areas discussed in that guidance include patient-selection criteria, size and duration of phase 3 trials, and definitions of efficacy of a weight-control drug.

On January 26, 2004, FDA issued a notice in the **Federal Register** requesting public comment on the September 1996 draft guidance for the purpose of incorporating the latest scientific and clinical advances in weight-management drug development (69 FR 3588). In September 2004, FDA convened an advisory committee meeting to discuss the public comments

received and to identify specific scientific, clinical, and regulatory issues that should be incorporated into an updated guidance document.

As a result, this revised draft guidance discusses several key areas of interest that are not covered in the September 1996 draft guidance. These areas include recommendations on the development of products for weight management in pediatric patients and in patients with medication-induced weight gain, and recommendations on the development of combinations of weight-management products.

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 developing products for weight management. 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 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.

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: 2/7/07
February 7, 2007.

Jeffrey Shuren,
Assistant Commissioner for Policy.

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Dawn P. Hawkins