

number (1192) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes "Special Control Guidance Document on Encapsulated Amalgam, Amalgam Alloy, and Dental Mercury Labeling," device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH home page may be accessed at <http://www.fda.gov/cdrh>.

IV. Comments

Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments regarding this draft guidance by May 21, 2002. Two copies of any 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 The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 7, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02-4029 Filed 2-19-02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D-0003]

Draft Guidance for Industry on Exercise-Induced Bronchospasm (EIB)—Development of Drugs to Prevent EIB; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Exercise-Induced Bronchospasm (EIB)—Development of Drugs to Prevent EIB." The draft

guidance is intended to assist sponsors in developing clinical trials for drugs that prevent EIB. The draft guidance addresses the types of trials that should be performed. It also discusses such issues as exercise testing, efficacy end points, and statistical analyses.

DATES: Submit written or electronic comments on the draft guidance by April 22, 2002. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the 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 Dockets Management Branch (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: Sandra L. Barnes, Center for Drug Evaluation and Research (HFD-570), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1050.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Exercise-Induced Bronchospasm (EIB)—Development of Drugs to Prevent EIB." This draft guidance is intended to assist sponsors in designing clinical development programs to achieve an indication for the "prevention" of EIB. Drugs that are given chronically to control asthma may also lessen the propensity to develop EIB, as a general consequence of decreasing bronchial hyperreactivity. An important distinction is made, however, between such chronically administered drugs and shorter acting drugs that are given acutely to prevent or treat EIB. This guidance document is intended to provide trial design suggestions to help guide sponsors who are interested in developing drugs that are given acutely to prevent EIB.

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 EIB and the development of drugs to

prevent EIB. 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 Dockets Management Branch (address above) written or electronic comments on the draft guidance. Two copies of any 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 Dockets Management Branch 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: January 30, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Fiscal Year (FY) 2002 Funding Opportunities

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice of Funding Availability.

SUMMARY: The Substance Abuse and Mental Health Services Administration (SAMHSA) Center for Mental Health Services (CMHS) announces the availability of FY 2002 funds for grants for the following activity. This notice is not a complete description of the activity; potential applicants must obtain a copy of the Guidance for Applicants (GFA), including Part I, Partnerships for Youth Transition, and Part II, General Policies and Procedures Applicable to all SAMHSA Applications for Discretionary Grants and Cooperative Agreements, before preparing and submitting an application.

Activity Partnerships for Youth Transition