ANDA No.	Drug	Applicant
74–579	Betamethasone Dipropionate Cream USP, 0.05% (base)	Clay-Park Laboratories, Inc.
75–263	Midazolam HCl Injection, 5 mg (base)/mL	AstraZeneca LP.
75–348	Ketorolac Tromethamine Injection USP, 15 mg/mL and 30 mg/mL.	Apothecon, Inc., P.O. Box 4500, Princeton, NJ 08543–4500.
75–355	Labetalol HCl Injection USP, 5 mg/mL	Do.
75–620	Midazolam HCl Injection, 1 mg (base)/mL and 5 mg (base)/mL.	Do.
75–641	Midazolam HCl Injection, 5 mg (base)/mL	Do.
75–642	Bisoprolol Fumarate and Hydrochlorothiazide Tablets	Do.
75–707	Famotidine Injection, 10 mg/mL	Do.
75–708	Famotidine Injection, 10 mg/mL (preservative free)	Do.
83–115	Niacin Tablets USP, 500 mg	Impax Laboratories, Inc., 30831 Huntwood Ave., Hayward, CA 94544.
84–968	Nitrofurazone Ointment USP, 0.2%	Clay-Park Laboratories, Inc.
85–130	Nitrofurazone Topical Solution USP, 0.2%	Do.
86–424	Triple Sulfa Vaginal Cream	Altana Inc., 60 Baylis Rd., Melville, NY 11747.
86–810	Fluocinolone Acetonide Cream USP, 0.01%	Clay-Park Laboratories, Inc.
86–811	Fluocinolone Acetonide Cream USP, 0.025%	Do.
89–784	Meperidine HCl Injection USP, 50 mg/mL	AstraZeneca LP.
89–788	Meperidine HCl Injection USP, 1,000 mg/mL	Do.

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) and under authority delegated to the Director, Center for Drug Evaluation and Research (21 CFR 5.82), approval of the applications listed in the table in this document, and all amendments and supplements thereto, is hereby withdrawn, effective March 22, 2002.

Dated: February 12, 2002.

Steven K. Galson,

Deputy Director, Center for Drug Evaluation and Research.

[FR Doc. 02–4091 Filed 2–19–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0064]

Draft Special Control Guidance Document on Encapsulated Amalgam, Amalgam Alloy, and Dental Mercury Labeling; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Special Control Guidance Document on Encapsulated Amalgam, Amalgam Alloy, and Dental Mercury Labeling.'' This draft guidance is neither final nor is it in effect at this time. Elsewhere in this issue of the **Federal Register**, the agency is proposing to classify encapsulated amalgam into class II, to amend the classification regulation for amalgam alloy to provide for special controls, and to reclassify dental mercury into class II. The draft guidance document is intended to serve as a special control for these devices.

DATES: Submit written or electronic comments on the draft guidance by May 21, 2002. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the draft guidance entitled ''Special Control Guidance Document on Encapsulated Amalgam, Amalgam Alloy, and Dental Mercury Labeling'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. 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. Comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Susan Runner, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–827–5283.

SUPPLEMENTARY INFORMATION:

I. Background

Elsewhere in this issue of the **Federal Register**, the agency is proposing to classify encapsulated amalgam into class II, to amend the classification regulation for amalgam alloy to provide for special controls, and to reclassify dental mercury into class II. The draft guidance document is intended to serve as a special control for these devices. The guidance document contains recommendations concerning the content and format of labeling for these devices.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This draft guidance document represents the agency's current thinking on encapsulated amalgam, amalgam alloy, and dental mercury labeling. 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 applicable statutes and regulations. This draft guidance document is issued as a level 1 guidance consistent with the GGP regulations.

III. Electronic Access

In order to receive the draft guidance entitled ''Special Control Guidance Document on Encapsulated Amalgam, Amalgam Alloy, and Dental Mercury Labeling '' via your fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document

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]

BILLING CODE 4160–01–S

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.

[FR Doc. 02–4090 Filed 2–19–02; 8:45 am]

BILLING CODE 4160–01–S

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