This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Circulatory System Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on December 7, 1998, 8 a.m. to 5 p.m.

Location: Holiday Inn, Ballroom, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: John E. Stuhlmuller, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8243, ext. 157, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12625. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss and make recommendations on clinical trial requirements for future approval of coronary stents. An outline of the types of issues to be discussed by the committee can be found on the FDA website at ''http://www.fda.gov/cdrh/upadvmtg.html''. Single copies of this outline are also available to the public by contacting the Division of Small Manufacturers Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 1–800–638–2041 or 301–443–6597.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by November 30, 1998. Oral presentations from the public will be scheduled between approximately 8 a.m. and 8:30 a.m., on December 7, 1998. Near the end of committee deliberations, a 30-minute open public hearing will be conducted for interested persons to address issues specific to the topics before the committee. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 30, 1998, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: November 12, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98–30936 Filed 11–18–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0336]

Agency Information Collection Activities; Announcement of OMB Approval; Premarket Notification Submission 510(k), Subpart E

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Premarket Notification Submission 510(k), Subpart E'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

FOR FURTHER INFORMATION CONTACT: Margaret R. Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 1, 1998 (63 FR 46462), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the PRA (44 U.S.C. 3507). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

OMB has now approved the information collection and has assigned OMB control number 0910–0120. The approval expires on October 31, 2001.

Dated: November 11, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–30879 Filed 11–18–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0168]

Agency Information Collection Activities; Announcement of OMB Approval; Supplements to Premarket Approval Applications for Medical Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Supplements to Premarket Approval Applications for Medical Devices'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

FOR FURTHER INFORMATION CONTACT: Margaret R. Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 8, 1998 (63 FR 54042), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the PRA (44 U.S.C. 3507). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0385. The approval expires on October 31, 2001.

Dated: November 11, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–30989 Filed 11–18–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–1001]

Draft Guidance for Industry: In Vivo Drug Metabolism/Drug Interaction Studies—Study Design, Data Analysis, and Recommendations for Dosing and Labeling; 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 ''In Vivo Drug Metabolism/Drug Interaction Studies—Study Design, Data Analysis, and Recommendations for Dosing and Labeling.'' This draft guidance is intended to provide recommendations to sponsors and applicants of new drug applications (NDA's) and biologics license applications (BLA's) for therapeutic biologics (hereafter drugs) on carrying out in vivo drug metabolism and metabolic drug-drug interaction studies. The draft guidance reflects the current view that the metabolism of a new drug should be defined during drug development and that its interactions with other drugs should be explored as part of an adequate assessment of the safety and effectiveness of the drug.

DATES: Written comments may be submitted on the draft guidance by January 19, 1999. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of ''In Vivo Drug Metabolism/Drug Interaction Studies—Study Design, Data Analysis, and Recommendations for Dosing and Labeling'' are available on the Internet at ''http://www.fda.gov/cder/guidance/index.htm'' or ''http://www.fda.gov/cber/guidelines.htm''. Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; or the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), 1401 Rockville Pike, Rockville, MD 20852–1448, FAX 888–CBERFAX or 301–827–3844. 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.

FOR FURTHER INFORMATION CONTACT: Shiew Mei Huang, Center for Drug Evaluation and Research (HFD–850), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5671, or David Green, Center for Biologics Evaluation and Research (HFM–579), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–5349.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled ''In Vivo Drug Metabolism/Drug Interaction Studies—Study Design, Data Analysis, and Recommendations for Dosing and Labeling.'' Previous guidance from FDA on the use of in vitro approaches to study metabolism and metabolic drug-drug interactions is available in a document entitled ''Drug Metabolism/Drug Interaction Studies in the Drug Development Process: Studies in Vitro.'' The present guidance should be viewed as a companion to this earlier guidance. The present guidance discusses study design, choice of interacting drugs, and data analysis and provides recommendations for dosing and labeling.

This draft level 1 guidance document is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). It represents the agency's current thinking on drug metabolism and drug-drug interactions. 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 statute, regulations, or both.

Interested persons may, at any time, submit written comments on the draft guidance to the Dockets Management Branch (address above). 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: November 13, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–30937 Filed 11–18–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0997]

Draft Guidance for Industry on Metered Dose Inhaler (MDI) and Dry Powder Inhaler (DPI) Drug Products; Chemistry, Manufacturing, and Controls Documentation; 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 ''Metered Dose Inhaler (MDI) and Dry Powder Inhaler (DPI) Drug Products; Chemistry, Manufacturing, and Controls Documentation.'' This draft document provides guidance for industry on the chemistry, manufacturing, and controls (CMC) documentation to be submitted in new drug applications (NDA's) and abbreviated new drug applications (ANDA's) for metered dose inhalation aerosols, metered dose nasal aerosols, and inhalation powders.

DATES: Written comments may be submitted on the draft guidance document by February 17, 1999. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of this draft guidance are available on the Internet at ''http://www.fda.gov/cder/guidance/index.htm.'' Written requests for single copies of the draft guidance should be submitted to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. 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.

FOR FURTHER INFORMATION CONTACT: Guirag Poochikian, Center for Drug Evaluation and Research (HFD–570), Food and Drug Administration, 5600 Fishers Lane, rm. 10B45, Rockville, MD 20857, 301–827–1050.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled ''Metered Dose Inhaler (MDI) and Dry Powder Inhaler (DPI) Drug Products; Chemistry, Manufacturing, and Controls Documentation.'' This draft guidance sets forth information that should be provided to ensure continuing drug product quality and performance characteristics for MDI's and DPI's. In addition to providing guidance on CMC documentation to be submitted in NDA's and ANDA's for DPI's and MDI's, the draft guidance covers CMC information recommended for inclusion in the application with regard to the components, manufacturing process, and the controls associated with each of these areas. The document does not address inhalation solutions or aqueous nasal sprays.

FDA intends to sponsor a public meeting in 1999 on MDI and DPI drug products. The comments submitted on