Information and Regulatory Affairs, Attn: OMB Desk Officer for ACF, Office of Management and Budget, Paperwork Reduction Project, 725 17th Street N.W., Washington, D.C. 20503, (202) 395–7316.

Dated: July 28, 1997.

Robert Driscoll,

Reports Clearance Officer.

[FR Doc. 97–20315 Filed 7–31–97; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0201]

Agency Information Collection Activities: Proposed Collection; Comment Request; Extension; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a reopening of the comment period on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reopening of an existing collection of information, and to allow 60 days for public comment in response to the notice. The notice is reopening the comment period for a data collection effort consisting of consumer surveys regarding preferences for, and comprehension of information contained in different formats and methods for communication in over-the-counter (OTC drug labels), studies C and D.

DATES: Submit written comments on the collection of information studies C and D by September 30, 1997.

ADDRESSES: Submit written comments of information for studies C and D to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, ATTN: OTC Drug Labeling Data Collection. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–19, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 23, 1997 (62 FR 28482), FDA published a notice soliciting comments on a data collection effort consisting of four consumer surveys regarding preferences for, and comprehension of information contained in different formats and methods for communication in over-the-counter (OTC) drug labels. To give interested persons additional time to submit comments on the proposed data collection for studies C and D. The agency is reopening the comment period for studies C and D only until September 30, 1997.

Dated: July 28, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–20389 Filed 7-31-97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0304]

Draft Guidance on Medical Device Labeling—Suggested Form and Content; 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 medical devices entitled ''Medical Device Labeling—Suggested Form and Content.'' The draft guidance is intended to assist the device manufacturers in designing labeling and FDA in evaluating labeling and to promote clarity and uniformity in medical device labeling. The draft guidance identifies a suggested content for device labeling and each element of the suggested labeling is discussed.

DATES: Written comments concerning this draft guidance must be received by October 30, 1997.

ADDRESSES: Written comments concerning this draft guidance must be submitted to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Comments should be identified with the docket number found in brackets in the heading of this document. Submit written requests for single copies of ''Medical Device Labeling—Suggested Form and Content'' 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. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Dan A. Spyker, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8320, or e-mail: dxs@cdrh.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

There are labeling requirements for medical devices in the Federal Food, Drug, and Cosmetic Act (the act) and in the regulations issued under the act in Title 21 of the Code of Federal Regulations (CFR). General labeling requirements can be found in 21 CFR part 801, while detailed and specific labeling requirements for in vitro diagnostic products appear in 21 CFR 809.10. In 1991 FDA issued a Blue Book Memorandum #G91–1, entitled ''Device Labeling Guidance.'' The ''Device Labeling Guidance'' has been in use since it was issued, but CDRH studies and experience have demonstrated a need for greater direction in the format and content of device labeling. Therefore, this updated and expanded guidance has been drafted. Neither the act nor the regulations provide specific definitions or explanations of some significant labeling terms such as warnings, precautions, contraindications and adverse events. Because labeling is a key factor in the FDA clearance of premarket notifications (510(k)'s) and approval of premarket approval applications (PMA's), it is important that manufacturers and FDA personnel have a common understanding of how these terms and other elements of labeling are defined. An alternative approach may be used if such approach satisfies the applicable statute and regulations. Furthermore, this draft guidance will not be retrospective; it is intended for use in the preparation and review of labeling prior to the issuance of a final FDA decision.

This draft guidance represents the agency's current thinking on device 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 statute, regulations, or both.

II. Comments

Interested persons may, on or before October 30, 1997, submit to the Dockets Management Branch (address above) written comments regarding this 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 may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

In order to receive the ''Medical Device Labeling—Suggested Form and Content'' draft guidance 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 access DSMA Facts, at second voice prompt press 2, and then enter the document number 119 followed by the pound sign (#). Then 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 World Wide Web (www). CDRH maintains an entry on the World Wide Web for easy access to information including text, graphics, and files that may be downloaded to a PC with access to the Web. Updated on a regular basis, the CDRH homepage includes the ''Medical Device Labeling—Suggested Form and Content'' draft guidance, 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 homepage may be accessed at ''http://www.fda.gov/cdrh''. The ''Medical Device Labeling—Suggested Form and Content'' draft guidance is available at ''http://www.fda.gov/cdrh/draftgui.html''.

A text-only version of the CDRH Web site is also available from a computer or VT–100 compatible terminal by dialing 800–222–0185 (terminal settings are 8/1/N). Once the modem answers, press Enter several times and then select menu choice 1: FDA BULLETIN BOARD SERVICE. Select menu choice 1–FDA Bulletin Board Service. At login prompt type ''bbs'' and hit Enter, at password prompt type ''bbs'' and hit Enter, at this screen, hit Enter (brings you to FDA Home Page), using tab key, select Medical Devices/Radiological Health—hit Enter, using
tab key, select Topic Index—hit Enter, using tab key, select ''L''—hit Enter, under ''Labeling'' is the title of the draft guidance ''Medical Device Labeling-Suggested Form and Content''—select text file—hit Enter, use space bar to move page to page, in order to view the whole document.

Dated: July 2, 1997.

Joseph A. Levitt.

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 97–20313 Filed 07–31–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0312]

Medical Devices; Device Labeling Requirements; Notice of Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing an open public meeting to discuss the draft guidance entitled ''Medical Device Labeling—Suggested Format and Content,'' which is being announced elsewhere in the issue of the **Federal Register**, and to identify other concerns that manufacturers and others may have regarding the medical device labeling regulation or the labeling procedures used by the Center for Devices and Radiological Health (CDRH). Revision of the labeling requirements for in vitro diagnostic products is not being considered at this time. Health care practitioners and lay users of medical devices are encouraged to participate in the public meeting.

DATES: The public meeting will be held on September 5, 1997, from 9 a.m. to 5 p.m. Written notices of participation should be filed by August 22, 1997. Submit written comments by September 24, 1997.

ADDRESSES: The public meeting will be held at the Double Tree Hotel, 1750 Rockville Pike, Rockville, MD 20852. Submit written notices of participation and written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Patricia A. Kingsley, Center for Devices and Radiological Health (HFZ–230), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–2436, or via Internet at ''PAK@cdrh.fda.gov''.