

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]

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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]

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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