

C. Availability of Funds

Approximately \$200,676 is available in FY 2001 to support this project. It is expected that the award will begin on or about September 1, 2001, and will be made for a 12-month budget period within a one year project period. Funding estimates may change.

D. Where To Obtain Additional Information

To obtain business management technical assistance contact: Michael Smiley, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Room 3000, MS-E13, Atlanta, GA 30341-4146, Telephone: (770) 488-2694, Email address: znr6@cdc.gov.

For program technical assistance, contact: Liane Hostler, Air Pollution and Respiratory Health Branch, Division of Environmental Hazards and Health Effects, National Center for Environmental Health, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-E17 Atlanta, GA 30333, Telephone: (404) 639-2503, Email address: lch2@cdc.gov.

Dated: May 25, 2001.

Henry S. Cassell, III,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N-0078]

Agency Information Collection Activities; Proposed Collections; Reopening of Comment Period; Direct-to-Consumer Promotion of Prescription Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; Reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening the comment period to June 5, 2001, the comment period for the two proposed collections of certain information by the agency. This notice reopens the comment period on surveys of physicians and patients to examine the impact of direct-to-consumer (DTC) promotion of prescription drugs. The purpose of the proposed information

collection is to followup on the agency's 1999 patient survey and expand information collection to include physicians.

DATES: Submit written or electronic comments on the collection of information by June 5, 2001.

ADDRESSES: Submit electronic comments on the collection of information to: <http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm>. Submit written comments by June 5, 2001, on the collection of information to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Karen Nelson, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

SUPPLEMENTARY INFORMATION: FDA needs information from physicians and patients about their reactions to, and behaviors that stem from, DTC prescription drug advertising in order to develop policy on appropriate requirements for regulating drug product promotional materials. The agency is reopening the comment period for the proposed collections due to technical problems encountered on the electronic comment submission site during the previous comment period.

Dated: May 29, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01-13908 Filed 5-30-01; 11:29 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D-0232]

Medical Devices Premarket Guidance: Reprocessing and Reuse of Single-Use Devices; Draft Guidance for Industry and FDA Staff; 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 "Premarket Guidance: Reprocessing and Reuse of Single-Use

Devices." This draft guidance document provides premarket guidance to the medical device industry, including third party and hospital reproprocessors, and to Center for Devices and Radiological Health (CDRH) staff, who are responsible for the premarket evaluation of submissions for reprocessed single-use devices (SUDs) or related enforcement activities. This draft guidance is neither final nor is it in effect at this time.

DATES: Submit written comments on the draft guidance by August 30, 2001.

ADDRESSES: Submit written requests for single copies on a 3.5" diskette of the draft guidance document entitled, "Premarket Guidance: Reprocessing and Reuse of Single-Use Devices" to the Division of Small Manufacturers Assistance (HFZ-220), Center for Devices and Radiological Health, 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 information on electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Tim Ulatowski, Center for Devices and Radiological Health (HFZ-480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-8879.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of August 14, 2000 (65 FR 49583), FDA published a final guidance entitled "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals" ("the Enforcement Priorities document"). The Enforcement Priorities document provides guidance to third parties and hospital reproprocessors about their responsibilities as manufacturers engaged in reprocessing devices labeled for SUDs under the Federal Food, Drug, and Cosmetic Act. This draft guidance document entitled "Premarket Guidance: Reprocessing and Reuse of Single-Use Devices," expands upon the summary premarket information in the Enforcement Priorities document.

II. Significance of Guidance

This draft guidance document represents the agency's current thinking on policies and recommendations regarding premarket regulatory and technical issues for reprocessed SUDs. 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