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).

[FR Doc. 01–13736 Filed 5–31–01; 8:45 am]

BILLING CODE 4163–18–P

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]

BILLING CODE 4160–01–S

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 reprocessors, 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 reprocessors 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

such approach satisfies the applicable statute and regulations.

The agency has adopted good guidance practices (GGPs), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (21 CFR 10.115; 65 FR 56468, September 19, 2000). This draft guidance document is issued as a Level 1 guidance in accordance with the GGP regulations.

III. Electronic Access

In order to receive ''Premarket Guidance: Reprocessing and Reuse of Single-Use Devices'' via your fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number (1331) 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 access to the Internet. Updated on a regular basis, the CDRH home page includes the civil money penalty guidance documents package, 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. Guidance documents are also available on the Dockets Management Branch Internet site at http://www.fda.gov/ohrms/dockets/default.htm.

IV. Comments

Interested persons may submit to Dockets Management Branch (address above) written comments regarding this draft guidance by August 30, 2001. Submit two copies of any comments, 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 document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 22, 2001.

Linda S. Kahan,

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

[FR Doc. 01–13731 Filed 5–31–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–906]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, DHHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Revision of a Currently Approved Collection; *Title of Information Collection:* The National Data Reporting Requirements (NDRR). We are requesting the name of the collection be changed to the Fiscal Soundness Reporting Requirements (FSRR). and Supporting Regulations in 42 CFR 417., .126.478,. 162; *Form No.:* HCFA–906 (OMB# 0938–0469); *Use:* HCFA needs this information to establish an on-going fiscal soundness of the Managed Care Organizations in the Medicare+Choice Program; *Frequency:* Quarterly; *Affected Public:* Business or other for-profit; *Number of Respondents:* 300; *Total Annual Responses:* 300; *Total Annual Hours:* 301.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Attention: Melissa Musotto, Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: May 17, 2001.

John P. Burke, III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 01–13762 Filed 5–31–01; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–10008]

Agency Information Collection Activities: Submission For OMB Review; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Reinstatement, without change, of a previously approved collection for which approval has expired;

Title of Information Collection: Medical Equipment and Supplies Consumer Survey;