

d. Detailed Line-Item Budget and Justification.

e. Additional Requested Information.

2. Financial status report, no more than 90 days after the end of the budget period.

3. Final financial and performance reports, no more than 90 days after the end of the project period.

Send all reports to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

Additional Requirements

The following additional requirements are applicable to this program. For a complete description of each, see Attachment 1 of the program announcement as posted on the CDC Web site.

AR-9 Paperwork Reduction Act Requirements

AR-10 Smoke-Free Workplace Requirements

AR-11 Healthy People 2010

AR-12 Lobbying Restrictions

AR-15 Proof of Non-Profit Status

Executive Order 12372 does not apply to this program.

J. Where to Obtain Additional Information

For this and other CDC announcements, the necessary applications, and associated forms can be found at the CDC Internet address: <http://www.cdc.gov>.

Click on "Funding" then "Grants and Cooperative Agreements".

For general questions about this announcement, contact: Technical Information Management, CDC Procurement and Grants Office, 2920 Brandywine Rd, Atlanta, GA 30341-4146, Telephone: (770)488-2700.

For business management and budget assistance, contact: Glynnis Taylor, Grants Management Specialist, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Road, Atlanta, GA 30341-4146, Telephone: (770)488-2752, e-mail address: GLD1@CDC.GOV.

For program technical assistance, contact: Amy Harris, MPA, Office of Program and Policy Information, Division of Cancer Prevention and Control, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, 4770 Buford Highway, NE., Atlanta, Georgia 30341-3717, Telephone: (770)488-4226, e-mail: ABHarris@CDC.GOV.

Dated: March 5, 2003.

Sandra R. Manning,

CGFM, Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN RESOURCES

Food and Drug Administration

[Docket No. 03N-0079]

Agency Information Collection Activities; Proposed Collection; Comment Request; Consumer and Producer Surveys on Economic Issues

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on proposed voluntary surveys of consumers and producers in order to help FDA comply with Executive Order 12866, the Regulatory Flexibility Act (RFA), and the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA).

DATES: Submit written or electronic comments on the collection of information by May 12, 2003.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm>. Submit written comments 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: Peggy Robbins, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal

agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506 (c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity, of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Consumer and Producer Surveys on Economic Issues (OMB Control Number 0910-0478)—Extension

Under section 903(d)(2) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 393), FDA is authorized to conduct research relating to regulated articles and to collect information relating to responsibilities of the agency. Executive Order 12866, RFA, and SBREFA direct Federal agencies to conduct regulatory impact analysis, and to consider flexible regulatory approaches. In order to perform the mandatory analysis it is often necessary to survey regulated producers to determine existing practices and the changes in those practices likely under various policy options, both consumers and manufacturers to explore attitudes towards policy proposals, and industry experts to solicit expert opinion. FDA is seeking OMB clearance to conduct future surveys to implement Executive Order 12866, RFA, and SBREFA. Participation in the surveys will be voluntary. This request covers regulated

entities, such as food processors, dietary supplement manufacturers, health professionals, or other experts and consumers.

FDA will use the information gathered from these surveys to identify

current business practices, expert opinion, and consumer or manufacturer attitudes towards existing or proposed policy. FDA projects approximately 2 to 6 surveys per year, with a sample of between 10 and 1,000 respondents each

for mail and telephone surveys, and a sample of up to 3,000 respondents for cable or Internet surveys.

FDA estimates the upper bound burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

Type of Survey	No. of Respondents	Annual Frequency per Response	Hours per Response	Total Hours
Mail Questionnaire	1,000	1	3	3,000
Phone Survey	1,000	1	.5	500
Internet or Cable Survey	3,000	1	1	3,000
Total				6,500

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

These estimates are based on the expected number of respondents necessary to obtain a statistically significant stratification of the average to large size industries—including small business entities covered by FDA regulations—and consumers of regulated products.

Dated: March 4, 2003.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 03-5790 Filed 3-11-03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03N-0050]

Agency Information Collection Activities; Proposed Collection; Comment Request; Investigational Device Exemptions Reports and Records

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing information collection, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection requirements for

investigational device exemptions (IDE) reports and records.

DATES: Submit written or electronic comments on the collection of information by May 12, 2003.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm*. Submit written comments 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: Peggy Robbins, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

SUPPLEMENTARY INFORMATION:

I. Background

Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this

requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Investigational Device Exemptions Reports and Records—21 CFR Part 812 (OMB Control No. 0910-0078)—Extension

Section 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(g)) establishes the statutory authority to collect information regarding investigational devices, and establishes rules under which new medical devices may be tested using human subjects in a clinical setting. The Food and Drug Administration Modernization Act of 1997 added section 520(g)(6) to the act and permitted changes to be made to either the investigational device or to the clinical protocol without FDA approval of an IDE supplement.

An IDE allows a device, which would otherwise be subject to provisions of the act, such as premarket notification or premarket approval, to be used in investigations involving human subjects in which the safety and effectiveness of