

vitae for existing staff who are assigned to this project.

c. (5 points) The extent to which the applicant provides an organizational chart that identifies lines of communication, accountability, reporting, authority, and describes management and control systems within the organization and discusses how the proposed placement of the project in the organization will increase its likelihood of success.

#### 4. Collaboration (20 Points)

a. (15 points) The extent to which the applicant describes current collaboration with states' health, education, and agricultural departments, the organization's collaboration with other federal agencies, national non-profit organizations, foundations, community-based groups, and others who have an interest in or whose mission includes food safety programs, and discusses how the current collaborative relationships can compliment the proposed project. The extent to which the applicant indicates proposed collaborative relationships that will support the proposed operational plan and includes letters of participation and support documenting these anticipated collaborations especially with proposed activities.

b. (5 points) The extent to which the applicant describes collaborative activities or anticipated relationships with other national organizations who support school-based health education programs, and includes letters of participation and support documenting these anticipated collaborations. The extent to which the applicant describes how the organization can compliment the activities of existing organizations and how their expertise can support this proposed project.

#### 5. Evaluation Plan (5 Points)

The extent to which the applicant describes their plan to evaluate progress in meeting objectives and conducting activities during the budget period including their ability to describe: (1) What data will be obtained; (2) how the data will be obtained; (3) how evaluation information will be disseminated; (4) how the evaluation data will be used to improve the program; and (5) who will implement the evaluation plan and when.

#### 6. Budget and Justification (Not Scored)

The extent to which the budget is reasonable and consistent with the purposes and activities of the program.

## H. Other Requirements

### Technical Reporting Requirements

1. Provide CDC with original plus two copies of the progress report, submitted on an annual basis and due 90 days after the end of the budget period. The progress reports must include the following for each program, function, or activity involved:

- A comparison of actual accomplishments to the objectives established for the period;
- Documentation on why established objectives were not met; and
- A summary of the project's annual progress in achieving performance measures, which will be developed and established in collaboration with CDC during the first budget period.

2. Provide CDC with original plus two copies of the financial status report, no more than 90 days after the end of the budget period.

3. Final financial and progress reports, no more than 90 days after the end of the project period, should be sent to the business management contact listed in Section J, "Where to Obtain Additional Information."

The following additional requirements are applicable to this program. For a complete description of each, see Attachment I in the application kit.

- AR-7 Executive Order 12372 Review
- AR-8 Public Health System Reporting Requirement
- AR-9 Paperwork Reduction Act Requirements
- AR-10 Smoke-Free Workplace Requirements
- AR-11 Healthy People 2010
- AR-12 Lobbying Restrictions
- AR-14 Accounting System Requirements
- AR-15 Proof of Non-Profit Status
- AR-20 Conference Support

### I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under sections 301(a), 311(b) and (c), and 317 (k)(2) [42 U.S.C. 241(a), 243(b) and (c), and 247b(K)(2)] of the Public Health Service Act, as amended. The Catalog of Federal Domestic Assistance number is 93.938.

### J. Where To Obtain Additional Information

If you have questions after reviewing the contents of all documents, business management technical assistance may be obtained from: Jesse Robertson, Grants Management Specialist, Grants Management PA00109, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Rd, M/S E18, Atlanta,

Georgia 30341-4146, telephone (770) 488-2747, jtr4@cdc.gov.

This and other CDC announcements can be found on the CDC Homepage Internet address: <http://www.cdc.gov> Also, CDC Guidelines to Promote Healthy Eating: <http://www.cdc.gov/nccddphp/dash/nutguide.htm> and CDC Guidelines to Promote Physical Activity: <http://www.cdc.gov/nccddphp/dash/physact.htm>

For program technical assistance, contact: Pete Hunt, Chief, School Program Section, Program Development and Services Branch, Division of Adolescent and School Health, National Center for Chronic Disease Prevention and Health Promotion, Announcement 00109, Centers for Disease Control and Prevention, 4770 Buford Highway, NE MS K31, Atlanta, GA 30341, telephone: 770-488-3253, pch0@cdc.gov.

Dated: June 13, 2000.

**John L. Williams,**

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

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 00N-1311]

### Agency Information Collection Activities; Proposed Collection; Comment Request; Export of Medical Devices—Foreign Letters of Approval

**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 collection of information requirements for reporting requirements for firms that intend to export certain unapproved medical devices.

**DATES:** Submit written comments on the collection of information by August 21, 2000.

**ADDRESSES:** 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 Schlosburg, 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.

**Export of Medical Devices—Foreign Letters of Approval—Federal Food, Drug, and Cosmetic Act—21 U.S.C. 381(e)(2) (OMB Control No. 0910-0264)—Extension**

Section 801(e)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21

U.S.C. 381(e)(2)) provides for the exportation of an unapproved device under certain circumstances if the exportation is not contrary to the public health and safety and it has the approval of the foreign country to which it is intended for export.

Requesters communicate (either directly or through a business associate in the foreign country) with a representative of the foreign government to which they seek exportation, and written authorization must be obtained from the appropriate office within the foreign government approving the importation of the medical device.

FDA uses the written authorization from the foreign country to determine whether the foreign country has any objection to the importation of the device into their country.

The respondents to this collection of information are companies that seek to export medical devices.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

Statute	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Section 801(e)(2) of the Federal Food, Drug, and Cosmetic Act	20	1	20	2.5	50
Total					50

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

These estimates are based on the experience of FDA's medical device program personnel, who estimate that completion of the requirements of this collection of information should take approximately 2.5 hours to complete. Prior to the enactment of the Food and Drug Export Reform and Enhancement Act of 1996, FDA received approximately 800 requests from U.S. firms to export medical devices under section 801(e)(2) of the act. The enactment of the Food and Drug Export Reform and Enhancement Act of 1996 has greatly reduced the number of export permit requests made to the present estimated 20 per year.

Dated: June 14, 2000.

**William K. Hubbard,**

*Senior Associate Commissioner for Policy, Planning, and Legislation.*

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**BILLING CODE 4160-01-F**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**[Docket No. 99N-4166]**

**Agency Information Collection Activities; Announcement of OMB Approval; Electronic Records; Electronic Signatures**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Electronic Records; Electronic Signatures" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:**

JonnaLynn P. Capezutto, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of October 1, 1999 (64 FR 53392), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0303. The approval expires on May 31, 2003. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.