

By order of the Board of Governors of the Federal Reserve System, October 22, 2003.

**Jennifer J. Johnson,**  
Secretary of the Board.  
[FR Doc. 03-27123 Filed 10-27-03; 8:45 am]  
BILLING CODE 6210-01-C

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**National Task Force on Fetal Alcohol Syndrome and Fetal Alcohol Effect: Cancellation of Meeting**

This notice announces the cancellation of a previously announced meeting.

*Federal Notice Citation of Previous Announcement:* September 16, 2003 (Volume 68, Number 179) [Notices] [Page 54231] from the **Federal Register** online via GPO Access.

*Previously Announced Times and Dates:* 8:30 a.m.–4 p.m., November 6, 2003, 8:30 a.m.–12:30 p.m., November 7, 2003.

*Change in the Meeting:* This meeting has been canceled.

*Contact Person for More Information:* R. Louise Floyd, D.S.N., R.N., Executive Secretary, Fetal Alcohol Syndrome Prevention Team, Division on Birth Defects and Developmental Disabilities, National Center on Birth Defects and Developmental Disabilities, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, NE., Mailstop E-86, Atlanta, Georgia 30333, telephone 404/498-3923, fax 404/498-3040.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: October 22, 2003.

**Alvin Hall,**  
Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 03-27106 Filed 10-27-03; 8:45 am]  
BILLING CODE 4163-18-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Proposed Information Collection Activity; Comment Request**

**Proposed Projects**

*Title:* April 2004 Current Population Survey Supplement on Child Support.

*OMB No.:* 0992-0003.

*Description:* Collection of the data will assist legislators and policymakers in determining how effective their policymaking efforts have been over time in applying the various child support legislation to the overall child support enforcement picture. This information will help policymakers determine to what extent individuals on welfare would be able to leave the welfare rolls as a result of more stringent child support enforcement efforts.

*Respondents:* Individuals and Households.

**ANNUAL BURDEN ESTIMATES**

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Survey .....	47,000	1	.0246	1156

*Estimated Total Annual Burden Hours:* 1156.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: [rsargis@acf.hss.gov](mailto:rsargis@acf.hss.gov). All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the

information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: October 21, 2003.

**Robert Sargis,**  
Reports Clearance Officer.  
[FR Doc. 03-27084 Filed 10-27-03; 8:45 am]  
BILLING CODE 4184-01-M

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 2003D-0263]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Channels of Trade Policy for Commodities With Residues of Pesticide Chemicals, for Which Tolerances Have Been Revoked, Suspended, or Modified by the Environmental Protection Agency**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by November 28, 2003.

**ADDRESSES:** OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202-395-6974.

**FOR FURTHER INFORMATION CONTACT:** Peggy Robbins, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

**Channels of Trade Policy for Commodities With Residues of Pesticide Chemicals for Which Tolerances Have Been Revoked, Suspended, or Modified by the Environmental Protection Agency**

Under the pesticide tolerance reassessment process that the Environmental Protection Agency (EPA) was mandated to carry out under the

Food Quality Protection Act of 1996 (FQPA), EPA is expected to revoke, suspend, or modify tolerances for the pesticide chemicals on various food commodities. Section 408(l)(5) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 346a) includes a provision, referred to as the "channels of trade provision," that addresses the circumstances under which a food will not be deemed unsafe solely due to the presence of a residue from a pesticide chemical whose tolerance has been revoked, suspended, or modified by EPA.

In general, FDA anticipates that the party responsible for food found to contain the previously mentioned pesticide chemical residues (within the former tolerance) after the tolerance for the pesticide chemical has been revoked, suspended, or modified will be able to demonstrate that such food was handled, e.g., packed or processed, during the acceptable timeframes cited in the draft guidance by providing appropriate documentation to the agency as discussed in the draft guidance document. FDA is not suggesting that firms maintain an inflexible set of documents where anything less or different would likely

be considered unacceptable. Rather, the agency is leaving it to each firm's discretion to maintain appropriate documentation to demonstrate that the food was so handled during the acceptable timeframes.

Examples of documentation which FDA anticipates will serve this purpose consist of documentation associated with packing codes, batch records, and inventory records. These are types of documents that many food processors routinely generate as part of their basic food-production operations.

*Description of Respondents:* The likely respondents to this collection of information are firms in the produce and food-processing industries that handle food products that may contain residues of pesticide chemicals after the tolerances for the pesticide chemicals have been revoked, suspended, or modified.

In the **Federal Register** of July 23, 2003 (68 FR 43535), FDA published a 60-day notice requesting public comment on the information collection provisions. One comment was received that did not pertain to this information collection.

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

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

No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
652	1	652	3	1,956

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

FDA does not know which pesticide chemicals will have their tolerances revoked, suspended, or modified in the future. Instead of calculating the paperwork burden for any one pesticide, FDA calculated the cost for an "average" pesticide by looking at test results for 417 pesticide chemicals on domestic products and 450 pesticide chemicals on imported products. FDA then used the average percent of samples found with residues as a substitute for the rate of residues found from a specific pesticide chemical.

The estimated annual reporting burden was determined using the average percent of samples found with residues for all pesticides for domestic

and imported products. Using 1999 pesticide monitoring data, domestic products were tested for residues of 417 pesticide chemicals. On average, 1.02 percent of samples tested positive for a given pesticide chemical. For 450 pesticides tested for residues on imported products, on average 2.40 percent of samples contained a given pesticide chemical residue. This rate of positive findings for product samples was applied to the number of potentially affected establishments, 3,730 importers and 23,201 domestic businesses, giving an expected number of 326 potentially-affected businesses per revocation, suspension, or modification of a tolerance. FDA

expects this number to be an overestimate of the number of affected businesses for two reasons. First, the positive residue test may be below the new tolerance. Second, tolerances may not be altered for all products. If the tolerance was altered for only vegetables but not fruit, then the number of affected establishments would be smaller. We assume two pesticide tolerances are altered per year, resulting in 652 businesses reporting per year. To date, tolerances have been revoked for two pesticide chemicals. However, FDA expects the total number of pesticide tolerances that are revoked, suspended, or modified by EPA to increase.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN <sup>1</sup>

No. of Record-keepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours	Capital Costs
65	1	65	16	1,042	\$32,571

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

In determining the estimated annual recordkeeping burden, FDA estimated that at least 90 percent of firms maintain documentation, such as packing codes, batch records, and inventory records, as part of their basic food production or import operations. Therefore, the recordkeeping burden was calculated as the time required for the 10 percent of firms that may not currently be maintaining this documentation to develop and maintain documentation, such as batch records and inventory records. For firms that do not maintain documentation, such as batch records and inventory records, as part of their normal manufacturing operations, it was estimated that with \$500 or less, the necessary software and hardcopy filing systems could be obtained to implement a system.

Dated: October 9, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 03–27120 Filed 10–27–03; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 1994N–0418]

#### Medical Devices; Reclassification of Automated External Defibrillators

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

**ACTION:** Notice of intent.

**SUMMARY:** The Food and Drug Administration (FDA) announces an opportunity to submit information and comments concerning FDA's intent to initiate a proceeding to reclassify automated external defibrillators (AEDs) from class III (premarket approval) to class II (special controls). AEDs are devices that deliver an electric shock to correct an arrhythmia.

**DATES:** Submit written or electronic information or comments by January 26, 2004.

**ADDRESSES:** Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit

electronic comments to <http://www.fda.gov/dockets/ecomments>.

**FOR FURTHER INFORMATION CONTACT:** Megan Moynahan, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8517, ext. 180.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

In the **Federal Register** of August 14, 1995 (60 FR 41984 and 41986), FDA published two orders for certain class III devices requiring the submission of safety and effectiveness information in accordance with the preamendments class III strategy for implementing section 515(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(i)) (FDA published two updated orders in the **Federal Register** of June 13, 1997 (62 FR 32352 and 32355)). The orders describe in detail the format for submitting the type of information required by section 515(i) of the act so that the information submitted would either support reclassification or indicate that a device should be retained in class III. The orders also scheduled the required submissions in groups, at 6-month intervals, beginning on August 14, 1996. Arrhythmia detectors and alarms, which included AEDs, were among the devices for which information was to be submitted.

In response to this document, FDA received three petitions to reclassify arrhythmia detectors and alarms from the following petitioners: (1) Health Industry Manufacturers Association (HIMA) (now known as Advamed), (2) Quinton Instrument Co., and (3) Zymed Medical Instrumentation. The Advamed petition also requested reclassification of AEDs. Additionally, Datascope Corp., Hogan and Hartson L.L.P., Life Sensing Instrument Co., Medical Data Electronics, Inc., Mennen Medical Ltd., Mortara Instrument, Inc., and Olsson, Frank, and Weeda, P.C. submitted safety and effectiveness information (515(i) submissions).

In the **Federal Register** of December 13, 2002 (67 FR 76706), FDA proposed to reclassify arrhythmia detector and alarm devices from class III to class II. These devices are used to monitor an electrocardiogram and to produce a visible or audible signal or alarm when

an atrial or ventricular arrhythmia exists. FDA also proposed to separate AEDs from the identification of the arrhythmia detector and alarm. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule reclassifying arrhythmia detector and alarm devices into class II with a special controls guidance document. The final rule also establishes a separate classification regulation for AEDs.

AEDs, primarily designed for an intended use (i.e., to correct an arrhythmia) different from arrhythmia detector and alarm devices, have a shock advisory algorithm, automatically detect a shockable cardiac rhythm, and automatically deliver an electric shock (fully automated device) or deliver a shock when activated by the operator (semiautomated device). FDA regulates AEDs as class III devices. In response to Advamed's petition (Ref. 1), FDA stated that it would publish a notice of a panel meeting that would discuss the possible reclassification of AEDs. In the December 13, 2002, proposed rule (67 FR 76706), FDA stated that it intended to propose the reclassification of the AED at a later time.

FDA is publishing this document to provide interested persons with an opportunity to submit any new information concerning the safety and effectiveness of AEDs. After FDA reviews any information that it receives in response to this notice, FDA will determine whether it should go forward with the reclassification of AEDs and whether a panel meeting is necessary before taking any action.

##### **II. Reference**

The following reference has been placed on display in the Division of Dockets Management (see **ADDRESSES**). Interested persons may view this reference between 9 a.m. and 4 p.m., Monday through Friday.

1. HIMA (Health Industry Manufacturers Association) (now known as Advamed), reclassification petition, Docket No. 1994N–0418, vol. 1–7, Washington, DC, August 14, 1996.

Dated: October 2, 2003.

**Linda S. Kahan,**

*Deputy Director, Center for Devices and Radiological Health.*

[FR Doc. 03–27116 Filed 10–27–03; 8:45 am]

**BILLING CODE 4160–01–S**