Atmosphere has delegated authority to sign material for publication in the **Federal Register** to the Assistant Administrator for Fisheries, NOAA (AA).

Classification

Pursuant to 5 U.S.C. 553 (b)(B), the AA waives prior notice and opportunity for public comment because this action is a rule of agency organization, procedure or practice. Because this rule makes only minor, non-substantive changes and does not change operating practices in any fishery, it is unnecessary to provide for prior notice and opportunity for public comment. Because this final rule, technical amendment does not constitute a substantive rule, pursuant to 5 U.S.C. 553(d), this final rule is not subject to the 30–day delay in effectiveness. This final rule, technical amendment makes no substantive changes to existing regulations, but rather updates OMB control numbers associated with NMFS information collections, all of which OMB has previously approved during implementation of regulations appearing in the individual parts of title 50 of the Code of Federal Regulations.

Because prior notice and opportunity for public comment are not required pursuant to 5 U.S.C. 553 or any other law, the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) are inapplicable. Therefore, a regulatory flexibility analysis is not required and has not been prepared.

This rule is exempt from review under Executive Order 12866.

Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB control number.

List of Subjects in 15 CFR Part 902

Reporting and recordkeeping requirements.

Dated: October 21, 2003.

John Oliver

Deputy Assistant Administrator for Operations, National Marine Fisheries Service.

■ For the reasons stated in the preamble, 15 CFR chapter IX is amended as follows:

15 CFR Chapter IX

PART 902—NOAA INFORMATION COLLECTION REQUIREMENTS UNDER THE PAPERWORK REDUCTION ACT: OMB CONTROL NUMBERS

■ 1. The authority citation for part 902 continues to read as follows: Authority: 44 U.S.C. 3501 *et seq.*

■ 2. In § 902.1, the table in paragraph (b) under 50 CFR is amended by:

■ a. Removing the following CFR parts or sections in the left hand column and their related current OMB control number(s) in the corresponding positions in the right hand column, for: 50 CFR 216.24(d), 216.24(e), 216.114, 216.155, 222.201(c) and (d), 222.202, 222.204 (f) and (g), 229.7, 663.6, 679.4, 679.4(b)(5)(vi), 679.4(k)(6)(iii), 679.4(k)(6)(iv), 679.4(k)(7)(iii), 679.5, 679.5(n)(2)(iii), 679.24, 679.28, 679.28(f)(3)(i), 679.28(f)(3)(ii), 679.28(f)(3)(iii), 679.28(f)(4), (f)(5), and (f)(6), and 679.32;

■ b. Adding the CFR part or sections in numerical order in the left hand column and its related OMB control number(s) in the corresponding right hand column in numerical order: 50 CFR 216.26, 223.203(b), 229.4, 260.15, 260.36, 260.37, 260.96, 260.97, 300.107, 600.745, 679.4(b), (f), (h), and (i), 679.4(d) and (e), 679.4(l), 679.5(a), 679.5(b), (c), (d), (g), (h), (i), (j), (k), and (m), 679.5(e), (f), and (o), 679.5(l)(1), (l)(2), (l)(3), (l)(4), and (l)(5), 679.5(l)(7), 679.5(n), 679.5(p), 679.24(a), 679.24(e), 679.28(b) and (d), 679.32(c), 679.32(d), 679.32(f), 679.45, 679.61(c) and (f), 679.61(d) and (e), 679.62(b)(3) and (c) and 679.63(a)(2); and,

■ c. Revising the control number entries in the right hand column for the following parts or section identified in the left hand column: 50 CFR 229.5, 300.34, 300.35, 300.108(a), 300.108(c), 300.125, 622.4, 622.18, 635.5(c), 640.6, 648.8, 648.9, 648.10, 648.58, 648.80, 648.84, 654.6, 660.16, 660.24, 660.25, 660.305, 660.322, 679.4(g), 679.40, 679.43, and 679.50 to read as follows:

(b) *Display*

CFR part or section where the information collection requirement is located	Current OMB control number (all numbers begin with 0648–)
* * * *	*
50 CFR	
* * * *	*
216.26	–0084
* * * *	*
223.203(b)	–0399
* * * *	*
229.4	–0293
229.5	–0292
* * * *	*
260.15	–0266
260.36	–0266
260.37	–0266
260.96	–0266
260.97	–0266
* * * *	*
300.34	–0218
300.35	–0361
* * * *	*
300.107	–0194
300.108(a)	–0368
300.108(c)	–0367
* * * *	*
300.125	–0358
* * * *	*
600.745	–0309
* * * *	*
622.4	–0205
* * * *	*
622.18	–0205
* * * *	*
635.5(c)	–0328
* * * *	*

[FR Doc. 03–27181 Filed 10–27–03; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1 and 20

[Docket Nos. 2002N–0276 and 2002N–0278]

Interim Final Regulations Implementing Title III, Subtitle A, of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002—Section 305: Registration of Food Facilities and Section 307: Prior Notice of Imported Food Shipments; Notice of Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Public meetings on interim final rules.

SUMMARY: The Food and Drug Administration (FDA) is announcing a series of domestic meetings to discuss

the interim final regulations, issued on October 10, 2003, to implement two sections of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act) regarding the registration of food facilities and prior notice of imported food shipments. The purpose of these meetings is to provide information on the rules to the public and to provide the public an opportunity to ask questions of clarification.

DATES: See table 1 of the **SUPPLEMENTARY INFORMATION** section of this document.

ADDRESSES: See table 1 of the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Marion V. Allen, Center for Food Safety and Applied Nutrition (HFS–32), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2277, FAX: 301–436–2605, e-mail: *CFSAN-FSS@cfsan.fda.gov* for general questions about the meeting.

SUPPLEMENTARY INFORMATION:

I. Background

The events of September 11, 2001, highlighted the need to enhance the security of the U.S. food supply. Congress responded by passing the Bioterrorism Act (Public Law 107–188), which was signed into law on June 12, 2002. On October 10, 2003, FDA published in the **Federal Register** two interim final rules to implement sections 305 (Registration of Food Facilities) and 307 (Prior Notice of Imported Food Shipments) of the Bioterrorism Act. During the public meetings, FDA will explain the interim final rules on the registration of food facilities and prior notice of imported food shipments, and the agency will answer questions of clarification.

Information about the public meetings, contact information, and the provisions of the Bioterrorism Act under FDA's jurisdiction can be accessed at *http://www.fda.gov/oc/bioterrorism/bioact.html.*

II. Interim Final Rules

The interim final rules that will be discussed at the public meetings announced in this document concern the following provisions of the Bioterrorism Act:

Section 305: Registration of Food Facilities—The Bioterrorism Act requires the owner, operator, or agent in charge of domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States to register with FDA no later than December 12, 2003. Farms, restaurants, retail food establishments, nonprofit food establishments that prepare or serve food directly to the consumer, and fishing vessels not engaged in processing, as defined in 21 CFR 123.3(k), are exempt from this requirement. Also exempt are foreign facilities if the food from the facility undergoes further processing or packaging by another facility outside of the United States and such processing is of more than a de minimis nature.

Section 307: Prior Notice of Imported Food Shipments—The Bioterrorism Act specifies that beginning on December 12, 2003, FDA must receive prior notice of each article of food imported or offered for import into the United States.

III. Registration for the Meetings

All attendees are asked to register for these meetings by submitting registration information (including name, title, firm name, address, telephone number, e-mail address, and fax number) at least 2 workdays before the particular meeting date. You may register online at *http://www.cfsan.fda.gov/dms/fsbtac15.html* or by fax at 202–479–6801. Space is limited, and registration will be closed at a site when maximum seating capacity for that site is reached (between 100 and 200 persons per site).

If you need special accommodations due to a disability, please notify the contact person listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

IV. Dates, Times, and Addresses of Public Meetings

A list of dates, times, and addresses for the domestic meeting is provided in table 1:

TABLE1.—NOVEMBER 2003, DOMESTIC OUTREACH MEETINGS—SECTION 305: REGISTRATION OF FOOD FACILITIES AND SECTION 307: PRIOR NOTICE OF IMPORTED FOOD SHIPMENTS

Meeting Address	Date and Local Time	FDA Contact Person
DETROIT: Marriott Detroit Metro Airport, 30559 Flynn Rd., Romulus, MI 48174	Wednesday, November 12, 2003, 9 a.m. to 12 noon	Marion Allen
LOS ANGELES: Hilton-Los Angeles Airport, 5711 West Century Blvd., Los Angeles, CA	Friday, November 14, 2003, 9 a.m. to 12 noon	Do.
JAMAICA QUEENS: La Guardia Airport Marriott Hotel, Ditmars Blvd., East Elmhurst, NY 11369	Monday, November 17, 2003, 9 a.m. to 12 noon	Do.
SAN ANTONIO: Westin Riverwalk, 420 West Market St., San Antonio, TX 78205	Tuesday, November 18, 2003, 9 a.m. to 12 noon	Do.
MIAMI: Marriott Miami Airport, 1201 NW LeJeune Rd. Miami, FL	Thursday, November 20, 2003, 9 a.m. to 12 noon	Do.
BALTIMORE: Hyatt Regency, 300 Light St., Baltimore, MD	Friday, November 21, 2003, 9 a.m. to 12 noon	Do.

Dated: October 22, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–27182 Filed 10–23–03; 3:49 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 870

[Docket Nos. 1994N–0418 and 1996P–0276]

Medical Devices: Cardiovascular Devices: Reclassification of the Arrhythmia Detector and Alarm

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is reclassifying arrhythmia detector and alarm devices from class III to class II (special controls). This device is used to monitor an electrocardiogram (ECG) and to produce a visible or audible signal or alarm when an atrial or ventricular arrhythmia occurs. An atrial or ventricular arrhythmia occurs during a premature contraction or ventricular fibrillation. FDA is reclassifying this device based on new information contained in reclassification petitions regarding the device submitted by the Health Industry Manufacturers Association (HIMA) (now known as Advamed), Quinton Instrument Co., and Zymed Medical Instrumentation. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the guidance document that will serve as the special control for this device. FDA is taking this action under the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments), the Safe Medical Devices Act of 1990 (the SMDA), the Food and Drug Administration Modernization Act of 1997 (the FDAMA), and the Medical Device User Fee and Modernization Act of 2002 (MDUFMA).

DATES: This rule is effective November 28, 2003.

FOR FURTHER INFORMATION CONTACT: Elias Mallis, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8517, ext. 177.

SUPPLEMENTARY INFORMATION:

I. Background

The act (21 U.S.C. 301 *et. seq.*) established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360(e)) established three categories (classes) of devices as a function of the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513 of the act, FDA refers to devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), as ''preamendments devices.'' FDA classifies these devices after the agency initiates the following procedures: (1) Receives a recommendation from a device classification panel (an FDA advisory committee), (2) publishes the panel's recommendation for comment, along with a proposed regulation classifying the device, and (3) publishes a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

FDA refers to devices that were not in commercial distribution before May 28, 1976, as ''postamendments devices.'' These devices are classified automatically by statute (section 513(f)) of the act) into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval, unless FDA initiates the following procedures: (1) Reclassifies the device into class I or II, (2) issues an order classifying the device into class I or II in accordance with section 513(f)(2) of the act, or (3) issues, under section 513(i) of the act, an order finding the device as substantially equivalent to a predicate device that does not require premarket approval. As delineated in section 510(k) of the act (21 U.S.C. 360(k)) and under part 870 of the regulations (21 CFR part 870), FDA determines whether new devices are substantially equivalent to previously offered devices by means of premarket notification procedures. Through premarket notification procedures, a person may, without submission of a premarket approval application (PMA), market a preamendments device that has been classified into class III until FDA issues a final regulation under section 515(b) of the act (21 U.S.C. 360e(b)) requiring premarket approval.

Section 513(e) of the act governs reclassification of classified preamendments devices. This section provides that FDA may, by rulemaking, reclassify a device based on ''new information.'' Under section 513(e) of the act, FDA can initiate a reclassification or an interested person can petition FDA to reclassify a preamendments device. The term ''new information,'' as used in section 513(e) of the act, includes information developed after the date of the device's original classification. This information could include a reevaluation of the original data or information from the time of the original classification that was not presented, available, or deemed applicable. (See, e.g., *Holland Rantos* v. *United States Department of Health, Education, and Welfare,* 587 F.2d 1173, 1174 n.1 (D.C. Cir. 1978); *Upjohn* v. *Finch*, 422 F.2d 944 (6th Cir. 1970); *Bell* v.*Goddard*, 366 F.2d 177 (7th Cir. 1966).)

Reevaluation of the data previously used by FDA is an appropriate basis for subsequent regulatory action where the reevaluation is made in light of newly available regulatory authority (see *Bell* v. *Goddard*, *supra*, 366 F.2d at 181; *Ethicon, Inc.* v. *FDA*, 762 F.Supp. 382, 389–391 (D.D.C. 1991)), or in light of changes in ''medical science.'' (See *Upjohn* v. *Finch*, *supra*, 422 F.2d at 951.) Whether data before the FDA are past or new data, the ''new information'' to support reclassification under section 513(e) of the act must be ''valid scientific evidence,'' as defined in section 513(a)(3) of the act and § 860.7(c)(2) (21 CFR 860.7(c)(2)) (See, e.g., *General Medical Co.* v. *FDA*, 770 F.2d 214 (D.C. Cir. 1985); *Contact Lens Assoc.* v. *FDA*, 766 F.2d 592 (D.C. Cir.), cert. denied, 474 U.S. 1062 (1985)).

FDA relies upon ''valid scientific evidence'' in the classification process to determine the level of regulation for devices. When reclassifying a device, FDA can only consider valid scientific evidence that is publicly available. Publicly available information excludes trade secret and confidential commercial information, e.g., the contents of a pending PMA. (See section 520(c) of the act (21 U.S.C. 360j(c).) Section 520(h)(4) of the act provides that 6 years after the date FDA has approved an application FDA may, for reclassification of a device, use certain information contained in a PMA. Useable information includes data from clinical and preclinical tests or studies that demonstrate the safety or effectiveness of the device. This information does not include descriptions of methods of manufacture, product composition, and other trade secrets.