

document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: April 9, 1996.

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

[FR Doc. 96-17474 Filed 7-9-96; 8:45 am]

BILLING CODE 4160-01-F

[Docket No. 96M-0202]

Intermedics, Inc.; Premarket Approval of Res-Q™ ACD (Arrhythmia Control Device) Epicardial Patch and Non-thoracotomy Lead (NTL) Systems

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Intermedics, Inc., Angleton, TX, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of Res-Q™ ACD (Arrhythmia Control Device) Epicardial Patch and NTL Systems. After reviewing the recommendation of the Circulatory System Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of November 28, 1995, of the approval of the application.

DATES: Petitions for administrative review by August 9, 1996.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Carole C. Carey, Center for Devices and Radiological Health (HFZ-450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-8609.

SUPPLEMENTARY INFORMATION: On March 17, 1994, Intermedics, Inc., Angleton, TX 77515, submitted to CDRH an application for premarket approval of Res-Q™ ACD Epicardial Patch and NTL Systems which consists of the following: Model 101-01 and 101-01R

Res-Q™ implantable arrhythmia control device; model 531-30 Rx2000 GRAPHICS program module to be used with Intermedics commercially available model 522-06 Rx2000 GRAPHICS programmer; models 497-05, 497-06, and 497-09 right ventricular (RV) defibrillation/pacing leads; model 497-15 subcutaneous patch lead; model 49716 superior vena cava (SVC) leads; models 497-01, 497-02, 497-11, and 497-12 epicardial patch leads; models A67 and L67 commercially available CPI® epicardial patch leads; model 370-01 adapter; model 370-21 Y-adapter; model 370-04 Test Box; models 370-03 and 370-23 Patient Cables; model 370-05 Test Load; model 370-02 Accessory Kit; model 370-10 Lead Caps; and models 370-11, 370-12, 370-13, 370-14, 370-15, 370-16, 370-48, and 370-49 Stylets. The device is an automatic, implantable cardioverter-defibrillator (ICD) system and is indicated for use in patients who are at high risk of sudden death due to ventricular arrhythmias and have experienced one of the following situations: (1) Survival of at least one episode of cardiac arrest (manifested by a loss of consciousness) due to a ventricular tachyarrhythmia; or (2) recurrent, poorly tolerated sustained ventricular tachycardia (VT).

Note: The clinical outcome for hemodynamically stable, sustained-VT patients is not fully known. Safety and effectiveness studies have not been conducted.

On August 21, 1995, the Circulatory System Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, review and recommended approval of the application. On November 28, 1995, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act (21 U.S.C. 360e(g)), for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under part 12 (21 CFR part 12)

of FDA's administrative practices and regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the Federal Register. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before August 9, 1996, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: April 9, 1996.

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

[FR Doc. 96-17473 Filed 7-9-96; 8:45 am]

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Health Resources and Services Administration

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

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443-1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Faculty Loan Repayment Program (FLRP) Application (0915-0150)

Extension and Revision—Under the HRSA FLRP program, disadvantaged

graduates from certain health professions schools may enter into a contract under which HRSA with the Department of Health and Human Services will make payments on eligible graduate educational loans in exchange for a minimum of two years of service as a full-time faculty member of a health professions school. Applicants must

complete an application and provide information on all eligible education loans. Once HRSA has selected the participants, HRSA will request verification from their lenders of loan balances and terms of their outstanding educational loans.

Estimated annual response burden is as follows:

Type of respondent	Number of respondents	Responses per respondent	Hours per response	Total annual hour burden
Applicants	75	1	1	75
Lenders	100	1	.5	50
Total	175	125

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: Virginia Huth, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: July 1, 1996.

J. Henry Montes,

Associate Administrator for Policy Coordination.

[FR Doc. 96-17470 Filed 7-9-96; 8:45 am]

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ADVISORY COMMISSION ON INTERGOVERNMENTAL RELATIONS

Notice of Meeting of the Advisory Commission on Intergovernmental Relations (ACIR)

SUMMARY: The Advisory Commission on Intergovernmental Relations (ACIR) will hold a meeting on Tuesday, July 23, 1996, beginning at 10:00 AM and concluding at 2:00 PM in the Hall of the States, Room #383/385, 444 North Capitol Street, NW, Washington, DC. The ACIR meeting agenda will focus on two items: (1) Discussion and action on release of the ACIR final report, The Role of Federal Mandates in Intergovernmental Relations, to the President and the U.S. Congress; and (2) discussion of ACIR's programs, products, and services after September 30, 1996.

FOR FURTHER INFORMATION CONTACT: Advisory Commission on Intergovernmental Relations, 800 K Street, NW, Suite 450, South Tower, Washington, DC 20575, Phone: (202) 653-5540/FAX: (202) 653-5429, Internet:ir002529@interramp.com.

SUPPLEMENTARY INFORMATION: As directed by Section 302 of the Unfunded

Mandates Reform Act of 1995 (Pub. L. 104-4), the Advisory Commission on Intergovernmental Relations (ACIR) was "to investigate and review the role of federal mandates in intergovernmental relations" and to make a final report to the President and Congress on the findings, conclusions, and recommendations of the Commission. During this meeting, the Commission will discuss and take action on the release of the final report and recommendations to the President and the Congress. Also, in response to the 1996 Treasury, Postal Service and General Government Appropriations Act calling for the "prompt and orderly termination" of ACIR, the Commission will discuss ACIR's programs, products, and services after September 30, 1996.

The ACIR meeting will be held in Tuesday, July 23, 1996, in the Hall of the States, Room 383/385, 444 North Capitol Street, NW, Washington, DC. The meeting will begin at 10:00 AM and conclude at 2:00 PM.

Dated: July 3, 1996.

William E. Davis,

Executive Director.

[FR Doc. 96-17516 Filed 7-9-96; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Convention on International Trade in Endangered Species (CITES) Notification; Rescinding of Prohibition of Trade in CITES Listed Species With Thailand and Recommendation From CITES Secretariat on Prohibition of Trade in Greek Turtles From Turkey

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of Information No. 26.

SUMMARY: This Notice of Information (NOI) is an update from the prohibitions identified in NOI 22 and NOI 25. Specifically, this NOI removes the prohibition on trade in CITES listed species and their products with Thailand identified in NOI 22, published on July 15, 1991 (56 FR 32260) and, removes the prohibition on imports of Greek tortoises from Turkey identified in NOI 25, published on January 23, 1996 (61 FR 1780). This Notice includes a revised Summary Of U.S. Prohibitions Pursuant To Notices Of Information (NOI).

DATES: This notice is effective on July 10, 1996 and will be effective until further notice.

ADDRESSES: U.S. Fish and Wildlife Service, Office of Management Authority, Mail Stop 430 ARLSQ, 1849 C Street NW, Washington, DC 20240 regarding Notifications to the Parties, or U.S. Fish and Wildlife Service, Division of Law Enforcement, P.O. Box 3247, Arlington, VA 22203-3247, regarding enforcement actions.

FOR FURTHER INFORMATION CONTACT: Dr. Susan S. Lieberman, U.S. Fish and Wildlife Service, Office of Management Authority, telephone (703) 358-2095, regarding Notifications to the Parties, or Thomas L. Striegler, Special Agent in Charge, Investigations, U.S. Fish and Wildlife Service, Division of Law Enforcement, telephone (703) 358-1949, for enforcement actions.

SUPPLEMENTARY INFORMATION: On April 22, 1991, the CITES Secretariat issued Notification to the Parties No. 636, which recommended that all Parties prohibit trade with Thailand in any specimens of species included in the CITES Appendices. On April 2, 1992, the CITES Secretariat issued Notification to the Parties No. 673, which recommended to the Parties that the prohibition of trade with Thailand on specimens of species included in the