

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 805

[Docket No. 85N-0322]

DMB

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Publication Date	11-24-99
Certifier	SNKeese

**Medical Devices; Revocation of Cardiac Pacemaker Registry**

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

**ACTION:** Final rule.

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**SUMMARY:** The Food and Drug Administration (FDA) is issuing a final rule to revoke a regulation requiring a cardiac pacemaker registry. The registry, which was mandated by the Deficit Reduction Act of 1984, requires any physician and any provider of services who requests or receives Medicare payment for an implantation, removal, or replacement of permanent cardiac pacemaker devices and pacemaker leads to submit certain information to the registry. The information is used by FDA to track the performance of permanent cardiac pacemakers and pacemaker leads and by the Health Care Finance Administration (HCFA) to administer its Medicare payment program for these devices. This action is being taken to implement an act to Repeal An Unnecessary Medical Device Reporting Requirement passed by Congress in 1996 to remove the cardiac pacemaker registry to eliminate duplicative and unnecessary reporting.

**DATES:** This regulation is effective (*insert date 30 days after date of publication in the Federal Register*).

**FOR FURTHER INFORMATION CONTACT:** Rosa M. Gilmore, Center for Devices and Radiological Health (HFZ-342), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301-827-2970.

## SUPPLEMENTARY INFORMATION:

**I. Background**

In the **Federal Register** of July 23, 1987 (52 FR 27756), FDA and HCFA jointly issued a final rule to establish a national cardiac pacemaker registry as mandated by the Deficit Reduction Act of 1984 (Public Law 98-369). The new law, which was enacted on July 18, 1984, amended title XVIII of the Social Security Act, by adding section 1862(h) (42 U.S.C. 1395y(h)) to the Social Security Act . FDA and HCFA jointly issued a proposed rule announcing the establishment of this registry in the **Federal Register** of May 6, 1986 (51 FR 16792).

The final rule for the cardiac pacemaker registry was codified in part 805 (21 CFR part 805). Briefly summarized, the scope of the regulation provides that FDA establish a nationwide registry for cardiac pacemakers and pacemaker leads. FDA used the information submitted to the registry to track the performance of permanent pacemakers and pacemaker leads and to perform studies and analysis regarding the use of the devices. The agency transmitted data to the HCFA to administer its Medicare program and to other Federal components to carry out statutory responsibilities.

On October 2, 1996, an act to Repeal An Unnecessary Medical Device Reporting Requirement (Public Law 104-224), which amended title XVIII of the Social Security Act (42 U.S.C. 1395), became law. The purpose of the new law was to remove section 1862(h) (42 U.S.C. 1395y(h)) of the Social Security Act to eliminate duplicative and unnecessary reporting.

When section 1862(h) was added to the Social Security Act, there was a need to identify and keep track of defective pacemakers. In particular, there was a need to identify circumstances in which a defective pacemaker was surgically implanted in a patient, and then surgically removed, with both procedures being paid for by Medicare. One of the main reasons for this early pacemaker registry was that there was no good way to track defective implantable medical devices, and no viable way for HCFA to recover costs in those circumstances where a defective product was used. Congress enacted an act to repeal section 1862(h) of the Social Security Act because the SMDA

of 1990 (Public Law 101-629) added section 519(e) to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i(e)), which requires among other things that manufacturers track and collect data for certain devices, including permanently implanted pacemakers and pacemaker leads from the manufacturer through the distribution chain to the patient using the device.

Notice and comment rulemaking on the revocation of part 805 is unnecessary. The statutory authority for this rule has been revoked. Therefore, FDA concludes under 5 U.S.C. 553(b)(8) and 21 CFR 10.40(e)(1), that there is a good cause for revoking part 805 without notice and comment rulemaking.

## **II. Environmental Impact**

The agency has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

## **III. Analysis of Impact**

FDA has examined the impacts of the final rule under Executive Order 12866, and the Regulatory Flexibility Act (5 U.S.C. 601-612) (as amended by subtitle D of the Small Business Reform Act of 1995 (Public Law 104-4)). Executive Order 12866 directs agencies to assess all costs and benefits of available approaches that maximize net benefits (including potential economic, environmental, public health and safety and other advantages distributive impacts and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. The final rule removes the medical device regulation requiring a national cardiac pacemaker registry from part 805. The agency certifies, under the Regulatory Flexibility Act, 5 U.S.C. 605(b), that this final rule will not have a significant economic impact on a substantial number of small entities. In addition, this final rule will not impose expenditures of \$100 million or more on either the private sector or State, local, and tribal governments in

the aggregate and, therefore, a written statement under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

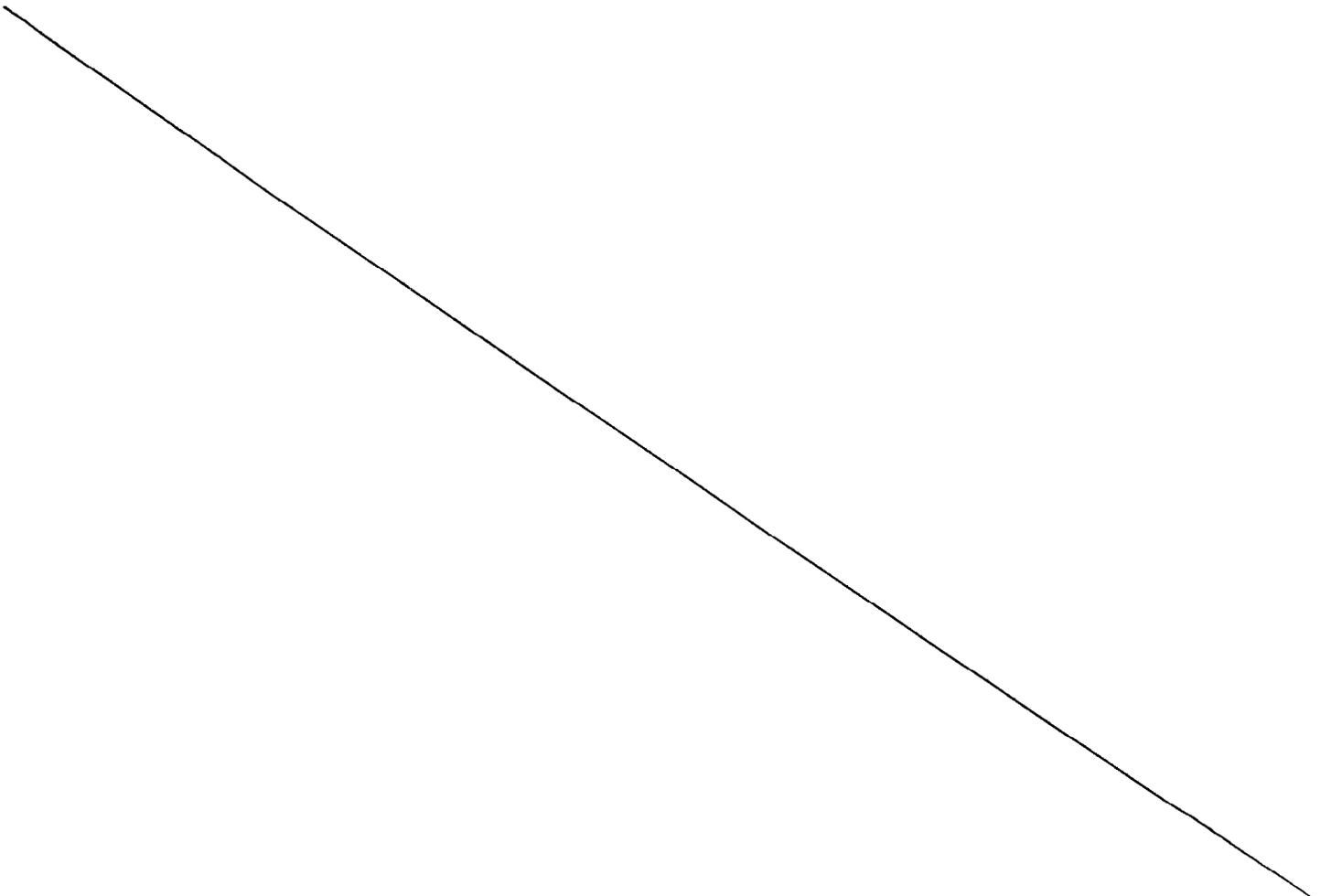
**IV. Paperwork Reduction Act of 1995**

FDA concludes that this final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required (Public Law 104-13).

**List of Subjects in 21 CFR Part 805**

Medical devices, Reporting and recordkeeping requirements.

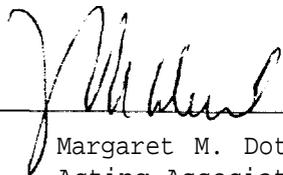
Therefore, under the Federal Food, Drug, and Cosmetic Act and the authority of Public Law 104-224, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR Chapter 1 is amended as follows:



**PART 805—CARDIAC PACEMAKER REGISTRY**

1. Part 805 is removed.

Dated: 11/17/99 9  
November 17, 1999



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Margaret M. Dotzel  
Acting Associate Commissioner for Policy

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