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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Contact A. Cerbin

[Docket No. FDA-2008-N-0607]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Reclassification Petitions for Medical Devices**

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

**ACTION:** Notice.

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**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 *[insert date 30 days after date of publication in the Federal Register]*.

**ADDRESSES:** 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: FDA Desk Officer, FAX: 202-395-6974, or e-mailed to *oira\_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910-0138. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Denver Presley, Jr., Office of Information Management (HFA-710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-796-3793.

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**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.

**Reclassification Petitions for Medical Devices—21 CFR Section 860.123 (OMB Control Number 0910–0138)—Extension**

FDA has responsibility under sections 513(e) and (f), 514(b), 515(b), and 520(l) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(e), and (f), 360d(b), 360e(b), and 360j(l)) and part 860 (21 CFR part 860), subpart C, to collect data and information contained in reclassification petitions. The reclassification provisions of the act allow any person to petition for reclassification of a device from any one of the three classes i.e, I, II, and III, to another class. The reclassification procedure regulation requires the submission of specific data when a manufacturer is petitioning for reclassification. This includes a “Supplemental Data Sheet,” Form FDA 3427, and a “Classification Questionnaire,” Form FDA 3429. Both forms are a series of questions concerning the safety and effectiveness of the device type. Further, the reclassification content regulation (§ 860.123) requires the submission of sufficient, valid scientific evidence demonstrating that the proposed reclassification will provide a reasonable assurance of safety and effectiveness of the device type for its indications for use. Thus, the reclassification provisions of the act serve primarily as a vehicle for manufacturers to seek reclassification from a higher to a lower class, thereby reducing the regulatory requirements applicable to a particular device type, or to seek reclassification from a lower to a higher class, thereby increasing the regulatory requirements. The reclassification petitions requesting classification from class III to class II or class I, if approved, provides an alternative route to the market in lieu

of premarket approval for class III devices or from class I or II, to one or the other class, which may increase requirements.

In the **Federal Register** of December 4, 2008 (73 FR 73938), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

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

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

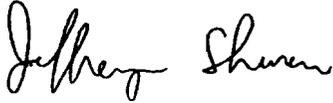
21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
860.123	6	1	6	500	3,000

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

Based on the last 3 years, and actual reclassification petitions received, FDA anticipates that six petitions will be submitted each year. The time required to prepare and submit a reclassification petition, including the time needed to assemble supporting data, averages 500 hours per petition. This average is based upon estimates by FDA administrative and technical staff that:

(1) Are familiar with the requirements for submission of a reclassification petition, (2) have consulted and advised manufacturers on these requirements, and (3) have reviewed the documentation submitted.

Dated: MAR - 2 2009  
March 2, 2009.



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Jeffrey Shuren,  
Associate Commissioner for Policy and Planning.

[FR Doc. 09-????? Filed ??-??-09; 8:45 am]

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