

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

21 CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeepers	Total Annual Records	Hours per Record-keeper	Total Hours
101.82(c)(2)(ii)(B)	25	1	25	1	25

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

Based upon its experience with the use of health claims, FDA estimates that only about 25 firms would be likely to market products bearing a soy protein/CHD health claim and that only, perhaps, one of each firm's products might contain nonsoy sources of protein along with soy protein. The records required to be retained by 21 CFR 101.82(c)(2)(ii)(B) are the records, e.g., the formulation or recipe, that a manufacturer has and maintains as a normal course of its doing business. Thus, the burden to the food manufacturer is that involved in assembling and providing the records to appropriate regulatory officials for review or copying.

Dated: October 9, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N-0309]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Reclassification Petitions for Medical Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

DATES: Submit written comments on the collection of information by November 15, 2002.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Stuart Shapiro, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (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.

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

FDA has the 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, II, and III) to another class. The reclassification content regulation (§ 860.123) requires the submission of sufficient, valid scientific evidence demonstrating that the proposed classification will provide a reasonable assurance of safety and effectiveness of the device for its intended use. 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. The reclassification petitions requesting classification from class III to class II or class I, if approved, provide an alternative route to the market in lieu of premarket approval for class III devices.

Description of respondents: Device manufacturers.

FDA estimates the burden of this collection as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

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

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

Based on current trends 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 who are familiar with

the requirements for submission of a reclassification petition, have consulted and advised manufacturers on these requirements, and have reviewed the documentation submitted.

Dated: October 9, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

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