allows for scientific and/or medical review of devices, subject to section 510(k) of the act, to confirm that the new devices are as safe and as effective as legally marketed predicate devices. This review process, therefore, prevents potentially unsafe and/or ineffective devices, including those with fraudulent claims, from entering the U.S. market.

This information will allow FDA to collect data to ensure that the use of the device will not present an unreasonable risk for the subject's rights. The respondents to this information collection will primarily be medical device manufacturers and businesses.

FDA Form 3514 was developed to assist respondents in categorizing 510(k) data for submission to FDA. This form also assists respondents in organizing and submitting data for other FDA medical device programs such as premarket approval applications, investigational device exemptions, and humanitarian device exemptions.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
807 Subpart E (807.81 & 807.87–510(k))		4,000	1	4,000	80	320,000
	FDA 3514	2,000	1	2,000	.5	1,000
Submission of Validation Data (2003)		20	5	100	40	28,000
Totals						349,000

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN [2]

21 CFR Section	Form No.	No. of Record-keepers	Annual Frequency per Record-keeping	Total Annual Records	Hours per Record-keeper	Total Hours
807.93		2,000	10	20,000	.5	10,000
Totals						10,000

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

FDA has based these estimates on conversations with industry and trade association representatives, and from internal review of the documents listed in tables 1 and 2 of this document.

The total burden for using voluntary FDA Form 3514 is estimated to be approximately 1,000 hours and has been included in this collection of information. Once this collection of information has been approved, the burden for FDA Form 3514 will be reported and approved in each of the following OMB information collections: (1) Investigational device exemption reports and records (OMB control number 0910–0078), (2) premarket approval of medical devices OMB control number 0910–0231), and (3) medical devices, humanitarian devices (OMB control number 0910–0332).

Dated: March 2, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–5196 Filed 3–8–04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0222]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Product Jurisdiction: Assignment of Agency Component for Review of Premarket Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Product Jurisdiction: Assignment of Agency Component for Review of Premarket Applications'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 15, 2003 (68 FR 53980), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0523. The approval expires on February 28, 2007. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: March 2, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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