TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses[2]	Hours per Response	Total Hours
11.2	25	5.62	140	.08	11.2

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Electronic submissions received between July 1, 2005, and June 30, 2006.

The number of respondents in table 1 of this document is the number of sponsors registered to make electronic submissions (25). The number of total annual responses is based on a review of the actual number of such submissions made between July 1, 2005, and June 30, 3006. (140 x hours per response (.08) = 11.2 total hours.)

Dated: February 7, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–2470 Filed 2–13–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0277]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Food Labeling; Notification Procedures for Statements on Dietary Supplements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Food Labeling; Notification Procedures for Statements on Dietary Supplements'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 1, 2006 (71 FR 69569), 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 0910–0331. The approval expires on January 31, 2010. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: February 7, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–2480 Filed 2–13–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0433]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; How to Use E-mail to Submit a Notice of Final Disposition of Animals Not Intended for Immediate Slaughter

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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 March 16, 2007.

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.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

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:

Guidance for Industry on How to Use E-mail to Submit a Notice of Final Disposition of Animals Not Intended for Immediate Slaughter—21 CFR 514.117(b)(2) and 21 CFR 511.1(b)(5); (OMB Control Number 0910–0453)—Extension

The Center for Veterinary Medicine (CVM) monitors the final disposition of investigational animals where such animals do not enter the human food chain immediately at the completion of the investigational study. CVM's monitoring of the final disposition of investigational food animals is intended to ensure that unsafe residues of new animal drugs do not get into the food supply. CVM issues a slaughter authorization letter to investigational new animal drug (INAD) sponsors that sets the terms under which investigational animals may be slaughtered (21 CFR 511.1(b)(5)). Also in this letter, CVM requests that sponsors submit a notice of final disposition of investigational animals not intended for immediate slaughter (NFDA). NFDAs have historically been submitted to CVM on paper. CVM's guidance on ''How to Use E-mail to Submit a Notice of Final Disposition of Animals Not Intended for Immediate Slaughter'' provides sponsors with the option to submit an NFDA as an e-mail attachment to CVM via the Internet.

In the **Federal Register** of November 9, 2006 (71 FR 65827), FDA published a 60-day notice soliciting public comment on the proposed collection of information requirements. In response to that notice, no comments were received.

The likely respondents for this collection are are INAD sponsors.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section / Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses[2]	Hours per Response	Total Hours
511.1(b)(5)/ Form FDA 3487	25	1.44	36	.08	2.88

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.
[2]Electronic submissions received between July 1, 2005, and June 30, 2006.

The number of respondents in Table 1 are the number of sponsors registered to make electronic submissions (25). The number of total annual responses is based on a review of the actual number of such submissions made between July 1, 2005, and June 30, 2006. (36 x hours per response (.08) = 2.88 total hours).

Dated: February 7, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–2485 Filed 2–13–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0380]

Agency Information Collection Activities: Submission for Office of Management and Budget Review; Comment Request; Export of Medical Devices-Foreign Letters of Approval

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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 March 16, 2007.

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.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

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:

Export of Medical Devices-Foreign Letters of Approval (OMB Control Number 0910–0264)—Extension

Section 801(e)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 381(e)(2)) provides for the exportation of an unapproved device under certain circumstances if the exportation is not contrary to the public health and safety and it has the approval of the foreign country to which it is intended for export.

Requesters communicate (either directly or through a business associate in the foreign country) with a representative of the foreign government to which they seek exportation, and written authorization must be obtained from the appropriate office within the foreign government approving the importation of the medical device. An alternative to obtaining written authorization from the foreign government is to accept a notarized certification from a responsible company official in the United States that the product is not in conflict with the foreign country's laws. This certification must include a statement acknowledging that the responsible company official making the certification is subject to the provisions of 18 U.S.C. 1001. This statutory provision makes it a criminal offense to knowingly and willingly make a false or fraudulent statement, or make or use a false document, in any manner within the jurisdiction of a department or agency of the United States.

FDA uses the written authorization from the foreign country or the certification from a responsible company official in the United States to determine whether the foreign country has any objection to the importation of the device into their country.

In the **Federal Register** of September 22, 2006 (71 FR 55487), FDA published a 60-day notice soliciting public comments on the proposed information collection provisions for this requirement. In response to this notice, no comments were received. The agency is also correcting an error. The operating and maintenance cost, which was inadvertently omitted in the burden table for the 60-day notice, has been added as a column to the burden table for this notice.

The respondents to this collection of information are companies that seek to export medical devices.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency Per Response	Total Annual Responses	Hours per Response	Total Hours	Total Operating & Maintenance Costs
801(e)2	25	1	25	2.5	62.5	$6,250

[1]There are no capital costs associated with this collection of information.

These estimates are based on the experience of FDA's medical device program personnel. There are no capital costs associated with this collection of information. In addition, the respondent's costs of submission of a request to the foreign country for approval to import into that country, and subsequent submission of such approval to FDA, vary and are considered operating and maintenance costs. On average, it appears that it can cost a requester approximately $125 per page of translation. From review of our records, it appears that foreign approval letters average two pages. Therefore, the ''other'' estimated cost to requestors for processing a foreign approval letter is