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

approximately $6,250 (25 submissions per year x 2 pages = 50 pages x $125 per page = $6,250).

Dated: February 7, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–2489 Filed 2–13–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N -0431]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Substantial Evidence of Effectiveness of New Animal Drugs

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:

Substantial Evidence of Effectiveness of New Animal Drugs—21 CFR 514.4(a) (OMB Control Number 0910–0356)—Extension

Section 512(d)(1)(E) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360(d)(1)(E)), requires FDA to issue an order refusing to approve a new animal drug application (NADA), if there is a lack of substantial evidence that a new animal drug will have the effect it is purported or represented to have under the conditions of use prescribed in the proposed labeling. Therefore, substantial evidence must be submitted to us as part of the NADA to establish effectiveness of a drug. Section 21 CFR 514.4(a) specifies requirements for submitting adequate and well-controlled studies to provide substantial evidence of effectiveness for a new animal drug. This information collection requirement provides for submissions of substantial evidence of effectiveness information via electronic submissions to the Center for Veterinary Medicine (CVM).

CVM is continuously seeking ways through advances in information technology to reduce the burden on the government and sponsors. The Center continues to look at what information can be submitted electronically and will permit electronic submission of data to NADA files as technology and resources permit.

In the **Federal Register** of November 2, 2006 (71 FR 64535), FDA published a 60-day notice in the **Federal Register** soliciting public comment on the proposed collection of information collection requirements. In response to that notice, no comments were received.

The likely respondents for this collection of information are sponsors of NADA applications.

FDA estimates the 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
514.4(a)	190	4,546	860	632.6	544,036

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

The estimate for the annual reporting burden for this collection of information was derived from discussion with industry and agency records.

Dated: February 7, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–2497 Filed 2–13–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Bureau of Primary Health Care (BPHC) Uniform Data System (OMB No. 0915–0193) Revision

The Uniform Data System (UDS) contains the annual reporting requirements for the cluster of primary care grantees funded by the Health Resources and Services Administration (HRSA). The UDS includes reporting requirements for grantees of the following primary care programs: Community Health Centers, Migrant Health Centers, Health Care for the Homeless, Public Housing Primary Care, and other grantees under Section 330.