Description of Respondents: Businesses or others for-profit.

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
814.102	20	1	20	40	800
814.104	8	1	8	320	2,560
814.106	8	2	16	50	800
814.108	20	1	20	80	1,600
814.116(e)(3)	1	1	1	1	1
814.124(a)	5	1	5	1	5
814.124(b)	1	1	1	2	2
814.126(b)(1)	35	1	35	120	4,200
Total					9,968

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR Section	No. of recordkeepers	Annual frequency per recordkeeping	Total annual records	Hours per record	Total hours
814.126(b)(2)	35	1	35	2	70

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

Dated: June 9, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–11861 Filed 6–15–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0441]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Application for Food and Drug Administration Approval to Market a New Drug

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Application for FDA Approval to Market a New Drug'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Karen Nelson, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 31, 2005 (70 FR 4853), 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 0910–0001. The approval expires on May 31, 2008. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: June 9, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–11862 Filed 6–15–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0208]

Agency Information Collection Activities; Proposed Collection; Comment Request; Dissemination of Information on Unapproved/New Uses for Marketed Drugs, Biologics, and Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the reporting and recordkeeping requirements associated with the dissemination of unapproved or new

uses for marketed drugs, biologics, and devices.

DATES: Submit written or electronic comments on the collection of information by August 15, 2005.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Dissemination of Information on Unapproved/New Uses for Marketed Drugs, Biologics, and Devices (OMB Control Number 0910–0390)—Extension

In the **Federal Register** of November 20, 1998 (63 FR 64556), FDA published a final rule that added a new part 99 (21 CFR part 99) entitled ''Dissemination of Information on Unapproved/New Uses for Marketed Drugs, Biologics, and Devices.''

The final rule implemented section 401 of the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Public Law 105–115). In brief, section 401 of FDAMA amended the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360aaa through 360aaa–6) to permit drug, biologic, and device manufacturers to disseminate certain written information concerning the safety, effectiveness, or benefits of a use that is not described in the product's approved labeling to health care practitioners, pharmacy benefit managers, health insurance issuers, group health plans, and Federal and State Government agencies, provided that the manufacturer complies with certain statutory requirements. For example, the information that is to be disseminated must be about a drug or device that is being marketed legally; it must be in the form of an unabridged reprint or copy of a peer-reviewed journal article or reference publication; and it must not be derived from another manufacturer's clinical research, unless that other manufacturer has given its permission for the dissemination. The information must be accompanied by certain information, including a prominently displayed statement that the information discusses a use (or uses) that has not been approved or cleared by FDA. Additionally, 60 days before dissemination, the manufacturer must submit to FDA a copy of the information to be disseminated, any other clinical trial information that the manufacturer has relating to the safety or effectiveness of the new use, any reports of clinical experience that pertain to the safety of the new use, and a summary of such information.

The final rule sets forth the criteria and procedures for making such submissions to FDA. Under the final rule, submissions include certification that the manufacturer has completed clinical studies necessary to submit a supplemental application to FDA for the new use, and will submit the supplemental application within 6 months after its initial dissemination of information. If the manufacturer has planned, but not completed, such studies, the submission includes proposed protocols and a schedule for conducting the studies, as well as a certification that the manufacturer will complete the clinical studies and submit a supplemental application no later than 36 months after its initial dissemination of information. The final rule also permits manufacturers to request extensions of the time period for completing a study and submitting a supplemental application, and to request an exemption from the requirement to submit a supplemental application. The final rule prescribes the timeframe within which the manufacturer shall maintain records that would enable it to take corrective action. The final rule requires the manufacturer to submit lists pertaining to the disseminated articles and reference publications, the categories of persons (or individuals) receiving the information, and a notice and summary of any additional research or data (and a copy of the data) relating to the product's safety or effectiveness for the new use. The final rule requires the manufacturer to maintain a copy of the information, lists, records, and reports for 3 years after it has ceased dissemination of the information and to make the documents available to FDA for inspection and copying.

FDA based its estimates of the number of submissions it will receive, and the number of manufacturers who would be subject to part 99, on the average of the total number of required submissions received during 2002, 2003, and 2004. The estimated burden hours for these provisions are based on the following calculations:

Section 99.201(a)(1) requires the manufacturer to provide an identical copy of the information to be disseminated, including any information required under § 99.103. Because the manufacturer must compile this information in order to prepare its submission to FDA, FDA estimates that 40 hours will be required per submission. Because 10 annual responses are expected under § 99.201(a)(1), the estimated total burden for this provision is 400 hours (10 annual responses x 40 hours per response).

Section 99.201(a)(2) requires the manufacturer to submit clinical trial information pertaining to the safety and effectiveness of the new use, clinical experience reports on the safety of the new use, and a summary of the information. FDA estimates 24 burden hours per response for this provision for assembling, reviewing, and submitting the information and assumes that the manufacturer will have already acquired

some of this information in order to decide whether to disseminate information on an unapproved use under part 99. The estimated total burden for this provision is 240 hours (10 annual responses x 24 hours per response).

Section 99.201(a)(3) requires the manufacturer to explain its search strategy when assembling its bibliography. FDA estimates that only 1 hour will be required for the explanation because the manufacturer would have developed and used its search strategy before preparing the bibliography. Because 10 annual responses are expected under § 99.201(a)(3), the estimated total burden for this provision is 10 hours (10 annual responses x 1 hour per response).

Section 99.201(b) simply requires the manufacturer's attorney, agent, or other authorized official to sign its submissions, certifications, and requests for an exemption. FDA estimates that only 30 minutes are necessary for such signatures. Because 10 annual responses are expected under § 99.201(b), the estimated total burden for this provision is 5 hours (10 annual responses x 0.5 hours per response).

Section 99.201(c) requires the manufacturer to provide two copies with its original submission. Copying the submission should not be time-consuming, so FDA estimates the burden to be 30 minutes. Because 10 annual responses are expected under § 99.201(c), the estimated total burden for this provision is 5 hours (10 annual responses x 0.5 hours per response).

While the act requires manufacturers to provide a submission to FDA before they disseminate information on unapproved/new uses, it also permits the following actions for manufacturers: (1) To have completed studies and promise to submit a supplemental application for the new use within 6 months after the date of initial dissemination; (2) to provide protocols, a schedule for completing studies, and submit a supplemental application for the new use within 36 months after the date of initial dissemination; (3) to have completed studies and have submitted a supplemental application for the new use; or (4) to request an exemption from the requirement to submit a supplemental application. These possible scenarios are addressed in §§ 99.201(a)(4)(i)(A), (a)(4)(ii)(A), (a)(5), and 99.205(b). Based on the average of the total number of required submissions received during 2002, 2003, and 2004, FDA has made the following burden estimates:

Section 99.201(a)(4)(i)(A) requires the manufacturer, if the manufacturer has completed studies needed for the submission of a supplemental application for the new use, to submit the protocol(s) for the completed studies, or, if the protocol was submitted to an investigational new drug application (IND) or investigational device exemption (IDE), to submit the IND or IDE number(s), the date of submission of the protocol(s), the protocol number(s), and the date of any amendments to the protocol(s). FDA estimates that 30 hours will be required for this response because this is information that each manufacturer already maintains for its drugs or devices. The estimated total burden for this provision is 210 hours (7 annual responses x 30 hours per response).

For manufacturers who submit protocols and a schedule for conducting studies, § 99.201(a)(4)(ii)(A) requires the manufacturer to include, in its schedule, the projected dates on which the manufacturer expects the principal study events to occur. FDA estimates a manufacturer will need approximately 60 hours to include the projected dates because it would have to contact the studies' principal investigator(s) and other company officials. The estimated total burden for this provision is 420 hours (7 annual responses x 60 hours per response).

If the manufacturer has submitted a supplemental application for the new use, § 99.201(a)(5) requires a cross-reference to that supplemental application. FDA estimates that only 1 hour will be needed because manufacturers already maintain this information. The estimated total burden for this provision is 2 hours (2 annual responses x 1 hour per response).

FDA has not received any requests for an exemption under § 99.205(b). However, for purposes of this request for OMB approval, FDA estimates that annually one manufacturer may submit one exemption request under § 99.205(b). FDA estimates that the reporting burden for each exemption request will be 82 hours. The estimated total burden for this provision is 82 hours (1 annual response x 82 hours per response).

Under § 99.203, a manufacturer that has certified that it will complete studies necessary to submit a supplemental application within 36 months after its submission to FDA, but later finds that it will be unable to complete such studies or submit a supplemental application within that time period, may request an extension of time from FDA. Such requests for extension should be limited, occurring less than 1 percent of the time, because manufacturers and FDA, when developing or reviewing study protocols, should be able to identify when a study will require more than 36 months to complete. Section 99.203 contemplates extension requests under two different scenarios. Under § 99.203(a), a manufacturer may make an extension request before it makes a submission to FDA regarding the dissemination of information under part 99. The agency expects such requests to be limited, occurring less than 1 percent of the time (or one annual response), and that such requests will result in a reporting burden of 10 hours per request. The estimated total burden hours for this provision, therefore, is 10 hours (1 annual response x 10 hours per response). Section 99.203(b) specifies the contents of a request to extend the time for completing planned studies after the manufacturer has provided its submission to FDA. The required information includes a description of the studies, the current status of the studies, reasons why the studies cannot be completed on time, and an estimate of the additional time needed. FDA estimates that 10 hours will be needed for reporting the required information under § 99.203(b) because it would require consultation between the manufacturer and key individuals (such as the studies' principal investigator(s)). As in the case of § 99.203(a), the expected number of responses is very small (one annual response), and the estimated total burden hours for this provision is 10 hours (1 annual response x 10 hours per response).

Section 99.203(c) requires two copies of an extension request (in addition to the request required under section 554(c)(3) of the act (21 U.S.C. 360aaa–3)). FDA estimates that these copies will result in a minimal reporting burden of 30 minutes. However, this requirement would apply to extension requests under § 99.203(a) and (b), so the estimated total number of annual responses is two, resulting in an estimated total burden for this provision of 1 hour (2 annual responses x 0.5 hours per response).

The remaining reporting and recordkeeping burdens are shown in the following estimates:

Section 99.501(a)(1) requires the manufacturer to maintain records that identify recipients by category or individually. Under § 99.301(a)(3), FDA will notify the manufacturer if it needs to maintain records identifying individual recipients because of special safety considerations associated with the new use. This means that, in most cases, the manufacturer will only have

to maintain records identifying recipients by category. In either event, the manufacturer will know if it must maintain records that identify individual recipients before it begins disseminating information. The time required to identify recipients individually should be minimal, and the time required to identify recipients by category should be even less. Therefore, FDA estimates the burden for this provision to be 10 hours, and, because 8 annual records are expected under § 99.501(a)(1), the estimated total burden for this provision is 80 hours (8 annual records x 10 hours per record).

Section 99.501(a)(2) requires the manufacturer to maintain a copy of the information it disseminates. This task is not expected to be time-consuming, so FDA estimates the burden to be 1 hour. Because 8 annual records are expected under § 99.501(a)(2), the estimated total burden for this provision is 8 hours (8 annual records x 1 hour per record).

Section 99.501(b)(1) requires the manufacturer to submit to FDA semiannually a list containing the articles and reference publications that were disseminated in the preceding 6-month period. FDA estimates a burden of 8 hours for this provision. The burden may be less if the manufacturer develops and updates the list while it disseminates articles and reference publications during the 6-month period (as opposed to generating a completely new list at the end of each 6-month period), and if the volume of disseminated materials is small. The estimated total burden for this provision is 160 hours (10 responses submitted semiannually x 8 hours per response).

Section 99.501(b)(2) requires manufacturers that disseminate information to submit to FDA semiannually a list that identifies the categories of providers who received the articles and reference publications. Section 99.501(b)(2) also requires the list to identify which category of recipients received each particular article or reference publication. If each of the 10 submissions under part 99 results in disseminated information, § 99.501(b)(2) would result in 20 lists (10 submissions x 2 submissions semiannually) identifying which category of recipients received each particular article or reference publication. The agency estimates the burden to be only 1 hour per response because this type of information is maintained as a usual and customary business practice, and the estimated total burden for this provision is 20 hours (20 responses submitted semiannually x 1 hour per response).

In relation to § 99.201(a)(2), § 99.501(b)(3) requires the manufacturer to provide, on a semiannual basis, a notice and summary of any additional clinical research or other data relating to the safety and effectiveness of the new use and, if it possesses such research or data, to provide a copy to FDA. This burden should not be as extensive as that in § 99.201(a)(2), so FDA estimates the burden to be 20 hours per response, for an estimated total burden of 400 hours for this provision (10 responses submitted semiannually x 20 hours per response).

If a manufacturer discontinues or terminates a study before completing it, § 99.501(b)(4) requires the manufacturer to state the reasons for discontinuing or terminating the study in its next progress report. FDA estimates that annually this will affect only 1 percent of all applications (8 x 0.01 = 0.08, rounded up to 1) and only one manufacturer. FDA estimates 2 hours of reporting time for this requirement because the manufacturer should know the reasons for discontinuing or terminating the study and would only need to provide those reasons in its progress report. The estimated total burden hours for this provision is 2 hours (1 annual response x 2 hours per response).

Section 99.501(b)(5) requires the manufacturer to submit any new or additional information that relates to whether the manufacturer continues to meet the requirements for the exemption after an exemption has been granted. FDA estimates that 10 percent of all submissions will contain an exemption request (8 annual submissions x 0.10 = 0.8, rounded up to 1), and has assumed that all exemption requests will be granted, for a total of 1 annual response. The information sought under § 99.501(b)(5) pertains solely to new or additional information and is not expected to be as extensive as the information required to obtain an exemption. Thus, FDA estimates the burden for § 99.501(b)(5) to be 41 hours per response (or half the burden associated with an exemption request), for an estimated total burden of 41 hours for this provision (1 annual response x 41 hours per response).

Section 99.501(c) requires the manufacturer to maintain records for 3 years after it has ceased dissemination of the information. FDA estimates the burden for this provision to be 1 hour. Because eight annual records are expected under § 99.501(c), the estimated total burden for this provision is 8 hours (8 annual records x 1 hour per record).

The estimates for §§ 99.201(a)(1), (a)(2), (a)(3), (b), and (c), and 99.501(b)(1), (b)(2), and (b)(3) have been increased by two responses each to account for manufacturer resubmissions. In addition, the estimate for § 99.201(a)(4)(i)(A) and (a)(4)(ii)(A) has been increased by one response each to account for manufacturer resubmissions.

Description of Respondents: All manufacturers (persons and businesses, including small businesses) of drugs, biologics, and device products.

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 responses per respondent	Total annual responses	Hours per response	Total hours
99.201(a)(1)	5	1	10	40	400
99.201(a)(2)	5	1	10	24	240
99.201(a)(3)	5	1	10	1	10
99.201(a)(4)(i)(A)	6	1	7	30	210
99.201(a)(4)(ii)(A)	6	1	7	60	420
99.201(a)(5)	1	1	2	1	2

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

21 CFR section	No. of respondents	Annual responses per respondent	Total annual responses	Hours per response	Total hours
99.201(b)	5	1	10	0.5	5
99.201(c)	5	1	10	0.5	5
99.203(a)	1	1	1	10	10
99.203(b)	1	1	1	10	10
99.203(c)	1	1	2	0.5	1
99.205(b)	1	1	1	82	82
99.501(b)(1)	5	3	20	8	160
99.501(b)(2)	5	1	20	1	20
99.501(b)(3)	5	1	20	20	400
99.501(b)(4)	1	1	1	2	2
99.501(b)(5)	1	1	1	41	41
Total Hours					2,018

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
99.501(a)(1)	5	1	8	10	80
99.501(a)(2)	5	1	8	1	8
99.501(c)	5	1	8	1	8
Total Hours					96

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

The estimated burden associated with the information collection requirements for these regulations is 2,114 hours.

Dated: June 9, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–11863 Filed 6–15–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Support for Small Scientific Conference Grants; Availability of Grants; Request for Applications; Announcement Type: Modification of Notice; Funding Opportunity Number: HHS–GRANTS–110204–001; Catalog of Federal Domestic Assistance Number: 93.103

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

I. Funding Opportunity Description

The Food and Drug Administration (FDA) is revising the Request for Applications (RFA) published in the **Federal Register** of June 6, 2002 (67 FR 39013). This revised RFA supercedes the June 6, 2002, document in its entirety. FDA's authority to enter into grants and cooperative agreements is detailed under title XVII of the Public Health Service Act (42 U.S.C. 300u–1) or the Radiation Control for Health and Safety Act of 1968 (Pub. L. 90–602) (21 U.S.C. 360hh-ss, formerly 42 U.S.C. 263b-n).

1. Background

FDA recognizes the value of partially supporting scientific meetings and conferences designed to coordinate, exchange, and disseminate information when the objectives are clearly within the scope of the agency's mission. FDA's policy is to participate with other organizations to support meetings where practicable, rather than provide sole support. In view of the diversity of interests among the various FDA centers/offices, and in order to provide maximum flexibility, FDA will not set rigid requirements concerning the type of scientific meetings to be supported so long as they are within the agency's mission.

II. Award Information

FDA views the partial support of scientific conferences as an ongoing program and may award a limited number of grants each fiscal year. These awards are subject to availability of funds and range from $1,000 to $25,000 in direct costs only per conference. This announcement is intended to be a ''Standing Program Announcement'' and will be modified in the event of required changes to the program.

Support for this program will be in the form of a grant. These grants will be