

the State operates on a July–June fiscal year, or September 1 if the State operates on a Federal fiscal year). No specific format is required for the intended use plan. The intended use of SSBG funds—including the types of activities to be supported and the categories and characteristics of individuals to be served—must be provided. States vary greatly in the information they provide and the structure of the report. States are required to submit a revised intended

use plan if the planned use of SSBG funds changes during the year.

In order to provide a more accurate analysis of the extent to which funds are spent “in a manner consistent” with each of the States’ plan for their use, as required by 42 USC 1397e(a), we are requesting that States voluntarily use the format of the post-expenditure reporting form to provide estimates of the amount of expenditures and the number of recipients, by service category, that the State plans to use SSBG funds to support as part of the

intended use plan. Many States are already using the format of the post-expenditure reporting form as part of their intended use plan.

Respondents:

The post-expenditure reporting form and intended use plan are completed once annually by a representative of the agency that administers the Social Services Block Grant at the State level in each State.

Respondents:

State Governments

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Post-Expenditure Reporting Form	56	1	110	6,160
Use of Post-Expenditure Reporting Form as Part of the Intended Use Plan	56	1	2	112
Estimated Total Annual Burden Hours:	6,272

Additional Information:

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L’Enfant Promenade, SW., Washington, DC 20447, *Attn:* ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. *E-mail address:* infocollection@acf.hhs.gov.

OMB Comment:

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following:

Office of Management and Budget,
Paperwork Reduction Project, *Fax:* 202–395–7285, *E-mail:* OIRA_SUBMISSION@OMB.EOP.GOV,
Attn: Desk Officer for the Administration for Children and Families.

Dated: January 31, 2011.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2011–2555 Filed 2–7–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007–D–0429; Formerly Docket No. 2007D–0496]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Labeling of Nonprescription Human Drug Products Marketed Without an Approved Application as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act: Questions and Answers

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled “Labeling of Nonprescription Human Drug Products Marketed Without an Approved Application as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act: Questions and Answers” has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3792, Elizabeth.Berbakos@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 24, 2009

(74 FR 8264), 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 0910–0640. The approval expires on July 31, 2012. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: February 1, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–2662 Filed 2–7–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0049]

Agency Information Collection Activities; Proposed Collection; Comment Request; Presubmission Conferences, New Animal Drug Applications and Supporting Regulations, and Food and Drug Administration Form 356V

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 paperwork associated with applications for new animal drugs.

DATES: Submit either electronic or written comments on the collection of information by April 11, 2011.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. 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: Juanmanuel Vilela, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-7651, Juanmanuel.vilela@fda.hhs.gov.

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.

Presubmission Conferences, New Animal Drug Applications and Supporting Regulations, and FDA Form 356V—(OMB Control Number 0910-0032)—Extension

Under section 512(b)(3) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360b(b)(3)), any person intending to file a new animal drug application (NADA) or supplemental NADA or a request for an investigational exemption under section 512(j) of the FD&C Act is entitled to one or more conferences with FDA to reach an agreement acceptable to FDA establishing a submission or investigational requirement. FDA and industry have found that these meetings have increased the efficiency of the drug development and drug review processes.

Section 514.5 (21 CFR 514.5) describes the procedures for requesting, conducting, and documenting presubmission conferences. Section 514.5(b) describes the information that must be included in a letter submitted by a potential applicant requesting a presubmission conference, including a proposed agenda and a list of expected participants. Section 514.5(d) describes the information that must be provided by the potential applicant to FDA at least 30 days prior to a presubmission conference. This information includes a detailed agenda, a copy of any materials

to be presented at the conference, a list of proposed indications and, if available, a copy of the proposed labeling for the product under consideration, and a copy of any background material that provides scientific rationale to support the potential applicant's position on issues listed in the agenda for the conference. Section 514.5(f) discusses the content of the memorandum of conference that will be prepared by FDA and gives the potential applicant an opportunity to seek correction to or clarification of the memorandum.

Under section 512(b)(1) of the FD&C Act, any person may file an NADA seeking approval to legally market a new animal drug. Section 512(b)(1) sets forth the information required to be submitted in an NADA. FDA allows applicants to submit a complete NADA or to submit information in support of an NADA for phased review followed by submission of an Administrative NADA when FDA finds all the applicable technical sections are complete.

The regulations under 21 CFR 514.1 interpret section 512(b)(1) of the FD&C Act and further describe the information that must be submitted as part of an NADA and the manner and form in which the NADA must be assembled and submitted. The application must include safety and effectiveness data, proposed labeling, product manufacturing information, and where necessary, complete information on food safety (including microbial food safety) and any methods used to determine residues of drug chemicals in edible tissue from food-producing animals. Guidance #152 entitled "Evaluating the Safety of Antimicrobial New Animal Drugs With Regard to Their Microbiological Effects on Bacteria of Human Health Concern" outlines a risk assessment approach for evaluating the microbial food safety of antimicrobial new animal drugs. FDA requests that an applicant accompany NADAs, supplemental NADAs, and requests for phased review of data to support NADAs, with the FDA Form 356V to ensure efficient and accurate processing of information to support new animal drug approval.

FDA estimates the burden of the collections of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR section/FDA form No.	Number of respondents ⁴	Annual frequency per respondent	Total annual responses	Hours per response	Total hours
514.5(b), (d) and (f)	154	.6	92.4	50	4,620
514.1 and 514.6	154	.1	15.4	212	3,265
514.4 ²	154	0	0	0	0

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹—Continued

21 CFR section/FDA form No.	Number of respondents ⁴	Annual frequency per respondent	Total annual responses	Hours per response	Total hours
514.8(b)	154	2.84	437.36	35	15,308
514.8(c)(1)	154	.1	15.4	71	1,093
514.8(c)(2) and (c)(3)	154	.7	107.8	20	2,156
514.11	154	.2	30.8	1	31
558.5(i)	154	.01	1.54	5	8
514.1(b)(8) and 514.8(c)(1) ³	154	.21	32.34	90	2,911
FDA Form 356V	154	5.1	785.4	5	3,927
Total					33,319

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

² Substantial Evidence—Because 21 CFR 514.4 only defines substantial evidence, it should not be viewed as creating additional collection burden.

³ NADAs and supplements regarding antimicrobial animal drugs that use a recommended approach to assessing antimicrobial concerns as part of the overall preapproval safety evaluation.

⁴ Based on the number of sponsors subject to animal drug user fees, FDA estimates that there was an average of 154 annual respondents during the 5 fiscal years, from October 1, 2005, through September 30, 2010, on which these estimates were made. We use this estimate consistently throughout the table and calculate the “annual frequency per respondent” by dividing the total annual responses by the number of respondents.

Dated: February 1, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011-2664 Filed 2-7-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0067]

Agency Information Collection Activities; Proposed Collection; Comment Request; Data To Support Drug Product Communications, as Used by the Food and Drug Administration

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 and to allow 60 days for public comment in response to the notice. This notice solicits comments on a generic clearance to collect information to support communications used by FDA about drug products. This data collection will informally gauge public opinion on a variety of subjects related to consumer, patient, or healthcare professional perceptions and use of drug and biological products and related materials, including, but not limited to, direct-to-consumer

prescription drug promotion, physician labeling of prescription drugs, Medication Guides, over-the-counter drug labeling, emerging risk communications, patient labeling, online sales of medical products, and consumer and professional education.

DATES: Submit either electronic or written comments on the collection of information by April 11, 2011.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. 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:

Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3792, Elizabeth.Berbakos@fda.hhs.gov.

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 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.

Data to Support Drug Products Communications, as Used by the Food and Drug Administration (OMB Control Number 0910-New)

Testing of communication messages in advance of a communication campaign provides an important role in improving FDA communications as they allow for an in-depth understanding of individuals’ attitudes, beliefs, motivations, and feelings. The methods to be employed include individual in-depth interviews, general public focus group interviews, intercept interviews, self-administered surveys, gatekeeper surveys, and professional clinician focus group interviews. The methods to be used serve the narrowly defined need for direct and informal opinion on a