DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0236]

Agency Information Collection Activities; Proposed Collection; Comment Request; Presubmission Conferences, New Animal Drug Applications and Supporting Regulations and Guidance 152, and Form FDA 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 written or electronic comments on the collection of information by *September 7, 2007.*

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: 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: 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 Guidance 152, and Form FDA 356V—21 CFR 514.5, 514.1, 514.4, 514.8, (OMB Control Numbers 0910–0555, 0910–0032, 0910–0356, 0910–0522, and 0910–0600)—Extension

Under section 512(b)(3) of the Federal Food, Drug, and Cosmetic Act (the 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 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 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. The OMB control number for the collection of presubmission conference information is 0910–0555.

Under section 512(b)(1) of the 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.

Section 514.1 (21 CFR 514.1) interprets section 512(b)(1) of the act and further describes the information that must be submitted as part of a 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 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 Form FDA 356V to ensure efficient and accurate processing of information to support new animal drug approval. The OMB control number for the NADA and the form 356V is 0910–0032, and the control number for Guidance 152 ''Evaluating the Safety of Antimicrobial New Animal Drugs With Regard to Their Microbiological Effects on Bacteria of Human Health Concern'' is 0910–0522. This information collection also combines several other OMB control numbers: OMB control number 0910–0356 and OMB control number 0910–

0600 that will be assigned to the collection of information under revised § 514.8, effective February 12, 2007. The Animal Drug Availability Act of 1996 required FDA to further define the term ''substantial evidence'' of effectiveness. Following notice and comment rulemaking, FDA further defined substantial evidence at § 514.4 (21 CFR 514.4) (OMB control number 0910–0356). Because § 514.4 is only a definition, it should not be viewed as creating an additional collection burden; the collection of substantial evidence occurs as part of an NADA under § 514.1. FDA also recently revised § 514.8 (21 CFR 514.8) to implement the provisions of section 116 of the Food and Drug Administration Modernization Act of 1997 (71 FR 74766, December 13, 2006; OMB control number pending). Section 514.8 describes the information that must be submitted as part of a supplemental application to support proposed changes to an approved NADA. An applicant may reference existing information from the NADA in the supplemental NADA, but must submit some subset of information required in § 514.1 to support the proposed changes. The total burden hours for each of these CFR sections are found in table 1 of this document.

FDA estimates the burden of the collections of information described in this notice as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section/FDA Form No.	No. of Respondents	Annual Frequency per Respondent	Total Annual Responses	Hours per Response	Total Hours
514.5(b), (d), (f)	134	.7	93	50	4,650
514.1 and 514.6	134	.1	19	212	4,028
514.4	134	0	0	0	0
514.8(b)	134	3.2	425	35	14,875
514.8(c)(1)	134	0.1	14	71	994
514.8(c)(2) and (c)(3)	134	.4	53	20	1,060
514.11	134	.1	19	1	19
558.5(i)	134	.01	1.0	5	5
514.1(b)(8) and 514.8(c)(1)[2]	134	.1	10	90	900
FDA Form 356V	134	5.8	778	5	3,890
Total Hours					30,421

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] NADAs and supplements regarding antimicrobial animal drugs that use a recommended approach to assessing antimicrobial concerns as part of the overall preapproval safety evaluation.

Number of respondents. Based on the number of sponsors subject to animal drug user fees, FDA estimates that there are 134 respondents. We use this estimate consistently throughout the table and calculate the ''annual frequency per respondent'' by dividing the total annual responses by number of respondents. Following is a description of how we estimated the total annual responses and calculated total paperwork burden hours by type of submission.

Presubmission conferences (§ 514.5). Over the past 5 fiscal years, from October 1, 2001, through September 30, 2006, FDA estimates it has conducted an average of 93 presubmission conferences per year. FDA estimates that preparing the paperwork to request the meeting, providing the advance materials, and commenting on the memorandum of conference will take approximately 50 hours. Thus, the total burden hours for presubmission conferences is estimated to be 4,650 hours.

NADA (§ 514.1 and 21 CFR 514.6). Over the past 5 fiscal years, FDA has received an average of 19 NADAs per year. FDA estimates that preparing the paperwork required for an NADA under § 514.1, whether all of the information is submitted with the NADA or the applicant submits information for phased review followed by an Administrative NADA that references that information, will take approximately 212 hours. Thus, the total burden hours for the submission of an NADA with any amendments are estimated to be 4,028 hours.

Substantial evidence (§ 514.4). Because § 514.4 only defines substantial evidence, it should not be viewed as creating an additional collection burden. The collection of information to demonstrate substantial evidence occurs as part of an NADA under § 514.1. There is no additional paperwork burden under § 514.4.

Supplements fall into one of three categories:

- Manufacturing supplements described at § 514.8(b);
- Section 514.8(b)(1) supplements (i.e., supplements seeking changes, other than in manufacturing or labeling, in an established condition of an approval beyond the variations already provided for in the approved application) described at § 514.8(c)(1); and
- Labeling supplements described at 514.8(c)(2) and (c)(3).

An applicant may rely on information and data already filed to support those aspects of the NADA for which there are no changes. Thus, an applicant submitting a supplement should only have to prepare supporting information for those aspects of the application for which there are changes and the paperwork burden will be a percentage of the burden of preparing an NADA.

Manufacturing supplements (§ 514.8(b)). Over the past 5 fiscal years, FDA has received an average of 425 manufacturing supplements annually. FDA estimates that it takes on average 35 hours (1/6 of the time it takes to prepare the paperwork to support a full NADA) to prepare the paperwork to

support approval of manufacturing changes. This results in total of 14,875 burden hours.

Supplements seeking approval of changes in intended uses or conditions of use (§ 514.8(c)(1)). Over the past 3 fiscal years, October 1, 2003, through September 2006, FDA has received an average of 14 supplements annually seeking approval for changes in intended uses or conditions of use. FDA used a 3-year average for this calculation because data for the previous 2 years for this category of supplements was not tracked as an independent number. FDA estimates that it takes an average of 71 hours (approximately 1/3 of the time it takes to prepare the paperwork to support a full NADA) to prepare the paperwork to support approval for such changes. This results in a total of 994 burden hours.

Labeling Supplements (§ 514.8(c)(2) and (c)(3)). Over the past 5 fiscal years, FDA has received an average of 53 labeling supplements annually. FDA estimates that it takes an average of 20 hours (approximately 1 percent of the time it takes to prepare the paperwork to support a full NADA) to prepare the paperwork to support approval of a labeling change. This results in a total of 1,060 burden hours.

Freedom of Information Summary (§ 514.11 (21 CFR 514.11)). Regulations under § 514.11 require the preparation of a summary of the safety and effectiveness data and information submitted with or incorporated by reference in an approved NADA and that the summary be publicly released when the approval is published in the **Federal Register**. This summary, generally referred to as the Freedom of Information (FOI) Summary, may be prepared by FDA or FDA may require the applicant to prepare the summary (§ 514.11(e)(ii)). In the past, FDA has required the applicant to prepare the FOI Summary. Currently, FDA generally takes responsibility for preparing the FOI Summary. Thus, the paperwork burden on applicants to prepare an FOI Summary has significantly decreased. Based on the estimate of 19 NADAs received annually and an estimate that applicants now spend little or no time preparing the FOI summary, the estimated burden hours are 19 hours.

Requirements for liquid medicated feeds (§ 558.5(i) (21 CFR 558.5(i)). Generally, specific labeling is required to make sure that certain drugs, approved for use in animal feed or drinking water but not in liquid medicated feed, are not diverted to use in liquid feeds. Section 558.5(i) permits an applicant to seek a waiver from this requirement (§ 558.5(h)) if there is evidence that it is unlikely a new animal drug would be used in the manufacture of a liquid medicated feed. If FDA receives one NADA per year seeking approval of the use of a liquid medicated feed and on average it takes 5 hours to prepare the request for waiver, the estimated paperwork burden is 5 hours.

Risk assessment of antimicrobial new animal drugs with regard to their microbiological effects on bacteria of human health concern. (§§ 514.1(b)(8) and 514.8(c)(1)). FDA estimates that it receives 10 risk assessments evaluating the microbial food safety of antimicrobial new animal drugs per year. FDA estimates that it takes on average 90 hours to put together the references and other materials in the format recommended by Guidance 152 and to summarize the hazards and associated risk(s). Thus, the total burden hours for preparing such risk assessments for submission to FDA are estimated to be 900 hours.

Form FDA 356V. FDA requests that an applicant fill out and send in with NADAs and supplemental NADAs, and requests for phased review of data to support NADAs, a Form FDA 356V to ensure efficient and accurate processing of information to support new animal drug approval. Over the past 5 fiscal years, FDA has received an average of 511 NADAs and supplements and 267 submissions of data to support NADAs. FDA estimates that it takes an average of 5 hours to read the instructions and fill out Form FDA 356V and organize the information that it will accompany. This results in a total of 3,890 burden hours.

Dated: June 28, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0240]

Agency Information Collection Activities; Proposed Collection; Comment Request, Patent Term Restoration, Due Diligence Petitions, Filing, Format, and Content of Petitions

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 FDA's patent term restoration regulations on due diligence petitions for regulatory review period revision. Where a patented product must receive FDA approval before marketing is permitted, the Office of Patents and Trademarks may add a portion of the FDA review time to the term of a patent. Petitioners may request reductions in the regulatory review time if FDA marketing approval was not pursued with ''due diligence.''

DATES: Submit written comments on the collection of information by September 7, 2007.

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: Elizabeth Berbakos, Office of the Chief Information Officer (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