

include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Karen L. Nelson, Office of the Chief Information Officer (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4816.

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 Pharmacogenomic Data Submissions (OMB Control Number 0910-0557)—Extension

The guidance provides recommendations to sponsors submitting or holding investigational new drugs (INDs), new drug applications (NDAs), or biologic licensing applications (BLAs) on what pharmacogenomic data should be submitted to the agency during the drug development process. Sponsors holding and applicants submitting INDs, NDAs, or BLAs are subject to FDA requirements for submitting to the agency data relevant to drug safety and efficacy (§§ 312.22, 312.23, 312.31, 312.33, 314.50, 314.81, 601.2, and 601.12).

Description of Respondents: Sponsors submitting or holding INDs, NDAs, or BLAs for human drugs and biologics.

Burden Estimate: The guidance interprets FDA regulations for IND,

NDA, or BLA submissions, clarifying when the regulations require pharmacogenomics data to be submitted and when the submission of such data is voluntary. The pharmacogenomic data submissions described in the guidance that are required to be submitted to an IND, NDA, BLA, or annual report are covered by the information collection requirements under parts 312, 314, and 601 (21 CFR parts 312, 314, and 601) and are approved by OMB under control numbers 0910-0014 (part 312—INDs); 0910-0001 (part 314—NDAs and annual reports); and 0910-0338 (part 601—BLAs).

The guidance distinguishes between pharmacogenomic tests that may be considered valid biomarkers appropriate for regulatory decisionmaking, and other, less well developed exploratory tests. The submission of exploratory pharmacogenomic data is not required under the regulations, although the agency encourages the voluntary submission of such data.

The guidance describes the voluntary genomic data submission (VGDS) that can be used for such a voluntary submission. The guidance does not recommend a specific format for the VGDS, except that such a voluntary submission be designated as a VGDS. The data submitted in a VGDS and the level of detail should be sufficient for FDA to be able to interpret the information and independently analyze the data, verify results, and explore possible genotype-phenotype

correlations across studies. FDA does not want the VGDS to be overly burdensome and time-consuming for the sponsor.

FDA has estimated the burden of preparing a voluntary submission described in the guidance that should be designated as a VGDS. Based on FDA's experience with this guidance over the past few years, and on FDA's familiarity with sponsors' interest in submitting pharmacogenomic data during the drug development process, FDA estimates that approximately 8 sponsors will submit approximately 10 VGDSs and that, on average, each VGDS will take approximately 50 hours to prepare and submit to FDA.

In the **Federal Register** of August 21, 2007 (72 FR 46636), FDA published a 60-day notice requesting public comment on the information collection provisions. We received one comment which requested clarification of how the confidential information received in a VGDS will remain outside the public domain and not end up being cited in a publicly posted submission review.

FDA Response: Information received as part of a VGDS not to be used for regulatory decisionmaking and received in confidence is covered by the same confidentiality levels of INDs, NDAs, and BLAs. There is no publicly posted submission review associated with the data in a VGDS, and release of information associated with a VGDS is exclusively up to the sponsor of the VGDS and not to FDA.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

	Number of Respondents	Number of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
Voluntary Genomic Data Submissions	8	1.25	10	50	500

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

Dated: December 5, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7-23996 Filed 12-10-07; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N-0236]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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 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 January 10, 2008.

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, or e-mailed to baguilar@omb.eop.gov. All comments

should be identified with the OMB control number 0910–0032. Also include the FDA 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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance:

Presubmission Conferences, New Animal Drug Applications and Supporting Regulations and Guidance 152, and Form FDA 356V—(OMB Control Number 0910–0032)—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) 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) of the act 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 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 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 revised 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 revised Form FDA 356V is 0910–0032,

and the OMB 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 consolidates several other OMB control numbers: OMB control number 0910–0356 and OMB control number 0910–0600, for which the collection of information requirements under the new revised § 514.8 (21 CFR 514.8) has been approved for a final rule that became 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. As previously stated, FDA also recently revised § 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). Revised § 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 under § 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.

In the **Federal Register** of July 9, 2007 (72 FR 37240), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received in response to that notice.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section/FDA Form #	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
514.5(b), (d), and (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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹—Continued

21 CFR Section/FDA Form #	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
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
Form FDA 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 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 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 is 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 21 CFR 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 a 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 30, 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 ten 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 is 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: December 5, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7-23998 Filed 12-10-07; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N-0469]

Establishment of Fiscal Year 2008 User Fee Rates for Advisory Review of Direct-to-Consumer Television Advertisements for Prescription Drug and Biological Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing this notice, as required by the Food and Drug Administration Amendments Act of 2007 (FDAAA), to establish the fiscal year (FY) 2008 fees that will be charged for each FY 2008 advisory review submission to FDA and to fund the operating reserve established under FDAAA. The Federal Food, Drug, and Cosmetic Act (the act), as amended by FDAAA, authorizes FDA to collect user fees for certain direct-to-consumer (DTC) television advertisements submitted to FDA for advisory review.

ADDRESSES: Information about the DTC television user fee program is available on the Internet at http://www.fda.gov/cder/ddmac/user_fees/default.htm.

FOR FURTHER INFORMATION CONTACT: For questions about rates, invoices, or payments: Ashley Linkous, Office of Regulatory Policy (HFD-7), Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

For questions about where or how to submit proposed DTC television advertisements for advisory review, what to include in your submission, the status of pending DTC television advertisements submitted for advisory review, or your remaining balance of advisory reviews under the DTC television user fee program: Wayne Amchin, Division of Drug Marketing, Advertising, and Communications, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 1454, Silver Spring, MD 20993-0002, 301-796-1200, FAX: 301-796-9878, e-mail dtcp@fda.hhs.gov.

For questions about submissions to the Advertising and Promotional Labeling Branch (APLB) in the Center for Biologics Evaluation and Review (CBER): Ele Ibarra-Pratt, Advertising and Promotional Labeling Branch, Center for Biologics Evaluation and Research

(HFM-602), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6331.

SUPPLEMENTARY INFORMATION:

I. Introduction

On September 27, 2007, the President signed into law FDAAA (Public Law 110-85). Section 104 of this statute created new section 736A of the act, which in addition to reauthorizing the Prescription Drug User Fee Act (PDUFA) for FYs 2008-2012, also authorized a new and separate user fee program for the advisory review of DTC prescription drug television advertisements. Participation in the program is voluntary. Sponsors can decide, at their own discretion, whether to seek FDA advisory review of DTC prescription drug television advertisements in advance of publicly broadcasting them. However, under the new law, if a sponsor decides to seek FDA advisory review of a DTC television advertisement, the sponsor must pay all applicable fees for that review under the DTC television user fee program.

In the **Federal Register** of October 25, 2007 (72 FR 60677), FDA issued a participation notice asking companies: (1) To notify FDA by November 26, 2007, if they intend to participate in the DTC television user fee program during FY 2008 and (2) if they do plan to participate, to identify the number of DTC television advertisements for prescription drug and biological products they plan to submit to CDER or CBER for advisory review during FY 2008. The information gathered in response to the participation notice is the basis for the fees this notice establishes that will be charged for each FY 2008 advisory review submission to FDA and to fund the operating reserve established under FDAAA.

II. Establishing the Advisory Review Fee and Operating Reserves

A. Basis for the Fee

The advisory review fee for FY 2008 will be \$41,390 for each proposed television advertisement voluntarily submitted for advisory review. The fee is based on the number of advertisements identified by all companies in response to the participation notice. The advisory review fees in FY 2008 are set at a level to generate target revenues of \$6.25 million in the first year of the program. Individual fees have been determined by dividing the target revenue, established in the statute, by 151 (the number of television advertisements all