Dated: November 1, 2012.

Bryan Samuels,

Commissioner, Administration on Children, Youth and Families.

[FR Doc. 2012–28089 Filed 11–19–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–1131]

Agency Information Collection Activities; Proposed Collection; Comment Request; New Animal Drug Applications and Supporting Regulations, 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 either electronic or written comments on the collection of information by January 22, 2013.

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: Jonna Capezzuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PIFO, Rm. 410B, Rockville, MD 20850, 301–796–3794.

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, and 514.8 (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 of Title 21 of the Code of Federal Regulations 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 a NADA seeking approval to legally market a new animal drug. Section 512(b)(1) sets forth the information required to be submitted in a NADA. FDA allows applicants to submit a complete NADA or to submit information in support of a NADA for phased review followed by submission of an administrative NADA when FDA finds all the applicable technical sections are complete.

Section 514.1 of Title 21 of the Code of Federal Regulations interprets section 512(b)(1) of the FD&C 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.

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

TABLE 1—NADAS: ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section/FDA Form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
514.5(b), (d), and (f) Requesting presubmission conferences	169	0.41	69	50	3,450
514.1 and 514.6 Applications and amended applications	169	0.07	12	212	2,544
514.8(b) Manufacturing changes to an approved application	169	2.22	375	35	13,125
514.8(c)(1) Labeling and other changes to an approved application	169	0.06	10	71	710
514.8(c)(2) and (3) Labeling and other changes to an approved application	169	0.72	121	20	2,420
514.11 Submission of data, studies and other information	169	0.08	14	1	14
558.5(i) Requirements for liquid medicated feed	169	0.01	1.7	5	8.5
514.1(b)(8) and 514.8(c)(1) [2] Evidence to establish safety and effectiveness	169	0.15	25	90	2,250
FDA Form 356V	169	4.37	739	5	3,695
Total					28,217

[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.

Based on the number of sponsors subject to animal drug user fees, FDA estimates that there was an average of 169 annual respondents during the 5 fiscal years, from October 1, 2008 through September 30, 2012, on which these estimates were made. We use this estimate consistently throughout the table and calculate the ''total annual responses'' by multiplying the number of responses per respondent by number of respondents.

Dated: November 15, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–28199 Filed 11–19–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0847]

Draft Guidance for IRBs, Clinical Investigators, and Sponsors: IRB Responsibilities for Reviewing the Qualifications of Investigators, Adequacy of Research Sites, and the Determination of Whether an IND/IDE Is Needed; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Guidance for IRBs, Clinical Investigators, and Sponsors: IRB Responsibilities for Reviewing the Qualifications of Investigators, Adequacy of Research Sites, and the Determination of Whether an IND/IDE Is Needed.'' The draft guidance announced in this notice is intended to assist institutional review boards (IRBs), clinical investigators, and sponsors involved in clinical investigations of FDA-regulated products in fulfilling responsibilities related to reviewing the qualifications of investigators, adequacy of research sites, and the determination of whether an investigational new drug (IND) application or investigational device exemption (IDE) is needed in order to assure the protection of the rights and welfare of human subjects in clinical investigations.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by January 22, 2013.

ADDRESSES: Submit written requests for single copies of this draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002 (1–888–463–6332 or 301–796–3400); or the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448 (1–800–835–4709 or 301–827–1800); or the Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4622, Silver Spring, MD 20993 (1–800–638–2041 or 301–796–7100). Send one self-addressed adhesive label to assist the office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Doreen Kezer, Office of Good Clinical Practice, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5109, Silver Spring, MD 20993, 301–796–8524.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance entitled ''Guidance for IRBs, Clinical Investigators, and Sponsors: IRB Responsibilities for Reviewing the Qualifications of Investigators, Adequacy of Research Sites, and the Determination of Whether an IND/IDE Is Needed.'' This guidance is intended to assist IRBs, clinical investigators, and sponsors involved in clinical investigations of FDA-regulated