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

Section of the Federal Food, Drug, and Cosmetic Act	No. of Respondents	Annual Frequency per Response	Total Annual Respondents	Hours per Response	Total Hours
520(m)(6)(A)(iii)	1	1	1	100	100
520(m)(6)(C)	5	1	5	100	500
Total					1,250

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

FDA based these estimates on the number of original HDE applications that the Center for Devices and Radiological Health (CDRH) received for the period October 1, 2004, through September 30, 2007. During that time, CDRH received 16 original HDE applications or about 5 per year.

FDA estimates that for each year, CDRH will receive five HDE applications and that three of these applications will be indicated for pediatric use. One HDE holder will notify the agency that the number of devices distributed in the year has exceeded the ADN and five HDE holders will petition to have the ADN modified due to additional information on the number of individuals affected by the disease of condition.

The draft guidance refers also to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR part 803 have been approved under OMB control number 0910–0437; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; the collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 814, subparts A, B, and C, have been approved under OMB control number 0910–0231; the collection of information in 21 CFR parts 50 and 56 have been approved under OMB control number 0910–0130; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073; the collections of information in 21 CFR part 814, subpart H, have been approved under OMB control number 0910–0332; and the collection of information requirements in 21 CFR 10.30 have been approved under OMB control number 0910–0183.

Dated: February 4, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–3030 Filed 2–17–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0512]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Antimicrobial Animal Drug Distribution Reports Under Section 105 of the Animal Drug User Fee Amendments of 2008

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 March 22, 2010.

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: 202–395–7285, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910—NEW and title "Antimicrobial Animal Drug Distribution Reports Under Section 105 of the Animal Drug User Fee Amendments of 2008." Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3793.

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.

Antimicrobial Animal Drug Distribution Reports Under Section 105 of the Animal Drug User Fee Amendments of 2008—(OMB Control Number 0910–NEW)—Extension

Section 105 of the Animal Drug User Fee Amendments of 2008 (ADUFA) amended section 512 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b) to require that the sponsor of each new animal drug that contains an antimicrobial agent submit an annual report to FDA on the amount of each antimicrobial active ingredient in the drug that is sold or distributed for use in food-producing animals, including information on any distributor-labeled product. The legislation was enacted to address the problem of antimicrobial resistance, and to help ensure that FDA has the necessary information to examine safety concerns related to the use of antibiotics in food-producing animals (154 Congressional Record H7534).

Each report must specify: (1) The amount of each antimicrobial active ingredient by container size, strength, and dosage form; (2) quantities distributed domestically and quantities exported; and (3) a listing of the target animals, indications, and production classes that are specified on the approved label of the product.

The first report must be submitted not later than March 31, 2010. The report must cover the period of the preceding calendar year and include separate information for each month of the calendar year. The reports required under section 105 of ADUFA are required to be separate from periodic drug experience reports that are required under § 514.80(b)(4) (21 CFR § 514.80(b)(4) (OMB Control No. 0910–0284).

In the **Federal Register** of October 26, 2009 (74FR 55046), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received comments from two organizations. Both commenters supported the information collection and stated that the data to be collected would be useful in addressing

the problem of antimicrobial resistance. However, both comments suggested that more extensive measures are necessary to address this problem. For example, one of the comments stated that the practical utility of the data would be broadened in conjunction with a larger federal monitoring effort requiring manufacturers to report uses of their products in all food animal products, which would involve collecting data from end users such as veterinarians and animal owners. The other comment stated that the information collection would not be sufficient to show how much of each class of antimicrobial is sold for use in different types of food animals, and recommended that FDA collect distribution data on medicated feeds for this purpose because feeds are specific to animal species and class. The comment also recommended that FDA require all data to be submitted through a Web-based application directly into a form created by FDA, and that FDA create a publically accessible database that allows searches by drug class, dose form, and marketing status. FDA has considered the comments, but at this time we have decided to only require the submission of information that is expressly required to be submitted by section 512(l)(3) of the act. We are pursuing notice and comment rulemaking to codify these requirements, during which time we will assess any additional data requirements.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

FD&C Act Section 512(l)(3)	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours	Capital Cost
Annual Reports for Sponsors with Active Applications	29	6.7	194	80	15,520	$107,880
Annual Reports for Sponsors with Inactive Applications	23	4.0	92	1	92	
Total					15,612	$107,880

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

FD&C Act Section 512(l)(3)	No. of Respondents	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Record	Total Hours
All Applicants	34	1	34	2	68
Total					68

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

The reporting burden estimates, including the total number of annual responses, are based on the number of sponsors and approved applications for antimicrobial drug products in food-producing animals. The annual frequency of responses was calculated as the total annual responses divided by the number of respondents.

The agency arrived at the estimates for reporting as follows: There are 34 sponsors with approved applications for antimicrobial drugs for food-producing animals. There are 29 animal drug manufacturers with 194 approved applications for antimicrobial drugs for food-producing animals for which the drugs are being actively marketed (active applications). Additionally, there are 93 approved applications for antimicrobial drugs for food-producing animals for which the drugs are not being marketed (inactive applications), owned by 23 animal drug manufacturers.

Regarding the reporting burden associated with the collection of information, FDA believes that the large majority of the burden will be incurred by industry in the first year in which reporting is required to design a report that meets the requirements of section 512(l)(3) of the act. The agency has estimated this burden at 80 hours per applicant with active applications. The agency has factored into this estimate the time it will take industry to identify and locate the necessary information within existing records, and to develop a report that complies with section 512(l)(3) of the act. Once this has been accomplished, FDA believes that the process for producing reports in subsequent years will essentially be automated, and that it will take approximately 3 hours to run a report that satisfies the act's requirements. For sponsors of approved applications that are inactive (i.e., the approved drug is not being marketed), the sponsor would only have to submit a report stating that the drug is not being marketed, which FDA estimates will take approximately 1 hour.

FDA has developed a form to report the information required by section 512(l)(3) of the act. FDA plans to make the form available to animal drug manufacturers through FDA's Web site, however, use of the form would be entirely voluntary. The form contains various fields for information, including the drug manufacturer's name, NADA number, active ingredient name, National Drug Code number, container size, potency, and the number of units sold by month.

The animal drug manufacturers can meet the statutory requirements by submitting their information in paper format using either the FDA-provided form or one of their own design or by designing their own electronic form whose results could be submitted to the agency on a compact disc or on paper. The cost to animal drug sponsors for gathering the necessary information for report design and preparation or for completing FDA's form in the first year of reporting is $107,880 (29 active sponsors x 80 hours x $46.50 per hour = $107,880). This is a one-time cost for a computer or mathematic employees to design and prepare a report that satisfies

the statutory requirements of section 512(l)(3) of the act.[1] For subsequent years, the preparation of the report should take approximately 3 hours. Thus, the total cost in subsequent years would be $139.50.

Regarding the recordkeeping burden associated with this collection of information, FDA believes that most of the necessary information for the annual report required to be submitted under section 512(l)(3) of the act is already collected and maintained by animal drug manufacturers under existing requirements.

Animal drug manufacturers are already required to maintain distribution records for their drug products to comply with FDA's current good manufacturing practice regulations under § 211.196 (21 CFR § 211.96) (OMB Control No. 0910–0139), and to comply with regulations for periodic drug experience reports under § 514.80(b)(4)(i) (OMB Control No. 0910–0284). Therefore, FDA believes that manufacturers of animal drugs already possess the computers, software, and additional equipment necessary to collect and maintain the necessary records and to make reports.

Section 512(l)(3) of the act differs from § 514.80(b)(4)(i) in that it requires that records include separate information for each month of the calendar year. Under § 211.196 (OMB Control No. 0910–0139), manufacturers currently are required to maintain distribution records that include the dosage form and date the drug is distributed. Additionally, FDA believes that manufacturers already keep detailed records of the dates when antimicrobial drugs are distributed for marketing and recall purposes from which monthly reports can be prepared as part of their usual and customary practice. However, FDA estimates an additional hourly burden required by section 512(l)(3) of the act as shown in table 2 of this document.

Dated: February 4, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–3029 Filed 2–17–10; 8:45 am]

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[1] BLS Occupation Employment and Wages, May 2006, by occupation, for all industries (*http://www.bls.gov*). Wage ($46.50) includes mean hourly wage of $33.22 for Standard Occupational Classification 15–0000, computer and mathematics occupations, all industries; we add 40 percent to account for benefits.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2004–N–0390] (formerly Docket No. 2004N–0503)

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance on Consultation Procedures: Foods Derived From New Plant Varieties

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 the information collection provisions of FDA's consultation procedures for foods derived from new plant varieties, including the information collection provisions in the guidance entitled "Consultation Procedures: Foods Derived From New Plant Varieties," and in Form FDA 3665 entitled "Final Consultation For Food Derived From a New Plant Variety (Biotechnology Final Consultation)," which developers may use to prepare the final consultation in a standard format.

DATES: Submit written or electronic comments on the collection of information by April 19, 2010.

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: Denver Presley, Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3793.

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. In the **Federal Register** of November 24, 2004 (69 FR 68379), FDA published a previous 60-day notice requesting public comment on this proposed collection of information. FDA is publishing this notice to update comments. Comments previously submitted to the Division of Dockets Management do not need to be resubmitted because all such comments that are responsive to the comment request will be summarized and responded to in the Information Collection Request, i.e. 30-day notice, submitted to OMB.

Guidance on Consultation Procedures: Foods Derived From New Plant Varieties

Since 1992, when FDA issued its Statement of Policy: Foods Derived from New Plant Varieties (the 1992 policy) (57 FR 22984, May 29, 1992), FDA has encouraged developers of new plant varieties, including those varieties that are developed through biotechnology, to consult with FDA during the plant development process to discuss possible scientific and regulatory issues that might arise. In the 1992 policy, FDA explained that, under the Federal Food, Drug, and Cosmetic Act (the act), developers of new foods (in this