requests for advisory opinions made after November 3, 1997 and before August 21, 2000. Section 543 of the Benefits Improvement and Protection Act of 2001, Public Law 106–554, extended indefinitely the period during which the Department of Health and Human Services accepts requests for these advisory opinions. The collection of information contained in 42 CFR 411.372 and 411.373 is necessary to comply with this statutory mandate, and allow CMS to consider requests for advisory opinions and provide accurate and useful opinions. *Form Number:* CMS–R–216 (OMB#: 0938–0714); *Frequency:* Once; *Affected Public:* Business or other for-profit and not-for-profit institutions; *Number of Respondents:* 50 *Total Annual Responses:* 50; *Total Annual Hours:* 1,000.

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Plan Benefit Package (PBP) and Formulary Submission for Medicare Advantage (MA) Plans and Prescription Drug Plans (PDP); *Use:* CMS requires that MA and PDP organizations submit a completed formulary and PBP as part of the annual bidding process. During this process, organizations prepare their proposed plan benefit packages for the upcoming contract year and submit them to CMS for review and approval. To see the comprehensive list of changes from CY2007 to CY2008, please refer to the document entitled ''Appendix B—PBP-Formulary CY2008 List of Changes.'' *Form Number:* CMS–R–262 (OMB#: 0938–0763); *Frequency:* Yearly; *Affected Public:* Business or other for-profit and not-for-profit institutions; *Number of Respondents:* 450 *Total Annual Responses:* 4725; *Total Annual Hours:* 10,800.

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Individuals Authorized Access to the CMS Computer Services (IACS); *Form Number:* CMS–10173 (OMB#: 0938–0989) *Use:* The Centers for Medicare and Medicaid Services (CMS) is requesting the Office of Management and Budget (OMB) approval of the Individuals Authorized to Customer Service Application for Access to CMS Computer Systems. The IACS system provides a centralized user provisioning and administration service that supports the creation, deletion, and lifecycle management of enterprise identities. This service creates accounts, supports Role Based Access Control (RBAC), the form flow approval process and enterprise identity audit and recertification, and provides business application integration points. An application integration point allows business application owners to use the form flow process of the user provisioning service to approve or deny requests for access to business applications. The primary purpose of this system is to implement a unified framework for managing user information and access rights, for those individuals who apply for and are granted access across multiple CMS systems and business contexts. Information in this system will also be used to: (1) Support regulatory and policy functions performed within the Agency or by a contractor or consultant; (2) support constituent requests made to a Congressional representative; and (3) to support litigation involving the Agency related to this system. Although the Privacy Act requires only that the ''routine use'' portion of the system be published for comment, CMS invites comments on all portions of this notice. *Frequency:* As required; *Affected Public:* Individuals or households; Business or other for-profit and not-for-profit; State, Local or Tribal governments; *Number of Respondents:* 60,000,000 *Total Annual Responses:* 15,000,000; *Total Annual Hours:* 15,000,000.

4. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* State Children's Health Insurance Program and Supporting Regulations in 42 CFR 431.636, 457.50, 457.60, 457.70, 457.340, 457.350, 457.431, 457.440, 457.525, 457.560, 457.570, 457.740, 457.750, 457.810, 457.940, 457.945, 457.965, 457.985, 457.1005, 457.1015, and 457.1180; *Form Number:* CMS–R–308 (OMB#: 0938–0841) *Use:* States are required to submit title XXI plans and amendments for approval by the Secretary pursuant to section 2102 of the Social Security Act in order to receive funds for initiating and expanding health insurance coverage for uninsured children. States are also required to submit State expenditure and statistical reports, annual reports and State evaluations to the Secretary as outlined in title XXI of the Social Security Act. *Frequency:* Yearly and quarterly; *Affected Public:* State, Local or Tribal governments; *Number of Respondents:* 56; *Total Annual Responses:* 1,454,601; *Total Annual Hours:* 864,933.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web Site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995*, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov*, or call the Reports Clearance Office on (410) 786–1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received at the address below, no later than 5 p.m. on August 14, 2007.

CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development—C, Attention: Bonnie L Harkless, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: June 7, 2007.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

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BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0220]

Agency Information Collection Activities; Proposed Collection; Comment Request; Animal Drug User Fee Cover Sheet, FDA Form 3546

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 the hourly burden necessary to complete FDA Form 3546, ''Animal Drug User Fee Cover Sheet.''

DATES: Submit written or electronic comments on the collection of information by August 14, 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.

Animal Drug User Fee Cover Sheet; FDA Form 3546; 21 U.S.C. 379j–12 (OMB Control Number 0910–0539)—Extension

Under Section 740 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–12), as amended by the Animal Drug User Fee Act of 2003 (ADUFA), FDA has the authority to assess and collect for certain animal drug user fees. Because the submission of user fees concurrently with applications and supplements is required, review of an application cannot begin until the fee is submitted. The types of fees that require a cover sheet are certain animal drug application fees and certain supplemental animal drug application fees. The cover sheet, FDA Form 3546, is designed to provide the minimum necessary information to determine whether a fee is required for the review of an application or supplement, to determine the amount of the fee required, and to assure that each animal drug user fee payment and each animal drug application for which payment is made, is appropriately linked to that payment. The form, when completed electronically, will result in the generation of a unique payment identification number used for tracking the payment. FDA will use the information collected to initiate administrative screening of new animal drug applications and supplements to determine if payment has been received.

Respondents to this collection of information are new animal drug sponsors, applicants, or manufacturers.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 U.S.C. 379j–12	Number of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
740(a)(1) FDA Form 3546 (Cover Sheet)	69	1 time for each application	69	1	69

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

Based on FDA's database system, there are an estimated 140 manufacturers of products or sponsors of new animal drugs potentially subject to ADUFA. However, not all manufacturers or sponsors will have any submissions in a given year and some may have multiple submissions. The total number of annual responses is based on the number of submissions received by FDA in fiscal year 2003. The Center for Veterinary Medicine estimates 69 annual responses that include the following: 28 new animal drug premarket approval applications and 41 supplements. The estimated hours per response are based on past FDA experience with the various submissions, and range from 30 minutes to 1 hour. The hours per response are based on the average of these estimates.

Dated: June 8, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–11527 Filed 6–14–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0050]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Label Comprehension Study

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 July 16, 2007.

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. All comments should be identified with the OMB control number 0910–NEW and title ''Label Comprehension Study.'' 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