DemoProjectsEvalRpts/downloads/IAH_FactSheet.pdf

Please refer to file code [CMS–5048–N] on the Application. Applicants must submit at least 1 electronic copy on CD–ROM of the Application and are required to submit a paper version of the Application with an original signature. Because of staffing and resource limitations, we cannot accept applicationss by facsimile (FAX) transmission. Hard copies and electronic copies must be identical.

Applications for practices applying to the IAH Demonstration will be considered timely if they are received on or before 5 p.m., Eastern Standard Time (E.S.T.) on the date listed in the **DATES** section of this notice.

III. Collection of Information Requirements

Accordance to section 3024 of the Affordable Care Act this notice does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

Authority: Section 3024 of the Affordable Care Act.

(Catalog of Federal Domestic Assistance Program No. 93.778, Medicare—Supplementary Medical Insurance Program)

Dated: September 9, 2011.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2011–32568 Filed 12–20–11; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0902]

Agency Information Collection Activities; Proposed Collection; Comment Request; Prescription Drug Product Labeling: Medication Guide Requirements

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 regulations requiring the distribution of patient labeling, called Medications Guides, for certain products that pose a serious and significant public health concern requiring distribution of FDA-approved patient medication.

DATES: Submit either electronic or written comments on the collection of information by February 21, 2012.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.regulations.gov*. Submit written comments on the collection of information to 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: Juanmanuel Vilela, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, (301) 796–7651, *juanmanuel.vilela@fda.hhs.gov.*

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 collections 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: (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 assumption 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.

Prescription Drug Product Labeling; Medication Guide Requirements (OMB Control Number 0910–0393)—Extension

FDA regulations require the distribution of patient labeling, called Medication Guides, for certain prescription human drug and biological products used primarily on an outpatient basis that pose a serious and significant public health concern requiring distribution of FDA-approved patient medication information. These Medication Guides inform patients about the most important information they should know about these products in order to use them safely and effectively. Included is information such as the drug's approved uses, contraindications, adverse drug reactions, and cautions for specific populations, with a focus on why the particular product requires a Medication Guide. These regulations are intended to improve the public health by providing information necessary for patients to use certain medication safely and effectively.

The regulations contain the following reporting requirements that are subject to the PRA. The estimates for the burden hours imposed by the following regulations are listed in table 1 of this document:

- 21 CFR 208.20—Applicants must submit draft Medication Guides for FDA approval according to the prescribed content and format.
- 21 CFR 208.24(e)—Each authorized dispenser of a prescription drug product for which a Medication Guide is required, when dispensing the product to a patient or to a patient's agent, must provide a Medication Guide directly to each patient unless an exemption applies under 21 CFR 208.26.
- 21 CFR 208.26 (a)—Requests may be submitted for exemption or deferral from particular Medication Guide content or format requirements.
- 21 CFR 314.70(b)(3)(ii) and 21 CFR 601.12(f)—Application holders must submit changes to Medication Guides to FDA for prior approval as supplements to their applications.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
208.20	25	1	25	320	8,000
314.70(b)(3)(ii), 601.12(f)	5	1	5	72	360
208.24(e)	59,000	5,000	295 million	3 minutes	14,750,000
208.26(a)	1	1	1	4	4
Total					14,758,364

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

Dated: December 15, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–32548 Filed 12–20–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0656]

Animal Drug User Fee Act; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA or Agency) is extending to January 15, 2013, the comment period for the notice of public meeting; request for public comments that published in the **Federal Register** of September 20, 2011 (76 FR 58279). In that notice, FDA requested comments on the Animal Drug User Fee Act (ADUFA) program to date and solicited suggestions regarding the features FDA should propose for the next ADUFA program. The Agency is taking this action to ensure that interested persons have the option of submitting comments throughout the reauthorization of ADUFA.

DATES: Submit either electronic or written comments by January 15, 2013.

ADDRESSES: Submit electronic comments 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. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Donal Parks, Center for Veterinary Medicine (HFV–010), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, (240) 276–8688, *ADUFAReauthorization@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 20, 2011, FDA published a notice of public meeting; request for comments to solicit input from the public on what FDA should consider including in the reauthorization of ADUFA. FDA is interested in responses from the public on the following two general questions and welcomes other pertinent information that stakeholders would like to share:

1. What is your assessment of the overall performance of the ADUFA program thus far?

2. What aspects of ADUFA should be retained, changed, or discontinued to further strengthen and improve the program?

Additional background materials, including the transcript of the public meeting, are available on the FDA's Web site.

The Agency is reopening the comment period to allow members of the general public or of stakeholder groups the opportunity to provide comments throughout the process of reauthorizing ADUFA.

II. How to Submit Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments on this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 15, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–32567 Filed 12–20–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0655]

Animal Generic Drug User Fee Act; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA or Agency) is extending to January 15, 2013, the comment period for the notice of public meeting; request for public comments, published in the **Federal Register** of September 20, 2011 (76 FR 58277). In that notice, FDA requested comments on the Animal Generic Drug User Fee Act (AGDUFA) program to date and solicited suggestions regarding the features FDA should propose for the next AGDUFA program. The Agency is taking this action to ensure that interested persons have the option of submitting comments throughout the reauthorization of AGDUFA.

DATES: Submit either electronic or written comments by January 15, 2013.

ADDRESSES: Submit electronic comments 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. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Donal Parks, Center for Veterinary Medicine (HFV–010), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, (240) 276–8688, *AGDUFAReauthorization@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 20, 2011, FDA published a notice of