Estimated Total Annual Burden Hours: 476,351.

Additional Information

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: *infocollection@acf.hhs.gov*.

OMB Comment

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following:

Office of Management and Budget, Paperwork Reduction Project, Fax: 202–395–7285, E-mail: *OIRA_SUBMISSION@OMB.EOP.GOV,* Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2011–3664 Filed 2–17–11; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0082]

Draft Guidance for Industry on Clinical Pharmacogenomics: Premarketing Evaluation in Early Phase Clinical Studies; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Clinical Pharmacogenomics: Premarketing Evaluation in Early Phase Clinical Studies." The draft guidance is intended to assist the pharmaceutical industry and other investigators engaged in new drug development in evaluating how variations in the human genome could affect the clinical pharmacology properties and clinical responses of drugs.

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on any guidance at any time (*see* 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by April 19, 2011.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201,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 or the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the 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:

Lawrence J. Lesko, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 3178, Silver Spring, MD 20993–0002, 301–796–1565; or

Shiew-Mei Huang, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 3188, Silver Spring, MD 20993–0002, 301–796–1541; or

Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration (HFM–17), 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance entitled "Clinical Pharmacogenomics: Premarketing Evaluation in Early Phase Clinical Studies." Pharmacogenomics (PGx) broadly refers to the study of variations of DNA and RNA characteristics and their relation to drug exposure and/or response. Drug exposure refers to either the administered dose or levels in a body tissue or fluid (*e.g.,* blood, plasma, cerebrospinal fluid). Drug response results from the interplay of pharmacokinetics (*e.g.,* drug absorption, metabolism, and excretion), and pharmacodynamics (*i.e.,* all of the effects of the drug on various physiologic and pathologic processes, including effectiveness and adverse effects). Genetic variations can also influence the exposure-response (E/R) relationship of drugs. PGx studies can enhance the understanding of interindividual differences in the efficacy and safety of investigational drugs.

Drug development is commonly described as going through "phases" (21 CFR 312.21). The first two phases collect information about safety and dosing, so that the larger, later (phase 3) studies (the adequate and well-controlled studies needed to support marketing approval) can gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling. Much of the genomic information collected and assessed during the early phases is often described as "exploratory." Phase 2 studies that suggest genomic influences can lead to phase 3 trials that incorporate findings into prespecified hypotheses, such as enriching the study with genomically defined individuals, determining dose based on demonstrated variability in earlier studies, and defining a priori hypothesis testing of a primary endpoint in a genomic subset.

PGx information obtained from genomic investigations during the course of drug development (and from postmarketing studies) can improve the effectiveness and safety of drugs by identifying patients at high risk for a serious adverse event or absence of benefit; improving the benefit/risk relationship of drugs by using genomic tests to identify patients most likely to respond, or unable to respond to a drug; and by helping to select optimal doses based on genotype-driven differences in PK (pharmacodynamics) and/or PD (pharmacodynamics) of a drug. An important prerequisite to successful use of genetic information in drug development is appropriate collection and storage of DNA samples from all clinical trials, both exploratory and the adequate and well-controlled studies intended to support effectiveness and safety.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance represents the Agency's current thinking on conducting pharmacogenomic studies in

early phase clinical studies. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 201.57 have been approved under OMB control number 0910–0572.

III. Comments

Interested persons may submit to the Division of Dockets Management (*see* **ADDRESSES**) either electronic or written comments regarding 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.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances*, or *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances,* or *http://www.regulations.gov*.

Dated: February 14, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–3679 Filed 2–17–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0528]

Unapproved Animal Drugs; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Request for comments; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending to April 19, 2011, the comment period for the notice that appeared in the **Federal Register** of December 20, 2010 (75 FR 79383). In the notice FDA requested comments on strategies to address the prevalence of animal drug products marketed in the United States without approval or other legal marketing status. The Agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

DATES: Submit electronic or written comments by April 19, 2011.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2010–N–0528 by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- *FAX:* 301–827–6870.
- *Mail/Hand delivery/Courier (for paper, disk, or CD–ROM submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA–2010–N–0528. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting comments, see the "Request for Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Tracey H. Forfa, Center for Veterinary Medicine (HFV–1), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–9000, e-mail: *Tracey.Forfa@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of December 20, 2010 (75 FR 79383), FDA published a notice with a 60-day comment period to request comments from stakeholders on strategies to address the prevalence of animal drug products marketed in the United States without approval or other legal marketing status. The notice expressed FDA's interest in receiving comments on strategies that utilize FDA's existing regulatory framework for addressing this issue as well as on novel strategies not currently employed by the Agency.

The Agency has received requests for a 60-day extension of the comment period. The requests conveyed concern that the current 60-day comment period does not allow respondents sufficient time to address fully the many important issues FDA raised in the notice.

FDA has considered the requests and is extending the comment period for the notice for 60 days, until April 19, 2011. The Agency believes that a 60-day extension allows adequate time for interested persons to submit comments without significantly delaying the Agency's consideration of these important issues.

II. Request for Comments

Interested persons may submit to the Division of Dockets Management (*see* **ADDRESSES**) either electronic or written comments regarding 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: February 15, 2011.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2011–3712 Filed 2–17–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Correction of Burden Table.

SUMMARY: The Health Resources and Services Administration published an Agency Information Collection document in the **Federal Register** of