

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This draft guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction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]

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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