

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 20, 25, 201, 202, 207, 225, 226, 500, 510, 511, 515, 516, 558,
and 589

[Docket No. 2006N-0067]

RIN 0910-AF67

**Index of Legally Marketed Unapproved New Animal Drugs for Minor Species;
Extension of Comment Period**

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending to December 20, 2006, the comment period for the proposed rule that appeared in the **Federal Register** of August 22, 2006 (71 FR 48840). In the proposed rule, FDA requested comments on implementing regulations for the Federal Food, Drug, and Cosmetic Act (the act) entitled "Index of Legally Marketed Unapproved New Animal Drugs for Minor Species." The agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

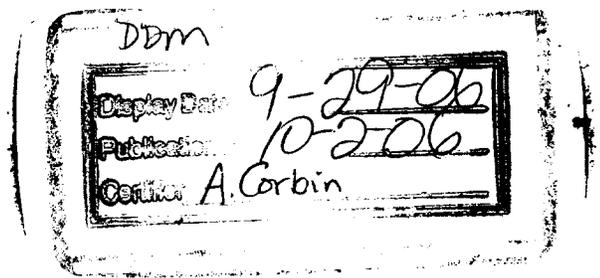
DATES: Submit written or electronic comments on the proposed rule by December 20, 2006. Submit comments regarding information collection by December 20, 2006, to the Office of Management and Budget (OMB) (see **ADDRESSES**).

ADDRESSES: You may submit comments, identified by [Docket No. 2006N-0067 and RIN number 0910-AF67], by any of the following methods:

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Electronic Submissions

Submit electronic comments in the following ways:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.
- Agency Web site: <http://www.fda.gov/dockets/ecomments>. Follow the instructions for submitting comments on the agency Web site.

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.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described in the *Electronic Submissions* portion of this paragraph.

Instructions: All submissions received must include the agency name and Docket No(s). and Regulatory Information Number (RIN) (if a RIN number has been assigned) for this rulemaking. All comments received may be posted without change to <http://www.fda.gov/ohrms/dockets/default.htm>, including any personal information provided. For additional information on submitting comments, see the "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.fda.gov/ohrms/dockets/default.htm> and

insert the docket number(s), 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.

Information Collection Provisions: Submit written comments on the information collection provisions to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB). 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.

FOR FURTHER INFORMATION CONTACT: Bernadette Dunham, Center for Veterinary Medicine (HFV-50), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9090, e-mail: *Bernadette.Dunham@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of August 22, 2006, FDA published a proposed rule with a 90-day comment period to request comments on implementing regulations for the indexing provisions of the Minor Use and Minor Species Animal Health Act of 2004. Comments on the proposed rule will inform FDA's rulemaking to establish regulations for the procedures and criteria for index listing a new animal drug for use in a minor species.

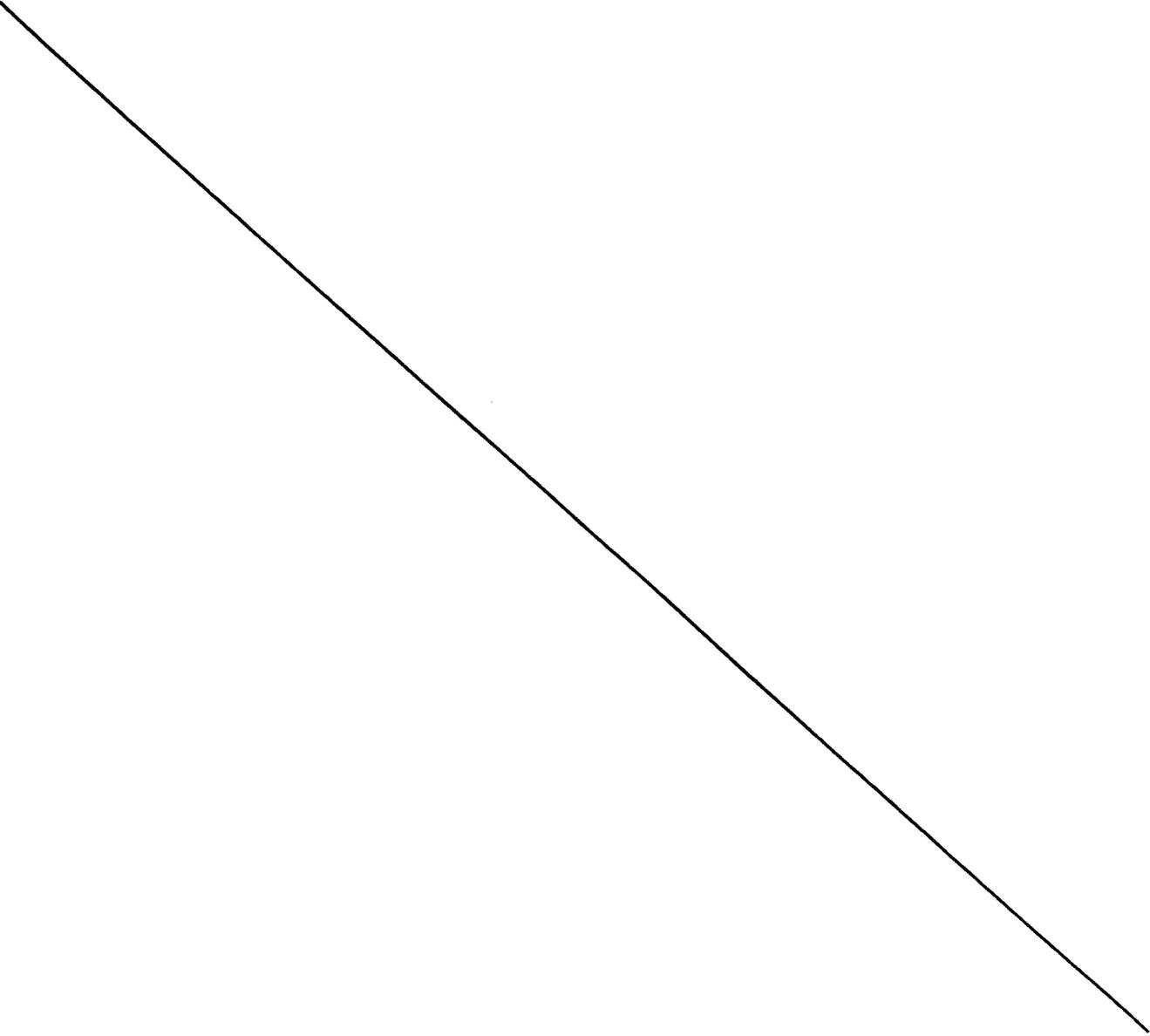
The agency has received requests for a 30-day extension of the comment period for the proposed rule. Each request conveyed concern that the current 90-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to the proposed rule.

FDA has considered the requests and is extending the comment period for the proposed rule for 30 days, until December 20, 2006. The agency believes

that a 30-day extension allows adequate time for interested persons to submit comments without significantly delaying rulemaking on these important issues.

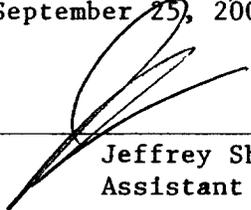
II. Request for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be



identified 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: 9/25/06
September 25, 2006.



Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 06-????? Filed ??-??-06; 8:45 am]

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