

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 530

[Docket No. FDA-2008-N-0326]

DDM

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Certifier D. Hawkins

**New Animal Drugs; Cephalosporin Drugs; Extralabel Animal Drug Use;
Order of Prohibition; Extension of Comment Period; Delay of Effective Date
of Final Rule**

AGENCY: Food and Drug Administration, HHS.

ACTION: Extension of comment period; delay of effective date of final rule.

SUMMARY: The Food and Drug Administration (FDA) is extending to November 1, 2008, the comment period for the order of prohibition. FDA is also delaying the effective date of this final rule to November 30, 2008. In the final rule, FDA requested comments on the document. The agency is taking this action in response to requests for an extension to allow additional time to submit comments.

DATES: The effective date of the rule amending 21 CFR 530.41 published at 73 FR 38110, July 3, 2008 is delayed until November 30, 2008. Submit written and electronic comments by November 1, 2008.

ADDRESSES: You may submit comments, identified by [Docket No. FDA-2008-N-0326], 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.

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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, as described previously, in the **ADDRESSES** portion of this document under *Electronic Submissions*.

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.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(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.

FOR FURTHER INFORMATION CONTACT: Neal Bataller, Center for Veterinary Medicine (HFV-230), Food and Drug Administration, 7519 Standish Pl., Rockville, MD, 20855, 240-276-9200, e-mail: neal.bataller@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:**I. Background**

In the **Federal Register** of July 3, 2008 (73 FR 38110), FDA published an order prohibiting the extralabel use of cephalosporin antimicrobial drugs in food-producing animals, with a 60-day comment period and a 90-day effective date for the final rule.

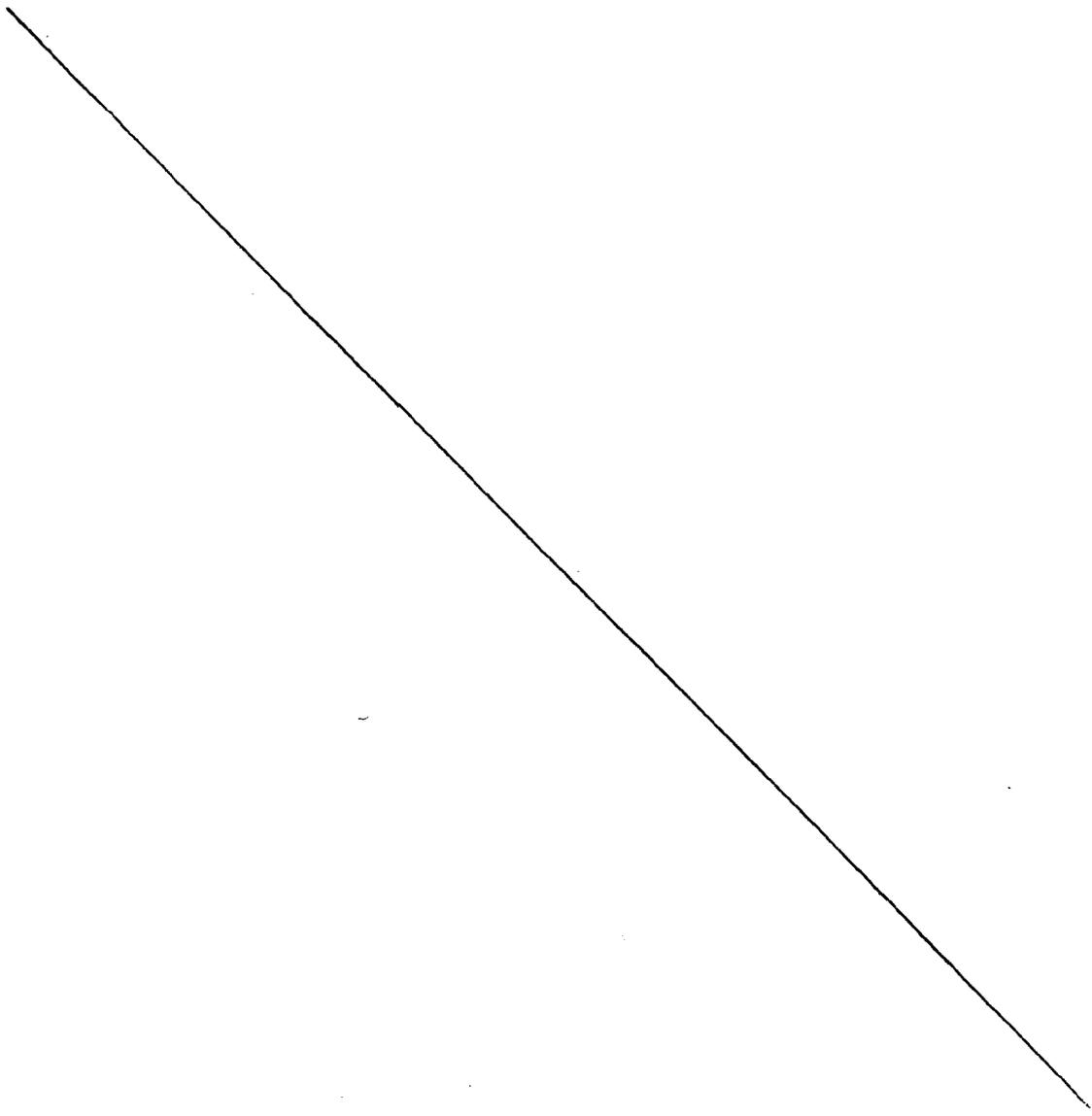
The agency has received requests for a 60-day extension of the comment period for the order of prohibition. The requests conveyed concern that the current 60-day comment period does not allow sufficient time to examine the available evidence, consider the impact of the ruling, and provide constructive comment.

FDA has considered the requests and is extending the comment period for the order for 60 days, until November 1, 2008. Accordingly, FDA is also delaying the effective date of the final rule 60 days, until November 30, 2008. The agency believes that a 60-day extension allows adequate time for interested persons to submit comments without significantly delaying implementation of the final rule.

II. Request for Comments

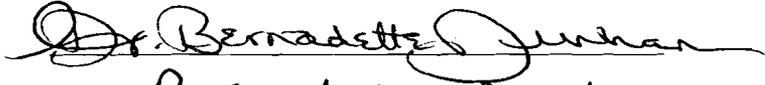
Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be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

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system.



Electronic comments or submissions will be accepted by FDA only through
FDMS at <http://www.regulations.gov>.

Dated: July 31/08
July 31, 2008



Bernadette Dunham,
Director, Center for Veterinary medicine.

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8/1/08

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