DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 530

[Docket No. FDA–2008–N–0326]

New Animal Drugs; Cephalosporin Drugs; Extralabel Animal Drug Use; Revocation of Order of Prohibition; Withdrawal

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is revoking the order prohibiting the extralabel use of cephalosporin antimicrobial drugs in food-producing animals. FDA received many substantive comments on the order of prohibition. The agency is taking this action so that it may fully consider these comments.

DATES: Effective [*insert date of publication in the* **Federal Register**], the final rule published July 3, 2008 (73 FR 38110), for which the effective date was delayed until November 30, 2008, in a document published August 18, 2008 (73 FR 48127), is withdrawn.

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SUPPLEMENTARY INFORMATION: 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 order. The order, that was to take effect

on November 30, 2008, would have resulted in a change to § 530.41 (21 CFR 530.41) to list cephalosporins as prohibited from extralabel use in food-producing animals as provided for in 21 CFR 530.25(f).

In response to publication of this order, the agency received requests for a 60-day extension of the comment period. The requests conveyed concern that the original 60-day comment period would not allow the requesters sufficient time to examine the available evidence, consider the impact of the order, and provide constructive comment.

FDA considered the requests and, in the **Federal Register** of August 18, 2008 (73 FR 48127), extended the comment period for the order for 60 days, until November 1, 2008. Accordingly, FDA also delayed the effective date of the final rule 60 days, until November 30, 2008.

The agency received many substantive comments on the order of prohibition. Therefore, to allow more time to fully consider the comments, FDA has decided to revoke the order so that it does not take effect November 30, 2008. This means that neither the order nor the change to § 530.41 that would have listed cephalosporins as prohibited from extralabel use will take effect on November 30, 2008. If, after considering the comments and other relevant information, FDA decides to issue another order of prohibition addressing this matter, FDA will follow the procedures in 21 CFR 530.25 that provide for a public comment period prior to implementing the order.

We note that, insofar as withdrawal of the amendment to § 530.41 might be considered a rule subject to 5 U.S.C. 553(b), the agency for good cause finds that prior notice and comment procedures are unnecessary because there is no need to amend § 530.41 since the order is being revoked.

Dated: November 21, 2008.

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Acting Director, Center for Veterinary Medicine.

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