DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 20, 510, 514, and 516

[Docket No. 2005N–0329]

RIN 0910–AF60

Designation of New Animal Drugs for Minor Uses or Minor Species;
Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until [insert date 30 days after date of publication in the Federal Register], the comment period for the proposed rule published in the Federal Register of September 27, 2005 (70 FR 56394), proposing implementing regulations for designation of new animal drugs for minor uses and minor species under section 573 of the Federal Food, Drug, and Cosmetic Act (the act). FDA is reopening the comment period to update comments and to receive any new information.

DATES: Submit written or electronic comments by [insert date 30 days after date of publication in the Federal Register].

ADDRESSES: Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

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SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of September 27, 2005 (70 FR 56394), FDA proposed implementing regulations for designation of new animal drugs for minor uses and minor species under section 573 of the act (21 U.S.C. 360ccc-2). Interested persons were originally given until December 12, 2005, to comment.

II. Request for Comments

Following publication of the September 27, 2005, proposed rule, FDA received requests to allow interested persons additional time to comment. The requesters asserted that the time period of 75 days was insufficient to respond fully to FDA’s specific requests for comments and to allow potential respondents to thoroughly evaluate and address pertinent issues.

III. How to Submit 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 to http://www.fda.gov/dockets/ecomments 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: December 21, 2005.

Jeffrey Shuren,
Assistant Commissioner for Policy.

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