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 January 27, 2006, 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 January 27, 2006.

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.

FOR FURTHER INFORMATION CONTACT: Andrew Beaulieu, Center for Veterinary Medicine (HFV–50), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–1550, FAX 240–276–2146, e-mail: Andrew.Beaulieu@fda.gov.

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 address 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.

[FR Doc. E5–7987 Filed 12–27–05; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–143244–05]

RIN 1545–BE93

Guidance Under Section 7874 for Determining Ownership by Former Shareholders or Partners of Domestic Entities

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking by cross-reference to temporary regulations and notice of public hearing.

SUMMARY: In the Rules and Regulations section of this issue of the Federal Register, the IRS is issuing temporary regulations relating to the disregard of affiliate-owned stock in determining the percentage of stock of a foreign corporation held by former shareholders or partners of a domestic entity, in order to determine whether the foreign corporation is a surrogate foreign corporation under section 7874 of the Internal Revenue Code (Code). The text of those regulations also serves as the text of these proposed regulations. This document also provides notice of a public hearing on these proposed regulations.

DATES: Written or electronic comments must be received by March 28, 2006. Outlines of topics to be discussed at the public hearing scheduled for April 27, 2006, at 10 a.m., must be received by April 6, 2006.

ADDRESSES: Send submissions to: CC:PA:LPD:PR (REG–143244–05), room 5203, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand-delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to: CC:PA:LPD:PR (REG–143244–05), Courier’s Desk, Internal Revenue Service, 111 Constitution Avenue, NW., Washington, DC, or sent electronically, via the IRS Internet site at: www.irs.gov/reg or via the Federal eRulemaking Portal at www.regulations.gov (IRS–REG–143244–05).

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, Jefferson VanderWolk at (202) 622–3810; concerning submission and delivery of comments and the public hearing, Robin Jones at (202) 622–7180 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background and Explanation of Provisions

Temporary regulations in the Rules and Regulations section of this issue of the Federal Register amend the Income Tax Regulations (26 CFR part 1) relating to section 7874. The temporary regulations set forth rules on disregarding affiliate-owned stock in determining the percentage of stock of a foreign corporation held by former shareholders or partners of a domestic entity by reason of holding stock or a partnership interest in the domestic entity. For purposes of determining whether the foreign corporation is a surrogate foreign corporation under section 7874(a)(2)(B). The text of those regulations also serves as the text of these proposed regulations. The preamble to the temporary regulations explains the amendments.

Special Analyses

It has been determined that this notice of proposed rulemaking is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It has also been determined that section