DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 500

[Docket No. 01N–0284]

Import Tolerances; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending to March 11, 2002, the comment period for the advance notice of proposed rulemaking (ANPRM) that appeared in the **Federal Register** of August 10, 2001 (66 FR 42167). The ANPRM gave notice that FDA was proposing a regulation for establishing import tolerances. The ANPRM was soliciting comments on issues related to the implementation of the import tolerances provision in section 4 of the Animal Drug Availability Act of 1996 (ADAA). The ADAA authorizes FDA to establish drug residue tolerances (import tolerances) for imported food products of animal origin for drugs that are used in other countries, but that are unapproved new animal drugs in the United States. Food products of animal origin that are in compliance with the import tolerance will not be considered adulterated under the Federal Food, Drug, and Cosmetic Act (the act) and may be imported into the United States. FDA is taking action because it has rescheduled the public meeting on the issue and wishes to allow time for the consideration of comments made after the meeting.

DATES: Submit written or electronic comments by March 11, 2002.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–235), 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: Frances Pell, Center for Veterinary Medicine (HFV–235), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0188, e-mail: *fpell@cvm.fda.gov.*

SUPPLEMENTARY INFORMATION:

I. Extension of Comment Period

In the **Federal Register** of August 10, 2001 (66 FR 42167), FDA published an ANPRM that gave notice that FDA intends to propose a regulation for establishing import tolerances. Interested persons were given until December 10, 2001, to comment on the ANPRM. The ANPRM is available on the Internet at: *http://www.fda.gov/OHRMS/DOCKETS/98fr/081001a.htm.* Because the agency has rescheduled the meeting of the Veterinary Medicine Advisory Committee (VMAC) from September 2001 to January 2002 (66 FR 58052, November 21, 2001), the agency is extending the comment period 90 days. The VMAC will be asked to discuss answers to questions similar to those posed in the ANPRM.

II. Comments

Interested persons may submit written or electronic comments regarding the ANPRM by March 10, 2002. Written or electronic comments should be submitted to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one 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 office above between 9 a.m. and 4 p.m., Monday through Friday.

Comments may also be submitted electronically on the Internet at: *http://www.fda.gov/dockets/ecomments.* Once on the Internet site, select 01N–0284 Import Tolerances and follow the directions.

Dated: November 30, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

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