overall revenues derived from their operations. Accordingly, pursuant to the Regulatory Flexibility Act, 5 U.S.C. 605(b), the Federal Aviation Adminsitration certifies that this rule would not have a significant economic impact on a substantial number of small entities. The FAA solicits comments from affected entities with respect to this finding and determination and requests that commenters provide supporting data or analyses.

**International Trade Impact Analysis**

The provisions of this proposed interpretive rule would have little or no impact of trade for U.S. firms doing business in foreign countries and foreign firms doing business in the United States.

**Federalism Implications**

The proposed interpretive rule would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this rule would not have sufficient federalism implications to warrant the preparation of a federalism assessment.

**Unfunded Mandates Reform Act**

Title II of the Unfunded Mandates Reform Act of 1995 (the Act), codified in 2 U.S.C. 1501–1571, requires each Federal agency, to the extent permitted by law, to prepare a written assessment of the effects of any Federal mandate in a proposed or final agency rule when such a mandate would be ''significant.'' A significant regulatory action under the Act is any provision in a Federal agency regulation that would result in an expenditure by State, local, and tribal governments, or by the private sector, in the aggregate of $100 million or more (adjusted annually for inflation) in any one year.

Since this proposed interpretive rule does not impose any cost, the requirements of Title II of the Unfunded Mandates Reform Act of 1995 do not apply.

**Paperwork Reduction Act**

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), the FAA has determined that there are no requirements for information collection associated with this proposed rule.

Issued in Washington, DC, on June 28, 1999.

**Nicholas G. Garaufis,**

*Chief Counsel.*

[FR Doc. 99–16807 Filed 7–1–99; 8:45 am]

BILLING CODE 4910–13–M

## FEDERAL TRADE COMMISSION

## 16 CFR Part 453

## Extension of Time for Comments Concerning Trade Regulation Rule on Funeral Industry Practices

**AGENCY:** Federal Trade Commission.

**ACTION:** Notice of extension of comment period.

**SUMMARY:** The Federal Trade Commission (''the Commission'' or ''FTC'') has extended the date by which comments must be submitted concerning the review of its Trade Regulation Rule on Funeral Industry Practices (''Funeral Rule''). This document informs prospective comments of the change and sets a new date of August 11, 1999, for the end of the comment period.

**DATES:** Written comments will be accepted until the close of business on August 11, 1999. Notification of interest in participating in the public workshop must be submitted separately on or before August 11, 1999.

**ADDRESSES:** Written comments should be identified as ''16 CFR part 453'' and submitted to: Secretary, Federal Trade Commission, Room H–159, 600 Pennsylvania Ave., NW, Washington, DC 20580. See **SUPPLEMENTARY INFORMATION** for future details.

All comments will be placed on the public record and will be available for public inspection in accordance with the Freedom of Information Act, 5 U.S.C. 552, and the Commission's Rules of Practice, 16 CFR 4.11, during normal business days from 8:30 a.m. to 5 p.m., at the Public Reference Room, Room 130, Federal Trade Commission, 600 Pennsylvania Ave., N.W. Washington, DC 20580. In addition, comments will be posted ont he Internet at the FTC's web site: ''*www.ftc.gov*.''

Notification on interest in participating in the Public Workshop-Conference should be submitted in writing on or before August 11, 1999, to Myra Howard, Division of Marketing Practices, Federal Trade Commission, 600 Pennsylvania Ave., N.W., Washington, DC 20580.

**FOR FURTHER INFORMATION CONTACT:** Myra Howard, (202) 326–2047, or Mercedes Kelley, (202) 326–3665, Division of Marketing Practices, Federal Trade Commission, 600 Pennsylvania Ave., N.W., Washington, DC 20580.

**SUPPLEMENTARY INFORMATION:** On May 5, 1999, the Commission published in the **Federal Register** a Request for Comment on its Funeral Industry Practices Rule (''Funeral Rule'' or ''Rule''), 16 CFR part 453, as part of its regulatory review program. 64 FR 24250. The Funeral Rule details a number of unfair and deceptive practices relating to providers of funeral goods and services, and sets forth preventive requirements in the form of price and information disclosures to ensure the funeral providers avoid engaging in the enumerated unfair or deceptive acts or practices. The **Federal Register** notice (''notice'') posed thirty questions in all; some were general regulatory review questions, while others asked about material issues that are specific to the Funeral Rule and the funeral industry. The notice requested commenters to provide answers where possible, and specifically asked for data, surveys and empirical evidence to support comments submitted to the Commission. Pursuant to the **Federal Register** notice, the comment period currently ends on July 12, 1999.

Between June 11, 1999, and June 16, 1999, staff have received requests for a modest extension of the comment period from four separate organizations representing a variety of viewpoints on the Rule—the National Funeral Directors Association (''NFDA''), the American Association of Retired Persons (''AARP''), the Funeral and Memorial Societies of America, Inc. (''FAMSA''), and the Monument Builders of North America (''MBNA''). The parties indicated that additional time was required to prepare thorough, thoughtful responses to the questions contained in the **Federal Register** notice.

The Commission is mindful of the need to deal with this matter as expeditiously as possible. However, the Commission is also aware that some of the issues raised by the **Federal Register** notice are rather complex, and it welcomes as much substantive input as possible to facilitate its decisionmaking process. Accordingly, in order to provide sufficient time for these and other interested parties to prepare useful comments, the Commission has decided to extend the deadline for comments by thirty (30) days, until August 11, 1999.

**Additional Comment Information**

The Commission requests that commenters submit the original plus five copies, if feasible. To enable prompt review and public access, all written comments should also be submitted, if possible, in electronic form. To submit

in electronic form, provide the comment on either a 5¼″ or a 3½″ computer disk. The disk should be labeled with the commenter's name and the name and version of the word processing program used to create the document. (Programs based on DOS or Windows are preferred. Files from other operating systems should be submitted in ASCII text format). Alternatively, the Commission will also accept comments submitted to the following E-Mail address: ''FUNERAL@ftc.gov.'' Individual members of the public who will be filing comments need not submit multiple copies and need not submit their comments in electronic form.

**List of Subjects in 16 CFR Part 453**

Funerals, Trade practices.

By direction of the Commission.

**Benjamin I. Berman,**

*Acting Secretary.*

[FR Doc. 99–16767 Filed 7–1–99; 8:45 am]

**BILLING CODE 6750–01–M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Parts 510, 514, and 558

**[Docket No. 99N–1591]**

### Animal Drug Availability Act; Veterinary Feed Directive

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is proposing to amend the animal drug regulations to implement the Veterinary Feed Directive (VFD) drugs section of the Animal Drug Availability Act (ADAA). A VFD drug is intended for use in animal feeds, and such use of the VFD drug is permitted only under the professional supervision of a licensed veterinarian. The proposed regulation would establish the requirements relating to the distribution and use of VFD drugs and animal feeds containing VFD drugs.

**DATES:** Written comments on this proposed rule must be submitted by September 30, 1999. Comments on the information collection provisions must be submitted by August 2, 1999.

**ADDRESSES:** Submit written comments on this proposed rule to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit written comments regarding the information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA. All comments must be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** George Graber, Center for Veterinary Medicine (HFV–220), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6651, e-mail: ggraber@cvm.fda.gov.

**SUPPLEMENTARY INFORMATION:**

#### I. Background

FDA has determined that certain new animal drugs, vital to animal health, should be approved for use in animal feed, but only if such medicated feeds are administered under a veterinarian's order and supervision. This limitation is important for a number of reasons. For example, control of the usage of certain antimicrobials is critical to reducing unnecessary use of such drugs in animals and to slowing or preventing the development of bacterial resistance to antimicrobial drugs. In addition, safety concerns relating to, among other things, difficulty in diagnosing disease conditions and high toxicity may also require that the use of a drug in animal feed be limited to use by order and under the supervision of a licensed veterinarian.

Before the passage of the ADAA, the Federal Food, Drug, and Cosmetic Act (the act) provided FDA only two options for regulating the distribution of animal drugs: Over-the-counter (OTC) and prescription. Although prescription status affords certain controls, the regulation of animal drugs for use in medicated feeds under traditional prescription systems has proven unworkable. The prescription legend invokes the application of State pharmacy laws, and FDA usually defers to State law concerning dispensing of prescription drugs. Pharmacy laws in a significant number of States prohibit feed manufacturers from possessing and dispensing prescription animal drugs and medicated feed containing those drugs. Pharmacy laws in other States require the presence of a pharmacist at the feed manufacturing facility that uses prescription drugs in the manufacture of medicated feeds. As a practical matter, the application of State pharmacy laws to medicated feeds would burden State pharmacy boards and impose costs on animal feed manufacturers to such an extent that it would be impractical to make these critically needed new animal drugs available for animal therapy. After considerable deliberation with, and support from, the Coalition for Animal Health, and with support from State regulatory agencies, Congress enacted legislation in 1996 establishing a new class of restricted feed use drugs that may be distributed without invoking State pharmacy laws. The ADAA (Pub. L. 104–250) amended the act to create section 504 (21 U.S.C. 354), VFD drugs.

Although statutory controls on the distribution and use of VFD drugs are similar to those for prescription animal drugs regulated under section 503(f) of the act (21 U.S.C. 353(f)), the proposed implementing VFD regulations are tailored to the unique circumstances relating to the distribution of animal feeds containing a VFD drug. This proposal would ensure the protection of public health while enabling animal producers to obtain and use needed drugs as efficiently and cost-effectively as possible. Unlike prescription drugs, VFD drugs would not be regulated by State pharmacy bodies. Historically, FDA has cooperated with State feed control offices in regulating the manufacture and use of medicated feeds. Investigations and inspections to measure compliance at FDA licensed feed manufacturing establishments are carried out by FDA or by State feed regulatory personnel commissioned by FDA. Most States maintain active inspection programs for medicated feed establishments that are not required to be licensed by FDA. We anticipate that State feed offices will continue assisting FDA by enforcing VFD regulations.

To date, one VFD drug has been approved; tilmicosin, an antimicrobial approved for administration via animal feed for control of swine respiratory diseases (§ 558.618 (21 CFR 558.618)). The regulation for tilmicosin, in addition to specifying the approved conditions of use, describes the information that the attending veterinarian must provide as part of the VFD form. At the time of publication of the final rule for VFD's, the regulation at § 558.618 will be amended, if needed, to be consistent with the final rule.

#### II. Discussion of the Proposed Rule

By amending part 558 (21 CFR part 558), the proposed rule would implement section 504 of the act, which created VFD drugs. Specifically, the proposed rule would amend § 558.3(b) by adding necessary definitions at § 558.3(b)(6) through (b)(11). The proposed rule would also redefine Category II drugs at § 558.3(b)(1)(ii) to include all VFD drugs, a reflection of