connection with the broadcast presentation, must contain a brief summary of all necessary information related to side effects and contraindications.

(ii) *Clear, conspicuous, and neutral manner.* Advertisements for prescription drugs intended for use by humans presented directly to consumers in television or radio format must present the major statement in a clear, conspicuous, and neutral manner. A major statement is clear, conspicuous, and neutral if:

(A) Information is presented in language that is readily understandable by consumers;

(B) Audio information is understandable in terms of the volume, articulation, and pacing used;

(C) Textual information is placed appropriately and is presented against a contrasting background for sufficient duration and in a size and style of font that allows the information to be read easily; and

(D) The advertisement does not include distracting representations (including statements, text, images, or sounds or any combination thereof) that detract from the communication of the major statement.

* * * * *

Dated: March 24, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–6996 Filed 3–26–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 514, and 558

[Docket No. FDA–2010–N–0155]

Veterinary Feed Directive

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA or the agency) is announcing an advance notice of proposed rulemaking (ANPRM) to solicit comments from the public regarding potential changes to its current regulation relating to veterinary feed directive (VFD) drugs. FDA's VFD regulation, which became effective on January 8, 2001, established requirements relating to the distribution and use of VFD drugs and animal feeds containing such drugs. FDA is undertaking a review of these requirements in an effort to identify possible changes to improve efficiency. Therefore, the agency is requesting public comment on all aspects of the VFD regulation, particularly suggestions relating to improving efficiency. This information may be used to help draft a proposed rule in the near future.

DATES: Submit electronic or written comments by June 28, 2010.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2010–N–0155, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301–827–6870.
- Mail/Hand delivery/Courier (for paper, disk, or CD–ROM submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov*, including any personal information provided. For additional information on submitting comments, see the "Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Neal Bataller, Center for Veterinary Medicine (HFV–230), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–9201, e-mail: *Neal.Bataller@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Before 1996, two options existed for regulating the distribution of animal drugs, including drugs in animal feed: (1) Over-the-counter (OTC) and (2) prescription. In 1996, Congress passed and the President signed into law the Animal Drug Availability Act (ADAA) (Public Law 104–250), to facilitate the approval and marketing of new animal drugs and medicated feeds. As part of the ADAA, Congress determined that certain new animal drugs should be approved for use in animal feed but only if these medicated feeds were administered under a veterinarian's order and professional supervision. Therefore, the ADAA created a new category of products called veterinary feed directive drugs (or VFD drugs). VFD drugs are new animal drugs intended for use in or on animal feed which are limited to use under the professional supervision of a licensed veterinarian in the course of the veterinarian's professional practice.

In the **Federal Register** of December 8, 2000 (65 FR 76924), FDA issued a final rule amending the new animal drug regulations to implement the VFD-related provisions of the ADAA. FDA reaffirmed that certain new animal drugs should be approved for use in animal feed only if these medicated feeds are administered under a veterinarian's order and professional supervision. Veterinarian oversight is important for assuring the safe and appropriate use of certain new animal drugs. For example, safety concerns relating to the difficulty of disease diagnosis, drug toxicity, drug residues, antimicrobial resistance, or other reasons may dictate that the use of a medicated feed be limited to use by order and under the supervision of a licensed veterinarian.

It has been 9 years since FDA began implementing the final rule regulating VFDs. Although, currently there are few approved VFD animal drug products, FDA has received a number of informal general comments that characterize the current VFD process as being overly burdensome. In addition, there are concerns that the process in its current form will become particularly problematic to administer in the future as the number of approved VFD animal drugs increases. When veterinary oversight of a medicated feed is determined to be necessary, it is critically important that such oversight be facilitated through an efficient VFD process. In response to these concerns, the agency is undertaking a review of the VFD regulations to determine whether changes are warranted to improve the program's efficiency.

II. Agency Request for Comments

The purpose of this document is to solicit public comment on whether such efficiency improvements are needed and, if so, on possible revisions to the VFD regulations. Such comments are welcome on all aspects of the VFD regulation. To facilitate FDA's review of

submitted comments, please organize your comments based on the major categories of requirements included in the current VFD regulation at 21 CFR 558.6. These categories of requirements are listed following this paragraph. (See A through F.) If your comment addresses an issue outside of one of these categories, please categorize your comment as G. "Other:"

A. Conditions that must be met by veterinarians issuing a VFD;

B. What veterinarians must do with a VFD (e.g., disposition of original VFD and copies);

C. Records that must be kept related to the VFDs;

D. Notification requirements for distributors of animal feeds containing a VFD drug;

E. Additional recordkeeping requirements that apply to distributors;

F. Cautionary statements required for VFD drugs and animal feeds containing VFD drugs; and

G. Other.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments regarding this document. Submit a single copy of electronic comments 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: March 24, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–6872 Filed 3–26–10; 8:45 am]

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DEPARTMENT OF STATE

22 CFR Parts 124, 126, and 129

[Public Notice: 6931]

RIN 1400–AC62

Amendment to the International Traffic in Arms Regulations: Removing Requirement for Prior Approval for Certain Proposals to Foreign Persons Relating to Significant Military Equipment

AGENCY: Department of State.

ACTION: Proposed rule.

SUMMARY: The Department of State is amending the International Traffic in Arms Regulations (ITAR) to remove the requirements for prior approval or prior notification for certain proposals to foreign persons relating to significant military equipment at section 126.8 of the ITAR.

DATES: *Effective Date:* The Department of State will accept comments on this proposed rule until May 28, 2010.

ADDRESSES: Interested parties may submit comments within 60 days of the date of the publication by any of the following methods:

- *E-mail: DDTCResponseTeam@state.gov* with an appropriate subject line.
- *Mail:* Department of State, Directorate of Defense Trade Controls, Office of Defense Trade Controls Policy, ATTN: Regulatory Change, Section 126.8, SA–1, 12th Floor, Washington, DC 20522–0112.
- Persons with access to the Internet may also view this notice by going to the U.S. Government regulations.gov Web site at *http://regulations.gov/index.cfm.*

FOR FURTHER INFORMATION CONTACT: Director Charles B. Shotwell, Office of Defense Trade Controls Policy, Department of State, Telephone (202) 663–2803 or Fax (202) 261–8199; E-mail *DDTCResponseTeam@state.gov.* ATTN: Regulatory Change, Section 126.8.

SUPPLEMENTARY INFORMATION: Effective September 1, 1977, the Department of State amended the International Traffic in Arms Regulations (ITAR) at 22 CFR 123.16, to require Department of State approval before a proposal or presentation is made that is designed to constitute the basis for a decision to purchase significant combat equipment, involving the export of an item on the U.S. Munitions List, valued at $7,000,000 or more for use by the armed forces of a foreign country (42 FR 41631, dated August 18, 1977). Also, 22 CFR 124.06, entitled "Approval of proposals for technical assistance and manufacturing license agreements," was amended to require similar prior approval requirements with respect to proposals and presentations for technical assistance and manufacturing license agreements involving the production or assembly of significant combat equipment.

"Proposals to foreign persons relating to significant military equipment" became section 126.8 in a final rule effective January 1, 1985 (49 FR 47682, dated December 6, 1984). Section 126.8 did not require prior approval of the Department of State when the proposed sale was to the armed forces of a member of the North Atlantic Treaty Organization (NATO), Australia, Japan, or New Zealand, except with respect to manufacturing license agreements or technical assistance agreements.

A prior notification requirement, instead of prior approval, was added to section 126.8 in a final rule effective March 31, 1985 (50 FR 12787, dated April 1, 1985). Prior notification to the Department of State was required 30 days in advance of a proposal or presentation to any foreign person where such proposals or presentations concern equipment previously approved for export.

The current section 126.8 requires prior approval or prior notification for certain proposals and presentations to make a determination whether to purchase significant military equipment valued at $14,000,000 or more (other than a member of NATO, Australia, New Zealand, Japan, or South Korea), or whether to enter into a manufacturing license agreement or technical assistance agreement for the production or assembly of significant military equipment, regardless of dollar value.

These types of proposals and presentations usually involve large dollar amounts. Before the defense industry undertakes the effort involved in formulating its proposals and presentations, if there is any doubt that the corresponding license application or proposed agreement would not be authorized by the Department of State, the industry may request an advisory opinion (*See* 22 CFR 126.9). The written advisory opinion, though not binding on the Department, helps inform the defense industry whether the Department would likely grant a license application or proposed agreement. Currently, the time between submitting a license application or proposed agreement and obtaining a decision from the Department of State whether to authorize such transactions has been decreased sufficiently that requiring prior approval or prior notification for proposals is unnecessary and imposes an administrative burden on industry.

References to § 126.8 have been removed at §§ 124.1(a), 126.13, and 129.8(c).

Regulatory Analysis and Notices

Administrative Procedure Act

This proposed amendment involves a foreign affairs function of the United States and, therefore, is not subject to the procedures contained in 5 U.S.C. 553 and 554.

Regulatory Flexibility Act

Since this proposed amendment involves a foreign affairs function of the United States, it does not require