

52-72 configuration) entails modifying the electrical wiring, replacing the switch operating cam in the pedestal, and modifying the warning annunciator panels on the central warning panels. The modification described in Fokker Service Bulletin F28/52-101 (for airplanes on which the passenger door lock warning system is in a post-SBF28/52-72 configuration) involves installing an additional signal from the door lock circuit to the central warning system. Accomplishment of the modification described in these service bulletins will enhance the door lock warning system by ensuring that the master warning is activated when the airplane is about to take off with an unlocked passenger door.

The RLD classified these service bulletins as mandatory and issued Dutch airworthiness directive BLA 1992-117/3 (A), dated February 28, 1995, in order to assure the continued airworthiness of these airplanes in the Netherlands.

This airplane model is manufactured in the Netherlands and is type certificated for operation in the United States under the provisions of section 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, the RLD has kept the FAA informed of the situation described above. The FAA has examined the findings of the RLD, reviewed all available information, and determined that AD action is necessary for products of this type design that are certificated for operation in the United States.

Since an unsafe condition has been identified that is likely to exist or develop on other airplanes of the same type design, the proposed AD would require modification of the passenger door lock warning system. The actions would be required to be accomplished in accordance with the service bulletins described previously.

The FAA estimates that 37 airplanes of U.S. registry would be affected by this proposed AD, that it would take approximately 22 work hours per airplane to accomplish the proposed actions, and that the average labor rate is \$60 per work hour. Required parts would cost approximately \$865 per airplane. Based on these figures, the cost impact of the proposed AD on U.S. operators is estimated to be \$80,845, or \$2,185 per airplane.

The cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the proposed requirements of this AD action, and that no operator would

accomplish those actions in the future if this AD were not adopted.

The regulations proposed herein would not have substantial direct effects 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 proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this proposed regulation (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption

**ADDRESSES.**  
List of Subjects in 14 CFR Part 39  
Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

#### **PART 39—AIRWORTHINESS DIRECTIVES**

1. The authority citation for part 39 continues to read as follows:  
Authority: 49 USC 106(g), 40113, 44701.

#### **§ 39.13 [Amended]**

2. Section 39.13 is amended by adding the following new airworthiness directive:  
Fokker: Docket 95-NM-152-AD.  
*Applicability:* All Model F28 Mark 1000, 2000, 3000, and 4000 series airplanes; certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in

accordance with paragraph (b) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

*Compliance:* Required as indicated, unless accomplished previously.

To prevent inadvertent opening of the passenger door while the airplane is in flight, accomplish the following:

(a) Modify the passenger door lock warning system at the time specified in paragraph (a)(1) or (a)(2) of this AD, as applicable.

(1) For airplanes in post-Fokker Service Bulletin F28/52-72 configuration: Accomplish the modification within 9 months after the effective date of this AD, in accordance with Fokker Service Bulletin F28/52-101, Revision 1, dated August 24, 1992.

(2) For airplanes in pre-Fokker Service Bulletin F28/52-72 configuration: Accomplish the modification within 1,500 landings after the effective date of this AD, in accordance with Fokker Service Bulletin F28/52-112, dated February 1, 1995.

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Standardization Branch, ANM-113, FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Standardization Branch, ANM-113.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Standardization Branch, ANM-113.

(c) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Issued in Renton, Washington, on March 29, 1996.

Bill R. Boxwell,

*Acting Manager Transport Airplane Directorate, Aircraft Certification Service.*  
[FR Doc. 96-8296 Filed 4-3-96; 8:45 am]

BILLING CODE 4910-13-U

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

#### **21 CFR Part 510**

[Docket No. 96N-0007]

#### **Labeling of Drugs for Use in Milk-Producing Animals**

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

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is proposing to revise two animal drug regulations to allow greater flexibility in the labeling of drugs for use in milk-producing animals. The 96-hour withdrawal time limitation would be removed from the regulations. The animal drug regulations would be further modified so that the withdrawal time is based only on hours after last treatment, not on a 12-hour milking schedule. This proposal is aligned with the goals stated by the National Performance Review.

**DATES:** Written comments by June 18, 1996.

**ADDRESSES:** Written comments to the Dockets Managements Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857. Comments should be identified with the docket number found in brackets in the heading of this document. Received comments may be seen at the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

**FOR FURTHER INFORMATION CONTACT:** Steven D. Vaughn, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1642.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

Under § 510.105(c)(2) (21 CFR 510.105(c)(2)), information is provided regarding the labeling of drugs used in milk-producing animals. Specifically, the regulation states that: "The label should bear the warning, 'Milk that has been taken from animals during treatment and within — hours (— milkings) after the latest treatment must not be used for food,' the blanks to be filled in with the number of hours (not to exceed 96) \* \* \*." Under § 510.106, information is provided regarding the labeling of antibiotic and antibiotic-containing drugs intended for use in milk-producing animals. The regulation states that:

\* \* \* the label of such drugs shall bear \* \* \* the statement "Warning: Milk that has been taken from animals during treatment and for — hours (— milkings) after the latest treatment must not be used for food", the first blank being filled in with the figure, which shall not be greater than 96, that the Commissioner has authorized the manufacturer of the drug to use, and the second figure shall be the first number divided by 12.

##### **II. Proposed Actions**

The maximum 96-hour limitation was based on FDA's perception of a practical withdrawal time for the dairy industry. However, FDA now recognizes that a

withdrawal time longer than 96 hours may be desirable and practical in certain circumstances. FDA is proposing to remove the 96-hour limitation to allow the possibility of longer withdrawal times to be considered for milk-producing animals. Withdrawal periods longer than 96 hours may be considered on a case-by-case basis depending on the use and safety of the drug.

In addition, a 12-hour milking schedule is used in § 510.106 to calculate the number of milkings that occur during the withdrawal period. While a 12-hour milking interval was reflective of dairy practice when this regulation was written, an 8-hour milking schedule also is in common use in the dairy industry today. FDA is proposing to revise the regulation so that the length of the milking cycle is not specified. This revision would allow any reasonable milking interval to be used as long as milk is discarded for the assigned number of hours after the latest drug treatment.

This proposal is aligned with the goals stated by the National Performance Review. This proposed rule is a result of the President's directive to conduct a comprehensive review of all rules to identify those that are obsolete and burdensome and to delete or revise them. The agency has determined that this rule is in need of revision as described herein.

##### **III. Environmental Impact**

The agency has determined under 21 CFR 25.24(a)(11) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

##### **IV. Analysis of Impacts**

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96-354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the proposed rule clarifies FDA policy and simplifies the process for submitting certain applications, the agency certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

##### **V. Paperwork Reduction Act of 1995**

FDA tentatively concludes that the labeling requirements proposed in this document are not subject to review by the Office of Management and Budget because they do not constitute a "collection of information" under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Rather, the proposed warning statements are "public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public" (5 CFR 1320.3(c)(2)).

##### **VI. Federalism**

FDA has analyzed this proposal in accordance with the principles and criteria set forth in Executive Order 12612 and has determined that this proposal does not warrant the preparation of a Federalism Assessment.

##### **VII. Request for Comments**

Interested persons may, on or before June 18, 1996, submit to the Dockets Management Branch (address above) written comments regarding this proposal. 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 are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

##### **List of Subjects in 21 CFR Part 510**

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 510 be amended as follows:

#### **PART 510—NEW ANIMAL DRUGS**

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 512, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e).

2. Section 510.105 *Labeling of drugs for use in milk-producing animals* is amended in the first sentence of paragraph (c)(2) by removing the phrase, "(not to exceed 96)".

3. Section 510.106 is amended by revising the first sentence to read as follows:

**§ 510.106 Labeling of antibiotic and antibiotic-containing drugs intended for use in milk-producing animals.**

Whenever the labeling of an antibiotic drug included in the regulations in this chapter suggests or recommends its use in milk-producing animals, the label of such drugs shall bear either the statement "Warning: Not for use in animals producing milk, since this use will result in contamination of the milk" or the statement "Warning: Milk that has been taken from animals during treatment and for — hours after the latest treatment must not be used for food", the blank being filled in with the figure that the Commissioner has authorized the manufacturer of the drug to use. \* \* \*

Dated: March 28, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96-8247 Filed 4-3-96; 8:45 am]

BILLING CODE 4160-01-F

## DEPARTMENT OF THE INTERIOR

### Office of Surface Mining Reclamation and Enforcement

30 CFR Parts 745, 900, 901, 906, 913, 926, 931, 934, 935, 936, 944, 946, 948, and 950

RIN 1029-AB84

### State-Federal Cooperative Agreements

**AGENCY:** Office of Surface Mining Reclamation and Enforcement, Interior.  
**ACTION:** Proposed rule.

**SUMMARY:** The Office of Surface Mining Reclamation and Enforcement (OSM) proposes to amend its regulations by revising the procedures for approval of State-Federal cooperative agreements, so as to remove from the Code of Federal Regulations (CFR) the entire text of these agreements. This removal of the full text of the State-Federal cooperative agreements would reduce the number of unnecessary pages in the CFR. The CFR would continue, however, to provide notice of the existence of a cooperative

agreement and the date it became effective. Although the full text of previously approved cooperative agreements would be removed, the cooperative agreements remain in effect and will continue to delineate State and Federal responsibilities with regard to surface coal mining and reclamation operations on Federal lands.

**DATES:** *Written comments:* OSM will accept written comments on the proposed rule until 5:00 p.m. eastern time on June 3, 1996.

*Public hearings:* Anyone wishing to testify at a public hearing must submit a request on or before 5:00 p.m. eastern time on April 25, 1996. Because OSM will hold a public hearing only if one is requested, hearing arrangements, dates and times, if any, will be announced in a subsequent Federal Register notice. Any disabled individual who has need for special accommodation to attend a public hearing should contact the individual listed under **FOR FURTHER INFORMATION CONTACT**.

**ADDRESSES:** *Written comments:* Mail or hand-deliver to the Office of Surface Mining Reclamation and Enforcement, Administrative Record Room 117, 1951 Constitution Avenue, NW., Washington, DC 20240. Comments also may be sent by e-mail via the Internet to: [osmrules@osmre.gov](mailto:osmrules@osmre.gov).

*Requests for public hearings:* Contact the person listed under **FOR FURTHER INFORMATION CONTACT** by the time specified under **DATES**. Because OSM will hold a public hearing only if one is requested, hearing locations, if any, will be announced in a subsequent Federal Register notice.

**FOR FURTHER INFORMATION CONTACT:** Andy DeVito, Rules and Legislation, Office of Surface Mining Reclamation and Enforcement, Room 117, South Interior Building, 1951 Constitution Avenue, NW., Washington, DC 20240; Telephone (202) 208-2701. E-Mail/Internet: [adevito@osmre.gov](mailto:adevito@osmre.gov).

#### SUPPLEMENTARY INFORMATION:

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#### I. Public Comment Procedures

##### *Written Comments*

Written comments should be specific and confined to issues pertinent to the

proposed rule. They also should include explanations in support of the commenter's recommendations. OSM appreciates any and all comments, but those most useful and likely to influence decisions on the content of a final rule will be those that either involve personal experience or include citations to and analyses of the Act, its legislative history, its implementing regulations, case law, and other pertinent State or Federal laws or regulations.

Where practicable, commenters should submit two copies of their comments. Comments received after the time indicated under **DATES** or at locations other than the OSM office listed under **ADDRESSES** will not necessarily be considered in the final decision or included in the administrative record.

#### *Public Hearing*

Persons wishing to testify at a public hearing must contact the person listed under **FOR FURTHER INFORMATION CONTACT** by the time indicated under **DATES**. If no one requests an opportunity to comment at a public hearing, no hearing will be held.

If a public hearing is held, it will continue until all persons scheduled to speak have been heard. Persons in the audience who were not scheduled to speak but who wish to do so will be heard following the scheduled speakers. The hearing will end after all scheduled speakers and any other persons present who wish to speak have been heard.

Filing of a written statement at the time of the hearing will assist the transcriber and facilitate preparation of an accurate record. Submission of written statements to OSM in advance of the hearing will allow OSM officials to prepare appropriate questions.

#### *Public Meeting*

If only one person requests an opportunity to comment at a hearing, public meeting, rather than a public hearing, may be held. Persons wishing to meet with OSM representatives to discuss the proposed rule may request a meeting by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**. All meetings will be open to the public and notices of the meetings will be posted at the location listed under **ADDRESSES**. A written summary of each public meeting will be made a part of the administrative record for this rulemaking.

#### II. Discussion of the Proposed Rule

##### *Why is This Rule Being Written?*

On March 4, 1995, the President announced a government-wide