STATE	COUNTY	RATE PER ACRE
	SAN JUAN	
	SKAGIT	
	SKAMANIA	
	SNOHOMISH	
	THURSTON	
	WAHKIAKUM	
	WHATCOM	
WEST VIRGINIA	ALL COUNTIES	25.35
WISCONSIN	ALL COUNTIES	19.02
WYOMING	ALBANY	6.32
	CAMPBELL	
	CARBON	
	CONVERSE	
	GOSHEN	
	HOT SPRINGS	
	JOHNSON	
	LARAMIE	
	LINCOLN	
	NATRONA	
	NIOBRARA	
	PLATTE	
	SHERIDAN	
	SWEETWATER	
	FREMONT	
	SUBLETTE	
	UINTA	
	WASHAKIE	19.02
	BIG HORN	
	CROOK	
	PARK	
	TETON	
	WESTON	
ALL OTHER ZONES		6.35

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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: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the new animal drug regulations to implement the veterinary feed directive (VFD) drugs section of the Animal Drug Availability Act of 1996 (ADAA). A VFD drug is intended for use in animal feed. Its use is permitted only under the professional supervision of a licensed veterinarian in the course of the veterinarian's professional practice. This new regulation states the requirements for distribution and use of a VFD drug and animal feed containing a VFD drug.

DATES: This rule is effective January 8, 2001.

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

In the **Federal Register** of July 2, l999 (64 FR 35966), FDA proposed regulations to establish the requirements relating to distribution and use of VFD drugs and animal feeds containing VFD drugs. We provided 90 days for comment on the proposed rule.

Prior to 1996, we had only two options for regulating the distribution of animal drugs: (1) Over-the-counter (OTC), and (2) prescription. However, we determined that certain new animal drugs, vital to animal health, should be approved for use in animal feed, only if these medicated feeds were administered under a veterinarian's order and professional supervision. For example, veterinarians are needed to control the use of certain antimicrobials. This control is critical to reducing unnecessary use of such drugs in animals and to slowing or preventing any potential for the development of bacterial resistance to antimicrobial drugs. Safety concerns relating to difficulty of diagnosis of disease conditions, high toxicity, or other reasons may also dictate that the use of a medicated feed be limited to use by order and under the supervision of a licensed veterinarian.

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. 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, an organization that represents major sectors of animal agriculture, and with support from State regulatory agencies, Congress enacted legislation in 1996 that amended the Federal Food, Drug, and Cosmetic Act (the act) in ways intended to facilitate the approval and marketing of new

animal drugs and medicated feed. This legislation, the ADAA (Public Law 104–250), among other things, established a new class of restricted feed use drugs that may be distributed without invoking State pharmacy laws (21 U.S.C. 354).

Although statutory controls on the use of VFD drugs are similar in some respects to those for prescription animal drugs regulated under section 503(f) of the act (21 U.S.C. 353(f)), the implementing VFD regulations are tailored to the unique circumstances relating to the manufacture and distribution of medicated animal feeds. This final rule will ensure the protection of public health while enabling animal producers to obtain and use needed drugs as efficiently and cost-effectively as possible.

To date, we have approved one VFD drug, tilmicosin, an antimicrobial approved for administration via animal feed for control of swine respiratory diseases (§ 558.618 (21 CFR 558.618)). The current regulation for tilmicosin, at § 558.618(d)(4), specifies required cautionary labeling for the VFD drug and any feed manufactured from the VFD drug and describes the information that the attending veterinarian must provide as part of the VFD. The proposed cautionary labeling in § 558.6(f) was in substance the same as the tilmicosin cautionary labeling but had minor word differences. To assure consistency in cautionary labeling for tilmicosin and any future VFD drugs, we have revised our proposed cautionary labeling in § 558.6(f) to conform to tilmicosin cautionary language in § 558.618(d)(4). Section 558.618(d)(4) is therefore being removed as its provisions are now a part of this final rule at §§ 558.6(a)(4) [content of VFD] and 558.6(f) [cautionary labeling].

II. Comments on the Proposed Rule

We received eight letters commenting on the proposed rule. One was from a feed manufacturer. The balance were from associations representing the veterinary profession, feed manufacturers, the animal health industry, animal producers, and feed control regulators. Generally, the comments were quite supportive of the VFD concept. Significant issues addressed in the comments involved the means of transmission of VFD's, the length of time a VFD would be valid, the appropriateness of refills or reorders, and our proposed automatic classification of VFD drugs as Category II drugs.

Following is our response to comments, grouped by issue:

A. Transmission of VFD's

(Comment 1) All eight comments mentioned this issue. Comments were evenly split, with the veterinary profession, producers, and drug industry desiring maximum use of paper, facsimile, phone, e-mail, and new technology as it develops. The feed industry and feed control regulators opted for paper copy with the possibility of facsimile transmission with proper safeguards. They did not support phone transmission.

Objections to facsimile and other electronic transmission of VFD's were based on a perceived lack of security of transmitted information, difficulty in substantiating authenticity of the VFD, and ability of the client to forward a VFD to multiple distributors. In the case of phone transmission, comments stressed the possibility of fraudulent orders, risk of error in reducing the order to writing, and the burden placed on the manufacturer/distributor to authenticate the VFD order. One comment stated that the oversight by the veterinarian is the underlying reason that Congress created VFD drugs. The comment contended that this oversight is lost when we allow a VFD feed to be distributed in the absence of a signed, original VFD physically present at the distributor at the time of distribution.

Proponents of the use of a wide range of methods for VFD transmission suggest that distribution would be unnecessarily delayed for lack of a written and signed form physically present at the distributor. Two comments suggested that FDA be open to new innovations in electronic transmission such as a web-based server that would require the use of secure user (veterinarian owned) accounts using user-names, passwords, and electronic signatures. We are not opposed to the use of new innovations and technologies. We would not object to a system that can be demonstrated as being in compliance with applicable regulations and practices that govern such systems.

We believe we must accommodate those situations where prompt hand delivery of a VFD is not possible, but immediate delivery of a VFD feed is necessary. To accomplish this, we will allow transmission by facsimile or other electronic means provided safeguards are in place to prevent misuse. The industry must provide assurances that these technologies, as appropriate, are in compliance with part 11 (21 CFR part 11). Using a computer as a web-based server to create, modify, maintain, or transmit required records as well as using electronic signatures for those records is subject to part 11. It would be up to industry to prove that a system is capable of its intended purpose. Part 11 ''applies to all records in electronic form that are created, modified, maintained, archived, retrieved, or transmitted under record requirements in any of the agency's regulations or records submitted to the agency,'' unless specifically excepted by regulation(s). In order for electronic records to be used in lieu of paper records, they must be in compliance with the provisions stated in § 11.2. These electronic records and signatures, computer systems (including hardware and software), controls, and accompanying documentation must be readily available for and subject to inspection by FDA.

We disagree with the comment that facsimile transmission of the VFD poses a significant problem as the client may reproduce the copy to place multiple orders. While the possibility exists that a client may submit the copy of the VFD to several distributors to obtain additional VFD feed, the distributor will become aware of the irregularity when an original VFD doesn't arrive within 5 days. Such a violation is difficult to hide.

One comment asked who is held responsible, the veterinarian, feeder (client), or feed distributor, if the actual VFD is not properly distributed. While all bear responsibility, the veterinarian is most in control. Thus, we believe it is the veterinarian's obligation to assure that the original VFD is distributed to the feed distributor with the timeliness required by § 558.6(b)(4). The client has responsibility for notifying the veterinarian where to send the original VFD. We recognize there may be instances where a VFD may not be presented to a distributor for several days, and there may be instances where the VFD is issued but never used. If it is determined that a VFD may be refilled, it is possible that the VFD may be required by one distributor first and later by another for refill. In these situations, the client must keep the issuing veterinarian advised when a VFD is moved from one distributor to another, to ensure that the original VFD is moved to the new distributor or a new VFD is issued.

Regarding telephone orders, one comment stated that there is precedence for telephone orders in that veterinarians currently telephone in prescription drug orders. The orders are reduced to writing by the pharmacist without a followup hard copy of the prescription being sent. We do not agree that the situations are the same. The pharmacist who fills a prescription has

extensive training in drug use and potential misuse. Further, a limited amount of information is required in a typical prescription order. Conversely, an extensive amount of information is required in a VFD. A feed mill employee, while skilled in manufacturing feed, may not have the necessary skills to routinely assure a complete and accurate transmission of a VFD or to recognize a potentially inaccurate VFD order. We believe that allowing a telephone order to the feed mill would jeopardize the integrity of the VFD process. Therefore, we have not included telephone orders as an option for transmitting a VFD and have added § 558.6(b)(5) to state that a VFD may not be transmitted by phone.

B. Refills and Length of Time VFD is Valid

(Comment 2) One comment suggested that FDA determine whether refills or reorders are appropriate. Another comment suggested that the veterinarian should be allowed to determine when refills or reorders are necessary. Two comments stated that a single VFD could cover multiple production groups when a disease outbreak is anticipated in subsequent groups of animals passing through a production facility. Concerning the length of time a VFD is valid, two comments stated that the VFD should be valid for up to 6 months. Two other comments stated the opinion that the duration of a VFD should be determined on a case-by-case basis as part of the VFD drug approval process.

We believe that there are situations when refills and expiration dates, possibly of several months, are appropriate to medicate multiple production groups and provide efficient treatment of sick animals. We further believe that allowances of this type will vary considerably depending on the drug and its use. Since we cannot predict what types of drugs and disease situations will be presented in the future, the issues of refills and reorders and the duration of time a VFD can be valid need to be considered on a drug-by-drug basis as part of the new animal drug approval process. We recognize this could result in different conditions for different VFD drugs, which is additional support for the role of the professional (veterinarian) and the need for a complete VFD. Therefore, we have not attempted to specify the allowable number of refills or reorders, or the duration of time a VFD can be valid. This will be dealt with when the new animal drug application (NADA) for the VFD drug is reviewed during the approval process.

C. Classification of VFD Drugs as Category II Drugs

(Comment 3) Two comments asked that we reexamine our decision to automatically classify VFD drugs as Category II drugs. We continue to believe that classifying VFD drugs as Category II drugs is appropriate. Classifying a drug as Category II adds additional regulatory controls because feed manufacturing facilities must possess a medicated feed mill license and be registered with FDA in order to manufacture a Type B or Type C medicated feed from a Category II, Type A medicated article. Registered feed mills are required to be inspected at least every 2 years. Such inspections will help the agency ensure that VFD requirements are met.

Therefore, our decision to automatically classify VFD drugs as Category II drugs remains and is so reflected in the final rule.

D. Responses to Remaining Comments

(Comment 4) Two comments suggested that the ''notification letter'' of proposed § 558.6(d)(1) and the ''acknowledgment letter'' of § 558.6(d)(2) be combined into a single letter to reduce the paperwork burden. We are unable to agree to this because these letters serve different purposes and are sent to different entities. The notification letter is sent by the distributor to FDA to notify the agency that the distributor has begun distributing VFD feeds. In contrast, the acknowledgment letter is sent to the distributor by a purchaser stating that it will sell the VFD feed only to a producer with a valid VFD, or to another distributor who provides a similar acknowledgment letter.

We are, however, combining § 558.6(d)(2)(i) and (d)(2)(ii) of the proposed rule, which required in paragraph (d)(2)(i) that a distributor obtain an acknowledgment letter and in paragraph (d)(2)(ii) that a distributor obtain a statement affirming that a consignee-distributor has complied with ''distributor notification'' requirements. Both requirements may now be met in a single letter under § 558.6(d)(2).

(Comment 5) Two comments asked for other changes in the VFD. One comment asked that § 558.6(a)(3) be changed to read: ''You must complete all of the information required on the VFD in writing, and sign it; VFD's that contain incomplete information will be considered invalid.'' A similar comment asked that we consider as unacceptable a VFD that is not filled out completely. We agree with these suggestions and have incorporated them into § 558.6(a)(3) and (a)(4) in the final rule.

(Comment 6) Two comments asked that the VFD drug sponsor provide VFD forms in triplicate to the veterinarian and that the veterinarian be required to use them. We agree with this comment in part. We addressed it in the proposed rule by revising the new animal drug regulations at § 514.1(b)(9) (21 CFR 514.1(b)(9)) to require the sponsor of a VFD drug to include in the NADA a format for a VFD form as described in § 558.6(a)(4) of this regulation. One comment additionally suggested that using the VFD drug sponsor's VFD form would eliminate the problem of partially completed forms generated by a veterinarian. While we have not made it mandatory that the VFD drug sponsor provide copies of this form for use by the veterinary profession, we believe that they will make the forms available in triplicate for the sake of efficiency and completeness of the veterinarian's VFD transmissions. Nevertheless, we continue to give the veterinarian the option of creating his/her own VFD.

(Comment 7) One comment asked that we clarify what we mean by the term ''immediately'' in § 558.6(b)(4), relating to length of time a veterinarian has to provide the signed original VFD to the distributor as followup to a facsimile or electronic transmission. One comment suggested that we use the term ''promptly.'' Another comment suggested that the time be 24 hours. We have revised the regulation to read, ''the distributor receives the original signed VFD within 5 working days of receipt of the facsimile or other electronic order.'' We feel this is sufficient time for the client to place the order and the distributor to receive the signed original mailed by the veterinarian.

Additionally, a comment suggested that the client should not be required to wait to receive the VFD medicated feed until the distributor receives the original VFD. We agree, but to alleviate concern that a client may receive medicated feed containing a VFD drug without receiving a copy of the VFD, we have added § 558.6(c)(4) that reads: ''All involved parties must have a copy of the VFD before distribution of a VFD feed to the ultimate user.'' The copy need not be an original and may be transmitted by facsimile or other electronic means.

(Comment 8) One comment recommended that the facsimile of the VFD order be on company letterhead. We anticipate that when veterinarians do not use the VFD drug sponsor's VFD, they will be issuing the VFD on their or their own firm's stationary. However, even if they do not use letterhead paper, the veterinarian is required to include

his/her name (and signature), address, and license number on the VFD. Therefore, we do not think it is necessary to require them to use company stationary.

(Comment 9) One comment objected to our inclusion of VFD drugs in § 510.300(a)(4) (21 CFR 510.300(a)(4)) because doing so would essentially confer prescription drug status on VFD drugs for submission of promotional materials. Proposed modifications to § 510.300 do not make a VFD drug a prescription drug. Section 504(c) of the act (21 U.S.C. 354(c)) states that VFD drugs cannot be prescription articles. Section 504(b) of the act establishes misbranding criteria for both labeling and advertising for VFD's. Thus, routine requirements for submitting advertising for VFD drug experience reports under § 510.300(a)(4) should be the same as requirements for submitting labeling. We have not changed the proposed provision in the final rule.

(Comment 10) One comment suggested that FDA consider a provision to revoke a veterinarian's right to order use of VFD drugs if the veterinarian fails to have a valid veterinarian-client-patient relationship (VCPR) or fails to provide complete VFD information to the feed distributor. Normally, this type of action would be handled by State veterinary license authorities. However, the act does provide FDA with other regulatory options.

Section 504 of the act states ''* * * When labeled, distributed, held, and used in accordance with this section, a veterinary feed directive drug and any animal feed bearing or containing a veterinary feed directive drug shall be exempt from section 502(f) [of the act].'' Under section 502(f) of the act (21 U.S.C. 352(f)) a drug or device is misbranded unless its labeling bears adequate directions for lay use. (See 21 CFR 201.5.)

VFD drugs and animal feed bearing or containing veterinary feed directive drugs are exempt from the statutory requirements for adequate directions for lay use only when they are distributed under a VFD issued by a licensed veterinarian within the confines of a valid VCPR and contain complete and accurate information as required by § 558.6.

If the order for a VFD drug is not based upon a valid VCPR or fails to provide complete information as required by § 558.6, then the VFD drug is subject to section 502(f) of the act. Since a VFD drug, by its very nature, cannot bear adequate directions for lay use, a VFD drug subject to 502(f) of the act is misbranded and the veterinarian who issued the VFD may be held responsible for causing the misbranding of the VFD drug or the feed containing the VFD drug in violation of the act.

We have made nonsubstantive wording and restructuring changes to §§ 514.1(b)(9), 558.3(b)(6), and 558.6(a)(2), (c)(1), (c)(2), and (c)(3) for the sake of clarity.

III. Conforming Changes

FDA has made conforming changes to §§ 514.1(b)(9) and 510.300, and is removing § 558.618(d)(4).

IV. Environmental Impact

We have carefully considered the potential environmental effects of this final rule and have determined 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.

V. Federalism

We have analyzed this final rule in accordance with the principles set forth in Executive Order 13132. We have determined that the rule does not contain policies that 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. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the order and, consequently, a federalism summary impact statement is not required.

VI. Analysis of Impacts

We have examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Public Law 104–121)), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). 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). We believe that this final rule is consistent with the regulatory philosophy and principles identified in the Executive order. In addition, the final 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 unless the rule is not expected to have a significant impact on a substantial number of small entities. As this final rule will not impose significant new costs on any firms under the Regulatory Flexibility Act (5 U.S.C. 605(b)), we certify that the final 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.

VII. Unfunded Mandates Reform Act of 1995

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare an assessment of the anticipated costs and benefits before requiring any expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation).

The Unfunded Mandates Reform Act of 1995 does not require FDA to prepare a statement of costs and benefits for the final rule, because the rule is not expected to result in any 1-year expenditure that would exceed $100 million adjusted for inflation. The current inflation-adjusted statutory threshold is $110 million.

VIII. Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). A description of these provisions is given below. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Animal Drug Availability Act; Veterinary Feed Directive

Description: FDA is publishing this final rule to implement provisions of the ADAA which, by adding section 504 to the act, created a new class of animal drugs called VFD drugs. This final rule establishes regulatory requirements for the distribution and use of VFD drugs. VFD drugs are new animal drugs intended for use in or on animal feed whereby such use is permitted only under the professional supervision of a licensed veterinarian operating within the confines of a valid VCPR.

The VFD ordered by the veterinarian must be issued in accordance with the format described under § 558.6(a). We are amending the new animal drug regulations at § 514.1(b)(9) to require the VFD drug sponsor to submit such format as part of the NADA. The format may be used by the sponsor to produce forms in triplicate for use by the veterinarian or it may be supplied to the veterinarian for use in preparing a practice-specific form. Veterinarians are required to complete the VFD in triplicate, authorizing a client-recipient to obtain and use a medicated feed containing a VFD drug. The original copy of the VFD must be forwarded either by the veterinarian or the client-recipient to the distributor providing the VFD. In addition, the veterinarian issuing the VFD and the client-recipient of the VFD must retain a copy of each VFD for 2 years from date of issuance. Any person who distributes medicated feed containing VFD drugs must file with us a one time notification letter of intent to distribute, and retain a copy of each VFD serviced or each consignee's acknowledgment letter for 2 years. Distributors are also required to keep records of receipt and distribution of medicated animal feeds containing VFD drugs for 2 years. An acknowledgment letter must be provided to a distributor by a consignee who is not the ultimate user of the medicated feed containing a VFD drug. The acknowledgment letter affirms that the consignee will not ship such medicated animal feed to an animal production facility that does not have a VFD, and will not ship such feed to another distributor without receiving a similar acknowledgment letter. To maintain an accurate data base for distributors of VFD drugs, a distributor is required to notify us of any change in name or business address.

In response to a comment, we combined § 558.6(d)(2)(i) and (d)(2)(ii) of the proposed rule, which required in paragraph (d)(2)(i) that a distributor obtain an acknowledgment letter and in paragraph (d)(2)(ii) that a distributor obtain a statement affirming that a consignee-distributor has complied with ''distributor notification'' requirements. Both requirements may now be met in a single letter under § 558.6(d)(2). This change does not entail a substantive modification to the reporting burden, so the estimates in table 1 of this document have not changed.

Description of Respondents: Veterinarians, distributors of animal feeds containing VFD drugs, and clients using medicated feeds containing VFD drugs. In the **Federal Register** of July 2, 1999 (64 FR 35966), FDA requested comments on the proposed collection of information. No comments were received on the estimated annual burdens. The annual burden estimates therefore remain unchanged.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
558.6(a)(3) through (a)(5)	15,000	25	375,000	0.25	93,750
558.6(d)(1)(i) through (d)(1)(iii)	5,000	1	5,000	0.25	1,250
558.6(d)(1)(iv)	100	1	100	0.25	25
558.6(d)(2)	5,000	1	5,000	0.25	1,250
514.1(b)(9)	1	1	1	3	3
Total Hours					96,278

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
558.6(c)(1) and (d)(2)	112,500	10	1,125,000	0.0167	18,788
558.6(e)(ii)	5,000	75	375,000	0.0167	6,263
Total Hours					25,051

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

Individuals and organizations may submit comments on this burden estimate or on any other aspect of these information collection provisions, including suggestions for reducing the burden, and should direct them to George Graber, Center for Veterinary Medicine (HFV–220), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. The information collection provisions in this final rule have been approved under OMB control number 0910–0363. This approval expires October 31, 2002. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

List of Subjects

21 CFR Part 510

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

21 CFR Part 514

Administrative practice and procedure, Animal drugs, Confidential business information, Reporting and recordkeeping requirements.

21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 510, 514, and 558 are amended to read as follows:

PART 510—NEW ANIMAL DRUGS

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

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

§ 510.300 [Amended]

2. Section 510.300 *Records and reports concerning experience with new animal drugs for which an approved application is in effect* is amended in

paragraph (a)(4) by adding the phrase ''or a veterinary feed directive drug'' following ''if it is a prescription new animal drug''.

PART 514—NEW ANIMAL DRUG APPLICATIONS

3. The authority citation for part 514 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 360b, 371, 379e, 381.

4. Section 514.1 is amended by adding paragraph (b)(9) to read as follows:

§ 514.1 Applications.

* * * * *

(b) * * *

(9) *Veterinary feed directive.* Three copies of a veterinary feed directive (VFD) must be submitted in the format described under § 558.6(a)(4) of this chapter.

* * * * *

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

5. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

6. Section 558.3 is amended by revising paragraph (b)(1)(ii) and by adding paragraphs (b)(6) through (b)(11) to read as follows:

§ 558.3 Definitions.

* * * * *

(b) * * *

(1) * * *

(ii) Category II—These drugs require a withdrawal period at the lowest use level for at least one species for which they are approved, or are regulated on a ''no-residue'' basis or with a zero tolerance because of a carcinogenic concern regardless of whether a withdrawal period is required, or are a veterinary feed directive drug.

* * * * *

(6) A ''veterinary feed directive (VFD) drug'' is a new animal drug approved under section 512(b) of the Federal Food, Drug, and Cosmetic Act (the act) for use in or on animal feed. Use of a VFD drug must be under the professional supervision of a licensed veterinarian.

(7) A ''veterinary feed directive'' is a written statement issued by a licensed veterinarian in the course of the veterinarian's professional practice that orders the use of a veterinary feed directive (VFD) drug in or on an animal feed. This written statement authorizes the client (the owner of the animal or animals or other caretaker) to obtain and use the VFD drug in or on an animal feed to treat the client's animals only in accordance with the directions for use approved by the Food and Drug Administration (FDA). A veterinarian may issue a VFD only if a valid veterinarian-client-patient relationship exists, as defined in § 530.3(i) of this chapter.

(8) A ''medicated feed'' means a Type B medicated feed as defined in paragraph (b)(3) of this section or a Type C medicated feed as defined in paragraph (b)(4) of this section.

(9) For the purposes of this part, a ''distributor'' means any person who distributes a medicated feed containing a VFD drug to another distributor or to the client-recipient of the VFD.

(10) An ''animal production facility'' is a location where animals are raised for any purpose, but does not include the specific location where medicated feed is made.

(11) An ''acknowledgment letter'' is a written communication provided to a distributor by a consignee who is not the ultimate user of medicated feed containing a VFD drug. An acknowledgment letter affirms that the consignee will not ship such medicated animal feed to an animal production facility that does not have a VFD, and will not ship such feed to another distributor without receiving a similar written acknowledgment letter.

7. Section 558.6 is added to subpart A to read as follows:

§ 558.6 Veterinary feed directive drugs.

(a) What conditions must I meet if I am a veterinarian issuing a veterinary feed directive (VFD)?

(1) You must be appropriately licensed.

(2) You must issue a VFD only within the confines of a valid veterinarian-client-patient relationship (see definition at § 530.3(i) of this chapter).

(3) You must complete the VFD in writing and sign it or it will be invalid.

(4) You must include all of the following information in the VFD or it will be invalid:

(i) You and your client's name, address and telephone and, if the VFD is faxed, facsimile number.

(ii) Identification and number of animals to be treated/fed the medicated feed, including identification of the species of animals, and the location of the animals.

(iii) Date of treatment, and, if different, date of prescribing the VFD drug.

(iv) Approved indications for use.

(v) Name of the animal drug.

(vi) Level of animal drug in the feed, and the amount of feed required to treat the animals in paragraph (a)(4)(ii) of this section.

(vii) Feeding instructions with the withdrawal time.

(viii) Any special instructions and cautionary statements necessary for use of the drug in conformance with the approval.

(ix) Expiration date of the VFD.

(x) Number of refills (reorders) if necessary and permitted by the approval.

(xi) Your license number and the name of the State issuing the license.

(xii) The statement: ''Extra-label use, (i.e., use of this VFD feed in a manner other than as provided for in the VFD drug approval) is strictly prohibited.''

(xiii) Any other information required by the VFD drug approval regulation.

(5) You must produce the VFD in triplicate.

(6) You must issue a VFD only for the approved conditions and indications for use of the VFD drug.

(b) What must I do with the VFD if I am a veterinarian?

(1) You must give the original VFD to the feed distributor (directly or through the client).

(2) You must keep one copy of the VFD.

(3) You must give the client a copy of the VFD.

(4) You may send a VFD to the client or distributor by facsimile or other electronic means provided you assure that the distributor receives the original signed VFD within 5 working days of receipt of the facsimile or other electronic order.

(5) You may not transmit a VFD by telephone.

(c) What are the VFD recordkeeping requirements?

(1) The VFD feed distributor must keep the VFD original for 2 years from the date of issuance. The veterinarian and the client must keep their copies for the same period of time.

(2) All involved parties must make the VFD available for inspection and copying by FDA.

(3) All involved parties (the VFD feed distributor, the veterinarian, and the client) must keep VFD's transmitted by facsimile or other electronic means for a period of 2 years from date of issuance.

(4) All involved parties must have a copy of the VFD before distribution of a VFD feed to the ultimate user.

(d) What are the notification requirements if I am a distributor of animal feed containing a VFD drug?

(1) You must notify FDA only once, by letter, that you intend to distribute animal feed containing a VFD drug.

(i) The notification letter must include the complete name and address of each business site from which distribution will occur.

(ii) A responsible person from your firm must sign and date the notification letter.

(iii) You must submit the notification letter to the Center for Veterinary Medicine, Division of Animal Feeds (HFV–220), 7500 Standish Pl., Rockville, MD 20855, prior to beginning your first distribution.

(iv) You must notify the Center for Veterinary Medicine at the above address within 30 days of any change in name or business address.

(2) If you are a distributor who ships an animal feed containing a VFD drug to another consignee-distributor in the absence of a valid VFD, you must obtain an ''acknowledgment letter,'' as defined in § 558.3(b)(11), from the consignee-distributor. The letter must include a statement affirming that the consignee-distributor has complied with ''distributor notification'' requirements of paragraph (d)(1) of this section.

(e) What are the additional recordkeeping requirements if I am a distributor?

(1) You must keep records of receipt and distribution of all medicated animal feed containing a VFD drug.

(2) You must keep these records for 2 years from date of receipt and distribution.

(3) You must make records available for inspection and copying by FDA.

(f) What cautionary statements are required for VFD drugs and animal feeds containing VFD drugs? All labeling and advertising must prominently and conspicuously display the following cautionary statement: ''Caution: Federal law limits this drug to use under the professional supervision of a licensed veterinarian. Animal feed bearing or containing this veterinary feed directive drug shall be fed to animals only by or upon a lawful veterinary feed directive issued by a licensed veterinarian in the course of the veterinarian's professional practice.''

§ 558.618 [Amended]

8. Section 558.618 *Tilmicosin* is amended by removing paragraph (d)(4).

Dated: November 30, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–31151 Filed 12–7–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 556

Tolerances for Residues of New Animal Drugs in Food; Moxidectin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is updating the animal drug regulations to correctly reflect the tolerance for moxidectin in cow's milk. This document amends the regulations to state the correct tolerance is 40 parts per billion (ppb). This action is being taken to improve the accuracy of the agency's regulations. Changes to a current format are also being made.

DATES: This rule is effective December 8, 2000.

FOR FURTHER INFORMATION CONTACT: Janis R. Messenheimer, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7578.

SUPPLEMENTARY INFORMATION: Moxidectin solution is approved for topical use in cattle for the treatment and control of infections and infestations of certain internal and external parasites. When the November 2, 1999, approval of the use of moxidectin in lactating dairy cows was published in the **Federal Register** of June 9, 2000 (65 FR 36616), the tolerance for parent moxidectin in the milk of cattle was incorrectly listed. At this time, the regulations are being amended in 21 CFR 556.426 to state the correct tolerance is 40 ppb and, editorially, to reflect current format.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 556

Animal drugs, Foods.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 556 is amended as follows:

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

1. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

2. Section 556.426 is amended by revising paragraph (b) to read as follows:

§ 556.426 Moxidectin.

* * * * *

(b) *Tolerances*—(1) *Cattle*—(i) *Liver (the target tissue*). The tolerance for parent moxidectin (the marker residue) is 200 parts per billion (ppb).

(ii) *Muscle*. The tolerance for parent moxidectin (the marker residue) is 50 ppb.

(iii) *Milk*. The tolerance for parent moxidectin (the marker residue in cattle milk) is 40 ppb.

(2) [Reserved]

Dated: November 29, 2000.

David R. Newkirk,

Acting Deputy Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 00–31248 Filed 12–7–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 876

[Docket No. 00P–1343]

Medical Device; Exemption From Premarket Notification; Class II Devices; Barium Enema Retention Catheters and Tips With or Without a Bag

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is publishing an order granting a petition requesting exemption from the premarket notification requirements for barium enema retention catheters and tips with or without a bag with certain limitations. This rule will exempt from premarket notification barium enema retention catheters and tips with or without a bag. FDA is publishing this order in accordance with procedures established by the Food and Drug Administration Modernization Act of 1997 (FDAMA).

DATES: This rule is effective December 8, 2000.