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

our safety concerns for all medicated feeds containing VFD drugs. A proposed new § 558.6 would be added to list the requirements for the distribution and use of VFD drugs and feeds that contain VFD drugs.

A VFD drug is limited to use under a valid veterinary-client-patient relationship where the veterinarian assumes the responsibility for safe and effective use of the VFD and the client has agreed to follow the instructions of the veterinarian. Proposed § 558.6(a)(1) through (a)(4) lists the responsibilities of the veterinarian issuing a VFD.

The information required to be included in the VFD will vary from drug to drug. Proposed § 558.6(a)(5) describes information that may be required in a VFD. The specific VFD approval regulation will identify the information required in a VFD for a particular animal drug. FDA is particularly concerned that VFD drugs be used only in accordance with the approved uses.

The length of time a VFD may be valid (expiration date) and the number of refills or reorders, if any, that will be permitted will be specific to the VFD drug. As part of the VFD drug approval process, FDA will determine whether refills or reorders are allowed, and if so, the number of refills or reorders. We request your comment on this proposed approach and on how much latitude should be given the veterinarian in ordering use of VFD drugs consistent with the control over drug use as envisioned by the ADAA; i.e., should reorders be permitted and for what length of time should the order be valid? The American Association of Swine Practitioners (AASP) addressed this issue in a response dated January 20, 1997, to the ADAA advanced notice of proposed rulemaking in the **Federal Register** of November 21, 1996 (61 FR 59209) (Docket No. 96N–0411). The AASP stated that it is imperative that the rule allow flexibility in issuance and content of the VFD in order to be practical in its application to various types of production systems. For example, the AASP inquired whether a single VFD can be applicable to multiple groups of pigs when a farm's history predicts recurring disease outbreaks in the transition between production stages, such as postweaning.

As a practical matter, FDA anticipates that practicing veterinarians would not want to attempt to create their own practice-specific VFD's because of the time involved and the amount of specific information required. We expect VFD drug manufacturers to provide veterinarians with preprinted VFD's in triplicate. We are thus proposing to amend § 514.1(b)(9) (21 CFR 514.1(b)(9)) to require submission of a VFD format as a part of the new animal drug application (NADA) for each VFD drug.

Proposed § 558.6(b)(1), (b)(2), and (b)(3) describe the proper distribution and recordkeeping requirements for each of the three copies of the VFD. The client and the veterinarian each keep a copy, and the original is given to the distributor supplying the VFD feed to the client. Under proposed § 558.6(b)(4), to expedite delivery, a veterinarian may fax a VFD to the distributor provided the veterinarian immediately forwards the original to the distributor and a copy to the client. Proposed § 558.6(c) would require that the involved parties (veterinarian, distributor, and client) keep the VFD for 2 years after the date of issuance and make it available for inspection and copying by FDA.

In addition to facsimile transmission of VFD's, we are considering permitting the veterinarian to telephone or e-mail VFD orders to the distributor. This would facilitate rapid movement of VFD feeds when immediate personal contact among the veterinarian, client, and distributor is not practical, and the situation demands the VFD feed be fed immediately to the animals. This approach would require that the veterinarian provide complete VFD information to the feed distributor by telephone or electronic means. In the case of telephone orders, the distributor would be responsible for reducing the telephone order to writing and keeping this order in its files. The veterinarian would follow the telephone call with prompt issuance of a signed, written VFD to the distributor and a copy to the client. Even though use of either electronic transmission or telephone will require that the veterinarian followup with signed written copies to both distributor and client, there is still concern about telephone orders. A concern is that there will be less control over the distribution process when the required information is not initially in writing, and reliance is placed on the client or distributor for proper interpretation of oral instructions. We are seeking comments on the policy reflected in the proposed rule allowing only fascimile transmission of VFD's, and whether that policy should be changed to allow use of the telephone and e-mail for transmitting VFD orders. Specifically, we invite comments on how to ensure transmission of clear, complete, and secure information via telephone or electronic means, and on the mechanics of promptly providing a signed copy of the VFD to all involved parties while avoiding undue duplication of effort and paperwork.

Proposed § 558.6(d)(1) discusses the statutory requirement of ADAA that all distributors of medicated feed containing VFD drugs, whether feed manufacturers or other suppliers in the feed distribution chain, notify us of their intent to distribute such feed upon first engaging in distribution. A ''distributor'' is defined in proposed § 558.3(b)(9) as any person who distributes a medicated animal feed containing a VFD drug to a client who presents a VFD or to another distributor. The term ''distributor'' includes all entities marketing VFD feeds, from the manufacturer of such feed to all suppliers in the distribution chain. To assist us in maintaining an accurate data base of distributors, proposed § 558.6(d)(1)(iv) would require that distributors notify us within 30 days if they change business name or address. We regard this as an extension of § 558.6(d)(1) notification requirement, necessary to keep original notification information current.

To accommodate the many levels of distribution, proposed § 558.6(d)(2) would allow a distributor to ship medicated feeds containing a VFD drug to a consignee in the absence of a VFD. The regulations would only allow this if the consignee furnishes an ''acknowledgment letter'' affirming that it will only distribute medicated feed bearing or containing a VFD drug to a VFD holder or another distributor who furnishes a similar acknowledgment letter. Proposed § 558.6(d)(2) also is intended to ensure that all parties involved in distribution of VFD drugs understand the requirement of shipping medicated animal feeds containing VFD drugs only to consignees who have notified FDA. Proposed § 558.6(e)(ii) would require that distributors keep records of receipt and distribution of all medicated animal feeds containing VFD drugs. We believe that the usual and customary records of purchase and sales kept by distributors will satisfy this requirement. FDA would examine receipt and distribution records to verify compliance with these proposed regulations.

Proposed § 558.6(f) would specify the wording of a cautionary statement that is required by statute to be included in all labeling and advertising for VFD drugs and medicated feeds containing VFD drugs. This ''cautionary'' labeling requirement is exempt from the scope of the Paperwork Reduction Act (the PRA) because it is a ''public disclosure of information originally supplied by the Federal Government for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)).

Under section 512(a)(1) of the act (21 U.S.C. 360b(a)(1)), an animal drug is unsafe unless it is approved and its labeling and use comply with the approval. In addition, section 512(a)(4) of the act, which allows for some extra-label use of animal drugs, specifically prohibits extra-label use in animal feed. This prohibits the extra-label use of VFD drugs in animal feed. Therefore, a VFD drug not used in accord with its approval would be an unapproved new animal drug and would be considered to be unsafe under section 512 of the act. Consequently, the VFD drug would be adulterated under section 501(a)(5) of the act (21 U.S.C. 351(a)(5)), and an animal feed bearing or containing such VFD drug would be adulterated under section 501(a)(6) of the act. A VFD drug and any feed bearing or containing a VFD drug would be considered to be misbranded under section 504(b) of the act if the labeling or advertising fails to contain the cautionary statements prescribed in these regulations or fails to conform to the approved conditions and indications for use.

In order to implement those provisions of the act prohibiting extra-label use and promotion of VFD drugs, and to clarify that reporting and recordkeeping requirements for labeling and promotional material under § 510.300 (21 CFR 510.300) are also applicable to VFD drugs, the proposed rule would revise § 510.300(a)(4) to add ''or a veterinary feed directive drug'' after ''if it is a prescription new animal drug.'' This would require that promotional material for VFD drugs be submitted at the time of initial dissemination and publication in accord with § 510.300(a)(4) and (b)(3), respectively.

III. Environmental Impact

The agency has determined under 21 CFR 25.30(h) 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 impact of the proposed rule under Executive Order 12866, under the Regulatory Flexibility Act (5 U.S.C. 601–612), and under the Unfunded Mandates Reform Act (Pub. L. 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). The Regulatory Flexibility Act requires agencies to examine regulatory alternatives for small entities if the rule may have a significant impact on a substantial number of small entities. The Unfunded Mandates Reform Act requires agencies to prepare an assessment of anticipated costs and benefits before enacting any rule that may result in an expenditure in any one year by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million (adjusted annually for inflation).

FDA concludes that this proposed rule is consistent with the principles set forth in the Executive Order and in these two statutes. We estimate that the present value of the proposed rule's annual compliance costs on industry in the first year would range from about $315,000 to $571,000. These costs will increase yearly as more VFD drugs are approved and should total about $2.8 million in year 10 (after amortization at a 7-percent discount rate). It is important to note that these costs will be incurred each year only if those using this new class of drugs believe that the accompanying health benefits outweigh these costs. As a result, 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. We have further determined that the proposed rule will not have a significant economic impact on a substantial number of small entities. Further, because this proposed rule makes no mandates on other government entities and will result in expenditures of less than $100 million by the private sector in any one year, we need not prepare additional analyses under the Unfunded Mandates Reform Act.

FDA is proposing to amend the animal drug regulations to reflect the creation of a new category of drugs for use in animal feeds, referred to as VFD drugs. A VFD drug is a drug intended for use in or on animal feed that is limited to use under the professional supervision of a licensed veterinarian. Certain drugs can be approved for feed use only if used under a veterinarian's supervision. Statutory creation of VFD drugs provides the agency with a means for controlling the distribution and use of certain animal drugs that is more practical and less burdensome to industry than the existing prescription system. The proposed new system would be as effective as the prescription drug system in controlling the distribution and use of VFD drugs, but with requirements tailored to the unique circumstances that exist for the distribution of medicated feeds. The most critical aspect of this system is the direct involvement of a veterinarian in the selection and use of the VFD drug. Thus, the proposal would maintain public health protection while enabling livestock producers to obtain needed drugs as efficiently and cost-effectively as possible.

A. Benefits

Quantifying the benefits of the new system for VFD drugs is difficult because it requires that the treatment benefits of each VFD drug be compared to the drug that it replaces in the treatment regimen. Because almost all of the VFD drugs are as yet unidentified, it is not possible to make these determinations. It is reasonable, however, to assume that because each VFD drug would be assigned the VFD classification during the drug approval process, each drug would have some safety or toxicity concerns that would prevent its approval as an OTC drug for use in feed. Because these drugs would otherwise have to be approved in a prescription drug form, the proposed VFD drug rules provide for greater availability and use. Moreover, because the rule does not require that a VFD drug be used in place of either OTC medicated feeds or prescription drugs in a nonfeed form, consumers (veterinarians and animal producers) are expected to use VFD drugs only where they believe that the VFD drug's benefits outweigh their costs.

B. Costs

Complying with the VFD drug provisions would impose some costs on industry and government. A percentage of these costs, however, or even an amount greater than the costs shown here, would be incurred independently of the VFD rules if the same animal drug and its approved indication for treatment were approved under the current animal drug approval system as a prescription drug intended for use other than in or on an animal feed. From a broader perspective, therefore, the rule may result in a decrease in net costs, or a net benefit to the industry, as the VFD drug rule requirements may be less costly than the prescription drug requirements.

The costs imposed by the VFD drug proposal are dependent on the number of drugs that would be approved each year as VFD drugs. Although it is difficult to predict this number, because the VFD drugs are a new creation, the agency estimates that the average number of animal drugs that would be approved as VFD drugs is about one per

year. Likewise, the number of VFD's that will be issued annually is dependent on many factors, some of which are difficult to predict. For purposes of this analysis, however, the agency assumes that each VFD drug will be issued from 250,000 to 500,000 times each year. Due to the uncertainty surrounding this initial estimate, the agency invites comment on the appropriate number of times an average VFD drug will be issued annually.

The VFD system is intended to retain the existing distribution mechanisms for drugs intended for use in feeds and for medicated feeds while maintaining more control over the availability of certain animal drugs that are intended for use in animal feed and that raise safety issues. The major cost of compliance would result from the paperwork that would be necessary to track the VFD drugs and feeds. One of the cost components would be the cost of filing the VFD's by the veterinarian, distributor, and animal producer. The agency estimates that filing each VFD by the veterinarian, distributor, and animal producer or their records clerks will take only about 1 minute. The first year cost of this task is estimated to total $218,000 to $437,000 based on the hourly wages for records clerks and animal producers calculated from data in *Employment and Earning*, pp. 206 and 209, January 1996; and *Monthly Labor Review*, p. 76, September 1997. After the VFD drug system becomes more routine and the total number of VFD's issued increases with the years, it is likely that the compliance time per VFD will decrease.

Another first year cost is the requirement that VFD drug distributors notify FDA of their intent to distribute the drugs. The agency estimates that there will be up to 20,000 distributors over time, but that only about 25 percent of them will notify the agency in the first year. Based on agency estimates of 15 minutes to write the notification at a middle manager's wage of about $19 per hour, and 10 minutes for a GS–7 Government employee to process the notification, total notification costs in the first year are estimated at about $35,000. We cannot estimate the cost of the requirement that distributors notify us when they change their business name or address, but believe it to be negligible. The compliance cost of the VFD, whether by the VFD drug manufacturer or the veterinarian, is estimated at about $1,000 for the initial one page layout and $0.05 for each triplicate form. This amounts to $14,000 to $26,000 per year per VFD drug. The $1,000 cost for the layout (format) would be incurred by the VFD drug sponsor under the proposal in § 514.1(b)(9) to require submission of the format with the NADA. Storage costs for the normal three copies of the VFD previously mentioned, and fax copies if that form of transmission is used, amount to $25,000 to $50,000 in the first year, assuming that about 15,000 copies fit into a large file cabinet at about $500 per cabinet.

The final compliance cost concerns the acknowledgment letters written by the distributors of the VFD drugs. We estimate that about 5,000 letters will be written annually for the first 3 years and that each letter will take 15 minutes to prepare. At the middle manager's wage rate mentioned previously, we estimate this provision to cost only about $24,000 annually for the first 3 years.

In sum, FDA estimates the total first year compliance costs to be from about $315,000 to $571,000, including costs to both industry and government, or about $1.25 per VFD issued. FDA has not included the cost of the veterinarian's time to write and explain the VFD to the animal producer because it is very likely that a comparable amount of time would be spent by veterinarians counseling animal producers in other animal treatments in the absence of the VFD drug system. Regardless, the net effect of the entire VFD drug system is expected to be a net benefit, or decrease in net costs, as the consumers of these drugs will only use them if they expect a greater net benefit over currently available treatment alternatives.

In future years, compliance costs would increase for several reasons. First, distributor notifications would increase in the second year as an estimated 75 percent of those that do not notify us in the first year perform this obligation (this rate may be overestimated to the extent that it takes more years before all distributors begin to handle medicated feeds containing VFD drugs). Second, and more importantly, there may be, on average, about one more VFD drug approved in each succeeding year that would steadily increase the total issuance and filing costs. Compliance costs per VFD issued, however, would decrease slightly in the future because the one-time-only costs already would have been incurred.

The estimated total nondiscounted compliance costs in year 2 range from about $640,000 to $1,151,000. Discounting these costs at 7 percent per year results in a final second year cost estimate of about $598,000 to $1,076,000. At some year in the future, the increasing number of VFD's issued will reach a point at which issuances of the newly approved VFD's will be offset by the decreasing issuances of older VFD's as their sales volume decreases. Although the agency does not know in which year this will occur, it can be determined that the present value of the annual compliance costs will not continue to increase. The agency invites comment on all compliance cost estimates included in this analysis.

C. Regulatory Flexibility Analysis

The Small Business Administration (SBA) defines all manufacturers of drugs and prepared feeds for animals having 500 employees or fewer to be a small business. We have included feed distributors in this category also. FDA estimates that only about 2 percent of the affected facilities belong to large conglomerates with an overall employee count of higher than 500. Therefore, the remaining 98 percent of the affected facilities would be considered small businesses according to SBA's standards. SBA defines veterinary services for livestock as small businesses if annual revenues are less than $5 million. Because, according to the American Veterinary Medical Association, ''Veterinary Market Statistics, 1997,'' large animal veterinarians earn about $60,000 per year on average, the agency assumes that virtually all large animal veterinary practices are small businesses. Likewise, most livestock production facilities would be considered small businesses by SBA, because SBA defines small business as those businesses with revenues under $500,000, except for beef cattle feedlots, for which the limit is $1.5 million. Consequently, the proposed rule would ultimately affect a substantial number of small businesses. The rule will not, however, have a significant effect on these small business, as the cost of the additional veterinary service and paperwork burdens are estimated at about $1.25 per VFD issued. Such costs would constitute an insignificant percentage of the revenue of the affected firms even if several VFD drugs are issued to a producer each year. Thus, in accordance with the Regulatory Flexibility Act, FDA certifies that this proposed rule would not have a significant economic impact on a substantial number of small entities.

D. Unfunded Mandate Reform Act

The Unfunded Mandates Reform Act requires (section 202) that agencies prepare an assessment of anticipated costs and benefits before proposing any expenditure by State, local, and tribal governments, in the aggregate, or by the private sector of $100 million (adjusted

annually for inflation) in any one year. The publication of the proposal creating the VFD drug system is not expected to result in expenditures of funds by State, local, and tribal governments or the private sector in excess of $100 million annually. Therefore, FDA is not required to perform a cost/benefit analysis according to the Unfunded Mandates Reform Act.

V. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by OMB under the PRA (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection provisions are shown in this section V with an estimate of the annual reporting and recordkeeping burden (Tables 1 and 2 of this document). 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.

FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of our functions, including whether the information will have practical utility; (2) the accuracy of our estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Veterinary Feed Directives.

Description: The proposed rule implements provisions of the ADAA of 1996 (Pub. L. 104–250), which, by adding section 504 to the act, created a new class of animal drugs called VFD drugs. The proposed 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 veterinarian-client-patient relationship.

The VFD ordered by the veterinarian must be issued in accordance with the format described under proposed § 558.6(a). We are proposing to amend the new animal drug regulations in § 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.

Certain capital costs are involved with respect to the reporting and recordkeeping requirements for VFD drugs. Specific details of cost estimates are found in section IV.B of this document. We estimate that approximately 375,000 VFD's will issue annually. The estimated cost for producing 375,000 VFD's in triplicate annually is $19,750 ($1,000 for the initial one-page layout and $0.05 for each triplicate form). For maintaining records of VFD's, the estimated cost is $37,500. This cost estimate is based on the fact that the veterinarian, client-recipient and distributor must each keep a copy of the VFD. Thus, a total of 1,125,000 copies of VFD's will be filed (375,000 VFD's x 3). We estimate that it will take 75 large file cabinets to store all copies of VFD's, assuming 15,000 copies can be stored in a large file cabinet. The estimated cost per file cabinet is $500, resulting in a total cost of $37,500 (75 cabinets x $500).

Description of Respondents: Veterinarians, distributors of animal feeds containing VFD drugs, and clients utilizing medicated feeds containing VFD drugs.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Sections	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours	Capital Costs
558.6(a)(3) through (a)(5)	15,000	25	375,000	0.25	93,750	$12,250
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	3.0	3	
Total hours/cost					96,278	12,250

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Sections	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours	Capital Costs
558.6(c)(1) and (d)(2)(i)	112,500	10	1,125,000	.0167	18,788	$37,500
558.6(e)(ii)	5,000	75	375,000	.0167	6,263	
Total hours/cost					25,051	37,500

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

To permit FDA to implement certain provisions of the VFD procedure, the OMB approved a portion of this collection of information under the emergency processing provisions of the PRA (5 CFR 1320.13), on a temporary basis, OMB control number 0910–0363. Estimates in the preceding burden chart have been changed from those in the emergency approval (62 FR 64847, December 9, 1997) based upon FDA's experience in implementing certain elements of the VFD procedure.

In compliance with section 3507(d) of the PRA (44 U.S.C. 3507(d)), FDA submitted to OMB the information collection provisions of this proposed rule for review. Interested persons are requested to send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing the burden, by August 2, 1999, to the Office of Information and Regulatory Affairs, (address above).

VI. Public Comments Procedures

On June 1, 1998, the President instructed all Federal agencies to ensure the use of ''plain language'' in all new documents. As part of this initiative, FDA has drafted the codified portion of this document using the principles of ''plain language'' set forth by the President. The agency seeks public comment on the clarity of this proposed rule.

FDA invites interested persons to submit comments regarding these proposed regulations to the Dockets Management Branch (address above). To ensure that public comments have maximum effect in developing the final regulations, FDA urges you to identify clearly the specific section or sections of the proposed regulation that each comment addresses. Comments should be confined to issues pertinent to the proposed rule and explain the reason for any recommended change. Comments are to be identified with the docket number found in brackets in the heading of this document. FDA will accept comments after the deadline September 30, 1999, but are not obligated to consider or include in the administrative record for the final rule those comments received after the close of the comment period. Received comments may be seen in the office above between 9 a.m. and 4:30 p.m., Monday through Friday.

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, it is proposed that 21 CFR parts 510, 514, and 558 be amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR 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,'' after the phrase ''if it is a prescription new animal drug''.

PART 514—NEW ANIMAL DRUG APPLICATIONS

3. The authority citation for 21 CFR 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 (VFD).* Three copies must be submitted in the format described under § 558.6(a)(3), (a)(4), and (a)(5) of this chapter.

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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 and general considerations applicable to this part.

* * * * *

(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 drug intended for use in or on animal feed and which is limited by an approved application filed under section 512(b) of the Federal Food, Drug, and Cosmetic Act to use by the order and 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 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 veterinary feed directive drug in or on an animal feed to treat the client's animals only in accordance with the Food and Drug Administration

approved directions for use. 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 the consignee 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 be met if I am a veterinarian issuing a veterinary feed directive?

(1) You must be appropriately licensed;

(2) You must issue a VFD only within the confines of a valid veterinarian-client-patient relationship (as defined in § 530.3(i) of this chapter) in accordance with the format described in paragraphs (a)(3), (a)(4), and (a)(5) of this section;

(3) You must complete the VFD in writing and sign it;

(4) You must produce the VFD in triplicate;

(5) You must include the following information in the VFD:

(i) Your name, address, and phone number and that of the client;

(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)(5)(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; and,

(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.

(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 client);

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

(3) You must give the client the second copy of the VFD;

(4) You may fax a VFD to the client or distributor, if you wish, provided you immediately forward the signed written original to the distributor and a copy to the client.

(c) What are the VFD recordkeeping requirements?

(1) The VFD must be kept by all involved parties (i.e., veterinarian, client, and VFD feed distributor) for a period of 2 years from date of issuance.

(2) The VFD must be made available by all involved parties for inspection and copying by FDA.

(3) VFD's transmitted by facsimile must be kept by all involved parties along with copies distributed by the veterinarian.

(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, prior to beginning your first distribution, to the Center for Veterinary Medicine, Division of Animal Feeds (HFV–220), 7500 Standish Pl., Rockville, MD 20855; and

(iv) You must notify the Center for Veterinary Medicine at the address provided in paragraph (d)(1)(iii) of this section 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:

(i) An ''acknowledgment letter,'' as defined in § 558.3(b)(11) of this chapter, from the consignee-distributor; and

(ii) A statement affirming that the consignee-distributor has complied with ''Distributor Notification'' requirements of paragraph (d)(1) of this section.

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

(1) You must keep information specified in paragraph (c)(1) or paragraph (d)(2)(i) of this section;

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

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

(4) 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 VFD drug product to use under the professional supervision of a licensed veterinarian. Medicated feed bearing or containing a VFD drug may be fed to animals only when there exists a lawful veterinary feed directive issued by a licensed veterinarian in the course of the veterinarian's professional practice.''

Dated: June 25, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy Coordination.

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DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1908

[Docket No. CO–5]

Consultation Agreements: Proposed Changes to Consultation Procedures

AGENCY: Occupational Safety and Health Administration (OSHA), U.S. Department of Labor.

ACTION: Proposed rule; request for comments.

SUMMARY: OSHA proposes to revise its regulations for federally-funded on-site