DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Veterinary Feed Directive

Docket No. FDA-2010-N-0155

Preliminary Regulatory Impact Analysis
Initial Regulatory Flexibility Analysis
Unfunded Mandates Reform Act Analysis

Economics Staff
Office of Planning
Office of Policy and Planning
Office of the Commissioner

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I. Introduction and Summary

FDA has examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104-4). Executive Orders 12866 and 13563 direct 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 not a significant regulatory action as defined by Executive Order 12866.

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 would impose average annualized costs that amount to significantly less than 0.1 percent of average annual revenues on small entities, FDA has determined that the proposed rule, if finalized, would not have a significant economic impact on a substantial number of small entities. Therefore, this analysis of impacts and other sections of the preamble constitute FDA's initial regulatory flexibility analysis.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $141million, using the most current (2012) Implicit Price

Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

II. Objective and Description of the Proposed Rule

The ADAA created a new category of products called VFD drugs. FDA finalized its regulation to implement the VFD-related provisions of the ADAA in December 2000. The VFD process provides a route for certain new animal drugs to be approved for use in animal feed but only if they are administered under the professional supervision of a licensed veterinarian in the course of the veterinarian's professional practice.

Only two new animal drugs for use in animal feed have been approved as VFD drugs so far. Since that time, FDA has received informal comments that the VFD process is overly burdensome. As a result, FDA published an ANPRM on March 29, 2010. That notice requested public comment on whether efficiency improvements need to be made to the VFD process, and if so, what improvements should be made. FDA received numerous public comments concerning efficiency improvements to the rule. FDA considered these comments in its preparation of the draft text of a proposed regulation, which it published for further public comment on April 13, 2012. FDA received additional comments on that draft text and has considered them as it prepared this proposed rule. Most of the revisions that were in the draft text are included in this proposed rule.

The proposed revisions to the VFD process in that draft were also intended to support the Agency's initiative to transition certain new animal drug products containing medically important antimicrobial drugs from an OTC status to a status that requires veterinary oversight. However, the proposed efficiency revisions to the VFD process have been determined to be necessary regardless of the antimicrobial initiative.

The proposed rule makes a number of changes to codified §§ 558.3 and 558.6. Among other things, it would remove the existing automatic Category II designation for VFD drugs. This would permit those antimicrobials used in animal feed that are currently Category I drugs to become VFD drugs consistent with FDA's judicious use policy but remain available through the current feed mill distribution system. It would provide greater flexibility for veterinary professionals by revising the requirement found in current part 558 for professional conduct for veterinarians issuing orders for VFD drugs, as discussed in section II B. It would reduce the recordkeeping requirement for all parties involved in the VFD process (veterinarian-distributor-client) by changing the length of time that copies of VFDs must be kept from 2 years to 1 year.[1] It would make several changes to the exact information that needs to be included on the VFD form by the veterinarian, including the deletion of the current requirement that the veterinarian must include on the VFD form the amount of feed to be provided by the VFD feed distributor. It would provide for the use of combination VFD products and any limitations that the veterinarian determines are necessary on any of those approved VFD drugs in combination with other approved VFD drugs or for use separately. It would delete the requirement that the veterinarian must ensure that a paper or hardcopy of the VFD order is received by the distributor within 5 days of the writing of the VFD order when the original VFD order is either faxed or sent electronically. It would also change the cautionary statement required on all labeling and advertising for VFD drugs, combination VFD drugs, and VFD feeds.

III. Summary of Preliminary Regulatory Impacts Analysis

[1] Distributors may receive an acknowledgment letter in lieu of a VFD when consigning VFD feed to another distributor. Such letters, like VFDs, would also be subject to a 1-year record retention requirement (see proposed § 558.6(c)(7)). Thus, the recordkeeping burden for acknowledgment letters is included as a subset of the VFD recordkeeping burden.

A. Industry Costs

The estimated one-time costs to industry from this proposed rule, if finalized, are $920,000, most of which are simply costs to review the rule and prepare a compliance plan. This equates to annualized costs of about $131,000 at a 7 percent discount rate over 10 years and about $108,000 at a 3 percent discount rate over 10 years (table 1).

B. Benefits

The proposed rule would introduce efficiency improvements into the VFD process. The intent is to provide more flexibility for the manner in which veterinarians can fulfill their professional obligations to their patients, while also reducing requirements that are either burdensome or are no longer necessary to ensure the proper oversight of VFD feeds. The benefits of this proposed rule would be the cost savings associated with the reduced requirements of the VFD process. FDA has not been able to quantify all of these benefits, but estimates the reduction in recordkeeping costs would amount to an annualized benefit of $40,000 over 10 years at a 7 percent discount rate (annualized at $37,000 over 10 years at a 3 percent discount rate). Additionally, the reduction in veterinarian labor costs due to this rule is expected to result in a cost savings of about $5.55 million annually.

Table 1.--Costs and Benefits of the Proposed Rule ($ million)

Type of Cost	1-Time Cost and Benefits	Total Annualized Costs and Benefits at 7%[1]
Industry Costs	$920,000	$131,000
Government Costs	$1,200	$1,200
Industry Benefits	$135,000	$5,595,000

[1]Total annualized costs and benefits are equal to annualized one-time cost at 7 percent over 10 years.

In table 2, FDA provides the Regulatory Information Service Center/Office of Information and Regulatory Affairs Consolidated Information System accounting information.

Table 2.--Economic Data: Costs and Benefits Statement

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits	Annualized	$5.59				7%		
	Monetized $millions/year	$5.59				3%		
	Annualized					7%		
	Quantified					3%		
	Qualitative							
Costs	Annualized	$0.13				7%		
	Monetized $millions/year	$0.11				3%		
	Annualized					7%		
	Quantified					3%		
	Qualitative							
Transfers	Federal Annualized					7%		
	Monetized $millions/year					3%		
	From/To	From:			To:			
	Other Annualized					7%		
	Monetized $millions/year					3%		
	From/To	From:			To:			
Effects	State, Local or Tribal Government: No Effect Small Business: No effect Wages: No effect Growth: No effect							

IV. Need for Regulation

Producers of animals used for human food and other products need adequate information to make decisions concerning the necessary medical care for their animals. Most lack the medical or scientific background necessary, in at least some instances, to make informed judgments concerning the safe use of animal drugs that are used in animal feeds. Because of this, Congress directed FDA to create the VFD system whereby a veterinarian can provide this medical judgment in the course of his or her professional practice, for those animal drugs intended for use in feed. This proposed rule would streamline the VFD process, which is expected to result in a more efficient allocation of production resources as animal producers can more accurately target the amount of VFD feeds manufactured and fed.

V Benefits of the Proposed Rule

The benefits of this proposed rule, if finalized, result from the efficiencies introduced by several of its provisions. These efficiencies are expected to result in a reduction in some of the compliance costs as discussed in the Regulatory Impact Analysis (RIA) for the 1999 proposed rule that implemented the VFD system. Those compliance costs were estimated as the sum of the following costs: The labor costs to file the completed VFD by the veterinarian, the distributor, and the client; the capital cost for file cabinets to hold the completed paper copies; the labor costs for the one-time letter notification by a distributor to FDA and FDA's labor processing cost for those letters; the cost to develop and print the VFD form for each individual VFD drug; and the labor cost for some distributors to write acknowledgement letters to supply to other distributors when receiving feed containing a VFD drug for further distribution.

In the RIA for the 1999 proposed rule, FDA made the assumption that a VFD for each VFD drug would be issued from 250,000 to 500,000 times annually. This estimate has been retained for this analysis. In the RIA, FDA estimated that one additional VFD drug would be

approved annually. However, FDA has approved only two VFD drugs, significantly less than one per year. At this rate, FDA believes it is unlikely that any new VFD drug products will be approved before this proposed rule would become final. This analysis, therefore, represents FDA's estimate of the proposed rule's efficiency improvements related to the two existing approved VFD drugs.

FDA is initiating the implementation of its current judicious use strategy for medically important antimicrobial drugs with the publication of final GFI #213[2] found elsewhere in this issue of the Federal Register. As a result of this judicious use strategy, we anticipate that currently approved OTC feed-use products that contain drugs within the seven antimicrobial drug classes that are the subject of GFI #213 will convert to VFD status; however, these changes are not expected to occur until after the finalization of this proposed rule.

This proposed rule would directly affect recordkeeping requirements. Proposed § 558.6(a)(4) would reduce the recordkeeping requirement for the veterinarian, the distributor, and the client to keep a copy of the VFD from 2 years to 1 year. Assuming that VFD recordkeeping remains in the same form (i.e., a paper copy for each recipient), this provision would clearly reduce the capital costs for file cabinets for an individual VFD for the veterinarian, distributor, and client by 50 percent as compared to the current codified. However, as included in proposed § 558.6(b)(7), the veterinarian would also no longer be required to assure that a paper copy is received by the distributor within 5 days of writing the VFD if the original was faxed or otherwise transmitted electronically. This requirement has become outdated by modern electronic communication and presents an unnecessary burden on the veterinarian.

[2] "New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI #209"

This provision would further reduce the number of paper copies requiring physical recordkeeping space than just the reduction from 2 years to 1 year. FDA does not have data or other information on the types of current recordkeeping processes employed by veterinarians, clients, and distributors, but assumes that on average each of the three types would currently have improved its capacity for electronic recordkeeping of sales and related documents since the original final rule was published in December 2000. Accordingly, FDA believes that the total reduction in recordkeeping costs for these two provisions would be about 75 percent of the recordkeeping costs estimated in 2000. Fifty percent would be due to the reduction in recordkeeping from two years to one. The remaining 50 percent would then be halved to 25 percent of the original total, as FDA anticipates about one-half of the animal food industry will use only electronic recordkeeping going forward. In total, there would be a 75 percent reduction.

To account for the reduction in recordkeeping from two years to one, FDA notes that in 2000, the one-time recordkeeping costs over the 2-year recordkeeping period for the issuance of 250,000 to 500,000 VFDs was estimated at $50,000 to $100,000 per approved VFD drug. For the two approved VFD drugs, the cost would be double this amount, or a one-time cost of $100,000 to $200,000. Updating the estimated cost of a file cabinet to $600, this equates to a one-time cost of $120,000 to $240,000, with a midpoint of $180,000[3]. By reducing these midpoint costs by one-half (due to the reduction in recordkeeping requirements from 2 years to 1 year), the benefit of these provisions is estimated at a one-time reduction in recordkeeping costs of $90,000. This cost reduction would amount to an annualized benefit of about $13,000 over 10 years at a 7 percent discount rate (annualized at approximately $11,000 over 10 years at a 3 percent discount rate). Additional annual cost savings would be realized in the reduction of

[3] We estimate it takes 300 large file cabinets to currently store these paper copy VFDs for 2 years, assuming 15,000 copies can be stored in a large file cabinet (See 64 FR 35966 at 35970).

rental space for these file cabinets. At an estimated $21.75 per square foot per year rental cost times 6 square feet times 150 file cabinets, the annual savings amounts to about $19,575. Rental costs for file cabinet space were not included in the analysis of the rule creating the VFD system.

To account for the estimated 50 percent reduction in the animal food industry that will use only electronic recordkeeping going forward, FDA estimates the one-time cost savings at $45,000. This results from reducing the file cabinet costs remaining after the original 50 percent reduction from $180,000 above (0.5 times $180,000 equals $90,000) by another 50 percent (0.5 times $90,000 equals $45,000). This results in an annualized cost savings of about $6,400 over 10 years at a 7% discount rate. Additional annual cost savings would be realized in the reduction of rental space for these file cabinets. At an estimated $21.75 per square foot per year rental cost times 6 square feet times 75 file cabinets, the annual savings amounts to about $9,788.

In summary, one-time cost savings for the reduction in file cabinet costs is about $135,000 (annualized to approximately $19,000 over 10 years at a 7 percent discount rate) and annual cost savings are about $29,363.

Proposed § 558.6(b)(3) includes various changes to the information that would need to be included on the VFD form that is filled out by the veterinarian in order for the VFD to be valid, including but not limited to, deleting the requirement that the veterinarian must include the amount of feed needed to treat the animals. Proposed § 558.6(b)(7) would allow veterinarians to send VFDs to the client or distributor via fax or other electronic means (as is currently permitted under § 558.6(b)(4)). However, if a VFD is transmitted electronically, the veterinarian would no longer be required to assure that the original, signed VFD is given to the distributor within 5 days. FDA estimates that a veterinarian currently requires about 0.25 hours to issue a VFD (i.e., research, fill out, and deliver all copies, including the original, signed VFD to the distributor).

At a compensation rate of about $59 (including an additional 50 percent for total overhead), the labor cost of currently issuing VFDs is estimated at $11.09 million. FDA estimates that the effect of this rule would be to reduce the average time to issue a VFD by 50 percent, or about 0.125 hours per VFD. This would result in a cost savings of about $5.55 million annually.

Other provisions of the proposed rule present opportunities for cost savings in the VFD system. In response to numerous public comments, as stated above, proposed § 558.6(b)(3)(x) would delete the current requirement that the veterinarian include on the VFD form the amount of VFD feed required to treat the animals. In practice, this would give food animal producers the option to initially buy smaller amounts of the VFD feed and to buy more at a later date after considering the animals' response to the VFD feed. If the animals do not respond as well as expected or consume the VFD feed at a rate that is lower than originally expected, the producer could reduce the total amount of feed needed for treatment. FDA does not have the data to estimate this reduction in feed costs to individual producers or the total industry, but believes it could be significant.

Other proposed changes in the proposed rule intend to give veterinarians more flexibility in fulfilling their professional obligations to their clients and patients. This benefit, while not quantified, can be found in proposed § 558.3(b)(7) that would revise the requirement found in current part 558 for professional conduct by veterinarians ordering the use of VFD drugs, and proposed § 558.6(b)(3)(viii) that would allow veterinarians to estimate an approximate number, rather than the absolute number, of animals to be treated on a VFD order.

VI. Costs of the Regulation

A. Administrative Costs to Review the Rule

Those industry members that currently handle VFD drugs and VFD feeds would be expected to review the rule that would streamline the VFD system and any affected production records to determine what regulatory actions would be necessary to comply with the requirements. FDA believes that because of the relatively straightforward nature of the proposed rule, if finalized, this review would not take a long time. We base estimated hours on the judgment of FDA personnel with experience in the regulation of medicated animal feeds. For sponsors of the two VFD drugs that FDA has already approved, FDA estimates that it would take about 6 hours for personnel at the general and operations manager level to perform the review and, to the extent necessary, develop a simple compliance plan. The hourly pay for general and operations managers at firms in the North American Industrial Classification System (NAICS) code 325400--Pharmaceutical and Medicine Manufacturing, is about $68. When adjusted for fringe benefits and other overhead costs at 50 percent, the resulting total compensation is about $102 per hour[4]. The 6 hours of review for the two current VFD sponsors at $102 per hour results in a one-time compliance cost of about $1,200, which equates to an annualized cost of about $175 when discounted at 7 percent over 10 years.

The feed distributors that currently distribute medicated feed containing these VFD drugs would also incur administrative review costs for the rule. Specifically, FDA has received 1,366 of the one-time notification letters from medicated feed distributors showing that they intend to distribute VFD feeds. Although some of them may no longer be distributing VFD feeds or may never have distributed VFD feeds, FDA assumes for purposes of this analysis that all 1,366 distribute VFD feeds and would review the rule. FDA estimates that this review would require about 4 hours to complete. FDA expects this task to be completed by personnel at the general

[4] The PRIA "Analysis of Economic Impacts – Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Foods" uses 50 percent for fringe benefits and other overhead costs on pp. 41-43.

and operations manager level. The NAICS code 311100--Animal Food Manufacturing, reports the hourly compensation (including a 50% increase for fringe benefits and other overhead costs) at about $71 per hour. The resulting one-time review cost for each distributor of VFD feeds would be about $284. For the entire 1,366 VFD feed distributors, the one-time cost would be about $387,000, which equates to an annualized cost of about $55,000 when discounted at 7 percent over 10 years. Although additional sponsors and medicated feed distributors (including animal feed manufacturers) may begin to manufacture new VFD drugs or VFD feeds over time, FDA does not include their administrative review costs as a result of this rule. Any future sponsors or distributors will have to spend the same amount of time reviewing the VFD regulation contained in this proposed rule as they would reviewing the current VFD regulation. As they will not have to review the current rules once they are replaced by the proposed rule, the proposed rule, if finalized, does not impose additional review times on these sponsors or distributors.

FDA expects food animal veterinarians to also review the rule. FDA estimates that there are about 3,050 veterinarians that exclusively treat food-producing animals, and who would be most likely to need to educate themselves about the rule. FDA expects them to review the rule by reading articles on the changes to the veterinarian's responsibilities in various trade journals, state agricultural newsletters, or other trade publications. FDA estimates that this would likely require no more than 1 hour of review. At the AVMA 2010 median veterinarian hourly compensation rate of $59 (including an additional 50% for fringe benefits and other overhead), this review would have a one-time compliance cost of about $180,000. This equates to an annualized cost of about $26,000 when discounted at 7 percent over 10 years.

VFD clients (food animal producers) that use VFD drugs are also expected to review the rule. FDA estimates that 10,000 food animal producers use one of the VFD drugs that are currently marketed. FDA expects that they would familiarize themselves by reading articles on the new rule in various trade publications. FDA estimates that this would require only about one-half hour. It would therefore require a total of 5,000 hours for the entire 10,000 food animal producers. Using the median wage of a first-line supervisor of farming, fishery, and forestry workers (adjusted for fringe benefits and other overhead by 50 percent) of about $31 per hour, the one-time compliance cost for food animal producers is about $154,000. This equates to an annualized cost of about $22,000 when discounted at 7 percent over 10 years.

For the entire VFD drug and VFD feed manufacturing industry subject to the proposed rule, if finalized, the estimated one-time administrative costs would amount to $723,000, which amounts to an annualized cost of about $103,000. This estimate may overstate total administrative review labor costs because those firms with more than one facility may not require the full administrative review effort at each facility.

B. Labeling and Advertising Change Costs

Proposed § 558.6(a)(6) would require that all labeling and advertising for VFD drugs and animal feeds containing VFD drugs display the cautionary statement: "Caution: Federal law restricts medicated feed containing this VFD drug to use by or on the order of a licensed veterinarian." The proposed rule would change the cautionary labeling statement that is currently required in § 558.6. As a result of this change, the sponsor of any currently approved VFD drug would be required to submit to FDA a labeling supplement containing the new cautionary statement on its labeling, the new specimen labeling for the Type A medicated article, the representative label for use by the feed manufacturer and the VFD form for use by the

veterinarian. We assume that each sponsor would submit a separate labeling supplement for each of the two indications for use of their approved VFD drugs. These labeling supplements are described in § 514.8(c) (21 CFR 514.8(c)) and are estimated to require about 20 hours to prepare, according to current FDA information collection activities estimates. Using the total wage and other overhead compensation rate of $103 per hour for personnel at the general and operations manager level, the one-time cost of preparing a labeling supplement would be about $2,000, or about $4,100 for both indications for an approved VFD drug. The total one-time cost for both sponsors would be about $8,200 (one labeling supplement times two indications times two approved VFD drugs). This equates to an annualized cost of about $1,200 when discounted at 7 percent over 10 years.

These same two sponsors would also incur a one-time labeling cost to change the cautionary statement in the actual labeling that accompanies the VFD drug product and the representative labeling that sponsors provide to distributors for them to use to create their proprietary labeling for VFD feeds. FDA believes that this would entail making a change to the wording in the production software that prints both types of labels. Because the only change to the labeling would be to the cautionary statement, and since the new cautionary statement is shorter than the current statement, FDA does not expect industry to have any difficulty in making this change. FDA estimates that the effort to make this change would require about 4 hours from personnel at the industrial production manager level for a pharmaceutical manufacturer. The one-time cost is estimated at about $300 for each of the two VFD sponsors, or about $600 in total. FDA acknowledges some uncertainty concerning the level of effort that this would entail and requests public comment and data on the effort involved.

Animal feed distributors that manufacture medicated feed containing VFD drugs would also need to make the cautionary statement change to their proprietary labeling that would accompany the feed based on the change to the sponsor's representative labeling. FDA estimates that this change would require about 2 hours from personnel at the industrial production manager level to update the cautionary statement language in the software used to print the labeling as part of the filling of the VFD order at the feed mill. At a total compensation (including fringe benefits and other overhead) rate of about $58 per hour, the 2 hours for each of the 1,366 VFD feed manufacturers would amount to a per facility cost of $116. For all of these feed manufacturers, it would result in a one-time cost of about $159,000, which equates to an annualized cost of $23,000 per year at a discount rate of 7 percent over 10 years. Again, FDA realizes there is some uncertainty surrounding the projected level of effort required by VFD feed distributors and requests public comment on this issue.

All advertising would also have to be changed to display the updated cautionary statement in proposed § 558.6(a)(6). FDA believes that the VFD drug sponsors are responsible for all or almost all advertising for VFD drugs, mostly in animal producer magazines. FDA may expect such advertising to be changed within two months pursuant to this proposed rule, if finalized. There would likely be some compliance costs due to the logistics of making changes to advertising in magazines over that period of time. Though VFD sponsors typically control the medium used for the specimen and representative labeling, they do not usually control the medium used in magazine advertising, which could require a longer transition time to coordinate the changes with the usual frequency of magazine advertising runs.

FDA does not have a cost model directly applicable to advertising of this sort, but uses the FDA-RTI Labeling Cost Model (LCM) to estimate the cost for changing VFD drug

advertisements (Ref. 1). FDA uses the shortest compliance period in the model (3 months or less) for a minor label change and uses a dry dog food product in the LCM as a proxy for a VFD drug advertisement. FDA does not include the cost for product label inventory losses from the LCM because they would not be applicable to magazine advertising. The LCM produces a compliance cost range with a midpoint of about $6,100 per product, with an annualized cost of about $900 when discounted at 7 percent over 10 years. Since each VFD drug has indications for use for two different species and the advertising is expected to target these individual species, there would be four VFD drug advertising changes. Total advertising compliance costs for the two existing VFD drugs over a short transition period are estimated at $24,600 with an annualized cost of $3,500. There is significant uncertainty concerning this estimate due to the cost differences between the printing of consumer packaging labels and printing of advertising in magazines. FDA requests public comment and data on the labeling and advertising costs associated with complying with proposed § 558.6(a)(6).

C. VFD Form Costs

Proposed § 558.6(b)(3) includes various changes to the information that would need to be included on the VFD form that is filled out by the veterinarian in order for the VFD to be valid, including but not limited to, allowing for combination VFD drugs and deleting the requirement that the veterinarian must include the amount of feed needed to treat the animals. The VFD form would have to be modified to address these changes. As described earlier, the VFD form would be included in the labeling supplement submitted to FDA. FDA does not have a firm cost estimate to create the VFD form beyond the one it used for the 1999 proposed rule that would create the VFD system, in which the initial VFD form layout would cost $1,000. FDA did not receive any comments on that estimate and used it in the 2000 final rule. VFD forms are

available on the Internet for use by veterinarians, implying that annual printing costs may be lower than originally predicted in 1999. However, the changes to the VFD form due to this rule would still require additional one-time labor costs. Although it could be less expensive to recreate the new VFD forms because the sponsors have many years of familiarity with their use, FDA will use an estimate of about $1,327per VFD form (taking into account inflation using the gross domestic product deflator since 1999). Because both approved VFD drugs would need two VFD forms, the total one-time cost for the four VFD forms would be about $5,308.

As the use of computers for electronic storage of records has increased substantially since 2000 and is expected to continue to do so regardless of this proposed rule, the only marginal cost that would offset some of the reduction in file cabinet storage space costs would be the additional computer storage space that may be needed for electronic VFD forms. Because the cost of electronic storage capacity on computers has become extremely low, FDA regards this as a negligible cost and has not estimated it.

D. Total Industry Costs

In table 3, total one-time costs for this proposed rule, if finalized, are estimated at $920,000, most of which are unavoidable costs for reviewing the rule and making a compliance plan. On an annualized basis, the cost of the rule is about $131,000 when discounted at 7 percent over 10 years.

Table 3.--Industry Compliance Costs[1]

Type of Cost		One-Time Cost	Annualized Cost
VFD Sponsors	Administrative Review of Rule	$1,200	$200
	Preparation of Labeling Supplements	$8,200	$1,200
	Changes to Specimen and Representative Labeling	$600	$100
	Changes to Advertising	$24,600	$3,500
	Change to VFD Form	$5,300	$800
	Subtotal	$39,900	$5,700
VFD Feed Distributors	Administrative Review of Rule	$387,000	$55,100
	Changes to Proprietary Labeling	$158,800	$22,600
	Subtotal	$546,000	$77,800
Veterinarians	Administrative Review of Rule	$180,400	$25,700
	Subtotal	$180,400	$25,700
VFD Clients	Administrative Review of Rule	$153,600	$21,900
	Subtotal	$153,600	$21,900
Total	Total Industry Costs	$920,000	$131,00

[1]Columns may not add to industry subtotals and total industry costs due to rounding.

E. Government Costs

FDA estimates that the review and other administrative costs associated with a labeling supplement submitted by a VFD drug sponsor would require 3 hours. Based on the Fiscal Year 2010 appropriation for the Center for Veterinary Medicine at FDA, the average annual cost of one of these employees is $213,000, including the cost of all overhead support of that full time employee. This equates to an hourly wage of about $100. The total review and filing effort for FDA employees for the four VFD drug labeling supplements that are expected to be submitted would be 12 hours, with a total cost of about $1,200.

VII. Analysis of Alternatives

An alternative to the proposed rule that would ease the burden on VFD drug sponsors would be to allow additional time to comply with the proposed labeling requirements for currently approved VFD drugs, for example, 1 or more years after the final rule becomes effective. This would not affect any new VFD drug approvals after the effective date of the final rule, and it could provide a transition period for current VFD sponsors to coordinate the labeling changes to the specimen labeling, representative labeling, the VFD form itself, and advertising

within the usual frequency of label changes. FDA does not have the data on the animal drug industry or the animal (livestock) food industry that could be used in the FDA-RTI Labeling Cost Model to estimate any reduction in costs with a longer transition period. However, FDA used the FDA-RTI Labeling Cost Model as a proxy to estimate the cost of changing drug advertising. That model showed that it would require more than one year for any meaningful reduction in costs to occur.

The animal drug industry is the only facility type affected by this rule whose estimated average annualized costs are expected to exceed $100 annually, and lengthening the transition period would not make a substantial difference to these facilities. In addition, the $2,800 in average annualized costs to the two current VFD sponsors who will be affected by this proposed rule, if finalized, represents an extremely small percent of the average revenues for firms in this industry.

VIII. Regulatory Flexibility Act

The Regulatory Flexibility Act requires Agencies to prepare a regulatory flexibility analysis if a rule is expected to have a significant economic impact on a substantial number of small entities. The discussion in this section and the previous sections of the economic analysis constitute the initial regulatory flexibility analysis.

One requirement of the Regulatory Flexibility Act is a succinct statement of any objectives of the rule. As stated previously in this preamble, FDA intends this proposed rule, if finalized, to produce efficiency improvements in the VFD system.

A. Description of Small Entities

The Regulatory Flexibility Act also requires a description of the small entities that would be affected by the rule, and an estimate of the number of small entities to which the rule would apply. The Small Business Administration (SBA) considers any pharmaceutical manufacturer (NAICS code 325412--Pharmaceutical Preparation Manufacturing, which includes Type A medicated article sponsors) with less than 750 employees to be small. It considers any animal feed manufacturer (NAICS code 311119--Other Animal Food Manufacturing, which includes feed mills) with less than 500 employees to be small and veterinary firms (NAICS code 541940--Veterinary Services) with less than $7 million in revenues to be small. Food animal producers are included under the NAICS subsector code 112--Animal Production. The SBA limit for small dairy and beef cattle producers, hog producers, and aquaculture producers is revenues of less than $750,000, and for cattle feedlots, it is revenues less than $2.5 million. Table 4 presents U.S. Census data from 2007. In 2007, there were 991 establishments in NAICS 325412 and 1,533 establishments in NAICS 311119. About 92 percent to 98 percent of the establishments in NAICS code 325412 had fewer than 750 employees and would be considered small business establishments. For NAICS 311119, 73 percent of the establishments had fewer than 500 employees and would be considered to be small business establishments. Within each of these NAICS codes, the existence of multi-establishment firms would reduce the number of firms that are considered small businesses. FDA does not have the distribution of veterinary service establishments by size, but Census data shows that the average firm has receipts of over $850,000. Census of Agriculture data from 2007 (not included in table 4) shows that 82 percent or more of those farms that sell cattle, hogs, or aquaculture species have sales of less than $500,000. FDA believes that a substantial number of firms across these affected industries would qualify as small business entities.

The U.S. Census Bureau reports an additional 1,303 non-employer establishments (e.g., cooperative enterprises with no employees) that manufactured animal food, including pet foods, and both non-medicated and medicated feeds for food-producing animals. These establishments were reported in NAICS 31111--Animal Food Manufacturing (which is the lowest classification level available for non-employer data, but which includes NAICS 311119 as a subset). These firms have average revenues of only $60,000, making it likely that all of them would qualify as small business entities. FDA believes it is unlikely that any of the 1,366 feed manufacturers that have notified the Agency that they intend to produce medicated feeds containing VFD drugs would be in this category, because it is unlikely that a feed mill that currently handles Type I medicated articles would have such low revenues. FDA requests public comment on the size of these non-employer establishments and the number that distribute medicated animal feeds.

Table 4 also illustrates the distribution of revenues by type and size of manufacturer establishment. Average annual revenues per firm for the pharmaceutical preparation manufacturers range from less than $1.0 million for small firms with fewer than 5 employees to over $1 billion for large firms with 750 or more employees. For the other animal food manufacturing industry, average per establishment receipts range from about $1.0 million annually for small firms with fewer than 5 employees to about $34.1 million annually for large establishments with 500 or more employees.

Table 4.--Establishments and Revenues for Drug Manufacturers and Animal Food Manufacturers

Employment size		No. of Establishments	Annual Revenues ($ mil)	Average Annual Revenues Per Establishment ($ mil)
NAICS–325412--Pharmaceutical Preparation Manufacturing[1]	0-4	284	240.0	0.8
	5-9	124	344.7	2.8
	10-19	77	429.2	5.6
	20-99	249	9,899.3	39.8
	100-499	182	44,927.5	246.9
	500+	75	87,035.2	1,160.5
	Industry total	991	142,876.3	144.2
NAICS-311119--Other Animal Food Manufacturing[2]	0-4	294	291.6	1.0
	5-9	200	508.7	2.5
	10-19	191	1,114.5	5.8
	20-99	261	3,703.8	14.2
	100-499	170	4,268.6	25.1
	500+	417	14,221.1	34.1
	Industry total	1,533	24,108.4	15.7

[1]2007 Economic Census--receipts per establishment.
[2]2007 County Business Patterns and 2007 Economic Census--value of shipments per establishment.

B. Costs to Small Entities

Table 5 shows the relative burden that establishments of different sizes can expect from the proposed rule. For pharmaceutical preparation manufacturers, the one-time costs are less than 1 percent of revenues for all but the very smallest establishments, and less than one one-hundredth of a percent for the average establishment having 100 or more employees, which are those manufacturers that are expected to be manufacturing VFD drugs. At the animal feed manufacturer level, the one-time costs as a percent of revenues are even lower. At its highest level, those establishments with less than 5 employees, the one-time costs of the rule represent only 0.04 percent of revenues, and even much lower for all establishments with more employees. Even if the average food animal veterinary service establishment has three veterinarians, the

compliance costs for the proposed rule, if finalized, would be less than about 0.03percent of receipts (not included in table 5). The cost of the one-half hour proposed rule review for VFD clients should equate to less than 0.1 percent of sales for all farms producing these animals, except those farms with average sales of about $10,000 or less. For these very small farms, the cost could equate to a range of 0.2 percent to 0.7 percent of sales. FDA concludes that it is very unlikely that the proposed rule, if finalized, would result in a significant impact on a substantial number of small entities.

Table 5.--One-time and Annualized Costs by Establishment Size

Employment Size		No. of Establishments	One-Time Costs as a Percent of Average Revenues	Annualized Costs as a Percent of Average Revenues
NAICS-325412--Pharmaceutical Preparation Manufacturing	0-4	284	2.36%	0.34%
	5-9	124	0.72%	0.10%
	10-19	77	0.36%	0.05%
	20-99	249	0.05%	<0.01%
	100-499	182	0.01%	<0.01%
	500+	75	<0.01%	<0.01%
NAICS-311119--Other Animal Food Manufacturing	0-4	294	0.04%	0.1%
	5-9	200	0.02%	<0.01%
	10-19	191	<0.01%	<0.01%
	20-99	261	<0.01%	<0.01%
	100-499	170	<0.01%	<0.01%
	500+	417	<0.01%	<0.01%

IX. Reference

The following reference has been placed on display in the Division of Dockets Management (5630 Fishers Lane, rm. 1061, Rockville, MD 20852) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and is available electronically at http://www.regulations.gov.

1. RTI International, “Model to Estimate Costs of Using Labeling as a Risk Reduction Strategy for Consumer Products Regulated by the Food and Drug Administration--Revised Final Report,” Contract No. GS-10F-0097L, Task Order 5, RTI Project No. 0211460.005, 2012.