DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Veterinary Feed Directive

Docket No. FDA-2010-N-0155

Final Regulatory Impact Analysis
Final Regulatory Flexibility Analysis
Unfunded Mandates Reform Act Analysis

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I. Introduction and Summary

FDA has examined the impacts of the final 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 final 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 final rule would impose average annualized costs that amount to about 0.1 percent or less of average annual revenues on small entities, FDA has determined that the final rule will likely 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 final 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 finalizing "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 $141 million, using the most current (2013) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

II. *Objective and Description of the Final Rule*

In 1996, the Animal Drug Availability Act (ADAA) created a new category of products called Veterinary Feed Directive (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 intended for use in or on animal feed to be limited to use under the professional supervision of a licensed veterinarian. Animal feed containing a VFD drug may only be fed to animals based upon a lawful VFD order issued by a licensed veterinarian.

Only a few new animal drugs intended for use in animal feed have been approved as VFD drugs. Since the final rule was published in 2000, 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 considered them as it prepared a proposed rule, published on December 12, 2013 (December 2013 NPRM).

FDA received numerous comments on the December 2013 NPRM, none of which directly address the cost and benefit estimates of the Preliminary Regulatory Impact Analysis (PRIA) that FDA posted to its web site. This Final Regulatory Impact Analysis (FRIA) is affected, though, by FDA's response to the comments that argued against reducing the recordkeeping requirement from two years to one year. In the preamble to the final rule, FDA

describes these comments, its agreement with these comments, and its conclusion that the recordkeeping requirement will remain at two years.

The final revisions to the VFD process are also intended to support the Agency's judicious use initiative to address antimicrobial resistance associated with the use of antimicrobial drugs in food-producing animals. FDA anticipates that, as a result of this initiative, new animal drug products containing medically important antimicrobial drugs will transition from an OTC marketing status to a status that requires veterinary oversight (either VFD or prescription (Rx)). However, these final revisions will increase the efficiency of the VFD process regardless of the Agency's judicious use initiative.

The final rule makes a number of changes to codified §§ 558.3 and 558.6. Among other things, it removes the existing automatic Category II designation for VFD drugs. This will permit many of the antimicrobials used in animal feed that are currently Category I drugs to become VFD drugs consistent with FDA's judicious use initiative but remain available through the current feed mill distribution system. It will provide greater flexibility for veterinary professionals by revising the veterinary-client-patient relationship (VCPR) requirement found in current part 558 describing professional conduct for veterinarians issuing orders for VFD drugs. The final rule also makes several changes to the 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 provides for the use of combination VFD drug products and any limitations that the veterinarian determines are necessary on the use of the VFD drug in combination with other approved drugs or for use separately. It deletes the requirement that the veterinarian must ensure that the original paper copy of the VFD is received by the distributor within 5 working days from

when the distributor received the VFD by facsimile or other electronic means. It also changes the cautionary statement required on all labeling and advertising for VFD drugs, combination VFD drugs, and VFD feeds.

III. *Summary of Final Regulatory Impacts Analysis*

A. Industry Costs

The estimated one-time costs to industry from this final rule are $1,411,000, most of which are simply costs to review the rule and prepare a compliance plan. This equates to annualized costs of about $201,000 at a 7 percent discount rate over 10 years and about $165,000 at a 3 percent discount rate over 10 years (table 1).

B. Benefits

The final rule will make the VFD process more efficient by providing more flexibility in 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 final rule are the cost savings associated with the more efficient requirements of the VFD process related to the two existing approved VFD drugs. FDA has not been able to quantify all of these benefits, but estimates the reduction in veterinarian labor costs due to this rule is expected to result in a cost savings of about $7.85 million annually.

Table 1.--Costs and Benefits of the Final Rule

Type of Cost	1-Time Cost and Benefits	Total Annualized Costs and Benefits at 7%[1]
Industry Costs	$1,411,000	$201,000
Government Costs	$2,000	$300
Industry Benefits	$90,000	$7,881,000

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

In table 1A, FDA provides the Regulatory Information Service Center/Office of Information and Regulatory Affairs Consolidated Information System accounting information.

Table 1A. Summary of Benefits and Costs of Final Rule

Category		Primary Estimate	Units			Notes
			Year Dollars	Discount Rate	Period Covered	
Benefits	Annualized	$7.88 M.	2013	7%	10 years	
	Monetized $millions/year	$7.88 M.	2013	3%	10 years	
	Annualized Quantified		2013	7%	10 years	
			2013	3%	10 years	
	Qualitative					
Costs	Annualized	$0.20 M.	2013	7%	10 years	
	Monetized $millions/year	$0.17 M.	2013	3%	10 years	
	Annualized Quantified		2013	7%	10 years	
			2013	3%	10 years	
	Qualitative					
Transfers	Federal Annualized		2013	7%	10 years	
			2013	3%	10 years	
	Monetized $millions/year	To:				
	Other Annualized		2013	7%	10 years	
			2013	3%	10 years	
	Monetized $millions/year	To:				
Effects	State, Local or Tribal Government: No effect					
	Small Business:					
	Wages: No estimated effect					
	Growth: No estimated 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 or on animal feeds. Because of this, Congress, through the ADAA, provided for veterinary feed directive drugs. FDA issued regulations implementing the VFD process 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 or on animal feed. This final rule streamlines the VFD process, which is expected to result in a more efficient allocation of production resources as the animal producer, working together with the veterinarian and feed mill, can more accurately target the amount of VFD feed to be manufactured and fed.

V Benefits of the Final Rule

The benefits of this final rule 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 final rule that implemented the VFD process. 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.

FDA initiated the implementation of its current judicious use strategy for medically important antimicrobial drugs with the publication of final GFI #213[1] in the same issue of the Federal Register as the 2013 proposed rule. As a result of this judicious use strategy, we explained our anticipation that currently approved OTC feed-use products that contain drugs within the seven antimicrobial drug classes that are the subject of GFI #213 would convert to VFD status. These changes would not be expected to occur until after the publication of the final rule; thus, this analysis represents FDA's estimate of the final rule's efficiency improvements related to the two currently approved VFD drugs.

Since the proposed rule was published, FDA approved two more new animal drug applications for VFD drugs. The first is a combination VFD drug for one animal species for the same sponsor of one of the previously approved VFD drugs. The second is a generic VFD drug for one animal species for a new VFD drug sponsor. This analysis represents FDA's estimate of the final rule's efficiency improvements related to the two approved pioneer VFD drugs, each of which has indications for two animal species, and the combination VFD drug and generic VFD drug, each of which has an indication for one animal species.

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. FDA retained this estimate for the 2013 PRIA. FDA did not receive any comments that lead us to change this estimate for this analysis.

In the proposed rule, § 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. After considering the public comments received on this issue, FDA has decided to not reduce the

[1] "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"

recordkeeping requirement from two years to one year in this final rule.[2] However, as included in proposed § 558.6(b)(7), FDA will finalize the proposed change in which the veterinarian would no longer be required to ensure that the original paper copy is received by the distributor within 5 days after the distributor receives the VFD by facsimile or other electronic means. The current requirement has become outdated by modern electronic communication and presents an unnecessary burden on the veterinarian. This provision will reduce the number of paper copies requiring physical recordkeeping space.

FDA did not receive substantive comments on the cost reduction methodology used for the PRIA, and retains it here for the FRIA, along with those changes that reflect the changes made to provisions in the codified rule. The recent approvals of the generic and combination VFD drug applications are not expected to add significantly to the total number of VFDs issued annually. The total number of the generic VFD drug products sold plus the pioneer VFD drug products sold may be slightly larger than the previous number of the pioneer VFD drug products sold alone, due to a likely price reduction. Although we do not have the information to estimate what the volume increase would be, we expect it to be small because these recent approvals did not add a new indication or species. Additionally, although we expect that the combination VFD drug approval could result in some animal producers substituting this combination VFD drug product for the single VFD drug that is a component of the combination VFD drug or an earlier approved injectable drug product with the same ingredient, we do not expect this combination VFD drug approval to significantly affect the total number of VFDs issued for the animal species and indications for which the VFD drugs are approved.

[2] Distributors may receive an acknowledgment letter in lieu of a VFD when distributing VFD feed to another distributor. Such letters, like VFDs, would also be subject to a 2-year record retention requirement (see proposed § 558.6(c)(7) and final § 558.6(c)(8)). Thus, the recordkeeping burden for acknowledgment letters is included as a subset of the VFD recordkeeping burden.

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 categories of recordkeepers would have improved their capacity for electronic recordkeeping of VFDs and related documents since the original final rule was published in December 2000. FDA estimates that the reduction in recordkeeping costs will be about 50 percent of the recordkeeping costs estimated in 2000, as FDA anticipates about one-half of the animal food industry will use only electronic recordkeeping going forward.

As noted above, in 2000 FDA estimated the one-time recordkeeping costs over the two-year recordkeeping period for the issuance of 250,000 to 500,000 VFDs at $50,000 to $100,000 per approved VFD drug. For the two approved VFD drugs, the combined cost would be 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 (to account for the estimated 50 percent reduction in recordkeeping costs estimated in 2000, based on our estimate that about one-half of the animal food industry will use only electronic recordkeeping going forward), FDA estimates the one-time cost savings at $90,000. Additional annual cost savings will 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 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 process.

[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).

In summary, one-time cost savings for the reduction in file cabinet costs is about $90,000 (annualized to approximately $12,800 over 10 years at a 7 percent discount rate), and annual cost savings are estimated at about $19,600.

Final § 558.6(b)(3) includes various changes to the information that will 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. Final § 558.6(b)(7) allows 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 will no longer be required to ensure 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 $84 (including an additional 100 percent for total overhead)[4], FDA estimates the current labor cost of issuing VFDs at $15.70 million. FDA estimates that the effect of this rule will be to reduce the average time to issue a VFD by 50 percent, or about 0.125 hours per VFD. This will result in a cost savings of about $7.85 million annually.

Other provisions of the final rule present opportunities for cost savings in the VFD process. In response to numerous public comments, as stated above, final § 558.6(b)(3)(x) deletes the current requirement that the veterinarian include on the VFD form the amount of VFD feed required to treat the animals. In practice, this gives 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

[4] HHS currently recommends using a 100% increase in labor rates to account for total overhead costs, including other labor (administrative and support) and capital costs associated with labor. FDA used a 50% increase in labor rates for the 2013 proposed rule on changes to the VFD program.

consume the VFD feed at a rate that is lower than originally expected, the producer can 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 final changes in the final 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 final § 558.3(b)(1)(ii) that revises the requirement found in current part 558 for professional conduct by veterinarians ordering the use of VFD drugs, and final § 558.6(b)(3)(viii) that allows veterinarians to estimate on a VFD an approximate number, rather than the absolute number, of animals to be treated.

FDA estimates total benefits as a one-time savings of $90,000 in capital costs for filing cabinets, which annualizes to about $12,800 over 10 years at a seven percent discount rate (and to about $10,600 at a three percent discount rate), an additional $19,600 in annual savings in rental costs, and $7.85 million in labor savings to veterinarians. FDA estimates total annualized benefits at about $7.88 million (over 10 years using both seven percent and three percent discount rates).

VI. Costs of the Regulation

Public comments on the 2013 proposed rule did not address the cost methodology used in the PRIA. As such, we retain its use in this FRIA. We also adjust the wage estimates from the year 2011 to 2013.

A. Administrative Costs to Review the Rule

All industry members that manufacture, distribute, order the use of, or use VFD drugs and VFD feeds are expected to review the rule that would streamline the VFD process to determine what regulatory actions would be necessary to comply with the requirements. Because of the relatively straightforward nature of the final rule, this review will 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 VFD drugs that FDA has 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 $70. When adjusted for total overhead costs at 100 percent, the resulting total compensation is about $140 per hour. The 6 hours of review for the three current VFD drug sponsors at $140 per hour results in a one-time compliance cost of about $2,500, which equates to an annualized cost of about $360 when discounted at 7 percent over 10 years.

The feed distributors that currently distribute medicated feed containing these VFD drugs will also incur administrative review costs for the rule. Specifically, as of October 2014, FDA has received 1,376 of the one-time notification letters from medicated feed distributors indicating their intent 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 1,376 distribute VFD feeds and will review the rule. FDA estimates that this review would require about 4 hours. FDA expects this task to be completed by personnel at the general and operations manager level. The NAICS code 311100--Animal Food Manufacturing, reports the hourly compensation (including the 100% increase for total overhead costs) at about $96 per

hour. The resulting one-time review cost for each distributor of VFD feeds will be about $384. For all 1,376 VFD feed distributors, the one-time cost is estimated to be about $529,000, which equates to an annualized cost of about $75,000 when discounted at 7 percent over 10 years. Although additional sponsors and VFD 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 final 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 final rule, it 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 they will 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 will likely require no more than 1 hour of review. We use the AVMA 2010 median veterinarian hourly compensation rate of about $39, and adjust it to include the additional 100% for total overhead costs, as well as adjust it to 2013 dollars. The result is an estimated compensation rate of about $84 per hour. Using this rate, we estimate the review to have a one-time compliance cost of about $255,000. This equates to an annualized cost of about $36,000 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 will familiarize themselves by reading articles on the new rule in various trade publications. FDA estimates that this will require only about one-half hour. It will, therefore, require a total of 5,000 hours for all 10,000 food animal producers to review the rule. Using the median wage of a first-line supervisor of farming, fishery, and forestry workers (adjusted for total overhead costs at 100% of labor costs)) of about $49 per hour, the one-time compliance cost for food animal producers to review the rule is about $244,000. This equates to an annualized cost of about $35,000 when discounted at 7 percent over 10 years.

For the entire VFD drug and VFD feed manufacturing industry subject to the final rule, the estimated one-time administrative costs are estimated at about $1,030,000, which amounts to an annualized cost of about $147,000 when discounted at 7 percent over10 years. 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

Final § 558.6(a)(6) requires 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 veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian." The final rule changes 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 will 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, and the representative label for use by the feed manufacturer. We assume that each VFD drug sponsor will submit a separate labeling supplement for each approved application's species and their related indication(s) for use. These labeling supplements are described in § 514.8(c) (21 CFR

514.8(c)). We estimate that each requires about 20 hours to prepare, based on current FDA information collection activities estimates. Using the total wage and other overhead compensation rate of about $140 per hour for personnel at the general and operations manager level, the one-time cost of preparing a labeling supplement is estimated at about $2,800 per species indication for a VFD drug. (For each VFD drug sponsor, each approved application's species and their related indication(s) would have separate labeling.) The total one-time cost for the three existing VFD drug sponsors will be about $16,700 (one labeling supplement times one VFD drug sponsor with one species indication, one VFD drug sponsor with two species indications and one VFD drug sponsor with three species indications). This equates to an annualized cost to the industry of about $2,400 when discounted at 7 percent over 10 years.

The three sponsors will 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 will 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 requires about four hours from personnel at the industrial production manager level for a pharmaceutical manufacturer. For the final rule, we base the estimate on the number of sets of labeling that would need to be changed for each of the three VFD drug sponsors, which, as stated above, is based on separate labeling for each approved species and their related indication(s). We estimate the one-time cost at $435 for the labeling for each approved species indication(s) for each VFD drug sponsor. Since the three sponsors have

six total sets of labeling, the result is a one-time cost of about $2,600 in total, which equates to an annualized cost of about $400 over ten years at a seven percent discount rate. FDA acknowledges some uncertainty concerning the level of effort that this would entail.

Animal feed distributors that manufacture medicated feed containing VFD drugs will also need to add the cautionary statement from the sponsor's representative labeling to their proprietary labeling that accompanies the VFD feed. For the proposed rule, FDA estimated that this change would require about two 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 at the feed mill. Because there has been an increase in the number of approved VFD drug labels since the proposed rule, FDA now uses an estimate of three hours per animal feed distributor to update the cautionary statement language in the software used to print the labeling at the feed mill. At a total compensation rate (including all overhead costs) of about $77 per hour, the three hours for each of the 1,376 VFD feed manufacturers amount to a per facility cost of $230. For all of these VFD feed manufacturers, it results in a one-time cost of about $316,000, which equates to an annualized cost of $45,000 per year at a discount rate of 7 percent over 10 years

All advertising will also have to be changed to display the updated cautionary statement in final § 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. The final rule will become effective 60 days after publication in the Federal Register. FDA expects such advertising to be changed within these two months. There will 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 same FDA-RTI Labeling Cost Model (LCM) it used in the analysis for the 2013 proposed rule to estimate the cost for changing VFD drug advertisements (Ref. 1). FDA requested public comment and data on this method due to the significant uncertainty concerning the cost differences between the printing of consumer packaging labels and printing of advertising in magazines. We did not receive any direct comments on this issue, and retain the methodology here for the FRIA. Additionally, we have updated the compliance cost estimates for the LCM to 2013 dollars using the gross domestic product deflator.

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 are not applicable to magazine advertising. The LCM produces a compliance cost range with a midpoint of about $6,200 per product, with an annualized cost of about $900 when discounted at 7 percent over 10 years. Since the advertising is expected to target the individual species and their related indication(s) for each approved VFD drug application, the total number of VFD drug advertising changes will be six. Total advertising compliance costs for the existing VFD drugs over a short transition period are estimated at $37,400 with an annualized cost of $5,300 when discounted at 7 percent over 10 years.

C. VFD Form Costs

Final § 558.6(b)(3) includes various changes to the information that needs to be included on the VFD form that is filled out by the veterinarian in order for the VFD to be valid. These

changes include, but are not limited to, the statement prohibiting extralabel use of the VFD feed, affirmation of intent for combination VFD drugs, and deleting the requirement that the veterinarian must include the amount of feed needed to treat the animals. The current VFD drug sponsors have created their own proprietary VFD forms. We assume for purposes of this FRIA that these will be modified to address these changes. FDA does not have a firm cost estimate to create the VFD form beyond the $1,000 cost it used for the 1999 proposed rule that codified the VFD process. 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 will 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 uses an estimate of about $1,331per VFD form (taking into account inflation using the gross domestic product deflator from 1999 to 2013). Because each sponsor of an approved VFD drug uses a separate VFD form for each species and their related indication(s), the total one-time cost to update the six VFD forms would be about $8,000, which equates to an annualized cost of about $1,100 over ten years at a seven percent discount rate.

As the use of computers for electronic storage of records has increased substantially since the initial VFD final rule issued in 2000 and is expected to continue to do so regardless of this final rule, the only marginal cost that will offset some of the reduction in file cabinet storage space costs will 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 does not estimate it.

D. Total Industry Costs

In table 2, total one-time costs for this final rule are estimated at $1,405,000, 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 $200,000 when discounted at 7 percent over 10 years. At a 3 percent discount rate, the annualized cost estimate is about $165,000.

Table 2.--Industry Compliance Costs1

Type of Cost		One-Time Cost	Annualized Cost at 7%[2]	Annualized Cost at 3%[2]
VFD Sponsors	Administrative Review of Rule	$2,500	$400	$300
	Preparation of Labeling Supplements	$16,700	$2,400	$2,000
	Changes to Specimen and Representative Labeling	$2,600	$400	$300
	Changes to Advertising	$37,400	$5,300	$4,400
	Change to VFD Form	$8,000	$1,100	$900
	Subtotal	$67,300	$9,600	$7,900
VFD Feed Distributors	Administrative Review of Rule	$528,900	$75,300	$62,000
	Changes to Proprietary Labeling	$316,400	$45,100	$37,100
	Subtotal	$845,300	$120,400	$99,100
Veterinarians	Administrative Review of Rule	$255,300	$36,400	$29,900
	Subtotal	$255,300	$36,400	$29,900
VFD Clients	Administrative Review of Rule	$243,500	$34,700	$28,500
	Subtotal	$243,500	$34,700	$28,500
Total	Total Industry Costs	$1,411,400	$201,000	$165,500

[1]Columns may not add to industry subtotals and total industry costs due to rounding.
[2] Annualized over 10 years.

E. Government Costs

FDA estimates that the review costs 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 $102. We have adjusted this wage to about $108 per hour in 2013 dollars. The total review and filing effort for FDA employees for the six VFD drug labeling supplements that are expected to be submitted would be 18 hours, with a total cost of about $1,900.

VII. Analysis of Alternatives

An alternative to the final rule that would ease the burden on VFD drug sponsors would be to allow additional time to comply with the final 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 uses 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 $3,200 in average annualized costs to the three current VFD sponsors who will be affected by this final rule 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 final 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 final rule to produce efficiency improvements in the VFD process.

A. Description of Small Entities

The Regulatory Flexibility Act also requires a description of the small entities that will 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 3 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

approximately $870,000, significantly less than the $7 million revenue limit for small businesses. 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 1,376 feed manufacturers that have notified the Agency that they intend to distribute medicated feeds containing VFD drugs would be in this category, because it is unlikely that a feed mill that currently handles Type A medicated articles would have such low revenues.

Table 3 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 3.--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 4 shows the relative burden that establishments of different sizes can expect from the final 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. For animal food manufacturers, 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 0.06 percent of revenues, and an even lower percent of revenues for all establishments with more employees. Even if the average food animal veterinary service establishment has three

veterinarians, the estimated compliance costs for the final rule will be about 0.03 percent of receipts (not included in table 4). The cost of the one-half hour final rule review for VFD clients should equate to less than 0.12 percent of sales for all farms producing these animals, except those farms with average sales of about $50,000 or less. For these very small farms, the cost could equate to a range of 0.21 percent to 1.07 percent of sales. FDA concludes that it is very unlikely that the final rule will result in a significant impact on a substantial number of small entities.

Table 4.--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	2.65%	0.38%
	5-9	124	0.81%	0.11%
	10-19	77	0.40%	0.06%
	20-99	249	0.06%	0.01%
	100-499	182	0.01%	<0.01%
	500+	75	<0.01%	<0.01%
NAICS-311119--Other Animal Food Manufacturing	0-4	294	0.06%	0.01%
	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.