



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

STATEMENT

OF

BERNADETTE M. DUNHAM, D.V.M., PH.D.

DIRECTOR, CENTER FOR VETERINARY MEDICINE

FOOD AND DRUG ADMINISTRATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

**“Animal Drug User Fee Agreements: Advancing Animal Health for the
Public Health”**

BEFORE THE

COMMITTEE ON HEALTH, EDUCATION, LABOR AND PENSIONS

UNITED STATES SENATE

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INTRODUCTION

Good morning, Chairman Harkin, Ranking Member Alexander, and Members of the Committee. I am Dr. Bernadette Dunham, Director of the Center for Veterinary Medicine (CVM) at the Food and Drug Administration (FDA or the Agency), which is part of the Department of Health and Human Services (HHS). Thank you for the opportunity to discuss FDA's proposals for the reauthorization of the Animal Drug User Fee Act (ADUFA III) and the Animal Generic Drug User Fee Act (AGDUFA II).

As you know, these fee programs are designed to expedite access to new therapies for food-producing animals and companion animals and foster innovation in drug development by enabling FDA to maintain a stable workforce to provide a predictable and timely review process. These programs have been highly successful and have enabled FDA to eliminate a backlog in applications, dramatically reduce the time needed to review animal drug applications and other submissions, improve timely communications with drug sponsors, and achieve other efficiencies in the drug approval process, while still ensuring that the drugs are safe and effective.

In my testimony today, I will provide the status of FDA's reauthorization activities. I will also provide some information about each program, our achievements to date, and our proposed changes.

STATUS OF FDA'S REAUTHORIZATION ACTIVITIES

The user fee provisions of ADUFA II and AGDUFA I will sunset on October 1, 2013, if not reauthorized. Timely reauthorization is needed to ensure there is no disruption to these important programs. FDA began the reauthorization process with a public meeting held on November 7, 2011. In February 2012, FDA began discussions to get input from our stakeholders to help us develop our recommendations for reauthorization. FDA consulted with representatives of patient and consumer advocacy groups, veterinary professionals, scientific and academic experts, and industry associations. FDA then published the negotiated recommendations in the *Federal Register* (FR) on December 5, 2012, and solicited public comment. We also held a second public meeting to get input on the recommendations on December 18, 2012. The final recommendations transmitted to Congress include, for each program, the goals letter outlining the performance metrics, the proposed legislative language, and a summary of public comments.

ADUFA BACKGROUND

FDA considers the timely review of the safety and effectiveness of new animal drug applications (NADA) to be central to the Agency's mission to protect and promote public health. One way we protect animal and human health is by approving safe and effective and properly labeled new animal drugs. Prior to 2004, the timeliness and predictability of the new animal drug review program was a concern. The original Animal Drug User Fee Act enacted in 2003 (ADUFA I) authorized FDA to collect user fees that were to be dedicated to expediting the review of NADAs in accordance with certain performance goals and to expand

and modernize the new animal drug review program. The Agency agreed, under ADUFA I, to meet a comprehensive set of performance goals established to show significant improvement in the timeliness and predictability of the new animal drug review process. The implementation of ADUFA I provided a significant funding increase that enabled FDA to increase the number of staff dedicated to the review of animal drug applications by approximately 30 percent since 2003.

In 2008, before ADUFA I expired, Congress passed ADUFA II, which included an extension of the program for an additional five years (FY 2009 to FY 2013), as well as several enhancements to the program.

ADUFA ACHIEVEMENTS

I am pleased to report that FDA has exceeded all of the performance goals established under ADUFA for each year of this critical program. Under the performance goals of ADUFA, FDA agreed to review and act on submissions within shorter periods of time each successive year. During the first five years of this program, the Agency was able to dramatically reduce review times from 500 days to 180 days and completely eliminate a backlog of 833 submissions within the first year.

With ADUFA II, FDA agreed to further enhance the review process. A key improvement under ADUFA II is the “end-review amendment” (ERA) process that allows FDA reviewers to work with the drug sponsor to amend certain pending submissions. By enhancing communication early in the process, the ERA process allows FDA to decrease the number of

review cycles, which ultimately leads to a shorter time to approval and significant cost-savings for the sponsor. The greatest impact of this new tool has been with submissions of investigational new animal drug (INAD) studies and study protocols. Greater than 90 percent of ERAs resulted in a favorable outcome in the first cycle.

Also as part of ADUFA II, FDA developed an electronic submission tool, which has enabled sponsors to submit applications and submissions electronically, allowing FDA reviewers to evaluate the submissions and correspond with sponsors electronically. Electronic submissions have provided substantial cost savings for both FDA and animal drug sponsors.

Approximately 18 percent of submissions were electronic in 2011, the program's first year, and over 50 percent were electronic in 2012. Submissions are received by FDA in minutes rather than days, and correspondence back to sponsors occurs in minutes rather than the several days required for mailing responses.

Further, FDA and the regulated industry participated in eight joint public workshops on mutually agreed-upon topics. This collaboration enhanced communication and transparency on topics critical to the animal drug review process. The workshops discussed in detail the data requirements necessary for drug evaluation and explored scientific approaches to challenges in pharmacokinetics, new emerging issues relative to antiparasitic resistance, and a novel question-based-review (QbR) process for certain reviews. The final two public workshops for FY 2013 will address the evaluation of drugs for use in animal production and data quality for animal drug submissions from sponsors.

ADUFA II also enabled FDA to improve the animal drug review and business processes by facilitating the timely scheduling and conducting of foreign pre-approval inspections.

Because of processes developed under ADUFA II, sponsors are now able to voluntarily submit an annual facilities list and notification 30 days prior to submitting an NADA, a supplemental NADA, or an INAD submission to inform FDA that the application or submission includes a foreign manufacturing facility. This advance notice gives FDA more time to plan for any necessary foreign inspections, thus helping to reduce costs and prevent delays during the review of an application or submission.

PROPOSAL FOR ADUFA III

FDA is proposing changes to the performance goals that ADUFA II established to further enhance the process for review of animal drug applications. Due to the current success of the program, FDA and industry agreed that only minor refinements were necessary.

The ERA procedure implemented as part of ADUFA II resulted in an increase in the number of one-cycle reviews; however, certain challenges associated with the process restricted its full utilization. The Agency is proposing, among other changes, to further improve the review process by replacing the ERA with shorter review times for certain resubmissions and reactivations beginning in FY 2015. To allow time for the programming and information management system changes required to make this and other changes, we are proposing to maintain the ADUFA II ERA process and associated review performance goals for FY 2014 for most applications.

FDA agrees to maintain the ADUFA II performance goals regarding work queue procedures, timely meetings with industry, review of administrative NADAs, and pre-approval foreign inspections. To enhance the exchange of scientific information, the Agency and industry agree on the need for industry to submit information earlier in development to enable the parties to reach agreement at a pre-submission conference or begin the review of study protocols. Additionally, FDA will provide increased flexibility for sponsors to submit scientific data or information concurrent with study protocol review.

Our recommendations relating to the financial enhancements of this program include a new statutory inflation adjuster that accounts for changes in FDA's costs related to payroll compensation and benefits as well as changes in non-payroll costs through use of a prescribed methodology that uses the Consumer Price Index as a guide. We also recommend modifying the base years for calculating the workload adjuster to ensure that it adequately captures changes in FDA's workload during ADUFA III.

Additionally, ADUFA III offers the following financial recommendations:

- A new provision for recovering collection shortfalls to ensure adequate funding for the animal drug review process. For example, when FDA sets fees for FY 2016, it may add to the fee revenue the amount of any shortfall in fees collected in FY 2014. This process would follow in subsequent years through the final year adjustment.
- A modified fee revenue distribution to increase revenue stream stability, reduce application fee costs, and minimize the potential for collection shortfalls. The proposed distribution will shift from 25 percent for each fee type in ADUFA II to 20

percent for application fees, 27 percent for product fees, 27 percent for sponsor fees, and 26 percent for establishment fees.

FDA's recommendation to Congress, after consultation with the regulated industry, is that the total fee revenue estimate for FY 2014 will be \$23,600,000, which includes one-time Information Technology (IT) funding in the amount of \$2,000,000. The proposed statutory language specifies annual revenue of \$21,600,000 for each of FY 2015 through FY 2018; however, this amount is subject to a number of possible adjustments, including for inflation, workload, and collection shortfall.

AGDUFA BACKGROUND

AGDUFA I authorized FDA's first-ever generic animal drug user fee program. AGDUFA I provided a significant funding increase that enabled FDA to increase the number of staff dedicated to the new generic animal drug application review process by approximately 45 percent. Furthermore, the authorization of AGDUFA I enabled FDA's continued assurance that generic animal drug products are safe and effective and provided consumers with greater access to lower-cost therapeutic drugs.

Under AGDUFA I, FDA agreed to meet performance goals for certain submissions over five years from FY 2009 through FY 2013. The purpose of establishing these performance goals was to expedite the review of abbreviated new animal drug applications (ANADA) and reactivations, supplemental ANADAs, and generic investigational new animal drug (JINAD) submissions without compromising the quality of the Agency's review.

AGDUFA ACHIEVEMENTS

AGDUFA I established increasingly stringent review performance goals. In the four years of AGDUFA I review performance evaluated to date (FY 2009 to FY 2012), FDA has exceeded every performance goal every year with one minor exception. During the program's first year, the Agency missed the performance goal by one day for one submission of an investigational generic new animal drug. Most importantly, the additional resources provided under AGDUFA I enabled FDA to completely eliminate a backlog of 680 submissions in 22 months. In addition, the Agency has been able to dramatically reduce review times from 700 days to 270 days. The timely approval of generic new animal drugs continues to be a critical component of animal health because it provides quicker access to additional sources of animal drugs at lower cost for ranchers, farmers, and pet owners.

PROPOSAL FOR AGDUFA II

FDA's goals for the legislative proposal to reauthorize AGDUFA I are to sustain and enhance the core program's operation and performance while providing predictable review times and resources sufficient to keep pace with actual costs. The Agency is proposing to maintain the AGDUFA I goals regarding work queue procedures, timely meetings with industry, review of administrative ANADAs, review of protocols without substantial data, and amendments of similar applications and submissions.

FDA and industry agreed to shorter review times for certain reactivations and resubmissions. The Agency also agreed to increased communication and transparency with industry through

timely meetings and question-based-review (QbR) for bioequivalence submissions, which are most often used when a sponsor proposes manufacturing a generic version of an approved off-patent product. The QbR incorporates the most important scientific and regulatory review questions that focus on critical pharmaceutical attributes essential for ensuring generic drug product quality. In addition, FDA further agreed to implement a process for timely foreign inspections as provided in ADUFA II.

Similar to AGDUFA I, our recommendations for financial enhancements for AGDUFA II include a fixed inflation adjuster of 4 percent each year to achieve the proposed revenue levels. We also recommend modifying the base years for calculating the workload adjuster to ensure that it adequately captures changes in FDA's workload during AGDUFA II.

Additionally, the fee revenue distribution has been modified from 30 percent for application fees, 35 percent for product fees, and 35 percent for sponsor fees under AGDUFA I to 25 percent for application fees and 37.5 percent for both product fees and sponsor fees under AGDUFA II. The purpose of changing the fee distribution is to increase the stability of the revenue stream and reduce application fee costs.

The total five-year revenue for AGDUFA I was \$27,100,000. The proposed total five-year revenue for AGDUFA II will be \$38,100,000, which also includes one-time IT funding in the amount of \$850,000 for FY 2014 for a first year planned total of \$7,328,000.

CONCLUSION

FDA's ADUFA and AGDUFA legislative proposals represent considerable input from and agreement of stakeholders, the public, and the Agency. ADUFA and AGDUFA are widely regarded as extremely successful programs. The recommendations we have submitted for reauthorization of these programs will ensure FDA has a stable workforce to provide the predictable and timely review process that drug sponsors need to foster innovation. They also will provide for expedited access to new therapies for food-producing animals and companion animals, while still ensuring that the drugs are safe and effective. FDA looks forward to working with you and your staff to achieve a timely reauthorization of these important human and animal health programs.

Thank you for the opportunity to discuss the ADUFA and AGDUFA programs. I would be happy to answer any questions.