

Animal Generic Drug User Fee
Act (AGDUFA) Public Meeting

*Monday,
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**Food and Drug Administration
Center for Veterinary Medicine
Animal Generic Drug User Fee Act (AGDUFA) Public Meeting
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A F T E R N O O N S E S S I O N

(1:00 p.m.)

*Call to Order**by Aleta Sindelar*

MS. SINDELAR: Okay. Okay, it is 1:00 o'clock, and that clock is fast, by the way, and I would like to welcome everyone to the afternoon meeting. This is the Animal Generic Drug User Fee Act Public Meeting. My name is Aleta Sindelar, and I serve the Center for Veterinary Medicine as the Exec Sec for the Veterinary Medicine Advisory Committee.

This afternoon, we are meeting to receive your comments on AGDUFA I program as we move forward with reauthorizing AGDUFA II. Your comments are intended to improve and strengthen the future program. Today's meeting will be structured as follows:

We, CVM, will be providing a brief review of the program to date.

This will be succeeded by the open public comment period.

The registered speakers for this session have been grouped according to stakeholder interests and will be first to the mike. Following the completion of their remarks, we will open the mike to the floor. Thank you very much for your efforts to attend this meeting and for commenting upon this very important program.

So it is with great pleasure that I introduce our Center Director, Dr. Bernadette Dunham again.

(Applause)

Welcome

by Dr. Bernadette Dunham

DR. DUNHAM: Déjà vu, we are back again. We welcome back everybody. Thank you so much. And right now we are going to look forward to your comments on the AGDUFA II public meeting.

So, once again, why has this particular program been so important to both human and animal health?

Well, CVM has been very successful at reducing the time for completing the review of submissions, accelerating the time to approval for generic animal drugs. AGDUFA has enabled CVM to provide a more efficient and timely evaluation of generic animal drugs and we have certainly removed an awful lot of the backlog, which has been a real forward motion.

We also have been able to, again, help to avoid some of the national animal drug shortages that negatively impact animal health and agriculture. We have also created a competition in the market, a place to keep animal drug affordable for the animal owner. I think we have seen the role of generics on the human side and it is opening up more and more on the animal side.

So at this point, because it is our first movement

for AGDUFA to go into its first reauthorization -- we are very thrilled to have this happen -- once again we are going to have Dr. Steven Vaughn, Director of the Office of New Animal Drug Evaluation, talk further about the accomplishments of this program and the performance measures that we have used for the AGDUFA program. And after Dr. Vaughn finishes, again we look forward to hearing from those that will present and also for you to present your comments to the docket. And again, the two questions that were provided in the *Federal Register* Notice are: What is your assessment of the overall performance of the AGDUFA program thus far? And, two, what aspects of AGDUFA should be retained, changed or discontinued to further strengthen and improve this important program?

So, once again I thank you for your participation and I look forward to your comments. Dr. Vaughn?

Comments

by Dr. Steven Vaughn

DR. VAUGHN: Good afternoon, and for those of you who were here this morning, welcome back, and I apologize that you are going to be sitting through, at least for the first 6 slides, remedial CVM drug review 101. Afterwards, I will show you a few new slides that I didn't show you this morning that have to do with AGDUFA.

(Slide)

So, first off, as we said this morning, we are

committed to a sustainable, world class pre-market review organization to meet the therapeutic and production drug needs in the U.S.

(Slide)

We protect public health by insuring an adequate amount of safe and effective new animal drugs to meet the therapeutic and production needs of animals.

(Slide)

We do this -- this means, basically, protecting public health, which includes human, animal and environmental health; employing the applicable science to make high quality decisions, and understanding the economics of the animal health industry. It also includes efficiently conducting quality reviews, keeping unsafe and ineffective drugs off of the market, and expeditiously approving those that are safe and effective.

(Slide)

AGDUFA, as ADUFA, is a program of fees to provide enhanced, predictable review performance that meets the industry, Congressional and public expectations. It is a stable revenue stream through the implementation of actually three fees, each generating the same level of income in a given fiscal year.

(Slide)

The performance goals for AGDUFA I are listed here.

Again, we use sentinel submissions, like we do in ADUFA. Then you can see the time frames that need to be met, and the time frames for performance are commensurate with the revenue that is generated from the user fee programs. And so you can see for the ANADAs, which are abbreviated New Animal Drug Applications, a little drop from 700 days to 270. The Administrative ANADAs will go down to 100 days. Manufacturing supplements will go down to 270. The JINAD is our internal coding in our tracking system for generic INADs, and those data submissions will go down to 270 days, and then for protocols will go down to 100 days.

The performance as of September 30th, 2010 -- again, at the bottom row is the denominator, is the total number of submissions that were reviewed, and the numerator, the number that were completed and were in the cohort and completed on time, showing a 99 percent on time.

(Slide)

Some other accomplishments. We have eliminated the backlog for generic animal drug submissions. We are continuing to work for increasingly challenged review, performance goals that are outlined in the previous chart, and we have developed a guidance for industry that is for generic drugs -- it is 169, Drug Substance Chemistry, Manufacturing, and Controls Information.

(Slide)

And starting in this fiscal year, as of October 1, we request an amendment to or incomplete certain submissions; a sponsor may request to amend other similar submissions it has pending. Then what this does is, because there was a long lag time from the time a sponsor submits an application or submission until we have time to be able to pick it up and review it, if there is a submission that is higher up in the queue that we go through and we find some things that need to be fixed, a sponsor has the ability to fix those in those submissions that may not yet have been reviewed so that we don't have to go through another review cycle. So that just started on October 1 as part of our negotiated goals in AGDUFA I. And I believe that is all I have. Thank you.

MS. SINDELAR: Okay. Okay, now we would like to begin with the open public comment period for this meeting. The presentation of remarks have been grouped by stakeholder interests. Those are regulated industry, scientific and academic experts, veterinary professionals, and patient and consumer advocates. Each group will be afforded up to 20 minutes for their presentations.

Our first speaker, and representing industry, is Ms. Stephanie Batliner, Teva, speaking on behalf of the Generic Animal Drug Alliance. Thank you.

Remarks

by Stephanie Batliner

MS. BATLINER: Good afternoon. It is such a big crowd. Can you hear me okay back there?

I am Stephanie Batliner. I am the Chairperson of the Generic Animal Drug Alliance. I am also employed at Teva Animal Health. However, my comments today are on behalf of Generic Animal Drug Alliance and represent the comments and the feelings of our membership, not of Teva Animal Health specifically, so there is my disclaimer, so I didn't have to bring lawyers with me to the meeting.

(Slide)

The Generic Animal Drug Alliance is an independent professional trade organization, in fact, the only trade organization representing the interests of generic animal health companies. Our members are focused on the development, approval and marketing of high quality generic drugs for livestock and pets, creating more options, and making the cost of care for all animals affordable for ranchers, farmers and pet owners.

(Slide)

Why are generic animal drugs important? They are a cost effective alternative providing our end users a choice in their animal health treatment options. We use a value equation in the direction of the pet owner and producer, value equaling benefit over cost.

Also, we would like to think that the increased

competition by generic companies could help shorten the innovation cycle, encouraging pioneer companies to develop new products and technologies as their existing products have generic competition.

(Slide)

And then, why a user fee program for generic drugs, generic animal drugs? At least at the time of this -- of the implementation of AGDUFA, there was no user fee program for generic human drugs. At that time, cost effective generic products were delayed in getting to the marketplace. Our review queues at CVM were long and getting longer. One review cycle was predicted to climb to over 700 days. So if you just think about what that really means, that you make a submission and it is more than 2 years, or nearly 2 years, before you hear back. So there was definitely a lack of predictability and timeliness of the review process, and this was discouraging developing of generics. Companies were looking at generic animal drugs and deciding not to pursue them because of the uncertainties in the length of time involved with the process. And for those of us generic animal drug companies that already had approved applications, those applications were also impacted by these long review times, making it difficult for us to maintain and make improvements to our existing products.

(Slide)

So the first question posed in the *Federal Register* Notice: What is your assessment of the overall performance of the AGDUFA program thus far? It is really almost a little too early to say.

We have been through about three years of the program and so far, generally, AGDUFA is working, and we are satisfied. CVM is outperforming the review queue performance goals dramatically, in many cases. Our CVM and sponsor communications have increased. This is helping us as sponsors to provide more quality applications to the review process. The regulatory process is more predictable.

However, I don't think that we are really seeing yet that overall time to approval is decreased, and so that certainly is something that we are going to keep an eye on as we move forward. However, we do feel like the AGDUFA I program was a good compromise for a comparably small generic animal drug industry. We didn't get all the way that we wanted to get in terms of review times. We didn't get where we wanted to be, but we feel like it was a really good first try.

(Slide)

So in terms of the impact of the user fee program in generic animal health for applications, the number of applications and reactivations has decreased, looking at the 5-year average from before the user fee program and now.

Before the program, there were 44 either applications or reactivations per year. Currently, there are 25 in that 5-year average. You know, a question that we asked ourselves as we look at this number is that, you know, has the number of approvable submissions going into that review queue really decreased? There was -- you know, now there is a lot more incentive to think carefully before you submit a product that may or not be viable to the review process. So we are hopeful that our sponsors are doing more homework and that those 25 applications and reactivations that are getting there are the truly viable and approvable products. And if that is the case, if that approvable number hasn't decreased, then maybe there isn't a negative impact in this number.

We do want to keep an eye on at what level does the application fee discourage the pursuit of an approved generic product? We are currently at \$124,900 for an application fee, and so just as a trade organization representing our members, we are looking at, you know, at what point does that application fee become a true decision factor to pursue or not pursue an ANADA?

(Slide)

In terms of other types of applications, it is important to note manufacturing supplements, so those post-approval changes has not changed significantly throughout the program, so the sponsors that have approved products are

maintaining those and continuing to work with those in the review cycles. The number of investigational study submissions has not changed, and I think this is really a positive sign. We are still getting the same number of investigational studies in those review queues. Investigational protocols have decreased by 25 percent.

However, you know, we suspect the protocol review queues were so long before, often sponsors would choose to proceed to studies without having protocol concurrence before they started. Maybe they wouldn't submit the protocols in advance at all, or if they did, they wouldn't wait on the response. And so we suspect as this -- as the review queues for protocols come down, we would expect this number to stabilize or even move in a positive direction.

(Slide)

In terms of listed products, so the list -- the products that are subject to the product fee part of the user fee program, those have decreased. In 2008, there were 626 and now there are 358. The product fee is actually relatively nominal. It is about, let us see, \$6,200. So it is not expected that the fee is truly reducing access to generic products.

Obviously, sponsors cleaned up their drug listings. There was no incentive to do that before. Now there is an incentive to do that. But this isn't a bad thing. This is --

it is good housekeeping. There just wasn't an incentive program behind it before.

And then there are some circumstances within animal health that are not a result of the user fee program that have reduced the number of drug-listed products as well. The thing we want to keep an eye on in terms of the health of the generic animal drug industry is that, you know, has this made it so that there is less generic representation in the marketplace overall? The generic products are still making it to the end users, but maybe not in multiple private label formats. That is okay, that is still -- still getting access to those products is the important measure that we want to keep an eye on.

(Slide)

In terms of sponsors, this is, I think, a really positive category to look at. The number of sponsors has increased.

Part of the generic user fee program implemented a tiered approach to assessing sponsor fees because we wanted to encourage those sponsors that were just getting started to maybe have a little extra help. And so sponsors that had 7 or more ANADAs in 2008, there were 11. There were 11 sponsors that held between 2 and 6 ANADAs, and there were 28 sponsors that held either 0 or 1 ANADA. Now, we have 12 with 7 or more, 13 with between 2 and 6, and 38 with either 0 or 1.

So our existing sponsors have gained approvals, moving them up a category in three instances. And then new entities have chosen to pursue generics. So we are really encouraged about what that has to say for our industry.

(Slide)

So the second question: What aspects of AGDUFA should be retained, changed or discontinued to further strengthen and improve the program? We believe that the performance goal in sentinel submission concepts are working. We would like to see continued progress toward a 180-day review cycle. Our first program got us to 270, and again I feel like that was a really good compromise and it got us a lot of the way to where we would like to be, but we would like to keep working on that. We would like to see the continued CVM and sponsor interaction.

You know, I am hopeful that CVM is seeing the benefits of that as much as I think I see it from our member companies and we are hopeful that those -- the submissions that are getting to CVM are of higher quality when they get there. And we would like to focus on reducing overall time to approval.

(Slide)

So, Generic Animal Drug Alliance is interested in sustaining and improving the health of the generic animal drug industry and we believe that a well designed AGDUFA program

can be an important component in meeting that objective.
Thank you very much.

MS. SINDELAR: Thank you, Ms. Batliner. Our next speaker representing scientific and academic experts is Dr. Ted Mashima, Associate Executive Director for Academic and Research Affairs, Association of American Veterinary Medical Colleges, AAVMC.

Remarks

by Dr. Ted Mashima

DR. MASHIMA: Good afternoon, everyone. I am Ted Mashima, the Associate Executive Director, as she has already said, for Academic and Research Affairs for the Association of American Veterinary Medical Colleges, AAVMC. The AAVMC represents all 28 colleges of veterinary medicine in the United States, 9 U.S. Departments of Veterinary Science, 8 U.S. Departments of Comparative Medicine, and other national and international veterinary academic institutions. We are grateful for this opportunity to provide comments to the Food and Drug Administration's Center for Veterinary Medicine.

Our AAVMC member institutions are supportive of the research that is necessary to bring to market the animal drugs that protect animal health, relieve animal suffering, conserves animal resources and promotes public health. Faculty at our member institutions are currently engaged in the research that leads to the development of animal drugs and

are interested in future collaborative research in these areas.

The AAVMC is supportive of the concepts and activities promoted under the Animal Generic Drug User Fee Act and we support the extension and enhancement of the user fee programs.

Again, thank you very much for allowing us to make comments.

MS. SINDELAR: Thank you. Thank you, Dr. Mashima. Next, remarks by the veterinary professionals will be represented by Dr. Ashley Shelton-Morgan, Assistant Director, American Veterinary Medical Association, AVMA. Welcome back.

Remarks

by Dr. Ashley Shelton-Morgan

DR. SHELTON-MORGAN: It like déjà vu.

(Laughter)

DR. SHELTON-MORGAN: Thank you. Good afternoon, everyone. As she said, my name is Ashley Morgan and I am an Assistant Director with the American Veterinary Medical Association's Governmental Relations Division. I am here this afternoon on behalf of the AVMA, the largest veterinary medical association in the world. The association is comprised of over 81,500 members which represents approximately 83 percent of veterinarians in the United States and who are involved in a myriad of areas of veterinary

medical practice including private, corporate, academic, industrial, governmental, military and public health services.

The FDA Center for Veterinary Medicine's procurement of drug sponsor user fees and how those user fees are utilized are topics of keen interest to the veterinary profession. The effective utilization of these fees is important to veterinarians because we are key purchasers, customers and end users of many of the drugs that are ultimately approved by the FDA.

I am here today to underscore that the AVMA supports user fees for new animal drug applications only if such fees are directed toward expediting the review and approval process for animal drug products. We support means to expedite drug approvals because our patients benefit when we have adequate medicinal options for patient care. We desire a greater number of approved animal drugs for use in veterinary medicine so that we can be certain we are treating our patients with the best care possible. Our clients expect the best care possible and our patients deserve it.

If antimicrobial animal drug sales and distribution data collection are to be continued through the AGDUFA process, the AVMA supports more specific data collection to improve usability of the data. As more specific data are collected, we encourage clarity and transparency in the interpretation and reporting of the data so that it is not

subject to misinterpretation.

The AVMA appreciates the FDA's work to utilize user fees towards expedited drug approvals, yet we contend that additional work is needed to attain the program's ultimate goal of increased and expedited drug approvals.

The AVMA looks forward to continuing to be a part of discussions related to the anticipated reauthorization of the AGDUFA, particularly any components to the program that would be anticipated to affect veterinary medicine specifically.

The AVMA appreciates the opportunity to provide feedback to the FDA today. Thank you.

MS. SINDELAR: Thank you, Dr. Morgan. Mr. Steve Roach, who was here earlier, prepared remarks on behalf of the patient and consumer advocates. He had to leave earlier today and noted that his remarks will be submitted to the docket. Those remarks will also be submitted on behalf of Food Animal Concerns Trust and of Keep Antibiotics Working.

So this concludes the presentations by the registered speakers.

At this time, we invite any additional comments from the floor. Please remember to state your name and your affiliation.

(No response)

MS. SINDELAR: Okay, this officially concludes the AGDUFA open public comment period and I invite Dr. Dunham back

to the mike. Thank you.

Wrap-Up and Closing Remarks

by Dr. Bernadette Dunham

DR. DUNHAM: Thank you very much. So once again I do thank you all for your critical and important feedback on the AGDUFA program and look forward to any further comments that you might want to submit to the docket.

So what is next? In Congress's wisdom and foresight, they have outlined a very interactive, transparent process for us to follow. Over the next few months, we will start negotiations with industry. Although the negotiations will not be public, there are several ways and touch points that will provide opportunities for all of us to stay involved in the process.

First, we will publish the Minutes of each negotiation session with the regulated industry on the FDA Internet website. These Minutes will seek to summarize any substantial proposals and/or significant controversies or differences of opinion during the negotiations and their resolutions.

Second, we will keep the AGDUFA public comment docket open during the entire process for any additional comments that you may want to provide to us.

And lastly, once agreement on AGDUFA has been reached and we anticipate this to also occur mid- to late

summer, we will do three things: First, publish such recommendations in the *Federal Register* and provide a public comment period of 30 days; hold another public meeting, at which time the public may present its views on such recommendations, and, three, after consideration of such public views and comments, we may revise the recommendations as necessary.

We anticipate that this process will in fact conclude by mid-January, 2013 and then we will transmit the AGDUFA package to Congress.

We at CVM once again extend a very sincere thank you for everybody coming out today to share your comments and we look forward to seeing you in any further public meetings. And for those that have come in from out of town, we thank you so much for doing so. Appreciate your sincerity, your comments, and we welcome further comments as this goes forward, and we also wish you very safe travels back home and we will see you again soon.

So, thank you for coming out today. Thank you,
Aleta.

(Applause)

(Whereupon, the meeting adjourned at 1:27 p.m.)