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PUBLIC MEETING ON RECOMMENDATIONS FOR GENERIC GRUD USER FEE AMENDMENTS (GDUFA) REAUTHORIZATION

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Welcome and Introduction

00:00:03 **Alison Lyndaker:** Good morning and welcome to this public meeting on the proposed enhancements for the reauthorization of the Generic Drug User Fee Amendments or GDUFA. My name is Alison Lyndaker and I will be your moderator for today.

00:00:18 GDUFA is the legislation that authorizes FDA to collect user fees to support the process for the review of generic drug products. The current authorization of the program, GDUFA III, expires in September 2027. Preparations are therefore underway to reauthorize the program for fiscal years 2028 through 2032. The purpose of today's hybrid meeting is to gather input and recommendations from the public following publication of the draft commitment letter. Today's meeting is an important step in engaging with public stakeholders on features of the GDUFA program.

00:00:56 We have a full agenda for our meeting today. We'll begin with Grace Graham, Deputy Commissioner for Policy, Legislation and International Affairs, who will provide opening remarks. Then, we will have FDA presentations given by Kathleen Davies, Senior Advisor to the CDER Director; Kendra Stewart, Director of the Office of Regulatory Operations; Rob Lionberger, Director of the Office of Research and Standards; Ashley Boam, Director of the Office of Policy for Pharmaceutical Quality; and Angela Granum, Division Director in the Office of Finance, Budget and Acquisitions.

00:01:35 We will then have presentations from regulated industry. A Public Stakeholder Perspective session will then occur at the end of the meeting for those who have submitted a request in advance. And, if time allows, we will hear open public comments from in-person attendees who would like to speak. I will then close this meeting at around 12:00 p.m.

00:02:00 Each speaker throughout this meeting has a time limit. As we do have a full agenda, we will need to adhere to that timeframe. It will be my job to let speakers know as they approach their time limit. On the podium, there is a timer countdown. At one minute

remaining, it will flash yellow and when your time has expired, it will be a flashing red light.

00:02:25 Policy issues are beyond the scope of GDUFA reauthorization. Therefore, the presentations should focus on process enhancements and funding issues, not on issues of policy. This meeting is an opportunity for FDA to listen to public perspectives. FDA will not ask questions nor answer questions raised in the meeting. Even if you cannot see us in person, please know that my colleagues who are leading and participating in the reauthorization process are here. We are listening and we very much so value your perspectives.

00:03:04 Please keep in mind that you can submit public comments to the public document up until October 17th. We encourage everyone to submit their perspectives to the public docket for FDA review. You will receive the link to the public docket in the follow-up meeting next-- Follow-up email next week.

00:03:24 A few housekeeping items. This public meeting is in a hybrid format. We thank all speakers for their efforts to prepare for this meeting and we thank viewing participants for your patience as we navigate this hybrid meeting. If your audio or visual connection diminishes, we recommend trying to reconnect through the system. If you experience other technical issues during the webcast, please email GDUFAreauthorization@fda.hhs.gov.

00:03:56 We will not have a formal Q&A session today. We will, however, have a 15-minute break at about 10:15. If schedule modifications are needed due to technical issues, we will communicate those verbally and through the meeting chat. For those of you attending the meeting in person, restroom facilities are down the hall to the right of the conference room. Also, for those of you attending in person, there is a kiosk outside the great room with coffee and snacks available for purchase.

00:04:28 A video recording and transcript of today's meeting as well as the slides presented will be published on the FDA website after this meeting. I will now turn it over to Grace Graham,

deputy commissioner for policy, legislation and international affairs for some opening remarks.

Opening Remarks

00:04:51 **Grace Graham:** Thank you, Alison. Good morning, everyone. Welcome to the public meeting on the proposed enhancements for GDUFA IV. I want to thank everyone for joining us today, both in person and virtually. This meeting marks an important step in our ongoing commitment to ensuring Americans have access to safe, effective, and affordable generic medicines. Making medicines more affordable is a top priority of this administration and increasing competition for generic drugs lowers drug prices and improves access for American patients and consumers.

00:05:22 Along with congressionally appropriated funding, the support of GDUFA user fees paid by the generic drug industry has helped the FDA accomplish so much. This includes advancing scientific research to support development of generic drugs, as well as taking a number of actions to bring greater predictability and timeliness to our assessment of generic drug applications. Over the course of GDUFA III thus far, we've approved, or tentatively approved, over 3,500 ANDAs, including over 350 first generic medicines, 500-- over 500 with competitive generic therapy designation, 400+ complex generics, and over 300 generics to address drug shortages.

00:06:07 In addition to our reviews, per our commitments under GDUFA III over the last four years, we've had over 70 additional performance enhancement commitments, whether it's guidances, public meetings and workshops, public reports, and updating programs or processes, all with the goal of timely access to more affordable generic medicines. The real-world impact of this work is significant. Generic drugs account for approximately 90% of prescription dispensed in the United States, saving patients and the healthcare system hundreds of billions of dollars annually.

00:06:40 The approval of the first generics I mentioned has increased drug competition and the focus on complex generics has expanded access to affordable versions of critical medications for conditions like cancer, HIV and rare diseases. And as we look toward GDUFA IV, we're building on this strong foundation while addressing emerging and ongoing challenges, such as supply chain vulnerabilities and dependencies.

00:07:02 I want to thank my FDA colleagues who work tirelessly to negotiate this agreement, keeping patients and stakeholders informed throughout the process through meetings and by posting minutes and have organized and put together this meeting today. We wouldn't be here without them and it's an agency-wide effort. While this meeting will get into further details, I want to highlight a few provisions in the proposed user fee recommendations.

00:07:26 First, as I mentioned already, onshoring critical generic medicines is a top priority and these recommendations reflect that goal in many ways by first making targeted process improvements for domestic manufacturing, waiving the fee for the first fully domestic application, earlier inspections for U.S. finished dosage and API facilities, and making sure the facility fees are more accurately reflecting the increased cost for FDA inspections at overseas facilities. In addition, the fee structures move toward more predictability by reducing reliance on application fees over time and better communication through streamlined meeting structures and controlled correspondence improvements.

00:08:07 As FDA prepares to transmit our recommendations for reauthorization to Congress and consider implementation of GDUFA IV, we look forward to the feedback today and reviewing comments submitted to the public docket mentioned earlier because the success of GDUFA is not on FDA alone. Stakeholders have and will continue to play a key role in coming up with these recommendations and it will take all of us working together to get the reauthorization done on time.

00:08:35 FDA will transmit GDUFA IV to Congress by the January 2027 deadline and look forward to working with our colleagues on the Hill to get the legislation signed into law by the

September 30th, 2027 deadline. Any delay can mean a delay in affordable medications for patients and I know we all share a desire to avoid that outcome. So, I look forward to the discussion, the feedback today, and I want to thank you again for attending.

GDUFA IV Background and Reauthorization Process

00:09:06 **Alison Lyndaker:** Thank you, Grace. I would like to now introduce Kathleen Davies, Senior Advisor to the Center Director in CDER to provide background on the GDUFA and an overview of the reauthorization process.

00:09:27 **Kathleen Davies:** Thank you, Alison, and thank you, Grace. So, I'm going to go through just a little bit of the background. I'm not going to spend a lot of time on it. We covered a lot of it in the initial public meeting in July, which is available online on our website for the GDUFA reauthorization. So, you're welcome to go back and look at any of that if you have further questions. But ideally, I want to get to the meat of the presentations, which is you all hearing about our recommendations.

00:09:55 So, moving through just the basic GDUFA background. So, user fees are important to the timeliness review of applications. Before GDUFA, similar to the other user fee programs, our medical product review timelines were big concerns. Enactment resulted in much more predictable and streamlined processes, and reduced our review and approval times. I want to remind folks that fee funds are added to appropriated non-fee funds, and are intended to increase staffing and other resources to speed and enhance our review process. And I also want to bear in mind that user fees pay for services that directly benefit the fee payers but are not a fee-for-service.

00:10:38 Just to briefly highlight what we've done throughout GDUFA since it was enacted in 2012, our first cycle, GDUFA I, which went through fiscal year 2013 to 2017, that was the first one that really created sort of the framework for us to have standardized review timelines and streamlined processes, and set programmatic goals. As we moved into GDUFA II, we further refined this process through fiscal years 2018 to 2022. We specifically were

focusing on reducing our review cycles to approval, increasing approvals for safe, high-quality, lower-cost generic drugs. We looked more at improving our review goals for priority applications, and we introduced communication touchpoints with industry and focused on our review of complex generic drugs.

00:11:28 The current reauthorization-- The current user fee cycle that we're in now, which is 2023 through 2027, continues to do further enhancements that we've done through GDUFA I and II. We also introduced some finance refinements in GDUFA III and we are looking forward to taking all of what we've learned from GDUFA I through III, and through our negotiation process to work into GDUFA IV.

00:11:55 Grace touched on this a little bit, but I wanted to specifically highlight how well the GDUFA program has worked and evolved over time and really emphasize some of these accomplishments. So, when we started GDUFA I, while we were increasing the timeliness of reviews, we were still at 40 months and we've increased-- I'm sorry, we've decreased this to over a year. So, we're down to about an average of 26 months for review, which I think is a huge accomplishment for the volume of generic products that we get for review.

00:12:26 And as of July 31st, Grace highlighted this, but I think it's really important to note that 3,500 ANDAs is a large volume of work that we are doing and it should be recognized, all the hard work that the review offices do to get these done. In addition to those ANDAs, they are also successfully reviewing prior approval supplements, other discipline review letters, information requests, and controlled correspondences. So, I think it's just really important to sort of take a moment and recognize the amount of work that gets done through the support of the user fee program.

00:13:08 I'd like to remind folks as they look through the presentations today and hear the presentations that these fee process renegotiations are done with industry and other stakeholders and they focus on enhancements in terms of the process for the review. As Alison noted, it's not specifically on policy content. We are looking specifically at-- So,

we've gone through this cycle, we're at the end of GDUFA III, what new or enhancements need to be done as we go to the next five years and the next reauthorization cycle. When we're doing that, we're looking to see what is technically feasible that we can do this with, and what resources do we need in order to sustain these enhancements.

00:13:52 So, moving on, I'm going to just walk through the reauthorization process. This shouldn't be new to anyone. We kicked off this reauthorization process with our public meeting back in July. As I noted, we have a website that has that on there with the transcript and a video of that if you'd like to watch that in more detail. We started negotiations in October of 2025. We met monthly with stakeholders. Those minutes are also on the website for anyone who would like to review those.

00:14:22 And we met with industry multiple times a week to work through this process and all of those minutes are detailed and listed on the website as well. We concluded negotiations with industry by the end of March 2026, and we have been working diligently with our partners at HHS and above to finalize the commitment letter into a draft state that we can present to the public, which was published over the summer.

00:14:47 So, we are at the public meeting stage. Once this public meeting has concluded, we will seek your feedback. We'll review every comment that we get through the docket. We'll review the comments we've heard today. Once the docket closes, we'll take into consideration those comments and we will go back into clearance with the document, make any changes that we deem may be necessary with that goal that Grace indicated of getting this to Congress by January 2027.

00:15:15 So, just to highlight, we have gone through various statutory requirements for the reauthorization. We are at the point now where we are getting ready to do our public review of recommendations, and that is this meeting today.

00:15:36 So, what I'll do quickly is I will go through the highlights of the recommendations and then I'm going to turn it over to the review teams that worked through this and the negotiations

to sort of walk through each section of the commitment letter. And, as we do that, I want to be mindful of the fact that there are sections toward the end of the commitment letter that relate to MAPPs and guidances. They will be highlighted throughout the process as we go, we're not going to do a separate section on those specifically.

00:16:02 So, for GDUFA IV, we are proposing to maintain the generic drug program resources, including the funding to support our critical technical and scientific staff. We are creating new efficiencies that will be discussed that do not increase the cost of the program, but instead focus on streamlining the program. We also have a goal of increasing financial transparency among industry, FDA, and the public. Across the commitment letter, you'll also note that we have removed one-time commitments completed under GDUFA III. We have replaced review goals that were phased out during GDUFA III with consistent goals that will be sustained in GDUFA IV, and we have maintained all of our established programs.

00:16:42 With that being said, the remainder of these FDA presentations will be an overview of these draft commitments that we've negotiated with industry and with feedback from stakeholders, and you will hear from the various FDA regulators and scientists that were vital to the successful completion of this negotiation. Thank you.

ANDA Assessment Enhancements (Commitment Letter (CL) Section I & II)

00:17:09 **Alison Lyndaker:** Thank you, Kathleen. Now, Kendra Stewart, Director of the Office of Regulatory Operations, will discuss the proposed enhancements to ANDA assessment as outlined in sections I and II of the proposed GDUFA IV Commitment Letter.

00:17:34 **Kendra Stewart:** Thank you, Alison. Good morning. As Alison mentioned, I'll be covering two key sections of the commitment letter, sections I and II, covering ANDA assessment enhancements, and I'll be highlighting some of the key changes being proposed for GDUFA IV.

00:17:52 So, starting with section I, enhancements have been proposed in the commitment letter that directly improve how FDA manages and responds to applicant inquiries. More specifically, GDUFA IV introduces a new tiered structure for controlled correspondence, which is our formal question-and-answer pathway between applicants and FDA. So, these levels, now referred to as Level 60, Level 90, Level 120, provide for clearer and more intuitive labels that align with FDA response times.

00:18:32 Under GDUFA IV, applicants will also be required to use a pre-assigned ANDA number allowing for connected records, which will make it easier to track prior communications across an application's life cycle. As well, a new 90-day response timeline for specific complex correspondence topics has been added to complement the existing 60- and 120-day tracks.

00:19:02 Lastly, definitions for all three levels have been updated in section X to provide clear eligibility criteria and avoid ambiguity in submission classification, and we've maintained the 90% goal for each level of the controlled correspondence. 90% performance goal.

00:19:23 So, turning now to section II, which contains the most significant operational changes to the ANDA Assessment Program. The enhancements in this section are designed to improve transparency and communication between FDA and ANDA applicants by implementing changes that both increase predictability, streamline the review process, reduce cycles to approval, and ultimately expand patient access to generic drug products.

00:19:54 Key themes that I intend to highlight across section II include earlier communication of deficiencies, more structured goal date management, and new pathways for applicants to engage with FDA following inspections. These changes reflect lessons learned from GDUFA I through III, as well as from stakeholder feedback.

00:20:17 So, as mentioned earlier, one of the key commitments of GDUFA has always been about reducing the number of review cycles required before an application reaches approval. Section II of the GDUFA IV Commitment Letter takes meaningful steps toward that goal

by providing for updated review timelines and introducing new communication touchpoints throughout the assessment process.

00:20:45 A significant addition is the establishment of targeted timelines for consult issuance and response with the aim to get responses to consults back before the midpoint of the review cycle. This is intended so that those results can be incorporated into the mid-cycle review letter and hopefully minimize the number of delays due to pending consults.

00:21:10 As well, labeling assessment timelines and processes have also been updated to provide for redline labeling reviews for prescribing information and patient labeling, and a commitment to issue DRLs by the midpoint of the review cycle. So, this should give applicants the opportunity to address any labeling deficiencies within the current review cycle.

00:21:35 And finally, the definition of review status updates has been revised in section X to clarify what information the regulatory project manager is expected to provide to an applicant requesting a status update, which is at a minimum, the categorical status of the relevant assessment discipline across labeling, bioequivalence, quality disciplines, now broken down by drug substance, drug product, and facilities, and then REMS, if applicable.

00:22:13 In addition to the reduction in review cycles, GDUFA IV also introduces a more structured and transparent framework for managing goal dates when review timelines are affected by unresolved issues. So, in GDUFA IV, there's a new option that allows applicants to elect a single 90-day goal date extension at the time of application submission. So, this is a proactive mechanism that supports better planning for both the applicant and FDA.

00:22:46 When FDA anticipates missing a goal date by more than 60 days, including in cases involving complex data issues, we are committing to assign a new goal date six months from the original. If that second goal date is also not met, FDA will offer a meeting with the applicant to discuss the path forward. So, this ensures transparency and shared accountability at every stage.

00:23:18 Two new extensions address inspection-related circumstances. First, we have a 90-day extension following a post-pre-approval inspection meeting, or post-PAI, as it is also known, as well as a 120-day extension for potential OAI or Official Action Indicated alerts, which will provide FDA the time needed to finalize inspection classifications and take appropriate action within the same review cycle. And collectively, these provisions give both FDA and applicants more structured tools to manage unexpected delays without losing progress made in the review.

00:24:03 As Kathleen mentioned, throughout the commitment letter, in different sections, it alludes to new guidances and MAPPs. And so, in section II, GDUFA IV includes specific commitments to update internal policies and issue new guidance to operationalize the program enhancements with defined deadlines included in the commitment letter for each.

00:24:27 So, MAPP 5200.12 will be updated to reflect refinements for review status updates, ensuring that both FDA reviewers and applicants share a consistent, current understanding of an application status at any given point in the review. There will also be a new guidance on best practices for ANDA submissions. This is intended to help applicants provide the information that FDA needs upfront, in particular for those issues requiring consults.

00:25:03 This guidance will also be supported by external FDA-led training on a recurring basis to ensure broad awareness across the industry. And additionally, a new MAPP on the imminent action process will formalize FDA's approach when only minor remaining issues stand between an application and approval, specifically issues that may be resolvable within 60 days after the goal date.

00:25:35 GDUFA IV significantly strengthens transparency and performance reporting through an expanded set of metrics across monthly, quarterly, and annual reporting. Monthly metrics will be delineated by complex and non-complex products across key approval categories, including final approvals, tentative approvals, first-cycle approvals, first-time generics, and imminent actions.

00:26:07 Quarterly reporting will similarly break down mean and median approval times by product complexity, providing industry and the public with a more precise and actionable view of program performance over time. The annual fiscal year performance report will include a new metric tracking missed goal dates for original ANDAs, the number of applications assigned, a second goal date, and how many of these second goal dates were ultimately met, strengthening our program accountability.

00:26:40 Taken together, these proposed enhancements for sections I and II represent a meaningful step forward in how FDA assesses generic drug applications, reducing unnecessary delays, improving communication, and strengthening accountability at every stage of the review. Thank you.

Application-Related Meetings & Additional Program Enhancements (CL Section II & IV)

00:27:08 **Alison Lyndaker:** Thank you, Kendra. Now, Rob Lionberger, Director of the Office of Research and Standards, will discuss application-related meetings and additional program enhancements as outlined in sections III and IV of the proposed GDUFA IV Commitment Letter.

00:27:27 **Rob Lionberger:** All right. Thank you, Alison. Before I talk about the proposed enhancements, I want to remind people that many of the foundations for complex generics and our scientific advice, our regulatory science program and our product-specific guidance program continue from GDUFA III into GDUFA IV, but where we focus the enhancements on our pre-submission advice is through the application-related meetings. And this is a significant change in GDUFA IV and it implements a new meeting structure that intends to simplify the many different types of meetings that we have.

00:28:03 Again, as you look through the commitment letter, the meetings that are already available to applicants in GDUFA III map into this new framework, and we will be issuing a guidance to provide an update on the new framework, and again, our metrics will also be linked into the new meeting framework.

00:28:18 So, this is an overview of the new meeting types. There are four different meeting types. And, from the high-level, to talk about what these meeting types are for. A TYPE 30 meeting is for a clarification. A TYPE 60 meeting is for a substantive follow-up, so asking questions, not asking clarifications. A TYPE 90 meeting is where you're able to bring a new topic into discussion with FDA, and the TYPE 120 meetings are for discussions of multiple topics or more complicated issues that require longer time to resolve.

00:28:52 And the table goes through the details of the format, the grant/denial timelines. Generally, in all of the meetings you'll get a decision on whether the meeting is granted within 14 days, and again, written responses to the meetings will be delivered by the timeline, 30, 60, 90, or 120 days. Again, there'll be some discussion around the-- Those-- Around the meeting minutes and the times that the meetings are held in detail.

00:29:16 So, what are some of the advantages of this new meeting program? One of the first ones is that these allow for faster meeting opportunities, and again, by adding a 60- and 90-day timelines to the meeting framework, we've moved away from where the GDUFA III meetings, almost all of the meetings, required 120 days for our meetings. And it's now by identifying the cases where the scope of the meeting is narrower or it's a follow-up to a previous interaction, we've identified times where we can engage faster on the meetings.

00:29:46 Again, another acceleration point is in GDUFA III, the meeting timelines began with the day you received the meeting grant letter, and here we've moved toward a more normalized format across FDA where the meeting timelines now run from the request, and so that the decision process is now included in that meeting timeline. Again, as part of this, to improve efficiency and allow us to go faster, FDA may convert a meeting to a different type or to a controlled correspondence without rejecting and resubmitting, if that makes the process more efficient or that's the more appropriate way to handle that issue. So, that gives, again, another way that we can move quicker and provide scientific advice for the development of complex generics more efficiently.

00:30:32 Another change in the meeting that allows us to go faster is a more focused meeting process. The TYPE 90 meeting specifically talks about bringing up a single new topic, and the commitment letter outlines these topics, and I've placed them here also for examples. So, an example of a single topic might be to discuss an alternative bioequivalence approach, discuss active ingredient sameness in a single meeting. So, with a more focused topic, then FDA can provide a faster response with a leaner meeting team, and we hope this will improve the overall process.

00:31:05 Again, if applicants want to discuss multiple topics in the same issue, then they can use the 120-day meeting, which is very similar to our current meeting process, which allows multiple topics to be grouped into a larger meeting with a timeline. But you have the opportunity to move faster by focusing the discussion on the most critical issues facing your development program.

00:31:25 We also added more follow-up options into the meeting process. And so, again, as I mentioned at the beginning, the TYPE 30 meeting is a clarification meeting. And so, it can be used across the various types that were already available in GDUFA III. For example, if you wanted to have a teleconference to clarify a complete response letter, that would now become a TYPE 30 meeting. We've added the opportunity to have a formal clarification for a meeting response. In GDUFA III, we already had a process for clarifying a controlled correspondence response, but we didn't have one for meetings.

00:32:00 Using the TYPE 30 meeting, now you can have the same framework for all of the different clarifications. Again, in GDUFA III, you were able to have a meeting to clarify the impact of a product-specific guidance posting, and now that becomes a TYPE 30 meeting in GDUFA IV.

00:32:16 And again, the TYPE 60 meeting, for substantive follow-up, that's where you can ask questions rather than clarifications. That now becomes more accessible to follow up to a controlled correspondence or especially a previous meeting where the meeting left

something unresolved. You can have a faster follow-up to that meeting because FDA has already engaged with the issue and we're just looking at the difference from the previous interactions. Again, all of this is designed to come up with a system where we can move faster under certain conditions.

00:32:47 But GDUFA IV also provides new meeting opportunities. And in the TYPE 30 meeting, you now can request a PSG clarification when the PSG revision changes the recommendations related to in vitro studies. In GDUFA III, this was limited to PSG changes related to in vivo studies. But as we move toward complex generics and in vitro bioequivalence approaches, more and more of the substantive discussion happens outside of the in vitro studies. And so, this expands the ability to get input on product-specific guidance changes affecting complex generics.

00:33:19 In the TYPE 60 meetings, there's a new meeting type in GDUFA IV called the Complex [Generic] Initial Advisory meeting. And this is a way to, before you've generated new data for a potential applicant to discuss a proposed strategy for a complex generic product. Is this strategy going to be feasible? What type of data would FDA need to see to really provide substantive feedback on it? So, this is intended to be earlier in the development process, and this is a new feature of GDUFA IV.

00:33:49 Also under the TYPE 60 meeting, you can request clarifications related to the implementation of a complex product product-specific guidance. We've noted that in many of the cases where we've introduced in our product-specific guidances new approaches for bioequivalence, new types of analytical methods, applicants sometimes have challenges in implementing those because they're not standardized. They're not a standard USP method yet because it's a more innovative approach.

00:34:15 This is a way where you're not saying, "What should I do for bioequivalence?" but "How should I implement that?" And then you can get faster feedback on those implementation

questions, which we hope will lead to better submissions and getting the evaluations correct the first time.

00:34:30 And again, the TYPE 60 meeting also has some improvements to the pre-submission discussions. In GDUFA III, there was a pre-submission meeting for complex generics, but it was mainly focused on orienting the application and didn't have the opportunity for questions. And so, now in GDUFA IV, there is also an opportunity for pre-submission meetings for complex products. We do, again, allow questions again that are follow-ups to previous interactions or summaries of the submission to prepare for a faster and more effective review.

00:34:57 Under the TYPE 90 meeting, we've added things that are not available for meetings in GDUFA III, specifically alternative approaches to a product-specific guidance for a non-complex generic product. So, this previously was something that you could address through controlled correspondence only. Now, there's an opportunity for a meeting around this area. And again, another area that requires more complex interactions is what we call bridging approaches for a non-complex product, when the reference listed drug or reference standard aren't available.

00:35:29 And in these cases, in order to continue generic competition, you have to have more innovative and more challenging discussions about what the appropriate pathway forward is. And we've explicitly called out that that's a topic that's best addressed through a meeting. Again, during GDUFA III, this is something that would have to be a controlled correspondence. So, this is moved into a meeting process where you'll have more discussion around these more challenging issues.

00:35:54 In section IV, there are other enhancements that we think will make the pre-submission process and product development more efficient. So, the first one is a continuation of things that are already in GDUFA III Commitment Letter, the commitment to continue to move the inactive ingredient database to a maximum daily exposure-based format. This is the

standard that FDA uses when we evaluate formulations and we'd like the inactive ingredient database to reflect that. This makes it clearer for product developers to understand what the acceptable levels of different excipients in the products would be.

00:36:33 But a significant challenge in expanding the inactive ingredient database is the need for maximum daily dose data to determine those maximum daily exposure values. And so, what's new in GDUFA IV is a commitment to provide a public database of the maximum daily dose values. This works in parallel with the inactive ingredient database.

00:36:53 And sometimes you think that maximum daily dose is more fundamental. You need the maximum daily dose to calculate the correct maximum daily exposure, but by moving toward a public database with commitments around making these data available, and we'll have a public input process through our regulatory science program to hear improvements in this with the idea that we'll be able to assess what we need to do this more fully.

00:37:18 And I think that there are a lot of opportunities here. Again, both the IID and the MDD are basically FDA trying to understand our internal data better. And as we have better tools and AI tools, we think that there are a lot of opportunities for improvements in there that will result in transparency to the developers as they're developing products. And so we look forward to improvements in both of these areas over the course of GDUFA IV.

00:37:44 Again, some of the other-- The last improvement that I'll talk about is we're going to offer several—in the commitment letter—standardized information formats for ANDA submission. So, these are information that our reviewers need and if it's better formatted in appropriate tables, then it allows them to do their job more effectively. And examples in the commitment letter are providing molecular structures for impurities in a standard format, providing lists of facilities that are used for bioequivalence studies, formatting the PK data correctly in a way that's efficient for the reviewers to analyze the results of bioequivalent studies.

00:38:21 And so, you'll be seeing-- In the commitment letter-- In the course of GDUFA IV, you'll be seeing more of these standardized tables being supported. And we already have several of them for bioequivalence submissions already, but you'll see more of them going forward in this area. And we think that these will make the review of the applications more effective. It puts the data in the format that the reviewers needed to look at it and do their assessment in the most efficient way possible.

00:38:50 So, with that, [I] look forward to our implementation of these new features of GDUFA IV.

DMF Assessment Program & Facilities (CL Section V & VI)

00:39:01 **Alison Lyndaker:** Thank you, Rob. Now, Ashley Boam, Director of the Office of Policy for Pharmaceutical Quality, will discuss the DMF Assessment Program and facilities as outlined in sections V and VI of the proposed GDUFA IV Commitment Letter.

00:39:24 **Ashley Boam:** Thank you, Alison, and good morning. So, the first section I'll talk about today is our DMF Assessment Program—DMF being Drug Master File—and then we'll move to section VI to talk about facilities.

00:39:39 So, in terms of the proposed enhancements in section V, I'll refer you back to GDUFA III, where we have a program that allowed, under certain conditions, the holder of a Drug Master File to submit that Drug Master File and seek FDA assessment ahead of the submission of the ANDA that would incorporate that DMF by reference. This was an important program in GDUFA III and a lot of our discussion centered around how we could expand this program to be even more effective as part of GDUFA IV.

00:40:10 So, in the proposed commitment letter, we propose to expand the eligibility criteria for those DMFs that could be eligible for this early review to include those incorporating a complex API as well as prior approval supplements that are seeking to add a new API source located in the United States.

00:40:30 The enhancements also include a provision for DMF submitters to use a cover letter template that is signed by the ANDA applicant to ensure that there is effective

communication between the DMF submitter and the end applicant that will be referencing that DMF, as well as Form FDA 3938, which includes important administrative information, including, for example, the location of manufacturing facilities, which will, again, make our review more efficient.

00:41:02 So, moving on to section VI, proposed enhancements in the facility section. So, we are introducing a proposal for a new post-pre-approval inspection meeting—sorry, post-PAI meeting—when those might be needed, to provide for a discussion of inspection findings that could impact our ability to approve the application and allow for a facilitative process to hopefully enable the facility to resolve those issues that might hold up an approval. This is an important opportunity for FDA to work with applicants and facilities to hopefully ensure that facilities can be in a state of GMP compliance to facilitate an approval of the ANDA in the most timely manner possible. We also propose to publish a draft guidance to outline this process and how it would work.

00:41:58 We've also included a proposal that is focused on existing facilities, both API and finished dosage form facilities, in the United States who are seeking to expand their capacity to be able to bring on new generic products. So, for such a facility that has not had a surveillance inspection in the last three years, the DMF submitter-- The facility, pardon me, could make a request to FDA for us to conduct a surveillance inspection in advance of the planned submission of the Drug Master File or the ANDA.

00:42:35 The timing around the surveillance inspection has been proposed in a way that would allow FDA to conduct the inspection and to reach a final inspection classification. The intent behind this provision is that if the inspection is a positive inspection, could greatly reduce or mitigate the need to do a pre-approval inspection when the DMF or the ANDA is submitted. If a pre-approval inspection is still needed, we anticipate that it would be a more focused and shorter inspection.

00:43:07 FDA has also proposed as part of the commitment letter that we would report metrics related to these inspection requests so that we and our stakeholders can collectively evaluate the effectiveness of this proposed program to both expanding domestic capacity of generic drugs and to speeding approvals. Thank you very much.

Continued Enhancement of User Fee Resource Management (CL Section VII & Statutory Recommendations)

00:43:37 **Alison Lyndaker:** Thank you, Ashley. Now, Angela Granum, Division Director in the Office of Budget, Finance, and Acquisitions, will discuss the continued enhancement of user fee resource management as outlined in section VII and the statutory recommendations of the proposed GDUFA IV Commitment Letter.

00:43:59 **Angela Granum:** Thank you, Alison. So, as Alison said, I'm going to talk about the finance sections of the commitment letter as well as the statutory recommendations that drive FDA's fee setting and administration activities.

00:44:14 So, starting with the statutory changes, GDUFA IV generally retains the fee structure that we had in GDUFA III. So, the types of fees that we are authorized to collect will continue into the new authorization. There are one-time fees that are paid related to a submission. So, there's a fee that's paid when a ANDA is submitted, and then there's also a Drug Master File fee that's due either when the first generic drug submission that incorporates or that references that associated DMF is submitted, or the date on which the DMF holder requests the initial completeness assessment, whichever comes first.

00:44:54 There are also two categories of annual fees currently authorized in GDUFA III that will continue under GDUFA IV. The generic drug applicant program fees are charged based on the number of ANDAs in an applicant's portfolio, and then facility fees are applied to facilities that are referenced in an approved generic drug submission, and this includes both API facility fees and finished dosage form facility fees, and contract manufacturing organizations pay a portion of the full FDF fee.

00:45:27 So, in GDUFA IV, we're generally aiming to keep the total target revenue for the program stable. The base target revenue for 2028 is going to be set to 730 million, which reflects inflationary growth from the end of GDUFA III and may be adjusted further for capacity planning and an operating reserve in FY 28. The agreement retains the inflationary adjustment, which allows the program to keep pace with any general increases in costs, as well as the capacity planning adjustment, which could provide additional resources for any sustained increase in workload that we see in GDUFA IV, but does not add any other negotiated funding for new positions. The agreement also retains the operating reserve adjustment throughout GDUFA IV and shifts to lower ANDA fees in order to stabilize program revenue.

00:46:19 So, getting into some of the details of the statutory changes here. The first two are related to FDA's domestic manufacturing priorities. The first is to increase the foreign fee differential that facilities pay for all API, FDF, and CMO facilities from the current 15,000 dollars to 25,000. That amount will not be adjusted for inflation during GDUFA IV and will stay at 25,000 for the duration of this authorization. The recommendations also include a one-time fee waiver for the original ANDA submission fee the first time that a domestic applicant satisfies requirements to have both the FDF manufacturer and API suppliers referenced in an application all located in the United States.

00:47:09 In order to improve GDUFA revenue predictability, we're shifting or proposing to shift the percentage of target revenue that's allocated to the ANDA submission fees to 26% from the current 33% and redistribute that allocation to the program fees. So, they'll go from 36% to 43%. The annual program fees are a much more predictable and reliable source of revenue than the submission-based ANDA fees. We're also establishing an annual set-aside of fee collections to support restaffing, and the unexpended amounts of fees will be subject to the operating reserve adjustment each year.

00:47:48 Finally, we're proposing to change the date that's used to establish program fee liability to be earlier in the fiscal year. Moving that earlier in the fiscal year allows us to account for any changes in companies' portfolios prior to setting fees and is expected to improve predictability of program fee collections in GDUFA IV.

00:48:09 In order to provide similar treatment for facilities and, again, allow the population of fee-paying facilities to be better understood at the time of fee setting, we will be-- Excuse me. Any facilities first identified in an approved generic drug submission after May 1st will also be exempt from the upcoming year's fee.

00:48:30 So, moving on to the commitment letter section. First, we have several commitments related to financial transparency. FDA is committing to a discussion of the consolidation effort for shared services in the GDUFA 5-year financial plan that's published each year. We're also committing to annual reporting on the funds that are set aside for restaffing and retaining technical excellence. And finally, we're proposing a technical staff meeting related to program finances in order to improve general stakeholder understanding of those finances and public meeting minutes to be published after.

00:49:09 And finally, in order to better align with some of the payment timelines that many companies have for their major invoices, FDA is committing to make the cover sheets for the annual GDUFA fees available no later than August 5th or the next business day each year. We're also going to be adding language to our website to ensure that all stakeholders understand those timelines and can adhere to them.

00:49:40 **Alison Lyndaker:** Thank you, Angela. The FDA's presentations have now concluded. We will take a 15-minute break before transitioning to presentations from regulated industry. We will reconvene promptly at 10:05.

Industry Presentations

01:04:58 **Alison Lyndaker:** Welcome back to our GDUFA public meeting. As a reminder, if you experience technical issues during the webcast, please email

GDUFAreauthorization@fda.hhs.gov. Folks in the room, can we quiet down please? Also, please keep in mind that you can submit comments to the public docket open until October 17th. We encourage everyone to submit their perspectives to the public docket for FDA review.

01:05:31 Before the break, we heard presentations from the FDA. Our next session will be regulated industry perspectives. First, we have Giuseppe Randazzo, Senior Vice President for Sciences and Regulatory Affairs from the Association for Accessible Medicines. Giuseppe, you may begin.

01:05:56 **Giuseppe Randazzo:** Thank you, and good pronunciation. Hi, everyone. Good morning. My name is Giuseppe Randazzo. I'm the Senior Vice President of Regulatory Affairs-- Sciences and Regulatory Affairs, at the Association for Accessible Medicines. Our members collectively manufacture over half of the FDA-approved generic medicines dispensed in the U.S. On behalf of our members, we thank you for the opportunity to speak here today to support the reauthorization of GDUFA IV. We strongly support the commitments we negotiated and that are reflected in the commitment letter.

01:06:26 Before I go any further, I would like to take a moment to congratulate Dr. Mike Davis on his recent appointment as Director of CDER. AAM welcomes his leadership and looks forward to working with him and the rest of his CDER team to advance our shared commitment to ensuring patients have timely access to safe, effective, high-quality, and affordable medicines.

01:06:45 A number of FDA offices participated in the GDUFA negotiations. I'm sure I'm going to miss a few, so I would like to thank, specifically, of course, OGD, OPQ, Office of Center Director, OII, and the Office of the Commissioner. For those I missed, my apologies.

01:07:02 This public meeting marks an important step in the reauthorization process. It offers us an opportunity to discuss the proposed enhancements to the Generic Drug Program. As everyone in this room knows, and online, GDUFA has played an essential role in

strengthening the generic review program and process, helping ensure that patients have timely access to safe, effective, and again, high-quality affordable medications.

01:07:27 Generic drugs and biosimilars represent 89% of all prescriptions dispensed in the U.S., but unfortunately only 11.6% of expenditures on prescription drugs. Over the past 10 years, savings from generic drugs and biosimilars have totaled 3.6 trillion dollars. These savings underscore the essential role generic medicines play in supporting and sustaining our healthcare system in the U.S. We deliver unparalleled value to patients, payers, and taxpayers alike. Continued investment in the generic program is critical for the American health system.

01:08:02 I had about a page and a half of background, but thankfully—Kathleen, thank you very much—I can skip most of that. You guys do know, and I'll mention briefly, of course, this all started prior to, but officially, in 2012. And the only thing I will reflect upon is, at that time, there were approximately 2,800 backlog applications and people from all over the center at that time, not just OPQ, not just OGD, really took a step up and reviewed many of those applications. So, we thank them for that.

01:08:34 Specifically GDUFA IV. Going into the GDUFA IV negotiations, we wanted to build upon the success of the current program and previous GDUFA iterations, recognizing, of course, despite its success, there's still room for us to improve. First-cycle approval rates for ANDAs remain significantly below the level industry and FDA should collectively seek to achieve. Multiple assessment cycles continue to consume both FDA and industry resources and, unfortunately, delay patient access to affordable medicines.

01:09:06 While we have made good strides on complex generics, as Rob mentioned, they continue to pose a challenge. They have fewer first-cycle approvals and make up a higher percentage of eligible generic drugs without generic competition. During these negotiations, we focus on how to enhance communications, how to streamline the assessment process, how to

improve the outlook for complex generics, and how to improve the inspection and post-inspection process.

01:09:35 At the start of these negotiations, we all realized that these were unique-- Recognized these negotiations were unique, recognizing the significant resource constraints facing FDA and the continued economic pressures on the generic sector. FDA and industry aim to achieve modest, meaningful, and cost-neutral improvements to the program, and we believe we did that. Maintaining a sustainable and predictable user fee structure is essential because disproportionate fee growth can discourage submissions, reduce market penetration and participation, and ultimately undermine competition and patient access.

01:10:12 Our overachieving objectives were to make the generic drug assessment process more transparent, more predictable, while ensuring the Generic Drug Program remains effective and agile in a rapidly evolving scientific and policy environment. The proposed commitment letter, or CL, addresses many of our objectives and I'll highlight some of those today. And again, fortunately, I may go through them rather quickly because Rob, Ashley, others went through quite a few, so thank you for that.

01:10:40 Several of the commitments are intended to help reduce the number of assessment cycles by identifying and resolving deficiencies earlier to reduce the number of CRLs—or Complete Response Letters—and minimize review cycles. For example, a number of the commitments address labeling deficiencies, which are to be identified and communicated earlier in the assessment process.

01:11:02 Recognizing that consults from OGD to other offices sometimes may delay application assessments, the proposed commitment letter seeks to identify the need for consults earlier in the process when feasible in order to obtain a timely response from these requests. FDA can then aim to convey deficiencies no later than the mid-cycle. Consistent implementation across consulting offices will be particularly important, so an applicant can respond

promptly to the FDA and, of course, that depends on receiving complete, coordinated, and actionable feedback.

01:11:37 Ashley discussed DMFs and, as we know, ANDAs rely on DMFs, some of which contain confidential information about the API used in the manufactured generic products and, unfortunately, is not always available to ANDA applicants. Obtaining a successful FDA assessment to the DMF early interview process can prevent delays in approvals. The previous GDUFA program included a provision for DMF prior assessment. Unfortunately, these are not widely used due to the restrictive eligibility.

01:12:08 We attempted to expand the utility of this program in GDUFA IV. Ideally, while some of the changes may be small, hopefully they are significant and will help expansion of the eligibility for this program.

01:12:21 As with other UFA programs, frequent and effective communication between applicants and FDA is crucial and critical. With this, goals of scheduling and holding meetings and handling controlled correspondence feature prominently in the current program, as Rob got into. The proposed GDUFA IV Commitment Letter streamlines the meeting process by folding in GDUFA III meeting types into a new structure. Again, as Rob mentioned, Type 30, 60, 90, and 120. We removed some of the rigid criteria and implemented new timelines.

01:12:55 We also established a new meeting such as the Complex Generic Initial Advisory meeting. This reflects that complex generic products often require earlier scientific engagement, coordinated advice across disciplines, and greater certainty that development recommendations will remain reliable as programs advance. The new meeting structure uses a consistent format and terminology and aims to create efficiencies and greater predictability, not only for FDA, but, of course, for the applicants.

01:13:26 As Kendra mentioned, we also enhanced the control correspondence process. For example, we moved a subset of Tier 2—now known as Tier 120—topics in a newer tier and shorter

90-day tier. Finally, we work to eliminate the need to provide copies of previous correspondence to FDA as long as a pre-assigned ANDA number exists.

01:13:50 Individuals in our space understand that issuing CRLs, or Complete Response Letters, leads to another complete review cycle. The proposed commitment letter updates this process and criteria for goal date extensions. This seeks to enhance the balance between predictability and avoiding unnecessary CRLs, which, from our perspective, helps the FDA and industry, and most importantly, the patient. For example, applicants will be able to choose between two approaches at the outset of the assessment cycle.

01:14:19 The first is the existing framework. This allows multiple goal date extensions under certain circumstances. While that may sound counterintuitive to some, those extensions can allow an application to be approved within a single cycle, which ultimately can be faster than receiving the CRL. Additionally, and alternatively, an applicant can choose a single 90-day extension, similar to the approaches used in PDUFA and BsUFA.

01:14:47 Separately, to provide additional process guardrails for ANDAs stalled by certain complex issues, the proposed letter would direct FDA to assign a new goal date to such ANDAs and issue outstanding unrelated IRs by the original goal date so an applicant can continue to work on its ANDA while the application remains pending. Additionally, if FDA has not acted by the new goal date, FDA will offer a meeting to discuss outstanding issues.

01:15:18 In the inspection realm, which I'll talk about in two ways, a new proposed provision offers a pre-- Excuse me, a post-pre-approval inspection meeting, as Ashley mentioned, again, to facilitate resolving any issues identified during the inspection that could be resolved during the same cycle. If additional information is submitted, the FDA may extend the goal date by 90 days.

01:15:42 We also worked through one of the industry's pain points and that had to do with pending OAIs. Sticking with the inspection realm in these pending OAIs, currently, if FDA conducts a surveillance inspection and identifies potential violations that could lead to an

OAI—or Official Action Indicated—and the goal date generally can sometimes fall between that 90-day timeline for classification; at this point, the practice is FDA will typically issue a CRL. We attempted to address this in GDUFA IV and we believe we did so. Instead of issuing a CRL, the FDA will extend the goal date to give FDA time to determine whether inspection is, in fact, OAI. If it isn't OAI, if it's VAI, for example, the application can be approved in that same cycle.

01:16:32 In addition to these enhancements, several of the provisions in the proposed commitment letter will increase transparency, ideally leading to increased efficiency in this process. In GDUFA IV, we negotiated what I see as better tools. Rob mentioned this. FDA will commit to certain enhancements to its IID—Inactive Ingredient Database—along with establishing a maximum daily dose database. The intent of these tools will be used to increase transparency and provide generic drug applicants with more information upon which to base their applications and meet FDA expectations, thus leading to more approvals.

01:17:11 As Grace mentioned to open up the session, the proposed commitment letter also contains provisions intended to encourage domestic manufacturing, such as providing for earlier inspections of certain U.S. manufacturing facilities, creating eligibility for DMF prior assessments for new U.S. API sources, and increasing the foreign di-- Fee differential.

01:17:33 AAM and our members support the administration's goal of increasing supply chain security and resiliency, although many essential incentives remain, unfortunately, outside of their FDA's purview.

01:17:44 In closing, GDUFA is a vital public health program that supports the development, assessment, and approval of generic medicines. AAM strongly supports the proposed GDUFA IV Commitment Letter and its practical incremental improvements. While this process was a huge undertaking for both sides, the true measure of success will be consistent implementation, earlier and more actionable communication, fewer avoidable

review cycles, greater transparency, and more timely access for patients to affordable medicines.

01:18:16 We look forward to continue to work with the FDA, Congress, patients, and other stakeholders to ensure GDUFA IV delivers the outcome while sustaining a competitive generic medicines market. Thank you.

01:18:34 **Alison Lyndaker**: Thank you, Giuseppe. We'll now have Gil Roth, President of the Pharma & Biopharma Outsourcing Association. Gil, you may join.

01:18:51 **Gil Roth:** Hi, I'm Gil Roth, the President of PBOA, or the Pharma & Biopharma Outsourcing Association, the organization that represents the contract manufacturing organizations out there. I want to thank FDA and our industry partners throughout this negotiation and for today's meeting. Giuseppe said most of what I would have gotten around to saying, so I'm going to keep my comments relatively brief.

01:19:14 This is my third GDUFA negotiation. I launched PBOA in order to bring CMOs to the table when it comes to negotiating GDUFA and making sure that we are part of the fees that are adjusted, part of the commitments that are made, and that we have a seat at the table. I'm not looking forward to a fourth negotiation because it means I'll be 60, which is not an age I'm looking forward to, but I am glad we can make this program work for the filers, for manufacturers and suppliers, and ultimately for patients.

01:19:49 So, among the aspects of this negotiation that were of particular interest to us was the-- We'll say the containment of costs and sustainability of the finances moving forward. Facility fees are something my members are very sensitive to and it's part of why we have a carve-out for CMOs within the finished dosage form space. We were glad to see that we could continue to negotiate effective improvements and sort of marginal enhancements to the program without significantly increasing the cost base going forward.

01:20:22 In addition, I was gratified that this time around, there's actually some agency given to CMOs as part of the enhancements that we've negotiated, specifically through the post-PAI

meetings that have been proposed under GDUFA IV. In this event, the facilities themselves will be able to request those meetings with FDA and it will not be subject solely to the filer's discretion. This is, from a CMO perspective, a significant change.

01:20:49 And it's something that I know it'll get Josh Brown mad over there because it's out of scope with GDUFA, but we hope it's a step in creating a direct pathway between CMOs and CDER when it comes to inspectional issues at facilities that could impact multiple filings, not just a single company's filing. This is something that we think with greater communication and a sort of meeting pathway that would stretch beyond GDUFA—because it would affect NDAs and BLAs also—would ultimately improve the ability to get more filings approved in a timely manner.

01:21:29 So, when we talk about manufacturing and some of the America First proposals that were included in these enhancements, we're in support of what the final package contains, including the increase in the foreign differential, the-- We'll say a sort of facility fee waiver if the first ANDA application in a facility is approved after May 1st of that year.

01:21:55 At the same time, this was a very different negotiation than the previous ones I was engaged in because of some of the staffing issues that have taken place at FDA. So, we have concerns with staffing back to GDUFA III levels and then how we're going to achieve some of the goals that we negotiated for GDUFA IV, but through quarterly implementation meetings and working closely with FDA, we hope to see this get back to full strength.

01:22:21 Along the same lines, we're hoping the shared services model that FDA is adopting is something that will ultimately provide significant enhancement going forward. But that is stuff for another day. Ultimately, the commitment letter that we've negotiated, the enhancements that are in place, PBOA is in support of. We believe it will enhance the inspection of facilities, make sure that the operations that are producing these drugs for so many patients are actually up to speed, quality, safe, and providing things in a timely manner.

01:22:53 So, thank you very much for your time and thanks again to our friends at FDA.

01:23:04 **Alison Lyndaker:** Thank you, Gil. Now we have Deborah Attwood from the Bulk Pharmaceuticals Task Force. Deborah, you may begin.

01:23:16 **Deborah Attwood:** Good morning. My name is Deborah Attwood, and thank you for the opportunity to speak today on behalf of the Bulk Pharmaceuticals Task Force.

01:23:23 BPTF represents manufacturers of active pharmaceutical ingredients, intermediates, and excipients. Our members share FDA's fundamental objectives, assuring the quality of medicines, improving the efficiency and predictability of the Generic Drug Program, and strengthening the supply of essential pharmaceutical ingredients to U.S. patients. BPTF thanks FDA for the productive discussions and collaborative effort to develop the performance goals and program enhancements that are now reflected in the GDUFA IV Commitment Letter.

01:23:56 BPTF wishes to highlight several components of the commitment letter that are particularly relevant to the API industry. While some of these items might seem minor, the collective impact is significant to a highly competitive industry. Simply put, every little bit makes a difference. The changes I will highlight will improve communications with the Agency, strengthen regulatory predictability, and support domestic API manufacturing competitiveness. Collectively, these efforts will lead to greater efficiency in generic drug review cycles and more timely access for U.S. patients to needed quality generic drugs.

01:24:39 First, as has been done already, I will highlight the improvements that will enhance the communications to resolve more effective and efficient resolutions. So, as you've already heard, FDA has committed to establishing post-pre-approval inspection meetings through which an eligible facility may discuss inspection observations, proposed corrective actions, and issues that could affect application approval. This ability to proactively discuss these matters with FDA and to receive specific actionable feedback during the meetings should enhance both parties' ability to resolve issues within the relevant assessment cycle.

01:25:25 And as also previously highlighted, FDA has committed to expanding the DMF Prior Assessment Program to provide review of four new DMFs for complex APIs and 12 prior approval supplements for a new domestically manufactured API source. So, that, while meeting the timeline commitments, provides manufacturers early agency feedback on what is a significant regulatory commitment. Adding a qualified API source diversifies the supply chain and protects against disruptions that impact U.S. patients.

01:26:02 The next group of enhancements I will highlight help to provide regulatory predictability for the API industry. Eligible U.S. generic API facilities that are expanding production may request a surveillance inspection before submitting the associated regulatory documentation. For a domestic manufacturer considering new capacity or a new generic API, the opportunity to establish inspection readiness earlier can reduce uncertainty at a critical point in the company's investment and product development cycle.

01:26:41 Additionally, the goal to provide reports from remote regulatory assessments helps facilities to understand FDA's thoughts and conclusions from its examination of potentially extensive documentation requests, particularly when these assessments are used in lieu of inspections.

01:26:59 And then finally, we appreciate—BPTF appreciates—FDA's recognition that regular surveillance GMP inspection supports the ability of U.S. API manufacturing to sell its quality products globally.

01:27:14 The final group of items I will address are on enhancing the competitiveness of the U.S. API supply chain-- We really do appreciate the seemingly minor commitment to make annual fee cover sheets available earlier. This is a small thing, but it does reduce the risk that qualified API manufacturers would be considered non-compliant with its GDUFA fee obligations. Second, as several people have highlighted, improving the Inactive Ingredient Database will streamline generic drug review and improve transparency, bringing needed drugs and their APIs to U.S. patients more quickly.

01:27:55 Then, as also previously discussed, the renegotiated fee structure provides substantial domestic facility registration fee reductions. Along with the one-year facility fee exemption for the first DMF for an API facility, these financial measures are significant to manufacturers operating in the highly competitive API market.

01:28:17 In closing, BPTF supports the negotiated GDUFA IV program. The proposal contains real improvements in communication and regulatory predictability and commits to actions that will strengthen the U.S. API supply chain. BPTF looks forward to continued engagement with FDA and appreciates the opportunity to provide its support for the progression of the GDUFA IV commitments. Thank you.

01:28:49 **Alison Lyndaker:** Thank you, Deborah. This concludes the regulated industry session. We are going to take a brief pause to set up for the virtual public commenters. We will resume in five minutes.

Public Stakeholder Perspectives

01:34:59 **Alison Lyndaker**: Thank you, everyone, for your patience. We will now resume the meeting. If you can take your seats in the room. Folks in the room, if you could please take your seats. Thank you.

01:35:12 We'll now hear comments from members of the public who have registered in advance of this meeting. I will call on each person individually at the start of their time, and they will have five minutes to give their remarks. At the five-minute mark, I will ask you to conclude, and then I will introduce the next speaker. If you are in person, please come up to the podium when I call your name. First, we will have Sumiya Mushtaq, an independent researcher, virtually present.

01:35:49 **Sumiya Mushtaq**: May I start? Good morning. I'm Sumiya Mushtaq, a pharmacist with an MBA and a decade of experience preparing generic drug submissions across international markets. I'm speaking in my individual capacity with no financial interest in how GDUFA

III's stated intent to reduce assessment cycles is measured. Cycles depend on applicants as well as FDA. So, I am asking about measurement, not targets.

01:36:25 My point comes from FDA's own Fiscal Year 2025 Performance Report. The GDUFA III cohorts cannot yet show whether cycles have fallen, and FDA's text says Table 20 reports mean approval times for fiscal year 2023 through fiscal year 2025 receipt cohorts as 533, 411, and 271 calendar days. Read quickly, that looks like steady improvement. The text introducing that table on page 39 says the figures include only applications approved or tentatively approved and that approval times and cycle counts will increase with each re-analysis.

01:37:10 Tables 2 through 4 show how early these cohorts are. Standard original ANDAs with a completed action: 569 of 569 in year 2023, 500 of 559 in year 2024, 29 of 400 in year 2025. But a completed action includes complete response letters while the approval time table counts only approvals. On FDA's own caveat, none of the three cohorts is yet mature on the approval measure and FDA labels the year 2025 results preliminary.

01:37:50 My first ask is a change to the letter. Table 20 reports an approval time and a cycle count by receipt cohort, but not how many applications produced them. Appendix C shows the fiscal year 2025 standard original cohort with one approval and no tentative approvals. I ask that section IX, Performance Reporting, require the number of applications behind each cohort figure.

01:38:15 Second, section IX(C)(3) commits FDA to report the mean and median number of assessment cycles to approval and to tentative approval by cohort, mean and median only. That sentence is carried forward word for word from GDUFA III's section X(C)(3), while the list around it was revised, and an average can fall while the multi-cycle tail does not move. I ask for one added item: the distribution of assessment cycles to approval, the share approved in one, two, three, and four or more cycles by receipt cohort. Both change how results are reported, not the goals, and neither reopens anything negotiated.

01:39:00 The letter is a floor, not a ceiling. If amending it is not practical, FDA can publish both in the performance report regardless. One caution on interpretation: goal date adherence and cycle count can diverge. Section II.B.3.b of the draft letter says, and I quote, "If an ANDA is approved or tentatively approved within 60 days after the goal date, the goal date will be considered to have been met," so an application can meet its goal date and still have taken several cycles.

01:39:33 My ask is only that goal date adherence not be read as evidence of the cycle reduction objective. In short, do not judge the intent on immature cohorts and publish the cycle distribution. That is one of the clearest ways to know whether generics reach patients sooner. I will file the detail as a supplemental comment to docket FDA-2025-N-0873. Thank you.

01:40:01 **Alison Lyndaker:** Thank you. Next, we have Michael Abrams, Senior Health Researcher from Public Citizen.

01:40:11 **Michael Abrams:** Yes, good morning. Can I be heard okay?

01:40:13 **Alison Lyndaker:** Yes.

01:40:15 **Michael Abrams:** Excellent, thank you. I'm Dr. Michael Abrams, Senior Health Researcher with Public Citizen. We are a nonprofit consumer research and advocacy organization with over a million supporters, and I have no financial conflicts of interest related to today's discussion.

01:40:31 Having reviewed the latest draft generic-- Or GDUFA commitments and having participated on the non-industry stakeholder side, such as it is, of these generic and other user fee negotiations over the last many months, I have two concrete suggestions related to GDUFA. First, the generics commitments should promise to create an FDA-based reporting structure that informs the public when manufacturers fail facility inspections. This system must be timely and must name the specific drugs implicated so that prescribers and consumers stay current on manufacturing problems related to their medications.

01:41:19 In 2025, the independent news service ProPublica created its own manufacturing database to fill this gap. That database allows users to look up medications by generic name, manufacturer name, National Drug Code numbers that appear on the bottles of their prescriptions, to determine the basic fact of where their drug was manufactured and whether or not there were any inspection concerns associated with that facility. ProPublica created this resource because their reporting in 2025, which we brought up during these GDUFA discussions, observed the following about the FDA. It sometimes quietly allows substandard factories to continue shipping drugs even if they were banned for importation. The FDA does not regularly test the quality of those imported generics even when they are sourced from concerning facilities. And the FDA, it seems, routinely redacts drug names from its inspection reports.

01:42:30 We believe, as part of these commitments, the FDA should fix these problems in great haste. Prescribers and patients depend upon the Agency for such critical information about the specific drugs they use. As I said, I and others have brought this up, this inspection database suggestion up during the non-industry stakeholder meetings, apparently to no avail. We thus encourage this apparent error of omission and the commitments to be corrected before any of these commitments in letter form or otherwise are transmitted to Congress.

01:43:03 Secondly, the FDA should make in its commitments specific regulatory promises to optimize the disclosure of the Drug Master File information so that generic makers can release pharmaceutically equivalent drugs sooner, as opposed to later, after a patent expires. Presently, the FDA's inactive ingredient database we think is only listing presumably inert chemical components of the drug. It's not-- Though it mentions the active ingredient and only gives maximum concentrations rather than more precise concentrations and rather than connecting it to the specific active ingredients that it may be used with.

01:43:55 Separately, the Orange Book does list patents connected to a given branded drug, but formal evaluation by the Federal Trade Commission recently suggests that those entries in the Orange Book are often incomplete and inaccurate. Because patent thickets, sometimes even including things like REMS protocols in these patents, are a key barrier to efficient generic drug creation, mediating reasonable information flow from brand to generic makers should be developed as an essential aspect of the FDA's drug regulatory effort, and thus added explicitly to written commitments that you're asking Congress to allow you to proceed on.

01:44:42 In summary, this comment suggests two straightforward additions to the generic drugs commitments draft, both proposing information resources, one for patients, one for prescribers-- One for patients and prescribers, that is, and the other for manufacturers. And the former advances the generic drug, we think, the one for prescribers and patients, advances generic drug safety and effectiveness. And the latter allows drugs to get to market sooner, reasonably priced generic drugs to get to market sooner. Finally, I would like to note that the two suggestions proposed here for GDUFA are also relevant to the biosimilar meetings that are going on now and the commitments that are going on now. We hope that FDA is harmonizing these certainly related efforts. Thank you.

01:45:44 **Alison Lyndaker:** Thank you, Michael. We will now transition to in-person presenters. First, we have Diana Zuckerman, President of the National Center for Health Research.

01:46:05 **Diana Zuckerman:** Thank you. Thank you very much, and I want to thank you for giving us a podium today, which we did not have at PDUFA yesterday. It's really much more helpful. I'm Dr. Diana Zuckerman, President of the National Center for Health Research, and our nonprofit think tank recognizes that generic drugs are the foundation of our healthcare system in the United States and that the regulation of these drugs is the most important work, I would say, the most important work of this very important agency of the FDA. So, GDUFA really deserves much more attention than it's received from stakeholders

thus far because all of us are stakeholders, because all of us use generic drugs. So, we appreciate that GDUFA has reduced the backlog of generic drug applications. Everyone agrees that that's terribly important and a very wonderful accomplishment.

01:47:09 But I personally, and our center, have growing concerns that many of us share that FDA has won this important battle, but we are losing the war. And what is the war? The war is public trust. That was a war that we won years ago. Everybody assumed that generic drugs were equivalent to brand-name drugs and not everybody assumes that anymore. There've always been patients who doubted it, but the doctors never doubted it. And at this point, there are doctors and researchers who have reason to doubt it.

01:47:47 So, let me give some examples. More than a year ago, we had-- Let me just say, more than a year ago, we had submitted a public comment for GDUFA to recommend enhancements to strengthen public trust in generic drugs. And despite considerable agreement from patient, consumer, and public health organizations involved in the stakeholder meetings, none of these recommendations focused on public trust were included in the commitment letter.

01:48:20 So, why has there been this loss of trust? There has been a series of devastating investigations of news articles and nonprofit, and for example, some of them from the nonprofit ProPublica media organization that Dr. Abrams mentioned. They've reported years of problems, not just that there were problems with manufacturing, but that FDA had learned about these problems and not publicly disclosed them. I'll give just a couple of examples. Sun Pharma was banned due to egregious problems on inspection reports, and yet more than two dozen of their drugs were shipped to the United States and sold to patients. And that included pills and injectable medications that otherwise should have been and would have been banned, but they went to unsuspecting patients across the country, including those with serious diseases such as cancer and epilepsy.

01:49:32 ProPublica asked, "Did FDA at least routinely test these medications that were going out to patients to find out about what was happening to the patients taking them?" They interviewed former CDER director, Janet Woodcock, who was quoted saying, "We felt that we didn't have to make it a public thing, so it was not made public." And those of us who know Janet Woodcock know that she can be very honest and are not too surprised that she said that.

01:50:07 In another example, the FDA determined that a testing company in India named Synapse faked and forged data submitted to the FDA. In that case, the FDA did the investigation. They withdrew bioequivalence ratings for 400 drugs that were tested by Synapse, but those drugs stayed on the market for over a year and patients weren't informed. This decision was very dangerous obviously to patients, but it was also unfair to the companies, the generic companies whose safe and effective medications were competing with those 400 drugs. And it's unfair to all generic companies that make excellent medications when patients don't know which generic drugs are safe and which ones aren't.

01:51:07 FDA should be on the forefront of conducting testing to make sure that generic drugs on the market are safe. And at the stakeholder meetings, several of us recommended that GDUFA IV pay for more inspections, more post-market testing, and for staff whose job it will be to warn patients and pharmacies about specific dangerous generic drugs, but that didn't happen.

01:51:35 The commitment letter does include some improvements, I think, for inspections, but this bigger issue of disclosure has not been addressed. I just want to quickly say I support Dr. Michael Abram's recommendations that GDUFA Commitment Letter should include an FDA-based reporting structure that informs the public when manufacturers fail inspections. If ProPublica can do it, surely FDA can do it and do it even better because they have access to information that no private entity would ever have.

01:52:10 To regain public trust, we urge the FDA to add performance goal metrics that focus on safety and equivalence in GDUFA IV in the ways that I've suggested, and it's not just enough to have the information. FDA needs to follow through on banning unsafe drugs even when it might result in shortages, because it's better to have a shortage than to have unsafe drugs on the market, and also that FDA make those decisions very public and accessible to all patients.

01:52:44 **Alison Lyndaker**: Your time has expired.

01:52:46 **Diana Zuckerman**: Yes, I know. I just have one more sentence. I just want to say we agree with Dr. Abrams also that GDUFA should make regulatory commitments to optimize the disclosure of the Drug Master File information so that generic drug makers can release their drugs as quickly as possible after the last patent on the drug expires. Thank you very much.

01:53:13 **Alison Lyndaker**: Thank you, Diana. Next, Suzanne Robotti, Founder of the MedShadow Foundation.

01:53:26 **Suzanne Robotti**: Hi, my name is Suzanne Robotti and I am the founder of MedShadow Foundation. I'm also the executive director of DES Action USA, and I served for seven years on the FDA Advisory Committee for Drug Safety and Risk Management.

01:53:42 The FDA states on its website that FDA-approved generic medicines work in the same way and provide the same clinical benefits and risks as their brand-name counterparts, but unfortunately that's not always true. For the past two years, MedShadow has been investigating the quality of generic drugs in the marketplace. What we have found is that after approval, generic drugs can perform differently from its brand-name equivalent, even differences between two generics based on the same brand-name drug.

01:54:11 GDUFA understandably puts enormous emphasis on creating clear pathways for approval. For generic drugs, approval is a snapshot in time. Safety follows the lifespan of the drug. Post-approval, manufacturing processes may change. Suppliers, equipment, and facilities can change. Drugs travel through complex supply chains. Quality can change all after

approval. Let's remember the therapeutic benefit is already available to patients in the brand drug.

01:54:42 GDUFA should shift its focus from speedy approvals, which you have achieved—congratulations—to stronger oversight of post-marketing safety. GDUFA is authorized to support post-market activities for ANDA-approved drugs, although we heard nothing about it earlier today. Post-marketing commitments were discussed in GDUFA meetings and negotiations on January 14th and February 19th of 2026, according to the minutes.

01:55:12 MedShadow and other investigative organizations have documented problems with generic drugs involving potency, purity, dissolution, contamination, manufacturing consistency, and whether products continue to perform as expected after approval. Differences can be especially consequential with drugs that have narrow therapeutic windows. For example, we reported on work by Lisa Salberg of the Hypertrophic Cardiomyopathy Association and Dr. Harry Lever involving generic tacrolimus. Independent laboratory testing of drugs obtained from the marketplace from different manufacturers showed substantial differences in dissolution in about 10% of the products tested.

01:55:55 And patients are telling us that they noticed problems. When MedShadow posted a TikTok about inconsistent effectiveness of generic ADHD medicines, it went viral. It was viewed by more than 186,000 people and more than 900 people shared their comments about their own experiences online, some of them sent videos. Most of the post-marketing quality and safety system now in place is reactive. It can be triggered by patient complaints, reports on patient harm, or problems discovered after a product has already reached patients. If patients have to be used as the early warning system for America's generic drug supply, then the response from manufacturers and the FDA must be early to minimize harm. It must be quick. It must be effective.

01:56:42 The proposed GDUFA IV agreement contains extraordinarily detailed performance goals for the FDA, deadlines for reviews, inspections, meetings, blah. Where are the comparable-

- Sorry about the blah. Where are the comparable performance goals for assuring the continuing quality of generic drugs after approval? Please measure and enforce the safety measures you already have in place. And how can the FDA and manufacturers find, read, and respond to safety signals much, much earlier? GDUFA recognizes accountability goes both ways already: the requirement for generic drug facilities to self-identify annually. There are no published metrics that I can find for compliance, however.

01:57:28 ARPA-H recently announced FASTPASS, an initiative to develop technology capable of rapidly screening pharmaceuticals for quality as they enter and move through the U.S. supply chain. That's amazing. GDUFA should be prepared to incorporate these new capabilities developed through FASTPASS and other emerging technologies.

01:57:47 Finally, we need transparency. In 2024, the FDA identified significant data integrity problems at Synapse, but I'm going to skip the story because we just covered it. What the FDA did was you had to go into the Orange Book, which is very complex, to determine whether the generic drug they needed for their health had a BX rating. MedShadow also did a TikTok on that and it got something like-- And I didn't write this down, I apologize, but something like 52,000 views on how to use the Orange Book correctly.

01:58:25 The FDA should take the lead in developing a system connecting every dispensed generic to current FDA qualification. A QR code could easily tell patients and pharmacists about dosage changes, about who manufactured the finished drug and where, whether the product or lot has been recalled, and whether FDA has changed its therapeutic equivalence determination. The FDA already has this information connected to the product in the patient's hand.

01:58:51 So, our request for GDUFA is simple. Increase resources for stronger oversight of post-marketing safety, add abilities to find, read, and respond to safety signals sooner, and make important product information easily available to the people who are taking the drugs. Patient harm should not be the quality control system for America's generic drug supply.

On a final note, in a recent survey conducted by Kantar for MedShadow, two-thirds of Americans said they would pay more for medicines if they were tested by an independent lab, and I bet you would too. Thank you.

01:59:34 **Alison Lyndaker**: Thank you, Suzanne. Finally, we have Patricia Kelmar, Senior Director, Health Care Campaigns, from U.S. PIRG.

01:59:47 **Patricia Kelmar**: Good morning. I'm Patricia Kelmar from U.S. PIRG, the public interest research group. We're a nonprofit consumer advocacy organization unaffiliated with any healthcare industry. We work to improve the ability of the American public to find good value. That means high quality products at lower costs. And that's why we participated in the public stakeholder section of the GDUFA process.

02:00:13 Last week, a report showed that in 2025 alone, generics and biosimilars created 496 billion dollars in savings for patients and the overall healthcare system. Over the last decade, those savings have added up to 3.6 trillion dollars. I work to lower the cost of healthcare, and let me tell you, there is nothing that Congress is considering right now that gets even close to that kind of savings in our healthcare system.

02:00:45 And so that's why it's so important that we get this GDUFA agreement working, and working effectively. Generic drugs are saving money for patients, meaning patients are more likely to fill their prescription when they receive it, and they're more likely to take that medication as directed instead of rationing their medications. So, this is lifesaving. These are real dollars back in patients' pockets, and we need to make sure that the FDA has the resources to ensure that we have opened more pathways to more approvals and that those generics on the market are safe for patients.

02:01:24 I read through the agreement carefully, and frankly, I found it quite difficult to evaluate whether the many meetings, timelines, and other metrics set out will actually result in more and safer generics. The new reporting metrics are extensive and frequent, but the numbers alone won't show the picture of whether we are actually getting the drugs that the people

need on the market to compete with the brand names. So, tying those numbers to public health goals would be really helpful for the public to be able to evaluate whether this agreement is actually resulting not just in more meetings or swift timelines, but in better health for the public.

02:02:13 We, during the public process and many meetings and-- Staff was great. We only get five minutes here, so I can't thank everybody like Pharma did, but thank you, everyone. We had great stakeholder meetings, but we emphasized a few things and I would just like to talk about a couple of them and then obviously we'll submit further comments. But not to reiterate, but you've already heard it already, but we did ask for greater transparency of facility inspections, especially when deficiencies may harm the public.

02:02:44 I won't restate the various things that Dr. Abrams mentioned, but it does bear repeating that the public does need to know the actionable details when a facility inspection shows some deficiencies. The FDA's practice of redacting drug names in inspection records should be eliminated and GDUFA IV should require greater transparency of inspection findings, outlining the required actions of the manufacturing facility, the drug companies themselves, and even FDA in informing the public about potentially tainted or substandard drugs.

02:03:22 We also asked the FDA to remove some of the impediments that patents play in blocking new generics. According to an FDA study, even when one generic enters the market, prices drop by 40%, but patent thickets stand in the way of these new generic approvals. The FDA may not control patent law, and I understand that, but there are two specific ways that the FDA could minimize patent gaming.

02:03:47 First, interagency collaboration with the Patent and Trademarks Office. A few years ago, the two agencies began an effort to identify and combat the doublespeak that brand-name pharma sometimes engages in, saying to the patent office, "I've got a brand-new drug and it's doing this totally unique thing, so I need a patent," while at the same time telling the

FDA, "Hey, this drug is just like the other drug you approved, and so you should approve this one as well."

02:04:14 We asked for, but didn't receive, an update on how that collaboration is going. We don't even know if it is still ongoing, but spending some portion of the user fees to support and expand that kind of interagency work and collaboration would limit patent gaming. It would put pharma on alert to know that they can't be double-speaking in their applications. And that would result in a win for the generic manufacturer that isn't blocked by a baseless patent and a win for the patients and the public payers who have a new, low-cost generic available to them.

02:04:50 The second FDA tool around patent gaming is the Orange Book. The Orange Book, as you may know, includes information on patents that may protect a brand-name drug from generic competition. The FDA should abandon its hands-off approach to the Orange Book as evidenced by the FTC's recent success in identifying hundreds of patents listed that should have never been in the book and that were blocking generic competition and making litigation more expensive and difficult. We don't have to waste the time of the FTC and use their resources to track down these violations. The FDA itself has specific powers in its own regulations which state that certain patents such as packaging and process patents must not be included. FDA professionals and scientists can certainly distinguish a packaging patent from a patent on a molecule. User fees should be used to better police submissions to ensure that the Orange Book isn't used as a way to block competition.

02:06:00 So, in conclusion, we do really value the FDA's role in supporting our greatest healthcare value today. That's the generic drug. And user fees should prioritize these recommendations to provide us the safest generics as soon as possible. Thank you.

Open Public Comment

02:06:25 **Alison Lyndaker**: Thank you, Patricia. We will now offer the opportunity for Open Public Comment. If anyone in the room did not register in advance and would like to make a

comment, please line up at the microphone stand. As time allows, we will give anyone else who would like to speak a maximum of five minutes to provide comment. Please begin by sharing your name and affiliation.

02:06:53 **Natalia Bk**: Thank you all for your comments and thank you to the FDA for hosting this wonderful collaborative event here today. My name is Dr. Nat Bk. I'm a representative of Sustainable Healthcare Corps. We have submitted and continue to collaborate with the FDA on generic drugs at this and prior conferences, and we've submitted these and several other suggestions on drugs for quite a while now, but here are some of the ones that we would want everyone to hear about today.

02:07:26 For the benefit of all Americans that currently have experienced healthcare adversities from coast to coast, we propose that fluoride recommendations by the American Dental Association be revisited as fluoride, we know, is a poor leaving group and can cause thyroid reductions and overall metabolic syndrome and drug adverse effects for many patients.

02:07:55 Additionally, we wanted safety CASp reports for all associated patients everywhere and for the benefit of Americans with disabilities and all Americans coast to coast, the landscape of American health is overwhelmingly prolonged. Growth and rapid escalation of metabolic syndrome needs to be revisited. And these are not circumstances that are currently required for pre-IND and IND assessments as metabolic syndrome can range from metabolic acidosis to alkalosis, and those are not typically assessed by industry and all submitted applications for INDs and ANDAs.

02:08:32 We've lost too many Americans due to sidelined care for bariatric patients and misclassifications of obesity by cause. If we have that classification standardized by BMI groups and also metabolic syndrome, lispro and glargine dosing, at the very least will have a more effective dosing schedule as well as dosing by some total body water. This will be a

required report for clinicians and will allow them to have more effective communications with their patients and vice versa.

02:09:10 We can then ask the FDA to put out a public statement with regards to-- Based on obesity classifications of Americans, what the best studied and safest vitamins are for them to purchase that they can have that align with that which was studied during the time of conducting the phase 1, which was toxicity; phase 2, which is efficacy; and then phase 3, the longer and larger cohort studies thereafter for long-term care and follow-up. This will reduce any means and medians for the reported safety effects that have been reported to all the IRBs that conducted this.

02:09:58 And also, we would request that the MAUDE safety report data be reported. That's the most often occurred safety event from those patient populations. They can reanalyze that and that can be requested from the clinical trial centers that were involved in the clinicaltrials.gov, allowing patients to then see what all the vitamins were tested on clinicaltrials.gov. That way they'll know, "Hey, this supplement was just something a guru recommended on TikTok and not necessarily something that the FDA has looked into." While I understand a consensus statement from the FDA for over-the-counter vitamins, which is an enormous undertaking.

02:10:40 It's going to be difficult, perhaps asking them to have a more reasonable conversation with their parents and their grandparents on vitamins that they may have taken historically. And that way they can then present that information to the clinician and make a consensus statement in the doctor's office. Certainly this will take a while, but we would think that finding these sorts of alignments will go a long way in making sure that we are all successful in our collective goals. Thank you so much for consideration of these comments.

Closing Remarks

02:11:21 **Alison Lyndaker**: That concludes our Public Comment session. Thank you all. Please be advised that the public docket to provide written comments is open until October 17th. If you would like to provide a public comment, please do so via the public document.

02:11:36 This concludes our meeting for today. Thank you all to the speakers who took the time to share their comments with us. Thank you to everyone who logged in to listen to the meeting today. We hope you enjoy the rest of your day.

[End of the recording.]