

*Public Meeting on the Recommendations for
GDUFA Reauthorization*

November 16, 2021

*A Matter of Record
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6	6 Data Scientist, Resource Capacity Planning
7 Carter Beach	7 Office of Program and Strategic Analysis
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11 Lisa Berry	11 Edward "Ted" Sherwood
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1 C O N T E N T S	1 PROCEEDINGS
2 AGENDA ITEM PAGE	2 (9:01 a.m.)
3 Welcome	3 Welcome – Carter Beach
4 Carter Beach 8	4 MR. BEACH: Good morning. Thank you for
5 Opening Remarks	5 joining us. I'm Carter Beach, Deputy Director of
6 Jacqueline Corrigan-Curay 10	6 CDER's Office of Executive Programs, and I'll be
7 GDUFA II Successes	7 leading you through the meeting today.
8 Maryll Toufanian 14	8 I'd like to thank the industry negotiators
9 GDUFA III Proposals	9 for a collaborative and productive 18 months,
10 Advancing Approvals	10 getting us to this point, from the initial public
11 Maximizing Each Review Cycle	11 meeting back in the summer of 2020. I'd also like
12 Ashley Boam 28	12 to thank those of you who joined us for the
13 Edward "Ted" Sherwood 30	13 stakeholder meetings throughout the negotiations.
14 Improving Regulatory Communication	14 Thank you in advance to those who will speak today
15 Maryll Toufanian 33	15 and to those who will submit comments to the
16 Manufacturing and Facilities	16 docket. We value all of the engagement and
17 Ashley Boam 36	17 feedback.
18 Alonza Cruse 39	18 We're here to present the proposed
19 Clarifying Questions 41	19 reauthorization package that we have developed
20 Enhancing Approval of Complex Generics	20 along with industry representatives. Today's
21 Robert Lionberger 43	21 agenda will start with opening remarks from
22 Clarifying Questions 60	22 Jacqueline Corrigan-Curay, the Principal Deputy

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1 Director at CDER. She led the GDUFA
2 reauthorization process for FDA. Jacqueline will
3 explain how we got to this point and what happens
4 next.
5 From there, we will highlight GDUFA II
6 successes, then we will summarize the key proposed
7 enhancements in the GDUFA III package. After that,
8 we will hear from industry representatives and
9 other stakeholders. There will be time for public
10 comments and finally closing remarks from Sally
11 Choe, Director of CDER's Office of Generic Drugs.
12 The schedule here is our best estimate for
13 these sessions. As you can see, there are breaks
14 sprinkled in. We will stick as closely to this as
15 possible, but may shift breaks here and there,
16 depending on the flow.
17 Throughout the meeting, you will be able to
18 submit clarifying questions in the Q&A box at the
19 bottom of the presentation screen. We will do our
20 best to address them. If you have substantive
21 comments, they should be submitted to the docket.
22 With that, here's Jacqueline Corrigan-Curay.

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1 Opening Remarks – Jacqueline Corrigan-Curay
2 DR. CORRIGAN-CURAY: Thank you, and good
3 morning. It's a real pleasure to be here to
4 present to you our proposed recommendations for the
5 enhancement for GDUFA III, but I want to just start
6 a little bit and talk about this is really just our
7 third reauthorization, so we've been rapidly
8 building the modern generic drug program.
9 Our first program was back in 2013, not that
10 long ago, and it was industry's and FDA's first
11 effort to design a modern generic drug program, the
12 first implementation of goal dates for ANDA
13 submissions and making progress on the review of
14 the ANDA backlog.
15 We are now in GDUFA II, reaching towards the
16 end of GDUFA II, and the improvements we made there
17 include simplified goal date structures; providing
18 shortened goal dates for priority submissions; the
19 launching of the pre-ANDA program for complex
20 products; and providing accountability and
21 reporting enhancements. As we entered into these
22 negotiations, our goal was really to take the best

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1 of what we've already built and build upon that,
2 and continue those successes.
3 As Carter mentioned, we started back in July
4 of 2020 with our initial public meeting and perhaps
5 some of you who joined us then. And then we spent
6 about a year really working with industry through
7 these negotiations, as well as meeting with our
8 stakeholders to get the package together that we'll
9 review with you today.
10 We had formal ratification between FDA and
11 the industry in September of 2021, and then went
12 through our internal clearance process. We
13 published the FRN, as you know, at the end of
14 October, and we're here today at our final public
15 meeting.
16 As you can see, the docket will not close
17 for public comments until December 12th, so you'll
18 have time to take back what you've heard during
19 this meeting and submit comments to the docket.
20 We'll carefully review those comments, and then our
21 goal is to transmit a final package to Congress in
22 January of 2022.

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1 We entered the negotiations, as I said, with
2 building on what we've achieved through GDUFA II
3 with the goal of maximizing the value of each
4 review cycle, and by that we mean our goal is
5 really to get as many approvals in earlier review
6 cycles. From a broad picture -- and we mentioned
7 this in our public meeting -- what we were trying
8 to do was advance those earlier cycle approvals
9 through enhanced communication and review
10 processes.
11 We also want to enhance the development,
12 assessment, and approval of complex generic
13 products, which you'll hear about a little bit
14 today, and then to assure a sound foundation for
15 GDUFA III.
16 I think as you listen to the presentations
17 today about the commitment letter, I think we've
18 accomplished much of what we set out to do, and I
19 think it's because these were really shared
20 objectives by FDA, industry, and also our public
21 stakeholders.
22 I'd just like to reiterate our thanks to our

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1 industry trade group negotiators from the
2 Association for Accessible Medicines, the Pharma
3 and Biopharma Outsourcing Association, and the Bulk
4 Pharmaceuticals Task Force, who really worked with
5 us to achieve what we have today.
6 So again, these slides will be available to
7 you. We'll have the links. Please review the
8 Federal Register if you haven't looked at it and
9 the commitment letter, and of course to submit
10 comments, you should go to the docket. We look
11 forward to hearing from you, and then we'll review
12 and analyze those public comments on the proposed
13 recommendations, take those into consideration
14 before we transmit a final proposed package to
15 Congress in January of '22.
16 It's really my pleasure to introduce some of
17 my fellow negotiators. This is really the brain
18 trust of the GDUFA negotiators. You'll hear today
19 from Alonza Cruse, who's our Director of Office of
20 Pharmaceutical Quality Operations; as well as
21 Ashley Boam, the Director of the Office of Policy
22 and Pharmaceutical Quality; Maryll Toufanian, the

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1 Director of the Office of Generic Drug Policy;
2 Edward "Ted" Sherwood, as many of you may know, the
3 Director of the Office of Regulatory Operations;
4 and Rob Lionberger, the Director of the Office of
5 Research and Standards.
6 Before we kick off into reviewing each of
7 the different sections of the commitment letter, we
8 thought it'd be really helpful to first provide an
9 update on where we are in GDUFA II, and just walk
10 through some of those continued successes of the
11 program that we're building on for GDUFA III.
12 With that, I'd like to hand it over to
13 Maryll Toufanian to walk us through, and we thank
14 you for your attention, and thanks for being here.
15 Presentation – Maryll Toufanian
16 MS. TOUFANIAN: Good morning. It's a
17 pleasure to be here. Today, as Jacqueline
18 indicated, I have the good fortune to update this
19 community on our activities under GDUFA II. At our
20 public meeting last July, we were able to provide
21 information up to this fiscal year, and thought, in
22 light of everything that has been accomplished this

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1 prior fiscal year, we could share an update with
2 you.
3 An update on GDUFA II, starting with what
4 has been the focus of so many of our actions and
5 our lives for the past several years, and that is
6 addressing COVID-19, what the generic drug program
7 has done to ensure that critical COVID-19
8 treatments are available to the American public.
9 I'll note that we've had 69 COVID-related
10 original ANDAs and over a thousand COVID-related
11 supplements. What this is, is really not only an
12 indication of the extraordinary effort that the
13 folks at FDA have done -- again, continuing to work
14 remotely -- for the entire fiscal year, but also an
15 acknowledgement to industry and the efforts that
16 the generic drug industry took in light of all of
17 the challenges facing supply chain and production,
18 really putting in an extraordinary effort to make
19 sure that the American public have the medicines
20 that they need during this public health emergency.
21 To facilitate those activities on behalf of
22 the agency and our industry partners, we issued

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1 three guidances really targeted on addressing the
2 drug development and ANDA review during the
3 COVID-19 pandemic, and in order to ensure that as
4 much information was available to the public, we
5 had two public presentations on COVID-19 related
6 development activities.
7 In addition to all of the extraordinary work
8 going on to address the global pandemic, we had the
9 rest of the work that is so critically important to
10 do. This year, we continued what we started in
11 GDUFA II, and that is making sure there's no
12 application left behind.
13 One of the real successes of the GDUFA II
14 program is that every single generic drug
15 application that is in our pipeline is now under
16 the user-fee paradigm, and that structure really
17 lends to a successful review process not only for
18 original applications, but the growing number of
19 supplements that we receive as a result of the
20 extraordinary efforts in GDUFA I and GDUFA II to
21 clear out older applications and make sure those
22 products continue to be updated through the

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1 supplement process.
2 In this year alone, we had over
3 670 approvals, over 150 tentative approvals, which
4 as many or most of you know is FDA's signal that an
5 application has met our scientific standards for
6 approval but cannot be approved because a patent or
7 exclusivity has yet run.
8 In addition, we had over 90 first-generic
9 approvals, and that's the first generic to specific
10 references to drug or RLD, really critical activity
11 on the part of both the agency and industry to get
12 those generics out for the first time; an
13 extraordinary number, over 1850 complete response
14 letters, those communications back to industry
15 identifying deficiencies that an applicant needs to
16 address before we can move to approval.
17 During the course of the assessment, we
18 issued over 4700 information requests and
19 discipline review letters. Those are communications
20 from FDA to applicants over the course of an
21 assessment cycle, where we're really trying to make
22 sure that we identify, to the extent possible,

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1 deficiencies/omissions in an application to move to
2 an action, hopefully an approval or tentative
3 approval in that cycle. And as a cornerstone to
4 all of our work is the review of the drug master
5 files, which is a foundational element of the
6 generic drug program, and our DMF team reviewed
7 over 550 DMFs.
8 In addition, we hit a really important
9 milestone this year, and that is over
10 100 cumulative competitive generic therapy
11 approvals. This was a new approval incentive that
12 was established in the reauthorization of GDUFA II
13 under FDARA to encourage the development of
14 products for which there's no generic competition,
15 older products.
16 We really have been very heartened and are
17 very committed to continuing the success of that
18 program, and I'll note that a significant number of
19 those products that were approved under the CGT
20 pathway did take advantage of the 180-day
21 exclusivity that comes after one applicant meets
22 certain criteria set forth in the statute. So that

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1 pathway is a success and one that we're really
2 excited about continuing to implement.
3 We had a significant number of notable
4 generic drug approvals. I won't read this list, but
5 I will encourage all to take a look. I think all of
6 us in the healthcare field can understand the
7 benefit of these products and their approval. So I
8 would say when these slides are available, to take
9 a closer look at some of these approvals, a number
10 of which are complex generic approvals, which I'll
11 be speaking about in a little bit. But it was an
12 exciting year for us with these and other approvals
13 coming to fruition.
14 This is what I referenced and I'm going to
15 talk about in a little bit more detail. This is
16 really all of the work FDA and our partners have
17 been doing for many years, but in particular in
18 GDUFA I, and then even the heightened pace of GDUFA
19 II, and that is really identifying the innovative
20 science, the innovative technologies, that are
21 necessary to get approvals for complex products,
22 products that are complex because of a complex

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1 dosage form, active ingredients, and route of
2 administration.
3 The agreement from GDUFA II really put a
4 significant amount of focus on those complex
5 generics, and those came to fruition this year in
6 the approvals that you see below, the first complex
7 generic of glucagon, for patients, to treat severe
8 hypoglycemia in patients with diabetes. This
9 approval was possible because of FDA research on
10 analytical methods for peptides and immunogenicity
11 studies testing for peptides.
12 We had our first complex generic for a
13 parenteral iron product that treats iron deficiency
14 anemia. FDA's investment into characterization and
15 advanced bioequivalent study designs was really
16 essential to this approval. The complex generic
17 loteprednol etabonate ophthalmic suspension really
18 resulted in investments we have made into particle
19 size characterization and eye models, supporting a
20 more efficient in vitro bioequivalence methodology.
21 Providing a little bit more detail on what
22 we refer to historically is the FDA's pre-ANDA

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1 program. But that's a little bit of a misnomer
2 because there's so much that goes on that is of
3 benefit to the good work that happens in the
4 pre-ANDA space to move complex generics from
5 development to assessment, and ultimately approval.
6 We found the pre-ANDA program, concentrating
7 on the science and technology behind complex
8 generics, reduces time from development to market;
9 helps address complex scientific issues; creates a
10 pathway for us to communicate with prospective
11 applicants; helps applicants develop more complete
12 submissions; and what is essential is clarifying
13 regulatory expectation in a very transparent way.
14 Also exciting, the Center for Research on
15 Complex Generics is up and running. In August of
16 2020, FDA awarded a five-year grant to the
17 University of Maryland and the University of
18 Michigan to establish this center, which aims to
19 enhance research collaborations with the generic
20 drug industry to further FDA's mission of
21 increasing access to safe and effective generic
22 products.

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1 The goal will be pursued through
2 collaborative research, training, and exchange of
3 resources between FDA and the generic industry and
4 stakeholders. It's the first of its kind, a
5 cutting-edge center. We hope to stimulate
6 innovative dialogue, disseminate current
7 understanding of complex products and practices,
8 and generate new knowledge, all with the goal of
9 ensuring safe and effective high-quality generic
10 drug products are available as soon as possible.
11 We've had a number of workshops, I'll note
12 very successful in the virtual space. We had in
13 the Generic Drug Forum the Lifecycle of a Generic
14 Drug in April of 2021, over 2,500 attendees from
15 77 countries. It was an opportunity for industry
16 and academia to interact with FDA subject matter
17 and receive information to help applicants submit
18 and ultimately pursue approval of their generic
19 drug products.
20 In addition, we had our Generic Drug
21 Regulatory Science Initiatives Public Workshop, and
22 this is a really important opportunity that we have

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1 to hear from industry, to hear from academia, and
2 to hear from external stakeholders about what their
3 thoughts are with respect to identifying novel or
4 innovative scientific methods that could be applied
5 to generic drug development in the future. We use
6 this input to develop our priorities for the
7 following year on an annual basis.
8 We also had a number of very focused
9 workshops, and these are interactive workshops, to
10 a large extent, that allow FDA to share scientific
11 information about a specific subject, and for
12 industry to participate in those dialogues and
13 learn a great deal about what our expectations are
14 with respect to specific elements of generic drug
15 development and review.
16 We have, as a general matter as I described,
17 really focused on enhancing research transparency
18 and industry engagement. The pre-ANDA program, as
19 I've described what its intent was, the goal has
20 come to fruition -- an estimated 500 meeting
21 requests for that pre-ANDA program -- and we met
22 our goal dates for product-specific guidances for

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1 new chemical entities.
2 Product-specific guidances, as most of us
3 are aware, are those recommendations on specific
4 drug products with respect to bioequivalence and
5 other elements of generic drug development for a
6 specific product. Making that information
7 transparent in the form of a product-specific
8 guidance is essential to timely development of
9 generic drug approval.
10 The good news is that we have been active
11 not only in our basements, but also globally. We've
12 been really proactive this year on a number of
13 international fronts. The first highlight of our
14 global engagement program is the Parallel
15 Scientific Advice (PSA) pilot program that we have
16 partnered with the European Medicines Agency, or
17 EMA, on.
18 This pilot program was designed to provide
19 parallel scientific advice to prospective generic
20 drug applicants for FDA's abbreviated new drug
21 applications and EMA's marketing authorization
22 applications for hybrid products for complex

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1 generics.

2 The PSA pilot program allows FDA and

3 EMA -- the assessors, the folks actually looking at

4 the applications or the data around development

5 related to specific products -- to concurrently

6 exchange their views on scientific issues during

7 the development phase of complex generics and share

8 that information with putative potential

9 applicants.

10 We also have been very active in the ICH

11 generic drug discussion group, which assesses

12 feasibility of harmonization and the impact of

13 public health for several complex generic products,

14 categories, creating a comprehensive map of topics

15 to recommend for the development of future ICH

16 guidelines.

17 I think ICH, as we all know, has been

18 incredibly successful in facilitating drug

19 development. I think over the past several years,

20 and this year in particular, the targeted focus on

21 potential areas of ICH for generic drug development

22 is really exciting and a really critical

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1 opportunity that we look forward to continuing to

2 embrace. We also have the ICH M13 expert working

3 group, which developed guidelines on bioequivalence

4 for immediate-release or oral dosage forms.

5 Excitingly, we launched the global generic

6 drug cluster in June of this year. It's the first

7 forum established for leading regulatory agencies

8 across the world specifically for generic drug

9 topics. We're active in two working groups for the

10 International Pharmaceutical Regulator Programme,

11 or IPRP, the IPRP bioequivalence for generic groups

12 and the nanomedicines working groups.

13 All of this work, really, we think will come

14 to great benefits to the American patients because,

15 as we know, the generic drug market place and the

16 development space is really a global endeavor, and

17 this work will all seek to make that as efficient

18 as possible for generic drug applicants in the U.S.

19 Now, what's essential in terms of our

20 activities under GDUFA II is making sure that

21 generic drug developers know our expectations to

22 the greatest extent possible. To that end, we have

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1 issued a significant number of final guidances.

2 I won't go through each, but as you can see,

3 focusing on several different elements of generic

4 drug development and review, how to submit your

5 application and what steps one takes to maximize

6 the different elements of FDA's work in the

7 development and review of generic drug products;

8 more specific heavily scientific guidancesto

9 describe our expectations on complex scientific

10 matters; and as I indicated previously, we sort of

11 nimbly finalized a guidance regarding elements of

12 generic drug review and development under the

13 COVID-19 pandemic paradigm.

14 We also continue to issue draft guidances,

15 including what was a critically important and very

16 exciting guidance for us to publish, and that was

17 new bioequivalence studies with PK endpoints for an

18 ANDA, really reflecting a significant amount of

19 innovative development in bioequivalence space over

20 the last several years, as well as additional drug

21 draft guidances. And as you all know, we try to

22 work as consistently and as efficiently as

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1 possible, and FDA MAPPs really gives an important

2 tool to FDA assessors, FDA policy developers, and

3 the industry. It gives transparency into how FDA

4 does its job.

5 With that, I am very happy to turn the

6 microphone over to three of my colleagues. As

7 Jacqueline thoughtfully introduced, Ashley and Ted

8 are going to be talking about maximizing each

9 review cycle, and I'll pop back in as a special

10 guest star on a specific topic.

11 So with that, I look forward to speaking

12 with you again in a few minutes.

13 Presentation – Ashley Boam

14 MS. BOAM: Thank you, Maryll.

15 It's a pleasure to be here with you today.

16 I'm excited to start us off in sharing some of the

17 proposed commitments in the GDUFA III commitment

18 letter, in this section, elements that would help

19 to, as was mentioned, maximize each review cycle.

20 In terms of Presubmission Facility

21 Correspondence (PFC), this was an element that was

22 actually included in GDUFA II. It was intended to

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1 provide a pathway for a shorter review goal for
 2 priority applications by allowing certain
 3 information related to manufacturing facilities and
 4 bioequivalence studies to be submitted ahead of the
 5 ANDA application itself, which would then enable
 6 FDA to provide an assessment of the need for a
 7 preapproval inspection. Then together, that would
 8 allow FDA time to conduct an inspection, if needed,
 9 and still meet that shorter goal date of 8 months.

10 During the GDUFA III negotiations, we
 11 discussed with our industry colleagues approaches
 12 that might help increase industry's use of this
 13 provision to have more ANDAs eligible, then, for
 14 that 8-month priority goal date.

15 Notably, the changes that we have proposed
 16 are to narrow our focus in terms of the information
 17 to be submitted on the manufacturing information
 18 and the bioequivalence study information that are
 19 critical for FDA in terms of making that assessment
 20 of whether an inspection is needed to support
 21 approval and to outline how non-substantial changes
 22 can be made in between the submission of the PFC

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1 and the ANDA, as long as that information does not
 2 change our assessment regarding the need for an
 3 inspection.

4 We hope that these changes will lead to an
 5 increase in the number of ANDAs using this pathway
 6 and being eligible for that shorter review
 7 timeline.

8 At this point, I'll turn the microphone over
 9 to my colleague, Ted Sherwood.

10 Presentation – Edward Sherwood
 11 MR. SHERWOOD: Great. Thank you.

12 Good morning, everyone. We are going to
 13 address a couple goal date extensions. We will
 14 start with major issues. In certain cases,
 15 applicants' responses to mid-cycle information
 16 requests or discipline review letters may trigger
 17 extensions of the first cycle.

18 These extensions will be based on the major
 19 amendment goals, and they will be applied from the
 20 date of amendment submission. FDA hopes that under
 21 this commitment, applicants will provide timely and
 22 thorough responses that allow for an increase in

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1 the number of first-cycle approvals.
 2 Further, we are allowing for goal date
 3 extensions for minor issues. Again, applicants'
 4 responses to certain information requests and
 5 discipline review letters may trigger extensions of
 6 the current cycle. Unlike the goal extensions for
 7 major issues, this extension is available for any
 8 appropriate cycle.

9 In this case, the extensions will be based
 10 on the minor amendment goals and they will also be
 11 applied from the date of amendment submission. FDA
 12 hopes that under this commitment we can reduce the
 13 number of cycles necessary for approval.

14 With a purpose similar to the extensions
 15 provisions just discussed, the imminent approval
 16 process for bringing applications to approval or
 17 tentative approval under GDUFA II was strengthened
 18 in GDUFA III as imminent actions. The name change
 19 appears subtle, but it allows for improved
 20 communications with applicants in situations where
 21 the agency may be able to take tentative approval
 22 by the goal date, or the agency could wait a little

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1 while past the goal date to issue a full approval
 2 on the first approvable date.

3 It also strengthens the ability to resolve
 4 small issues that are still needed towards the end
 5 of a cycle through information requests and
 6 discipline review letters, without penalty of
 7 missing a goal date, to provide applicants the
 8 opportunity to gain approval or tentative approval
 9 within the current cycle.

10 The opportunities discussed in the last two
 11 slides will reduce the number of complete response
 12 letters issued, the number of cycles needed, and
 13 help reduce the total time to approval. This is a
 14 win for industry, FDA, and the patients.

15 Here, we will pivot towards Controlled
 16 Correspondence. We are largely maintaining the
 17 current process and goals. To minimize confusion
 18 with complex products, we are replacing the
 19 standard and complex controlled correspondence
 20 designations with Level 1 and Level 2.

21 The biggest change to the Controlled
 22 Correspondence program will be an expansion of the

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1 definition of an eligible Controlled Correspondence
 2 to allow questions from applicants in certain
 3 circumstances after an application has been
 4 submitted. This expansion is designed to improve
 5 communication between applicants and the agency
 6 about next steps necessary for an applicant, such
 7 as the design of new bioequivalence studies or
 8 implementation of post-approval changes.
 9 Another change in GDUFA III will be that
 10 responses to requests to clarify ambiguities will
 11 increase from the current 14 calendar days to
 12 21 calendar days to allow FDA to catch its breath
 13 and prepare a thoughtful explanation of its
 14 response on the Controlled Correspondence.
 15 Now, I will turn this back over to Ashley
 16 for further updates.
 17 MS. BOAM: Thanks, Ted. Actually, I think
 18 this slide is for Maryll.
 19 Presentation – Maryll Toufanian
 20 MS. TOUFANIAN: That's right.
 21 An exciting element of the proposed
 22 commitment regards suitability petitions. These

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1 are the petitions, the existence of which was
 2 established in the statute. They permit prospective
 3 applicants a mechanism to request permission to
 4 submit an ANDA for a different route of
 5 administration, strength, dosage form, or a
 6 different active ingredient in a fixed-combination
 7 drug product from a reference-listed drug; and
 8 whether we can accept and approve such an ANDA that
 9 would not be pharmaceutically equivalent and
 10 therefore not be rated, but nonetheless could be
 11 submitted with much less data than would be
 12 required than, say, a full ANDA, and therefore
 13 creates a new product that might address public
 14 health need or a niche in the market that's not
 15 currently addressed.
 16 Starting in 2024, there will be goal dates
 17 for new suitability petitions. In order to obtain
 18 a goal date, prospective applicants can withdraw a
 19 previous petition and resubmit. We note there are
 20 a number of suitability petitions currently pending
 21 with the FDA. We understand the desire to move
 22 this more quickly as a result of the goal date, so

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1 we identified and negotiated a mechanism by which a
 2 petitioner can withdraw a petition and resubmit in
 3 2024 to get a goal date.
 4 In general, we will commit to addressing
 5 suitability petitions in the order that they are
 6 received, but we'll prioritize certain suitability
 7 petitions that fit one of the categories
 8 delineated, including one that can mitigate or
 9 resolve the drug shortage or prevent future
 10 shortages; address a public health emergency or
 11 anticipated to do so under the same criteria as
 12 would apply to a former declaration of emergency;
 13 that would be for a new strength of a parenteral
 14 product that could aid in eliminating
 15 pharmaceutical waste or mitigating the number of
 16 vials needed for dose by addressing differences in
 17 patient weight, body size, or age; or are the
 18 subject of a special review program under the
 19 PEPFAR program.
 20 So handing things back to Ashley, who you've
 21 just heard, and also Alonza Cruse, who Jacqueline
 22 introduced. He's our director and fellow negotiator

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1 of the Office of Pharmaceutical Quality Operations
 2 for ORA. Thank you.
 3 Presentation – Ashley Boam
 4 MS. BOAM: Thanks, Maryll.
 5 The proposed GDUFA III commitment letter has
 6 several provisions related to manufacturing and
 7 facilities. As you heard Maryll speak about in her
 8 opening remarks, drug master files and, in
 9 particular, type 2 drug master files are a key part
 10 of the generic drug program. We have a couple of
 11 provisions in the proposed letter to help
 12 streamline their assessments.
 13 We have found that DMFs can be a challenge
 14 for ANDA applicants because the response time from
 15 DMF holders and getting back to us related to
 16 questions that we raise can be longer -- for
 17 example, can be longer than 3 months -- which then
 18 can limit the ability for the DMFs to be adequate
 19 in a single review cycle, which then also can delay
 20 the ANDA's ability to be approved.
 21 GDUFA III would provide opportunities for an
 22 earlier review of certain drug master files for

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1 priority ANDAs to allow for that early start with
 2 the hopes of having DMFs be considered adequate
 3 early enough so that the ANDA, if also adequate,
 4 could move forward to approval or tentative
 5 approval.
 6 A second pain point that we discussed was
 7 that, in some cases, DMF holder would submit an
 8 amendment to their DMF that corresponds to a time
 9 that's late in the review cycle for the ANDA
 10 referencing that DMF. And because FDA then needs
 11 to assess that amendment to ensure that it doesn't
 12 have an impact on the ANDA, that can, in some
 13 cases, lead to a delay in our ability to move
 14 forward with an approval or tentative approval of
 15 the ANDA application.
 16 FDA has agreed to communicate to industry
 17 that prior to a DMF holder submitting what in many
 18 cases is a non-substantive amendment to the DMF,
 19 they should coordinate that timing with an ANDA
 20 applicant who is referencing that DMF in order to
 21 avoid unnecessary delays and approval.
 22 You heard my colleague, Ted Sherwood, talk

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1 about the controlled correspondence program. One of
 2 the major changes we proposed in GDUFA III is to
 3 expand the controlled correspondence program to
 4 include questions in the post-approval space.
 5 These questions typically focus on the
 6 manufacturing-related changes, so providing a
 7 mechanism for those questions to come in and
 8 receive a response with goal dates associated will
 9 help to facilitate development in the post-approval
 10 space.
 11 When an original application is submitted,
 12 you may be familiar with the Form FDA 356h, which
 13 includes a lot of information about the product
 14 being submitted in the application. It also
 15 includes information about the manufacturing
 16 facilities to be used to make that product.
 17 One of the questions that the applicant is
 18 asked to address on that form is whether all of the
 19 facilities are ready for inspection should an
 20 inspection be needed. We do have cases on occasion
 21 where a facility is marked as not ready for
 22 inspection at the time that the original ANDA is

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1 submitted, and this can lead to delays in our
 2 ability to approve or reach tentative approval for
 3 that application.
 4 GDUFA III would allow for an ANDA with a
 5 facility marked as not ready for inspection to
 6 receive an extended goal date to allow additional
 7 time for the facility to become ready. And if that
 8 does happen during the initial period, FDA will
 9 then set a new goal date, either 8 or 10 months, as
 10 appropriate priority or standard from the date of
 11 that amendment.
 12 If the application is not amended with all
 13 facilities being ready during that initial 15-month
 14 period, we will then extend the goal date by
 15 another 15 months, and then we'll proceed to take
 16 action during that overall 30-month period.
 17 With this, I will turn it over to my
 18 colleague, Alonza Cruse from ORA.
 19 Presentation – Alonza Cruse
 20 MR. CRUSE: Good morning, and thank you, and
 21 thank you, Ashley. Good morning, all.
 22 FDA has been working throughout to ensure

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1 that we are providing education and feedback on the
 2 status of our surveillance inspections. One of the
 3 further enhancements in GDUFA III, continuing
 4 something from GDUFA II, is providing that
 5 information to foreign regulators regarding our
 6 inspection processes to further support safe and
 7 effective pharmaceutical products by the US-based
 8 pharmaceutical industry.
 9 FDA's inspection classifications database
 10 under GDUFA II was updated on a monthly basis. The
 11 new version of our inspection classification
 12 database provides more frequent updates every week,
 13 whereas the former database was updated only
 14 monthly. This dashboard will continue to show the
 15 results from final classifications being as no
 16 action indicated, voluntary action indicated, or
 17 official action indicated for each of the areas
 18 within the inspection.
 19 As you know, FDA inspections play a vital
 20 role in the drug approval process, and it is with
 21 that, working to try and increase the rate at which
 22 the approvals can occur. If a facility is named in

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1 an application that has been found to be Official
2 Action Indicated, generally that ANDA cannot be
3 approved.
4 One of the enhancements of GDUFA III is to
5 post a new post-warning letter meeting, which will
6 provide an opportunity for the eligible facilities
7 to meet with FDA after making progress on their
8 corrective action plans in order to remediate some
9 of those deficiencies. Along with this
10 reinspection, it's commonly needed to show and to
11 resolve any OAI status that a firm may have, and it
12 allows for the application approval under GDUFA III
13 should that remediation be proved successful.
14 These include reinspection timelines for both
15 domestic facilities, as well as our international
16 facilities for inspections.
17 Clarifying Questions
18 MR. BEACH: Thank you, all. As you can see,
19 we've reached our break a little bit early here.
20 We have received a couple of questions in the chat.
21 I will read one of them now, and, Ashley, I believe
22 you have an answer to this one.

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1 "For priority ANDAs that is planned for
2 submission on or after October 2, 2023, when is the
3 earlier date by when a DMF holder submits a DMF to
4 prompt an early review of the DMF?"
5 MS. BOAM: Thanks, Carter.
6 The provision of a commitment letter would
7 allow for a DMF holderto submit a request for
8 assessment of that DMF 6 months prior to the
9 planned submission of the ANDA. There are a couple
10 of other provisions to make sure that the ANDA
11 would qualify for priority review, so I would refer
12 you to that section of the letter. But the idea is
13 that the request for assessment could come in
14 6 months prior to the planned ANDA submission.
15 Thanks.
16 MR. BEACH: Thank you, Ashley.
17 We received one other question about access
18 to the slides. We are going to request that they be
19 posted following this meeting. Please allow a day
20 or two for that to occur.
21 Let's call this 15-minute break until
22 10 a.m., so we will rejoin at 10 a.m. Thank you.

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1 (Whereupon, at 10:00 a.m., a recess was
2 taken.)
3 MR. BEACH: We are at 10 o'clock. Welcome
4 back. We will go to Rob Lionberger for proposed
5 enhancements to the complex generics program.
6 Rob?
7 Presentation – Robert Lionberger
8 DR. LIONBERGER: Good morning, everyone.
9 I'm happy to be here today to talk about the
10 enhancements in GDUFA III that we've made for our
11 complex generics.
12 We're only seeing part of the slides.
13 (Pause.)
14 DR. LIONBERGER: Great. We'll be on this
15 slide, so thanks very much for fixing that.
16 I want to talk a little bit about complex
17 generics. Just to remind you, in GDUFA III, the
18 definition of complex generics will remain the same
19 as it was in GDUFA II. It will cover
20 locally-acting products that are not solutions,
21 complex dosage forms, products with a complex
22 device constituent part, and products with complex

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1 active ingredients; so no change to the definition.
2 I also want to remind people of the scale of
3 complex generics relative to the non-complex
4 products. If you look at currently active
5 reference products in the Orange Book, about
6 25 percent of those are complex, but if you look at
7 products that don't have approved generics yet,
8 it's about 30 percent. But currently, only about
9 13 percent of our ANDA approvals are for complex
10 generics.
11 So we envision if we're moving toward an
12 environment where a complex product is equally
13 likely to have a generic as a non-complex product,
14 that you might have to double or triple the amount
15 of effort for applying to the complex ANDAs in the
16 submissions.
17 So there's still a gap between the complex
18 products available and the ANDAs that are being
19 approved for those products, and that leads to a
20 lot of the focus of the GDUFA III enhancements on
21 improving movement of the complex generics through
22 the system.

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1 There are a bunch of aspects of GDUFA III
 2 that help in complex generics. It begins with our
 3 regulatory science program that continues to
 4 develop the scientific foundations for our review
 5 of complex generics and providing appropriate and
 6 timely scientific advice for their development.
 7 The regulatory science program feeds into
 8 our product-specific guidances -- we'll talk a
 9 little bit about the improvements there for complex
 10 generics -- as well as we continue to maintain in
 11 GDUFA III the pre-ANDA product development meetings
 12 that have been very successful, where applicants
 13 can discuss the development programs for complex
 14 generics and potentially propose alternatives to
 15 product-specific guidances. We also, in the GDUFA
 16 III enhancements, will have some improvements to
 17 the product-specific guidance program, and
 18 transparency and communication around the
 19 product-specific guidances.
 20 As applications are submitted to FDA and
 21 move through the reviewer assessment process,
 22 you'll see several enhancements in GDUFA III

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1 related to complex products. First, we have
 2 improvements to our presubmission meetings to
 3 improve their use and link them more closely to the
 4 ANDA review process.
 5 We have enhanced options for the mid-cycle
 6 meetings for complex generics that will provide
 7 more interaction between FDA and the applicant in
 8 that process, and have a new post-CRL scientific
 9 meeting, that if you reach a point after you've
 10 gone through the first review cycle and there are
 11 still complex scientific issues that are resolved,
 12 you have the opportunity to engage with FDA on a
 13 similar level to the pre-ANDA product development
 14 meeting about complex scientific issues.
 15 We think that all of these, when put
 16 together, will help move complex generics through
 17 the system more efficiently and more transparently.
 18 I want to talk through, in a little bit more
 19 detail, some of the specific improvements in
 20 GDUFA III. As we start with the product-specific
 21 guidance, the GDUFA II goals on product-specific
 22 guidances remain. I want to remind you that these

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1 focus on non-complex, new molecular entities,
 2 essentially providing product-specific guidances
 3 two years after approval; a reminder that for most
 4 new molecular entities, the first filing date,
 5 legal filing date, is usually four years after the
 6 approval date. So this provides two years of
 7 development time for the products before
 8 submission.
 9 Again, the GDUFA II goal around complex
 10 products remains that we will provide PSGs for all
 11 complex products as soon as possible. We still
 12 aspire to do that. But what we've added in
 13 GDUFA III are new goals for complex products new
 14 drug applications as they're being approved after
 15 the beginning of GDUFA III. So we committed in the
 16 letter to provide 50 percent of those PSGs for new
 17 complex products in 2 years and 75 percent in
 18 3 years.
 19 So the idea of this is to evolve to a system
 20 where there are PSGs available for all products,
 21 and as new products get approved, then both for the
 22 non-complex and complex PSGs, the product-specific

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1 guidances appear relatively quickly; so they are
 2 there to frame development. If you have
 3 alternative approaches, you can use pre-ANDA
 4 meetings, and you have time to do that before you
 5 submit ANDAs.
 6 This is part of moving toward that type of
 7 system. We intend to continue to work on the older
 8 complex products that don't yet have
 9 product-specific guidances, but also begin to phase
 10 in a system that provides the PSGs for the complex
 11 products as the new drug products are approved.
 12 This new commitment will provide the resources to
 13 do this and, again, increase the rate at which
 14 complex products and PSGs become available.
 15 Just to remind people of the value for this,
 16 by having the product-specific guidance available,
 17 they provide clarity on the path toward an ANDA
 18 submission, but we want to make sure that the
 19 product-specific guidances themselves don't become
 20 barriers to innovation. Every product-specific
 21 guidance has alternative approaches that are
 22 allowed, so, again, it's not the intention of

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1 providing this clarity to restrict innovation.
2 The GDUFA II product development meetings
3 explicitly mention this, that one valid topic for a
4 pre-ANDA product development meeting is you want
5 feedback on pursuing an alternative approach to a
6 product-specific guidance. So that aspect already
7 exists in GDUFA II and will continue in GDUFA III,
8 that PSGs should not restrict innovative
9 approaches, but provide clarity around current
10 thinking.
11 But we've heard during our negotiations,
12 also, that sometimes the PSG revisions do create
13 uncertainty. So in GDUFA II, we began to provide a
14 process where we provide public notice of upcoming
15 PSG revisions, and we've expanded and integrated
16 this into the GDUFA III commitment. As well, we'll
17 talk about some of the other PSG enhancements to
18 provide more feedback on the interaction between
19 product-specific guidances and development
20 programs.
21 One new feature of GDUFA III is what we call
22 a product-specific guidance teleconference. This

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1 is a situation that can be involved if an applicant
2 has begun an in vivo study that differs from a
3 posted PSG recommendation.
4 If you've begun an in vivo study perhaps
5 following an older product-specific guidance, or in
6 cases where there was no product-specific guidance
7 available, and FDA posted product-specific guidance
8 that describes a different type of study, in this
9 situation we recognize, and through the negotiation
10 process heard from industry, that this can be a
11 particular pain point, so we've developed a system
12 to provide enhanced communications in this
13 situation.
14 In this situation, you the applicant would
15 be eligible for a new teleconference within 30 days
16 of your request to discuss the impact of the PSG
17 recommendation on your development program. So
18 there are various possibilities of how different
19 your study is from the recommended study, and this
20 will allow a discussion of the specific facts of
21 your situation in that light.
22 Then, if there is additional scientific

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1 follow-up needed after this initial triage of what
2 the difference is and what the potential impact is,
3 then there's an opportunity for additional
4 scientific meetings related to this study. And
5 again note, this is not just limited to complex
6 products; it does cover all products. But this
7 should improve transparency and help minimize
8 concern about what happens once a PSG revision is
9 posted, and provides a place to get clarity and
10 assign further discussion around this.
11 As we move into the meeting process and
12 closer to the ANDA submission, I just want to
13 remind you that in GDUFA III, pre-ANDA product
14 development meetings that are present in GDUFA II
15 remain essentially unchanged, so we're not really
16 going to talk about them today.
17 So we'll skip over them, but it doesn't mean
18 they don't exist, it doesn't mean they're not
19 important, and it doesn't mean they're not used
20 significantly, but just that there is no new
21 enhancement for the pre-ANDA product development
22 meeting.

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1 The product development meetings are those
2 that cover new approaches and provide scientific
3 advice, but as you move closer to submission, what
4 we noticed in GDUFA II is that the GDUFA II
5 presubmission meetings were not used very
6 significantly, and one of the possible reasons was
7 a very long timeline for these meetings that didn't
8 fit into efficient movement toward submission.
9 In GDUFA III, we proposed some revisions to
10 the presubmission meeting. In these revision
11 meetings, you can have the meetings within 60 days
12 of the request. The meetings will focus on
13 application orientation, preparing FDA to review
14 your application, and describing to FDA what's
15 unique.
16 You will get feedback from FDA staff at the
17 meeting or advice on how to present the innovative
18 approaches of your application more clearly in the
19 submission. The eligibility for the presubmission
20 meeting remains the same as the presubmission
21 meeting for GDUFA II. If you have a pre-ANDA
22 product development meeting, you have the option of

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1 having the presubmission meeting.
2 I would think that the value creation for
3 the presubmission meeting is really to help move
4 from the scientific advice that you've been getting
5 prior to application submission -- through
6 controlled correspondence, through meetings, to
7 reading the product-specific guidances -- to the
8 review team.
9 Internally, these presubmission meetings
10 will allow FDA to form the ANDA review team when
11 the meeting request comes in. This will enable
12 internal knowledge transfer and help FDA prepare
13 for unique or complex issues. If you flag to us
14 here's something unique about this submission and
15 FDA has more time to prepare for that, you're more
16 likely to get a first-cycle approval than if you
17 surprise us with a complex issue at the submission
18 time.
19 Again, all of this is focused on providing a
20 more efficient ANDA review for complex generics.
21 But again, it will only be effective if industry
22 uses this option. This is, again, a new feature.

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1 We hope that it will be useful. We intend to also
2 learn from this as well. But it is a new option
3 that will be available in GDUFA III.
4 As we move into the ANDA review process for
5 complex generics, GDUFA III provides some
6 enhancements to the current mid-cycle meeting.
7 Again, the improvements, the eligibility for the
8 mid-cycle meeting for complex products is the same
9 as GDUFA II. It's complex products that's used the
10 pre-ANDA meeting process; so not every complex
11 product, only ones that use the pre-ANDA meeting
12 process because we want to encourage those
13 pre-application discussions for the complex
14 products.
15 In the new system for the mid-cycle
16 meetings, within 7 days of the last mid-cycle
17 communication, an eligible applicant -- i.e., one
18 who's had a pre-ANDA meeting for a complex
19 product -- may request one of two mid-cycle
20 meetings. In this request, you'll describe the
21 specific deficiencies that you want to discuss.
22 The first option is the mid-cycle meeting.

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1 Similar to the current one, this meeting will be
2 held within 30 days of the request, but at this
3 meeting, the applicant may ask for the rationale
4 for any deficiency identified in the mid-cycle or
5 ask questions related to FDA's assessment of the
6 data that was submitted in the ANDA; so essentially
7 clarifications of the review; questions about data
8 that's already been submitted.
9 Again, we feel that compared to the current
10 mid-cycle meeting, this will increase interaction
11 between FDA and industry at this meeting. So again,
12 even though it's similar, it will have some
13 improvements in the interactions as well.
14 Or there's an enhanced option. We call this
15 the enhancement cycle meeting. This one allows
16 applicants to ask questions about potential new
17 data that they might submit in response to
18 deficiencies. In order to do this, since its data
19 that FDA has not seen yet, FDA will need more time
20 to look at this and provide appropriate answers.
21 This meeting will be held within 90 days of the
22 last mid-cycle DRL.

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1 Unfortunately, to fit this meeting within
2 our review cycle, we need to have a goal date
3 extension if you enhance this meeting. So this
4 doesn't fit within the 10-month cycle unless you
5 have an extension.
6 So it's up to the applicant which approach
7 they want to take. If they want to ask questions
8 related to the data that was already submitted, the
9 regular mid-cycle meeting is appropriate. If you
10 want the enhancement cycle meeting with additional
11 questions about new data or responses to
12 deficiencies, there's a 60-day goal date
13 inspection.
14 Again, these revisions will allow more
15 interactions at the mid-cycle meeting. Both options
16 provide more opportunities for applicants to
17 develop questions. But they allow also the
18 applicant to have some choice to optimize their
19 review process, more effort in the current cycle,
20 or will move quickly to a final decision in the
21 cycle. This, again, gives more control to the
22 applicant to help optimize the review process.

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1 After any complete response, we've added a
2 new feature of GDUFA III for complex products. If
3 you receive a complete response letter
4 where, basically, you learn that you did the wrong
5 study for whatever reason: proposed an alternative
6 approach, it wasn't accepted; you were doing
7 something different; something came up unexpectedly
8 that you have to do some different type of study in
9 your resubmission -- so this is not for a case
10 where you did a study, it failed, and you have to
11 repeat the study, and you're just repeating the
12 same study because there's an execution error.
13 It's really the situation where you're doing
14 a new study. You're changing the design of the
15 study because your first study failed and you want
16 to have feedback from FDA before you conduct that
17 next study. In these cases, for the new
18 study -- and it also can include a comparative
19 human factors study and you want to discuss the
20 potential design of that study, or a new approach
21 to active ingredient sameness.
22 Again, if you're doing something new that

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1 wasn't done in the original submission, and you
2 want scientific feedback before you submit that new
3 type of study, you can use this post-CR scientific
4 meeting.
5 Again, as was mentioned earlier, there's a
6 new controlled correspondence process that allows
7 you to ask written questions while you're in CR
8 status. Again, that will give you a faster answer
9 than this meeting, but if it's a more complex
10 issue, like the types of things you might discuss
11 in the current GDUFA II product development
12 meeting, this meeting might be appropriate. You
13 will get a grant/deny decision within 14 days, and
14 the meeting within 90 days after the decision.
15 Again, the value we think will be created by
16 this is the product development meetings have been
17 very successful and widely used pre-submission, but
18 they can't be used under GDUFA post-submission. So
19 now we're able to use them and provide this
20 opportunity for interaction while you're in CR
21 status if you've reached the same type of
22 scientific impasse.

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1 These are, again, meetings we believe will
2 help resolve complex scientific issues that are
3 blocking the path to approval. So if you find at
4 that first review cycle the study that you submitted
5 was not appropriate, you can get additional
6 feedback on a new approach and hopefully come back
7 toward approval faster.
8 To conclude, I just want to summarize the
9 progression that's been happening through the GDUFA
10 program for complex generics. In GDUFA I, we added
11 a research program that continues to advance the
12 science for complex generics. In GDUFA II, we
13 added the pre-ANDA meeting program to improve
14 scientific advice during product development. This
15 has been widely used and very successful.
16 In GDUFA III, we've added enhancements
17 post-submission to help move complex products
18 toward approval; so again, a progression building
19 the scientific foundations, more communication
20 during product development, and now adding in
21 GDUFA III more communication during product review
22 and assessment.

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1 Thank you all, and we're moving on to our
2 next topic.
3 Clarifying Questions
4 MR. BEACH: Thank you, Rob.
5 Rob, we have a couple questions here.
6 Before we move on, I will read them. They're
7 pretty similar questions, but I will read them
8 together, and you can answer them how you see fit.
9 The first one is, "How will the applicant
10 know that they have received their last mid-cycle
11 communication? Is there a process in place for the
12 request outside of the 7-day time request?"
13 DR. LIONBERGER: FDA's project managers will
14 make it clear to you when the next last mid-cycle
15 communication occurs if there's any ambiguity
16 around it. Again, if you want this meeting, you
17 must respond within 7 days, but FDA will make it
18 clear that this is the appropriate mid-cycle
19 communication to make that request on.
20 MR. BEACH: Okay. Thank you. I think that
21 answers both of the questions.
22 We have a couple of other questions on

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1 different topics.
2 Ted, the first one is for you, and they're
3 asking about the reports that you all put out and
4 wondering how things are counted; where there might
5 be an application in a tentative approval and
6 another in full approval, are they counted twice,
7 and then a variation on that same question, which
8 you've seen.
9 MR. SHERWOOD: Certainly. Thank you.
10 High level, we are counting each agency
11 action. It is possible for a tentative approval to
12 be issued early in the year, then later in the year
13 an approval is issued. In this case, each action
14 is counted.
15 When we issue the tentative approval, we
16 don't know for sure that an approval will be
17 sought. Further, those actions require considerable
18 agency resources. Also, it is possible for one
19 strength of an application to be approved, while
20 another strength may need to be tentatively
21 approved at the same time. Again, each action will
22 be counted.

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1 Thank you, Carter.
2 MR. BEACH: Thanks, Ted.
3 One for you, Ashley, a question about the
4 PFC program. "Can you provide more detail with
5 respect to the specific changes to the PFC
6 requirements? Will the current PFC guidance be
7 revised to reflect this critical information
8 necessary for inspection?"
9 MS. BOAM: Thanks, Carter.
10 While I'd love to delve into the details,
11 I'm not sure we are set up to do that today. So we
12 won't get into the weeds of how that will be
13 changed, but certainly we expect to communicate
14 those changes to our industry colleagues and a
15 mechanism that would allow for public comments
16 also; so be looking for that. Thank you.
17 MR. BEACH: Thank you, Ashley.
18 We have another question about availability
19 of the slides. Again, we will request that they
20 get posted following this meeting. You may want to
21 allow a day or two for that to actually occur.
22 There is a Q&A icon at the bottom of your

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1 presentation screen there. If you can ask the
2 questions in that, it's better for us to track in
3 there and make sure that we're answering them
4 efficiently.
5 We have one other question here. "Would FDA
6 also grant a post-CR meeting for pre-GDUFA III
7 complex ANDAs that are still under review, and
8 would FDA provide response to proposals from
9 applicants on any studies/technical queries to
10 address the CR questions?"
11 DR. LIONBERGER: We will clarify in guidance
12 the exact rules for the legacy products. But in
13 general, I think we anticipate that after GDUFA III
14 starts, if you're in CR status and it's a complex
15 product, that you'll be eligible for this meeting.
16 And that's what we've done through GDUFA II as we
17 implemented these transitions. You're not eligible
18 for these meetings until -- you have to be in CR
19 status after the start of GDUFA III.
20 In terms of the other question, I did talk a
21 little bit about getting feedback on studies. So
22 again, the commitment letter is very clear. This

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1 is not, oh, I'm repeating my study because I failed
2 the study and I want some feedback on that. It's
3 really, I'm doing a different study and I want
4 feedback on that study design. That's what the
5 meeting is for, a different type of study design.
6 Again, in GDUFA III, you also will have the
7 option to use the post-CR Controlled Correspondence
8 to ask general questions about the study that
9 you're conducting. Say that you're repeating a
10 failed bioequivalence study, and you have some
11 question about that study; the Controlled
12 Correspondence will get you a faster answer to that
13 question.
14 So again, the post-CR scientific meeting is
15 generally intended if you're doing some different
16 type of study. So based on the CR you received,
17 you had to change the approach that you're taking
18 because the approach that you're taking wasn't
19 adequate and you need feedback on the approach.
20 That's what the scientific meetings are for.
21 If I have to repeat a study or I'm doing
22 another study -- let's say you're doing another

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1 study and you're following our product-specific
 2 guidance, and you just want a clarification
 3 question on that. That's probably much more
 4 appropriate and a faster answer to the Controlled
 5 Correspondence process under GDUFA III.
 6 MR. BEACH: Thank you, Rob, and one more for
 7 you.
 8 "Will the proposed CR scientific meeting
 9 apply to complex ANDAs prior to GDUFA III?"
 10 DR. LIONBERGER: Yes. We don't intend to
 11 limit this meeting to complex products filed after
 12 GDUFA III, but you must complete the review status.
 13 So once you go into CR status in GDUFA III, then
 14 you can request this meeting if you otherwise meet
 15 the criteria that were in there. So there's no
 16 limitation in the commitment letter to applications
 17 submitted under GDUFA III. So it covers all
 18 complex products that enter into the CR status.
 19 MR. BEACH: Great. Thank you, Rob, and
 20 thank you for the questions.
 21 We will now move over to Lisa Berry and
 22 Bethany Rue to talk about the financial structure

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1 for GDUFA III.
 2 Presentation – Lisa Berry
 3 MS. BERRY: Hi. I'm Lisa Berry from CDER's
 4 Office of Management, and I'm here with Bethany Rue
 5 from CDER's Office of Strategic Programs. We'll be
 6 talking about how the negotiated financial changes
 7 set a sound foundation for GDUFA III.
 8 There are several key areas that we want to
 9 highlight. First, I'll be talking about
 10 modifications to the fee structure, additional
 11 resources to hire staff, and financial
 12 transparency; then Bethany will be talking about
 13 resource capacity planning and the two new target
 14 revenue adjustments, the annual capacity planning
 15 adjustment and the annual operating reserve
 16 adjustment; and then Bethany will wrap up the
 17 financial piece by showing how these two new
 18 adjustments are integrated into the annual
 19 fee-setting process.
 20 Overall, the GDUFA III fee structure remains
 21 largely unchanged from GDUFA II. As in GDUFA II,
 22 GDUFA III has five fee types, the abbreviated new

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1 drug application or ANDA filing fee; the ANDA
 2 program fee; the drug master file or DMF fee; the
 3 active pharmaceutical API facility fee; and the
 4 finished dosage form, FDF, facility fee.
 5 Modifications were made to the allocation of
 6 fee revenues among those five fee types. The first
 7 one is the ANDA program fee increased from
 8 35 percent of target revenue to 36 percent of
 9 target revenue. At the same time, the API facility
 10 fee decreased from 7 percent of target revenue to
 11 6 percent of target revenue. The other allocations
 12 remain unchanged.
 13 Overall, the FDF facility fee allocation
 14 remains at 20 percent. Within the FDF facility fee
 15 category, there are two types of facilities, the
 16 FDF and the contract manufacturing organization or
 17 CMO. In GDUFA III, there is a change to the CMO
 18 fee.
 19 In GDUFA II, the CMO fee is one-third of the
 20 FDF fee. And in GDUFA III, the CMO fee is
 21 24 percent of the FDF fee. For API and FDF
 22 facility fees, the foreign fee differential remains

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1 unchanged at \$15,000, which is the same as
 2 GDUFA II.
 3 As a result of the negotiations, 128 staff
 4 will be hired in fiscal year 2023 for the generic
 5 drug program and will support the program
 6 enhancements agreed to in GDUFA III that you've
 7 heard about earlier. FDA will provide progress
 8 updates in the hiring of these 128 staff that are
 9 to be hired as part of our commitment to financial
 10 transparency.
 11 FDA confirmed its commitment to financial
 12 transparency and will continue to, one, publish a
 13 5-year financial plan with updates each fiscal year
 14 and, two, hold a public meeting about the plan and
 15 other financial commitments. In addition,
 16 components of the capacity planning adjustment and
 17 the operating reserve adjustment that Bethany will
 18 be talking about will also be included in the GDUFA
 19 5-year financial plan.
 20 I will now turn it over to Bethany Rue, who
 21 will provide information on resource capacity
 22 planning, the capacity planning adjustment, and the

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1 operating reserve adjustment.
2 Presentation – Bethany Rue
3 MS. RUE: Thanks, Lisa.
4 As Lisa mentioned, I'll be walking through
5 two new annual adjustments to the target revenue
6 setting process that will begin during GDUFA III,
7 the capacity planning adjustment and the operating
8 reserve adjustment.
9 Beginning in GDUFA II, several foundational
10 steps were taken to support the development of the
11 first of these two adjustments, the CPA. During
12 GDUFA II, FDA committed to build a resource
13 capacity planning capability, which included
14 implementation of modernized time reporting and
15 development of a methodology to accurately assess
16 changes in the resource needs of the generic drug
17 program. This methodology is the methodology used
18 for the capacity planning adjustments.
19 In GDUFA III, the agency plans to continue
20 to develop this capability by publishing a plan
21 outlining the capacity planning adjustment
22 implementation and planned integration of resource

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1 capacity planning in the agency's resource and
2 operational decision-making processes. This plan is
3 scheduled to be published by March 2023. We will
4 provide annual updates on the plan and progress
5 made on the FDA website.
6 We will also conduct an independent
7 third-party evaluation of the resource capacity
8 planning capability and the capacity planning
9 adjustment, and we will publish for public comment
10 by the end of fiscal year 2025.
11 Now I'd like to provide some further details
12 about the capacity planning adjustment. It is a
13 methodology that would be used annually to adjust
14 target revenue for the additional resource needs
15 due to sustained increases in workload of the GDUFA
16 program. The CPA adjusts for specific categories of
17 direct review work, which are listed at the bottom
18 of the slide.
19 The CPA would be capped at 3 percent of
20 inflation-adjusted base revenue unless certain ANDA
21 submission conditions are met. These include the
22 total number of ANDAs submitted or the proportion

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1 of complex ANDAs submitted. The CPA will be
2 implemented for GDUFA III starting for fiscal
3 year 2024 fees. FDA would publish rationale for
4 any CPA adjustments in the annual fee rate Federal
5 Register notice for that fiscal year.
6 Now I'll provide some details on the
7 operating reserve adjustments. The operating
8 reserve adjustment will replace the final year
9 adjustment in GDUFA III. Beginning in fiscal
10 year 2024, the operating reserve adjustment would
11 allow FDA to increase target revenue to maintain
12 sufficient operating reserves of carryover user
13 fees.
14 The operating reserve adjustment would be
15 phased in and gives FDA the option to increase
16 target revenue to maintain at least 8 weeks of
17 reserve in fiscal year 2024, 9 weeks in fiscal year
18 2025, and 10 weeks for fiscal year 2026 and
19 thereafter.
20 If estimated carryover balance at the end of
21 the fiscal year for which fees are being set is
22 projected to be in excess of 12 weeks of operating

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1 reserve, FDA would be required to decrease the
2 target revenue for that fiscal year to reduce
3 operating reserve to be not more than 12 weeks. FDA
4 would provide the rationale for adjustments to the
5 operating reserve in the annual fee rate Federal
6 Register notice for that fiscal year.
7 The operating reserve adjustment is designed
8 to not be included in the base revenue for
9 subsequent years. This way the adjustment is made
10 for one fiscal year without creating a long-term
11 impact on revenue.
12 On this slide, we show an example of the
13 target revenue setting process and where the
14 capacity planning adjustment and operating reserve
15 adjustment fit in. Each fiscal year, the base
16 revenue is adjusted for inflation, then the
17 capacity planning adjustment is added, followed by
18 the operating reserve adjustment. Both of these
19 are, if taken, to arrive at an annual target
20 revenue.
21 For the subsequent fiscal year, the base
22 revenue would be the inflation-adjusted base

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1 revenue amount plus the capacity planning
2 adjustment from the previous fiscal year. Note that
3 the operating reserve adjustment would not go into
4 the subsequent fiscal year's base revenue.
5 This concludes my portion of the
6 presentation, and now I will turn it back over to
7 Carter Beach.
8 Clarifying Questions
9 MR. BEACH: Thank you, both.
10 Before we move to the next section of the
11 agenda, we do have one more question for Ashley.
12 "Can you please clarify how the DMF review
13 will work prior to ANDA submission under
14 GDUFA III?"
15 MS. BOAM: Thank you, Carter. I'd be happy
16 to.
17 There are additional details in the proposed
18 commitment letter, and I would certainly refer you
19 there. But briefly, the DMF holder would need to
20 submit a request for this early DMF assessment.
21 They would need to include at least one letter of
22 authorization with a pre-assigned ANDA number for

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1 that planned ANDA submission; a reference to the
2 corresponding reference-listed drug so we would
3 know in what context we were starting the
4 assessment of the DMF; and then obviously the
5 information about having paid the DMF fee.
6 With that information in hand, we agree that
7 the proposed ANDA submission that would then follow
8 would qualify for priority, and again, I refer you
9 to the commitment letter for some more of those
10 details. Then we would begin the assessment of the
11 DMF, and then begin interacting with the DMF holder
12 as appropriate if there were outstanding questions.
13 I hope that provides a little more clarity.
14 Thank you.
15 MR. BEACH: Thank you, Ashley.
16 We do have one other question. "Does FDA
17 intend to limit the number of Controlled
18 Correspondence for a product at two at a time, like
19 it is currently done in GDUFA II?" Will that carry
20 forward?
21 MR. SHERWOOD: Hi, Carter. This is Ted
22 Sherwood. I can address that one. We are not

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1 changing that aspect of GDUFA II.
2 MR. BEACH: Okay. Thank you, Ted.
3 With that, we will move on to the industry
4 perspective segment, and Lisa Parks from AAM will
5 speak.
6 (No response.)
7 MR. BEACH: We have you there, Lisa?
8 (Pause.)
9 MS. PARKS: Can you hear me?
10 MR. BEACH: Yes. There you go.
11 MS. PARKS: Great. Thank you.
12 Presentation – Lisa Parks
13 MS. PARKS: Good morning, and thank you for
14 the opportunity to speak today. I am Lisa Parks,
15 Vice President of Sciences and Regulatory Affairs
16 at the Association for Accessible Medicines. I am
17 speaking today on behalf of industry negotiators
18 and our respective member companies; so in other
19 words, I drew the short stick.
20 Our three industry groups, the Association
21 for Accessible Medicines, AAM; Bulk Pharmaceutical
22 Task Force, BPTF; and Pharma and Biopharma

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1 Outsourcing Association, PBOA, are pleased to have
2 developed with FDA the framework for a new 5-year
3 authorization of the Generic Drug User
4 FeeAmendments, GDUFA, for fiscal years 2023 through
5 2027.
6 As captured in the GDUFA III commitment
7 letter, the negotiations covered very specific
8 targeted areas to enhance the efficiencies of the
9 abbreviated new drug application, ANDA, review
10 process. The negotiated enhancements are designed
11 to bring timelier access to more affordable generic
12 medicines to America's patients by increasing
13 transparency and communication between applicants
14 and FDA during the presubmission, pending review,
15 and post-approval phases of the lifecycle of an
16 ANDA. We believe the added clarity to the agency's
17 expectation, coupled with more engagement
18 opportunities in the form of meetings, will advance
19 timelier access.
20 Negotiating the third iteration of GDUFA
21 involved refining and improving certain aspects of
22 the program that were developed during GDUFA I and

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1 II, while also identifying key processes that would
 2 benefit from additional resources. The hallmark of
 3 this negotiation was to refine the existing
 4 processes and build upon the lessons learned to
 5 make the already strong foundation stronger.
 6 I would like to take this time to briefly
 7 highlight several core areas of the agreement,
 8 starting with advancing approvals. As you have
 9 heard, FDA will continue assessment of an ANDA past
 10 the goal date if in FDA's judgment it may be
 11 possible to approve or tentatively approve an ANDA
 12 within 60 days after the goal date. FDA also
 13 committed to using information requests and
 14 discipline review letters to facilitate an approval
 15 or tentative approval. In addition, FDA will
 16 also issue a MAPP on the process for
 17 reclassification of facility-based major complete
 18 response letter amendments on or before the
 19 agreed-upon date.
 20 Last, under advancing approval, industry and
 21 FDA expanded the scope of Controlled
 22 Correspondences to include regulatory and/or

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1 scientific advice after issuance of a complete
 2 response letter or a tentative approval, or after
 3 ANDA approval, which were all considered General
 4 Correspondences prior to GDUFA III
 5 Drug master files or DMFs; FDA will enhance
 6 communication on the timing for submission of
 7 solicited and unsolicited amendments to type 2
 8 DMFs. The agency will also allow earlier
 9 submission of DMFs under certain conditions and
 10 will report in more detail on DMFs for which a user
 11 fee has been paid and for those that have undergone
 12 a completeness assessment.
 13 Moving on to inspections, under GDUFA III,
 14 FDA will provide a pathway for reinspection of
 15 facilities with deficiencies identified during
 16 inspection to assess remediation and potentially
 17 close out official action-indicated warning letters
 18 in a more timely manner. FDA will also provide
 19 enhanced reporting of surveillance inspections, as
 20 well as including more detailed information in its
 21 inspections classification databaseto better
 22 reflect compliance status.

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1 For complex generics, as Rob outlined, to
 2 facilitate the swift development of complex
 3 generics, FDA has committed to issue
 4 product-specific guidances, or PSGs, for 50 percent
 5 of complex new drug applications within 2 years of
 6 the date of approval and 75 percent of such new
 7 drug applications within 3 years of approval while
 8 prioritizing PSGs for complex products that include
 9 NCE over those that do not.
 10 The agency will also provide more
 11 opportunities for communication with applicants
 12 when a PSG is revised or a new PSG is issued after
 13 an ANDA applicant has already submitted an ANDA or
 14 commenced bioequivalence studies. The industry and
 15 FDA further developed various meeting types to
 16 accelerate the development and review of complex
 17 generic applications to ensure cost-effective
 18 alternative generic medicines are more timely
 19 accessible to patients.
 20 Moving on to stability or suitability
 21 petitions, industry and FDA were able to create an
 22 effective system for the timely resolution of

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1 suitability petitions, adding agreed-upon metrics
 2 and providing additional resources for the agency
 3 to meet the negotiated commitments.
 4 With respect to the financial stability of
 5 the generic drug program, industry worked with FDA
 6 to develop a robust funding model to provide the
 7 generic drug program with the revenue necessary to
 8 advance the approval of safe, effective generic
 9 medicines while addressing industry concerns about
 10 sustainability.
 11 Unlike previous iterations of GDUFA, where
 12 FDA would estimate resource needs for the full
 13 5 years and frontload all of those costs in year 1,
 14 adjusting for inflation fiscal year to fiscal year,
 15 GDUFA III will employ a capacity planning
 16 adjustment, or CPA, so there will be fewer upfront
 17 resources required and more flexibility from year
 18 to year to adjust the revenue base in order to
 19 accommodate FDA's projected resource needs.
 20 FDA and industry negotiated percentages-
 21 based caps on the annual increases to the program
 22 costs, providing a degree of business certainty for

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1 the generic sector. The agreement also requires the
2 agency to publish an implementation plan with
3 annual updates, as well as conducting third-party
4 evaluation of the CPA and their resource capacity
5 planning function.
6 Use of real-time reporting and modernized
7 time reporting will also aid in industry and
8 agency's ability to keep the lines of communication
9 open for financial transparency. Industry believes
10 these enhancements to GDUFA will lead to a more
11 effective program, while also taking into
12 consideration the sustainability concerns of our
13 industry and our suppliers and contract
14 manufacturers.
15 We are confident that the commitments and
16 resources in GDUFA III will benefit patients and we
17 support the reauthorization of the program. We look
18 forward to working with FDA to implement GDUFA III,
19 and we will work with our industry members to
20 ensure that the program brings maximum benefit to
21 patients.
22 Before concluding, I would like to thank

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1 Jacqueline and the entire FDA negotiating team for
2 the robust interaction and the continued
3 collaborative discussions to achieve our shared
4 mission to patient safety and access. We look
5 forward to the ongoing dialogue. Thank you.
6 MR. BEACH: Thanks so much, Lisa.
7 We've got a number of comments asking about
8 slides. Lisa did not have slides. So we're not
9 frozen here; there just weren't slides to share
10 here. And we have another question about slides
11 being available for download. We will have them
12 posted in the next day or two on the FDA website.
13 We will now move on to the stakeholder
14 comments. Part of the statutorily mandated steps
15 that we had to take throughout this reauthorization
16 process was to have ongoing collaboration with
17 stakeholders throughout the negotiations, so we
18 held monthly stakeholder meetings. One of the
19 consistent contributors there was Tonya Winders
20 from the Allergy and Asthma Network, so she will
21 now present.
22 Presentation – Tonya Winders

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1 MS. WINDERS: Thank you.
2 Again, Tonya Winders, President and CEO of
3 Allergy and Asthma Network and the President of
4 Global Allergy and Airways Patient Platform. It's
5 my pleasure to be with you today. I appreciate the
6 opportunity to speak.
7 Addressing health disparities has been our
8 mission at Allergy and Asthma Network since 1985,
9 and while many factors drive disparities, the high
10 out-of-pocket costs of medications are a core
11 issue, and increasing access to more affordable
12 generic medicines remains one of the most effective
13 ways to close the equity gap.
14 The Generic User Fee Act, GDUFA III, is
15 currently being negotiated between U.S. Food and
16 Drug Administration and the generic industry. This
17 presents an important opportunity to improve access
18 to complex generics, many of which treat asthma and
19 allergies.
20 The goal of GDUFA is to speed FDA approval
21 of new generic drugs, stimulate competition for
22 branded drugs, and reduce drug pricing for

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1 consumers. We applaud FDA for the success the
2 program has yielded to date, but there is more work
3 that needs to be done specifically for complex
4 generics; copies of complex medicines that are
5 drug-device combinations or have complex
6 formulations than conventional pills, many of which
7 have taken years to win approval due to
8 inefficiencies in the current process.
9 For example, our patient population relies
10 on complex asthma inhalers and epinephrine
11 auto-injectors as life-saving treatments, but a
12 generic version of Advair, a popular asthma
13 inhaler, was delayed in the approval process by
14 three years, during which time the cost of the
15 branded Advair increased by more than 50 percent.
16 The epinephrine auto-injector market is even
17 a more alarming example. It took FDA 10 years to
18 approve the first generic medicine, during which
19 time the cost increased by nearly 600 percent.
20 Rising medication costs has shed important light on
21 the challenges of accessibility and affordability.
22 For millions of Americans, access to

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1 medications such as epinephrine auto-injectors or a
2 quick-relief asthma inhaler can be a life or death
3 matter. According to U.S. GAO, the average rate of
4 first-cycle generic approvals is only 12 percent, a
5 figure which is most certainly lower for complex
6 generics. In fact, most applications take at least
7 three review cycles before approved, with each
8 review cycle adding 6to 10 months to the
9 development timeline for a typical complex drug
10 product.

11 Having to go through three review cycles to
12 achieve FDA approval significantly delays patient
13 access to much needed lower-cost complex generics.
14 Delayed access to affordable meds only exacerbates
15 the health and equity in our country. When it
16 comes to Black Americans, study findings reveal
17 they are already less likely to use controller
18 medications for asthma or to carry an epinephrine
19 auto-injector, and we know these care and treatment
20 plans are not nice to have but are absolutely
21 must-haves for our patient community.

22 It is important to understand that both

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1 asthma and allergies are conditions that require
2 daily maintenance through medication to remain
3 controlled. With the rising cost of branded
4 products, coupled with the financial stress from
5 the pandemic, we are at a critical inflection point
6 in the U.S. where genericizing treatments must be a
7 priority. Lower-cost treatment options will result
8 in greater adherence and less rationing of care, in
9 turn, creating a healthier population with less
10 burden to the overall healthcare system.

11 As we look forward to turn the tide on
12 public health, we should prioritize taking
13 important steps to close gaps in health equity.
14 Allergy and AsthmaNetwork is grateful to FDA for
15 its ongoing efforts to increase access to
16 lower-cost generic medications, and the time is now
17 to work with FDA to elevate a collective patient
18 voice so people of all backgrounds with chronic
19 conditions like asthma and allergies can have
20 access to safe, effective, and affordable complex
21 treatment options. Thank you.

22 Public Comment Period

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1 MR. BEACH: Thanks so much, Tonya.
2 We are approximately an hour ahead of
3 schedule here. We are prepared, I think, to move
4 on to the public comments section, but I don't want
5 to catch those presenters off guard. So if you're
6 not ready to present, we can certainly come back
7 after lunch, but first on our list here is Molly
8 Ventrelli.

9 MS. VENTRELLI: Thanks, Carter. Can you
10 hear me?

11 MR. BEACH: Yes Sorry to put you on the
12 spot.

13 MS. VENTRELLI: Oh, not at all; not at all.
14 It's fine.

15 Good morning, and thank you for the
16 opportunity to give me a few minutes to speak this
17 morning. I'm Molly Ventrelli. I'm the Senior Vice
18 President of Regulatory Affairs at Fresenius Kabi,
19 and one of the industry negotiators on behalf of
20 AAM for GDUFA III.

21 First, just very quickly, I want to take
22 this opportunity to thank Jackie and all of the FDA

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1 staff, as well as Lisa and Dave from AAM for their
2 leadership and commitment through this negotiating
3 process that was about a year long. There was a
4 lot of effort that was put in by all of the teams
5 that were involved, and I really appreciated the
6 collaborative spirit that persisted even when we
7 were talking about more difficult topics.

8 Negotiations by nature mean that it's a
9 compromise at some points to get to the best
10 possible path forward for everybody, and I think
11 that that was certainly the case with GDUFA III.

12 So to echo Lisa's comments and some from the FDA
13 presenters this morning, I really believe the
14 enhancements and progress that were made in
15 GDUFA III will lead to a much more effective
16 program overall that benefits patients, which is
17 ultimately both FDA and industry's goal.

18 I'm going to talk a little bit this morning
19 on a few key points around advancing approvals in
20 suitability petitions, and it may be a little
21 repetitious with what you've heard already from
22 Ted, and Maryll, and Ashley, and Rob, but I think

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1 these points specifically bear a little repeating
 2 for everybody so that you take note.
 3 GDUFA III brings a lot of enhancements
 4 around the current process on ANDA review and
 5 advancing approvals. There are a couple of points,
 6 again, that I want to make specifically in that
 7 area, and one is the imminent action pathway. That
 8 can be used to resolve some minor issues that are
 9 preventing approval, but in GDUFA II might have
 10 necessitated a complete response letter and another
 11 cycle.
 12 This will allow an action within 60 days of
 13 the goal date, while still meeting the intentions
 14 of the metrics in terms of approval timing, but
 15 should increase first-cycle approvals and hopefully
 16 reduce the time and effort for both agency and
 17 industry.
 18 FDA has also developed an approach to
 19 mid-cycle discipline review letters. If an
 20 applicant responds completely to a DRL by the given
 21 date, the agency will review that response within
 22 the first cycle and not defer it to a later cycle.

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1 It also gives the agency the ability to extend goal
 2 dates -- and I think Ted talked about this a little
 3 bit -- in order to complete a review of major
 4 responses. Again, it may extend a goal date, but
 5 it's eliminating another review cycle, which is
 6 ultimately the goal and will save us time in that.
 7 In the event a CRL is issued, FDA has added
 8 additional pathways for applicants so that we can
 9 get some clarity or talk about some of these
 10 scientific issues. I think Rob had mentioned the
 11 post-CRL scientific meeting.
 12 As an applicant, once you get a CRL, you can
 13 request a post-CRL meeting to just gain some
 14 clarity around a specific issue, and that's really
 15 the only option right now in GDUFA II that we have,
 16 but they've added some other ways to get some
 17 feedback on the CRL letter. You can submit a
 18 Controlled Correspondence or, as I said, for those
 19 more technical or scientific discussions, you can
 20 request a post-CRL meeting.
 21 Again, these options are going to make it
 22 easier and will assist the applicant in providing a

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1 complete and adequate response to the CRL and
 2 hopefully reducing those review cycles.
 3 Lastly, the last point under advancing
 4 approvals I want to make, in GDUFA III, the issue
 5 of late-cycle RLD labeling changes is also
 6 addressed. This has been a real source of
 7 frustration for both the agency and the industry
 8 for many years. In GDUFA III, FDA's going to
 9 concentrate the labeling review into the second
 10 half of the review cycle, and that will
 11 allow -- hopefully, what we're hoping for is a
 12 single labeling review.
 13 This later review, coupled with the ability
 14 to use the imminent action pathway, will give the
 15 agency and the industry some flexibility and
 16 hopefully the ability to make some late-stage
 17 labeling changes when these late RLD changes
 18 happen, without actually negatively impacting
 19 approval timing in many situations.
 20 I'd also like to talk a little bit about
 21 suitability petitions, and I know Maryll put up
 22 some slides for you guys, so I'm sure you'll see

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1 that, and it's also outlined in the letter.
 2 Suitability petitions have for many years
 3 been an area that's been a bottleneck for the
 4 generic industry, and these petitions generally
 5 provide for new strengths or versions of a product
 6 that actually has some value to either the
 7 healthcare industry or the provider, and also the
 8 patients. GDUFA III is going to address this and
 9 will improve the agency's ability to assess and
 10 take action on these petitions.
 11 Specifically starting in 2024, FDA is going
 12 to assess the petitions for completeness within
 13 21 days, and then will assign a 6-month goal date.
 14 FDA has tiered the percent completion by year in
 15 order to be able to ramp up to get the necessary
 16 resources to take care of that. This 6-month goal
 17 is not going to be applied retroactively to any
 18 petitions filed before 2024, so if you have a
 19 petition that was filed before 2024, you can
 20 withdraw it and resubmit it in order to obtain a
 21 goal date after 2024.
 22 As part of the implementation, FDA's going

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1 to look at some ways to determine if there's still
 2 interest in the backlog of pending petitions that
 3 exist today. We're hoping that also potentially
 4 getting a goal date may drive some of the
 5 withdrawal or resubmission of some of those
 6 petitions, but we would like to see a way to get
 7 that backlog down.

8 If there's a large number of petitions filed
 9 in a year, FDA will prioritize them based on drug
 10 shortage, public health emergency, PEPFAR, and by
 11 adding focus on these petitions, it's going to
 12 provide some additional options for patients and
 13 increase competition in the market.

14 In summary, again, thank you for giving me a
 15 few minutes today on GDUFA III. I hope it wasn't
 16 too repetitive for you, but we really feel that
 17 GDUFA III is going to bring some significant
 18 improvement over our current process in both
 19 efficiency and predictability, and then ultimately
 20 will deliver that value to the healthcare providers
 21 and patients.

22 Fresenius Kabi supports the reauthorization

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1 GDUFA III. You've heard a lot this morning from
 2 the FDA speakers, and a lot of what I'm going to
 3 tell you today is going to be repetitive, but it is
 4 important, as Molly mentioned, to emphasize the
 5 work that's been done and what would come out of
 6 this. It's important for the industry to take note
 7 of it.

8 I will be speaking specifically on the
 9 enhancements to the drug master file, otherwise
 10 known as DMF reviews and inspections. As Lisa
 11 mentioned in her statement, the negotiated
 12 enhancements are designed to bring timelier access
 13 to more affordable generic medicines to American
 14 patients by increasing transparency and
 15 communication between the applicant and FDA during
 16 the presubmission, pending review, and
 17 post-approval phases of the lifecycle of an ANDA.

18 I'll start with the DMF review enhancements
 19 agreed upon in GDUFA III. The agency and industry,
 20 as Jacqueline Corrigan mentioned this morning, have
 21 a collective goal of increasing the number of
 22 first-cycle actions that can lead to an approval or

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1 of GDUFA III, and I really look forward to
 2 continuing to work with FDA on implementation. So
 3 thank you very much for your time today.

4 MR. BEACH: Thanks, Molly, and thank you for
 5 your collaboration throughout the process.

6 Just one quick housekeeping item before we
 7 move along; Kiran, if you're ready, we'll move on
 8 to you, and then following Kiran, we will take a
 9 20-minute abbreviated break and then go through the
 10 rest of the program.

11 Kiran Krishnan, it's all yours.

12 MR. KRISHNAN: Thank you very much, Carter.

13 Good morning, and thank you again for the
 14 opportunity to speak this morning. My name is
 15 Kiran Krishnan. I'm the Senior Vice President for
 16 Global Regulatory Affairs at Apotex Corp. I'm
 17 speaking today on behalf of Apotex Corp. I was one
 18 of the industry participants representing AAM in
 19 the GDUFA III negotiating team.

20 I'm here to provide perspective on two
 21 topics that have been agreed upon by the
 22 stakeholders and the FDA as enhancements in

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1 a tentative approval. One area of continued concern
 2 is the timing of the review of the DMF in relation
 3 to the timing of the review of the ANDA. You've
 4 already seen some questions asked for the FDA
 5 panelists this morning.

6 Today, the DMF, as all of you are aware,
 7 undergoes substantial review once the ANDA is
 8 submitted. This, as you can appreciate, creates an
 9 inherent challenge in terms of timelines for both
 10 the agency and the industry, considering we have a
 11 10-month goal date.

12 The GDUFA III enhancements directly address
 13 these concerns by creating a mechanism for review
 14 of the DMF 6 months prior to the submission of ANDA
 15 referencing the DMF. It is envisioned that under
 16 this new paradigm, the review of the DMF, prior to
 17 the submission of the ANDA, will allow for the DMF
 18 holder and the FDA to work on issues prior to the
 19 ANDA submission.

20 Truly, this jumpstart of the DMF review not
 21 only gives the DMF holder the time to respond to
 22 the deficiencies, but also provides the agency

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1 adequate time to review the DMF response, and
 2 thereby allowing for more coordinated and efficient
 3 review of the ANDA. It is envisioned that this
 4 extra time will allow the DMF review to be
 5 completed and possibly be deemed adequate, allowing
 6 the applicant to work with the agency to resolve
 7 the ANDA comments during the review cycle.
 8 This enhancement will allow for a greater
 9 chance to increase the first-cycle approvals. In
 10 order to balance the negotiated enhancements with
 11 program costs, we had to place the brackets around
 12 the type of DMFs that could be submitted in the
 13 6 months in advance of the ANDA. The type of DMFs
 14 that can be submitted 6 months prior are the DMF
 15 that support the review of an original ANDA, an
 16 ANDA amendment containing a CR letter, and an ANDA
 17 amendment seeking approval for an ANDA that was
 18 previously tentatively approved.
 19 Now, the commitment letter, as you've heard
 20 this morning as well from Ashley, describes the
 21 specific conditions under which the DMF can be
 22 submitted 6 months prior to the submission of the

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1 ANDA or the amendment.
 2 The agency just did not stop for newer
 3 applications or applications pending review. They
 4 took it one step further and have agreed to allow
 5 this, where a DMF holder can also submit a request
 6 for assessment of a DMF 6 months prior to the
 7 submission of a prior approval supplement to add a
 8 new or an alternate API source. Now, this is
 9 limited mainly to drug-shortage products and to
 10 products to address the public health emergency.
 11 These enhancements for the DMF review we
 12 certainly believe will go a long way in helping
 13 both the industry and the agency, and we thank the
 14 agency for taking these pragmatic measures to
 15 create a pathway to enable more one-cycle
 16 approvals.
 17 The next aspect of GDUFA III that I want to
 18 highlight is on the transparency as it relates to
 19 the inspections. Now, in GDUFA II, as you all
 20 remember, the Office of Compliance, Office of
 21 Regulatory Affairs, and the Office of
 22 Pharmaceutical Quality did a stellar job and

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1 successfully implemented the 90-day decision
 2 letter.
 3 Now, to further enhance the transparency and
 4 to offer increased predictability, as you heard
 5 from Alonza this morning, the agency agreed to have
 6 a time-bound process for conducting post-warning
 7 letter meetings and also conducting reinspections
 8 of both domestic and foreign facilities on a
 9 time-bound manner, based on a tiered goal for the
 10 various fiscal years, pursuant to certain
 11 requirements to be met by the site or the applicant
 12 requesting the meeting.
 13 Now, this is very unique to the GDUFA
 14 program and provides the facilities that become
 15 non-compliant a formal pathway to seek agency's
 16 feedback on the adequacy of the remediation and its
 17 corrective action plans. More importantly, this is
 18 envisioned to prevent firms from prematurely
 19 requesting reinspection, which will enable the
 20 agency to better allocate its resources to remain
 21 focused on meeting its commitments.
 22 The meeting pathway is optional for the

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1 facility to take advantage of. The facilities that
 2 have responded to a warning letter and submitted
 3 the remediation and corrective action plan can
 4 request a meeting 6 months after the warning letter
 5 has been issued. In certain circumstances, the
 6 applicant can ask for a meeting prior to 6 months,
 7 and the agency can grant or deny the meeting at its
 8 discretion.
 9 These meetings will be granted or denied
 10 within 30 days of requests using a tiered goal for
 11 various GDUFA years to manage the workload. The
 12 agency will grant these meetings subject to its
 13 review of the firm's corrective and preventative
 14 action plan and the firm's progress with the
 15 remediation strategy.
 16 In the event the meeting request is denied,
 17 the agency has also agreed to provide high-level
 18 feedback in terms of what is expected or to provide
 19 insight into the areas where the agency feels the
 20 firms need to provide further information, or to
 21 evaluate further, before it submits a subsequent
 22 meeting. I do believe that this is a very positive

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1 step, and I thank the agency for considering and
2 including this as part of the commitment letter
3 language.
4 It is envisioned that these meetings will
5 help the firms gain additional clarity and insight
6 to its course of action and any adjustment it needs
7 to make to meet the agency's expectation. This
8 process is expected to provide the facilities that
9 need clarity to allow them to fully remediate the
10 agency's concern. And again, as I mentioned, it
11 avoids firms prematurely asking for reinspection.
12 Furthermore, the agency is also committed to
13 setting a time-bound process to act on the request
14 for for-cause reinspections, and they've agreed to
15 schedule these for-cause reinspections in a
16 time-bound manner. The agency will respond to a
17 request for reinspection within 30 days. If a
18 decision is to grant the reinspection, such
19 inspection will be scheduled within 4 months for
20 domestic facilities and 8 months for foreign
21 facilities, based on a tiered goal for each of the
22 fiscal years in GDUFA III.

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1 I would like to take this opportunity to
2 thank Dr. Jacqueline Corrigan, the FDA leadership
3 team from CDER, from ORA, and the Office of Generic
4 Drugs for working with the industry negotiating
5 team to develop these enhancements. These
6 enhancements will go a long way in creating
7 transparency and increasing predictability for the
8 industry.
9 We are confident that the commitments and
10 the resources in GDUFA III will improve access to
11 important generic medications for patients, and
12 therefore, Apotex Corp supports the reauthorization
13 of the GDUFA III program. We look forward to
14 working with the FDA to implement the commitments
15 in GDUFA III. Thank you again.
16 MR. BEACH: Thanks so much, Kiran.
17 We are going to take a 20-minute break right
18 now. We'll say 11:30 back here, and we will
19 continue with the public comment section, and next
20 up will be Diana Zuckerman. Thank you.
21 (Whereupon, at 11:09 a.m., a recess was
22 taken.)

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1 MR. BEACH: Welcome back, everyone. We will
2 continue now with the public comment session.
3 Diana Zuckerman, it's all yours.
4 DR. ZUCKERMAN: Thank you. Can you hear me?
5 MR. BEACH: We can.
6 DR. ZUCKERMAN: Okay. Great. Can you put
7 up my first slide, please?
8 I'm Dr. Diana Zuckerman, President of the
9 National Center for Health Research, and I
10 appreciate the opportunity to speak today. My
11 perspective is based on my 30 years of working on
12 issues pertaining to the safety and effectiveness
13 of medical products.
14 I have postdoctoral training in epidemiology
15 and public health and was a faculty member and
16 researcher at Vassar, Yale, and Harvard before
17 moving to Washington to work as a congressional
18 investigator on FDA issues in the U.S. Congress. I
19 also worked at HHS and the White House.
20 Our Center is a non-profit think tank that
21 scrutinizes the safety and effectiveness of medical
22 products, and we don't accept funding from

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1 companies that make those products. On a side
2 note, I'm one of FDA's biggest fans because I fully
3 appreciate the agency's importance.
4 As a founding board member of the Alliance
5 for a Stronger FDA, I work with non-profits and
6 industry to increase appropriations for the FDA,
7 and I'm going to talk for just one more minute
8 before getting to the rest of my slides.
9 Our center supports the GDUFA efforts to
10 ensure getting safe and effective generic drugs to
11 market as quickly as possible. We understand that
12 FDA needs user fees to achieve that goal, but today
13 I want to focus on the safety and effectiveness
14 issues in the GDUFA III commitment letter.
15 As you know, all the different user fee
16 negotiations are behind closed doors with public
17 health, consumer, and patient groups excluded.
18 During the pandemic, it's become even more obvious
19 that public trust is eroded when the public feels
20 it isn't getting all the information it needs to
21 make informed decisions, and today's GDUFA meetings
22 and presentations have been focused on what

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1 industry wants and needs, and what they're willing
 2 to pay for, and not on what patients and consumers
 3 want and need. Only one stakeholder comment was a
 4 patient group, although other groups would have
 5 appreciated the opportunity to speak during that
 6 time slot.

7 Our health care is the most expensive in the
 8 world. The U.S. spends more than \$3000 more per
 9 person on health care than the second highest
 10 country, which is Switzerland. Without generic
 11 drugs, the cost of U.S. health care would be even
 12 higher, so trust in generic drugs is absolutely
 13 essential to help make health care affordable.

14 For that reason, we encourage the FDA to
 15 talk more about what you are doing to ensure that
 16 generic drugs are truly identical to brand names in
 17 all the ways that matter to patients.

18 What are the metrics in the commitment
 19 letter? I pointed out just a few -- by the numbers
 20 that were included in the commitment letter -- of
 21 the things that seemed to be focused more on safety
 22 to us. The number 6 was the number of inspections

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1 conducted by domestic or foreign establishment
 2 location and inspection type and facility type, and
 3 number 7 was the median time from beginning of
 4 inspection to Form FDA 483 issuance. These are
 5 obviously very important to industry as well, but
 6 at least they seem to be a metric that says to us
 7 that these inspections are taking place in a way
 8 that's important.

9 Number 8 was the median time from Form
 10 FDA 483 issuance to the warning letter, et cetera,
 11 et cetera. You can all read; I don't need to read
 12 this to you, and number 9, the median time from the
 13 date of the warning letter, the import alert, or
 14 regulatory meeting to resolution.

15 Again, these are metrics of importance to
 16 industry and, obviously, to the FDA, but also can
 17 be very important to patients and consumers to feel
 18 that these inspections matter and that decisions
 19 are being made based on the information they are
 20 carefully gathering at these inspections.

21 The last two that I'm going to mention, the
 22 last two metrics, number 12, which is the number of

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1 citizen petitions to determine whether a listed
 2 drug has been voluntarily withdrawn from sale for
 3 reasons of safety or effectiveness, pending a
 4 substantive response for more than 270 days from
 5 the date of receipt.

6 The citizen petitions, obviously, are sort
 7 of a dual-edged sword because, on the one hand, you
 8 wouldn't need citizen petitions if things were
 9 moving as smoothly as one would like. But then
 10 again, the fact that there are citizen petitions
 11 means that the FDA needs to respond to them in a
 12 timely manner, but not just in a timely manner, but
 13 also in a meaningful way, so I encourage that to be
 14 reworded as well; then number 18, the percentage of
 15 facility reinspections carried out within 4 or
 16 8 months after the letter to the facility,
 17 indicating FDA's intent to reinspect.

18 So again, this is important to all
 19 stakeholders, but certainly carrying out
 20 reinspections shows that the FDA is on top of
 21 things and that these inspections, which we think
 22 are very, very important, are being done in a

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1 timely manner.

2 In conclusion, I want to say that we would
 3 have liked to see in the commitment letter some
 4 other metrics that are more specific to ensuring
 5 patients, consumers, and the public health
 6 community that these user fees are being used in a
 7 way that doesn't just speed the process along,
 8 doesn't just make life easier for industry -- that
 9 was very important -- but also ensures that the
 10 products being approved by the FDA are exactly as
 11 they've been described to us. That's what the
 12 public needs to continue to have trust in generic
 13 drugs, and as I said, that is so essential for our
 14 healthcare system. Thanks very much.

15 MR. BEACH: Thank you, Diana.
 16 Brian McCormick?

17 MR. McCORMICK: Good morning. Thanks,
 18 Carter.

19 My name is Brian McCormick. I am Vice
 20 President and Chief Regulatory Counsel for Teva
 21 Pharmaceuticals. I'm also Teva's head of Global
 22 Regulatory Policy. I had the privilege of serving

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1 as an AAM member company representative for the
2 GDUFA III negotiations.
3 I want to start by thanking FDA for its
4 collaboration in negotiating a well-thought-out and
5 robust commitment letter that will serve the agency
6 and industry well in the coming years. While
7 GDUFA II has been a great success, there are
8 aspects of the generic drug program that need more
9 attention moving forward.
10 Through the hours we spent at the
11 negotiating table, we arrived at an agreement that
12 builds upon the successes of GDUFA II and looks
13 ahead to the types of applications that FDA will be
14 assessing over the next five years. As GDUFA III
15 is adopted and implemented, I believe we will see a
16 more predictable, transparent, and scientifically
17 driven system to support the development and
18 approval of generic drugs.
19 I'll focus my brief remarks today on those
20 aspects of the GDUFA III commitment letter that
21 Teva believes will most improve the development and
22 approval of complex generic products. As many

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1 others have noted, the commitment letter offers a
2 number of new and enhanced meetings that will
3 provide FDA and industry with more opportunities to
4 discuss the novel scientific issues that arise
5 before and after the submission of ANDAs for
6 complex products.
7 For example, one significant issue that
8 industry hopes to address under GDUFA III is the
9 risk to generic entry created by the issuance or
10 revision of product-specific guidances applicable
11 to pending or tentatively approved ANDAs.
12 The PSG program is one of the great
13 successes of GDUFA to date, but when a PSG is
14 issued or revised, and the approval standards
15 change for an applicant midstream, it's difficult
16 to overstate the obstacles this creates, especially
17 for complex products.
18 The additional time and expense required to
19 meet the new standards can undermine the entire
20 business case for an applicant to bring a product
21 to market, and currently there is no opportunity to
22 discuss with FDA how to mitigate or address the

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1 changes in a way that would allow the application
2 to move forward.
3 Regulatory science must continue to advance,
4 and FDA should continue to develop new and revised
5 PSGs, but it must do so carefully with an
6 understanding of potential unintended consequences.
7 The improvements to the PSG program made under
8 GDUFA III will help to address these challenges.
9 FDA has committed to making the PSG revision
10 process more predictable and transparent for
11 industry. The agency's commitment to post on its
12 website when it intends to update a PSG will allow
13 industry to better plan for potential changes and
14 build them into the regulatory strategy when
15 possible.
16 We also appreciate that FDA will make
17 clearer how it intends to prioritize PSGs and how
18 industry can contribute to that prioritization. The
19 agency has also committed to publishing PSGs for
20 new chemical entities and complex products within
21 predictable time frames after NDA approval.
22 Most importantly, under GDUFA III, industry

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1 will have the opportunity to meet quickly with FDA
2 when the agency issues or revises a PSG applicable
3 to an applicant's product once in vivo work has
4 begun. The applicant and FDA will be able to
5 discuss the PSG, the impact on the development
6 program, and how to address gaps.
7 If this initial teleconference is not
8 enough, the dialogue can continue through
9 Controlled Correspondence or at another meeting to
10 discuss the scientific rationale for an approach
11 different from the one described in the new or
12 revised PSG. While these PSG meetings are not a
13 guarantee that an ANDA will be approved in the
14 current or even the next assessment cycle, they
15 represent a significant step forward.
16 Two other meeting types for complex products
17 have been enhanced under GDUFA III, which we
18 believe will go a long way toward improving the
19 assessment process and bring you more generics to
20 market in fewer cycles. These are the enhanced mid-
21 cycle meeting and the post-CRL scientific meeting.
22 While GDUFA II offers meetings at both of

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1 these points in the assessment cycle, the meetings
 2 tend to be perfunctory and do not offer meaningful
 3 opportunities to discuss scientific issues with
 4 FDA. In Teva's view, the ability to have a
 5 meaningful dialogue with FDA at both of these
 6 points could be a gamechanger for complex products.
 7 Under GDUFA II, the mid-cycle meeting is
 8 merely a chance for FDA to update an applicant on
 9 the status of its application. No additional
 10 questions are asked and industry cannot discuss
 11 with FDA how to address deficiencies during the
 12 current assessment cycle.
 13 Under GDUFA III, industry will have the
 14 option to discuss with FDA how to address
 15 deficiencies identified in the mid-cycle discipline
 16 review letters. This will allow an applicant to
 17 respond to FDA during the current cycle through an
 18 amendment or, at worst, more quickly begin
 19 developing the data needed to gain approval on the
 20 next cycle. Either way, this is a more efficient
 21 process than having to wait for a complete response
 22 letter.

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1 meet with FDA early and throughout the process is
 2 crucial, and the product development meeting offers
 3 a key forum to discuss substantive scientific
 4 issues.
 5 These interactions lead to improved ANDA
 6 quality and fewer assessment cycles. Especially in
 7 the absence of a PSG for a complex product, getting
 8 the agency's guidance prior to submission makes all
 9 the difference.
 10 In closing, Teva unequivocally supports the
 11 GDUFA III commitment letter. We were proud to
 12 participate in the GDUFA III negotiations with our
 13 industry and trade association colleagues, and
 14 we're looking forward to continuing our dialogue
 15 with the agency to bring more generics to market
 16 faster.
 17 We believe that complex generic products, in
 18 particular, play an important role in lowering
 19 healthcare costs and making room in the healthcare
 20 system for the innovative and more expensive
 21 therapies that come to market each year. Thank you
 22 very much.

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1 The same goes for the post-CRL scientific
 2 meeting. Many post-CRL meetings under GDUFA II are
 3 frustrating. They're restricted to clarifying
 4 questions with applicants' proposed questions often
 5 rejected by FDA, and do not offer an opportunity to
 6 discuss data or an applicant's strategy to address
 7 the issues raised in the CRL.
 8 Under GDUFA III, industry will have the
 9 option to discuss with FDA the new data needed to
 10 secure approval on the next assessment cycle.
 11 Moreover, the timing of this meeting will not be
 12 limited. An applicant can request a meeting at any
 13 time in this post-CRL development process. This
 14 will lead to fewer cycles and faster approvals
 15 because industry will be able to respond to CRLs
 16 with the information that FDA needs, taking the
 17 guesswork out of the development process.
 18 Finally, I wanted to take a moment to
 19 underscore the value of one meeting that will not
 20 be changing from GDUFA II to GDUFA III, the product
 21 development. The development process for complex
 22 products is long and challenging. Being able to

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1 MR. BEACH: Thanks so much, Brian. We
 2 appreciate your participation in the negotiations.
 3 Next, Raghuram Pannala?
 4 DR. PANNALA: Hello, everybody.
 5 MR. BEACH: We'll have your slides up in a
 6 moment.
 7 DR. PANNALA: Can everybody hear me?
 8 MR. BEACH: Yes.
 9 DR. PANNALA: Hello, everybody. Good
 10 morning. I'm Raghuram Pannala, working for ScieGen
 11 Pharmaceuticals. I've been working in the industry
 12 from the time of [indiscernible] filings, GDUFA I
 13 and II. Today I'm going to present our company's
 14 thoughts and my thoughts.
 15 This is the disclaimer. ScieGen
 16 Pharmaceuticals appreciates all the great work by
 17 the agency on GDUFA in the pandemic time. The
 18 thoughts presented are only for suggestions and for
 19 the betterment of the program.
 20 For the sake of convenience of this talk,
 21 I'll make the three categories. The initial filing
 22 on life cycle management may be covered by the

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1 filing fees. The scientific enhancements and
 2 complex generics may be covered by the program
 3 fees. Audits, emerging technologies, and
 4 continuous manufacturing may be covered by the
 5 facility fees.

6 Communicating internally on the forms in the
 7 ANDA review status is quite a task. If GDUFA can
 8 adapt the model of e-commerce, firms can check the
 9 current status of ANDA online, and it will be
 10 helpful if we can know about an upcoming event and
 11 predictable day on approval for launch
 12 preparations.

13 This is shaping out to be more critical in
 14 the new normal due to ongoing supply chain issues,
 15 which may live with us for some time. With CASA
 16 and AA [ph] tools in place, this may be an
 17 achievable task. A graphic presented below is a
 18 snapshot of how it may look like.

19 Our firm has received some first-cycle
 20 approvals and [indiscernible] approvals. We
 21 appreciate all the great work by the agency. The
 22 below case study [indiscernible] is a development

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1 opportunity. In this case, the initial goal date
 2 was 2018 December, and the approval of August 2019.

3 The delay may be reduced with 3 months if
 4 ScieGen Pharmaceuticals agreed with dissolution
 5 specs during the first deficiencies we got. Also,
 6 the 6 months would have been avoided if the DMF
 7 deficiencies would have been issued through all the
 8 ANDA filings in advance. Also, the DMF
 9 deficiencies would have been reviewed in context
 10 with the drug product. This is scope
 11 [indiscernible] development on this part, so that
 12 is the reason we present it.

13 Coming under the initial review process,
 14 that is from filing to approval, some points for
 15 consideration. Major review points on drug product
 16 and DMF, which may delay approval and be
 17 communicated in faster year, which will help the
 18 ANDA holder in attempting resolution. The
 19 facilities part may not be possible in our
 20 attempts, but it will be helpful. Mid-cycle review
 21 status updates are not guaranteed in GDUFA II, but
 22 it will be very helpful if mid-cycle status, along

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1 with discipline status, is updated automatically to
 2 all the ANDA filings.

3 In some [indiscernible] training sessions,
 4 major deficiencies are presented. It will be
 5 helpful for firms to develop the quality of filing
 6 if top 10 deficiencies are published periodically.
 7 Some of the other regulatory agencies are following
 8 this model.

9 Administrative form updates by FDA emails,
 10 like GDUFA emails, and [indiscernible] emails will
 11 be helpful. Some of these are from the
 12 [indiscernible] updates. The recent DMF 3938 form
 13 is appreciated. There may be some delays due to
 14 the PET and regulatory clearances. These delays
 15 may be avoided before just the end of the GDUFA
 16 goal date.

17 The text in gray is supporting data on
 18 ancillary points. [Indiscernible] management. FDA
 19 is advocating and increasing emerging technologies,
 20 which is very helpful. Some time and funds are
 21 also needed together to the aging facilities'
 22 upkeep and switching to new technologies. This

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1 will be a great help to small and medium-size
 2 organizations.

3 As cited here, the examples from changes to
 4 NDA and ANDA guidance, dated 2004, as we all know,
 5 with different levels of understanding on
 6 technologies and the equipment being used, the
 7 changes may be reclassified, increasing firms to
 8 embrace new technologies, which may save time,
 9 money, and ensure more compliance, and come back to
 10 the world of technologies.

11 Speaking on the DMF review, dealing with DMF
 12 changes allow DMF holders to file independently
 13 whenever possible, and the changes will help ANDA
 14 holders a lot. The guidance, [indiscernible], DMF
 15 changes guidance, [indiscernible] CBE supplements
 16 and accepting some changes from DMF holders in
 17 annual reports. Allowing facilities to be
 18 communicated to ANDA holders in 30 or 60 days on
 19 the day of filing will help ANDA holders to speak
 20 to the DMF holder and resolve the issues. We are
 21 very much thankful for the recent Form 3938
 22 [indiscernible] the DMF.

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1 Scientific enhancements [indiscernible],
 2 training programs are within our [indiscernible],
 3 and case studies presented are really appreciated.
 4 It will be really helpful and useful if model
 5 documents are released just like the QbD
 6 nitrosamine risk assessment and a few models have
 7 as requested. ICH quartile and established
 8 conditions is being advocated by FDA. Once we'll
 9 try to attempt if there is a model filing document
 10 developed.
 11 Coming to facilities and inspections, thanks
 12 to all the developments mentioned in the GDUFA III
 13 commitment letter on the facilities and also on the
 14 role of CPA. A few comments on the current
 15 scenario. In the facility inspection database, when
 16 they are searching for some of the firm's
 17 inspectional status, they're not updated, so maybe
 18 updating as I was told monthly or 15 days will be
 19 very helpful. Before filing, we can check the
 20 inspectional status of the firm which we are
 21 dealing with.
 22 OAI firms [ph] inspection to be finished and

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1 helping to decide on pending ANDAs and supplements.
 2 There may be some more transparency brought into
 3 the selection of firms for the inspection. The
 4 tools firms will use for inspection are the
 5 guidance documents. The inspectional guidance has
 6 released in the last [indiscernible]. Firms are
 7 relying more on the 483 issued to others. This is
 8 something like preparing for an exam on someone
 9 else's papers.
 10 So maybe the agency should look at the
 11 inspectional guidance documents some time before,
 12 and revising and bringing the current scenarios
 13 into them.
 14 I'm very much thankful for the FDA and
 15 management for allowing me to present my thoughts,
 16 and colleagues for sharing their thoughts during
 17 the presentation. I'm very much happy to present
 18 my thoughts to GDUFA III reauthorization process.
 19 ScieGen Pharmaceuticals supports GDUFA III
 20 reauthorization and looks forward to work with the
 21 agency as per the expectations and statute. Thank
 22 you.

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1 Clarifying Questions
 2 MR. BEACH: Thank you so much. We
 3 appreciate the input.
 4 We have some time here for questions and
 5 answers. I have one here for Lisa Berry.
 6 "What is the fee for type 3 DMF?"
 7 MS. BERRY: The DMF fees are only for type 2
 8 DMFs, and there is no fee for a type 3 DMF.
 9 MR. BEACH: Thank you, Lisa.
 10 Again, there's a Q&A icon at the bottom of
 11 the presentation screen here. If you have any
 12 questions, please enter them there.
 13 We will continue to keep an eye on that as
 14 we [inaudible – audio gap] here. But in the
 15 meantime, we want to have closing remarks from
 16 Sally Choe from OGD.
 17 Sally?
 18 Closing Remarks – Sally Choe
 19 DR. CHOE: I'm Sally Choe, Director of FDA's
 20 Office of Generic Drugs. It has been extremely
 21 valuable hearing from everyone today as we prepare
 22 to proceed with our work to implement GDUFA III.

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1 As we wrap up today's productive and
 2 insightful meeting, I want to give a special thank
 3 you to everyone who has made it possible to get to
 4 this stage. In particular, a sincere thank you to
 5 the FDA staff and industry members who worked over
 6 the past year to develop the set of recommendations
 7 we have discussed today.
 8 Thanks to your dedication, hard work, and
 9 long hours, we have a solid proposed commitment
 10 letter that was the foundation of our robust public
 11 discussion today. Thank you also to the patients,
 12 consumer groups, and all stakeholders who engaged
 13 in the process of negotiations and provided
 14 insights and input as well. And lastly, thank you
 15 to everyone who joined us today and provided
 16 feedback that we will most certainly take into
 17 account as we move forward.
 18 Because of the work done up to this point
 19 and input we've received, FDA is well equipped to
 20 build on the success of GDUFA II and take our
 21 generic program into the next era with GDUFA III.
 22 This includes the GDUFA III goals of achieving

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1 earlier approvals through enhanced communication
2 and assessment processes; enhancing the
3 development, assessment, and approval of complex
4 generic products; and assuring a sound financial
5 foundation for GDUFA III.
6 FDA is committed to meeting the performance
7 goals outlined in the proposed commitment letter.
8 Our next job, before GDUFA III implementation
9 starts, is to consider the public views we heard
10 today, as well as comments submitted to the docket,
11 and make any necessary changes to the commitment
12 letter needed.
13 We will then transmit the GDUFA III
14 recommendations to Congress no later than the
15 statutory date of January 15, 2022. We are
16 confident Congress will agree this proposal is a
17 positive step for FDA, industry, and public health.
18 We look forward to providing updates to FDA staff
19 and the public about how GDUFA III will be carried
20 out and how that will assist us in fulfilling our
21 mission of ensuring Americans have access to safe,
22 effective, high-quality, and more affordable

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1 medicines. Thank you again for your time today.
2 Thank you, Carter.
3 Clarifying Questions
4 MR. BEACH: Thanks so much, Sally.
5 We do have one question here in the chat.
6 "Can you explain more how regulatory science
7 research feeds into PSGs?"
8 Rob Lionberger, do we have you here?
9 DR. LIONBERGER: Yes. Most of our
10 product-specific guidances, especially for the
11 complex products where there's some novel aspect of
12 it, there is some regulatory science work that has
13 to be done before we can identify the appropriate
14 work.
15 Sometimes this is done through our
16 collaborations with FDA labs, where we need to
17 measure certain things to determine that they can
18 be measured. Some instances are a little more
19 advanced, that we want to develop techniques to
20 measure something that maybe hasn't been measured
21 before that's necessary for approaches to
22 bioequivalence. Sometimes this is done through

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1 external research collaborations with experts
2 outside of FDA as well.
3 Some of the product-specific guidances
4 really do require that level of effort in order to
5 provide a pathway in the product-specific guidance
6 that we know will be effective and leading toward a
7 generic drug product.
8 Adjournment
9 MR. BEACH: Thanks, Rob.
10 I appreciate everyone's flexibility as we
11 shifted the agenda here a little bit. I hope on
12 balance, you appreciate the earlier end time. At
13 the moment, we don't have any open questions, so we
14 will close out here.
15 Thank you for your attendance and
16 participation. We really value the engagement and
17 input. We look forward to your comments in the
18 Federal Register and going through those and
19 addressing them.
20 As mentioned, we will deliver the proposed
21 GDUFA III package to Congress in January, and then
22 we'll work toward a smooth transition from GDUFA II

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1 to GDUFA III.
2 Have a nice day. Thanks again.
3 (Whereupon, at 11:58 a.m., the meeting was
4 adjourned.
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