

*Public Meeting for Reauthorization of the Generic Drug
User Fee Amendments of 2012 (GDUFA II)*

October 21, 2016

*A Matter of Record
(301) 890-4188*

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<p>1 FOOD AND DRUG ADMINISTRATION</p> <p>2</p> <p>3</p> <p>4 Public Meeting for Reauthorization of the</p> <p>5</p> <p>6 Generic Drug User Fee Amendments of 2012 (GDUFA II)</p> <p>7</p> <p>8</p> <p>9</p> <p>10 Friday, October 21, 2016</p> <p>11 9:10 a.m. to 12:34 p.m.</p> <p>12</p> <p>13</p> <p>14</p> <p>15 FDA White Oak Campus</p> <p>16 10903 New Hampshire Avenue</p> <p>17 Building 31 Conference Center</p> <p>18 The Great Room (Rm. 1503 B & C)</p> <p>19 Silver Spring, Maryland</p> <p>20</p> <p>21</p> <p>22</p>	<p>1 Ann Marie Montemurro</p> <p>2 Office of Regulatory Affairs</p> <p>3</p> <p>4 Donal Parks</p> <p>5 Office of Management</p> <p>6</p> <p>7 Gil Roth</p> <p>8 Pharma & Biopharma Outsourcing Association</p> <p>9</p> <p>10 Ted Sherwood</p> <p>11 Office of Regulatory Operations</p> <p>12</p> <p>13 Kathleen Uhl</p> <p>14 Office of Generic Drugs</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p>
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<p style="text-align: right;">Page 5</p> <p>1 C O N T E N T S (continued)</p> <p>2 AGENDA ITEM PAGE</p> <p>3 Panel 3 - Facilities & Reporting</p> <p>4 Ashley Boam 90</p> <p>5 Open Public Comment 95</p> <p>6 Closing Remarks 102</p> <p>7</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p>	<p style="text-align: right;">Page 7</p> <p>1 go across the entire program both for application</p> <p>2 review and facility assessment; transparency and</p> <p>3 communication enhancements, which are extremely</p> <p>4 important and will provide greater accountability</p> <p>5 for the program for both our managers running the</p> <p>6 program and for our stakeholders, and for industry.</p> <p>7 And we'll also be talking about changes from</p> <p>8 GDUFA I to GDUFA II in the fee structure.</p> <p>9 I'd like to take a second and reflect back</p> <p>10 to a little over a year ago when we had our first</p> <p>11 open public meeting on June 15th of last year, and</p> <p>12 during that meeting, we opened up the process for</p> <p>13 this reauthorization.</p> <p>14 We spent some time talking about our</p> <p>15 experiences to date with implementing GDUFA I. We</p> <p>16 heard from industry. We heard from consumer</p> <p>17 representatives. We heard from individual members</p> <p>18 of the industry. And we also heard from healthcare</p> <p>19 payers. And several themes emerged from that, that</p> <p>20 were important for the agency to hear and that</p> <p>21 helped guide our negotiations, and I think we have</p> <p>22 responded to successfully in the new agreement.</p>
<p style="text-align: right;">Page 6</p> <p>1 P R O C E E D I N G S</p> <p>2 (9:10 a.m.)</p> <p>3 Welcome - Mary Beth Clarke</p> <p>4 MS. CLARKE: Good morning to everyone who's</p> <p>5 joining us. My name is Mary Beth Clarke. I'm the</p> <p>6 director of the Office of Executive Programs at the</p> <p>7 Center for Drug Evaluation and Research here at</p> <p>8 FDA. I want to welcome everyone, whether you're</p> <p>9 here in person or watching remotely, to the public</p> <p>10 meeting on our proposed agreement for the</p> <p>11 reauthorization of the Generic Drug User Fee</p> <p>12 Amendments. For the rest of this meeting, everyone</p> <p>13 will just be saying GDUFA II.</p> <p>14 This is an opportunity, for those of you</p> <p>15 here and the public, to make your views known about</p> <p>16 the agreement. We have a very full day planned for</p> <p>17 you with some of our FDA officials who were</p> <p>18 involved in the negotiations or who will be leading</p> <p>19 the new program, assuming that it is passed by</p> <p>20 Congress, and they'll be talking to you about a</p> <p>21 number of the new things in the agreement: the</p> <p>22 performance goals; the program enhancements, which</p>	<p style="text-align: right;">Page 8</p> <p>1 First and most importantly, generics are</p> <p>2 vitally important to today's healthcare system and</p> <p>3 to the health of the American public. They were</p> <p>4 important in June of last year as we opened this</p> <p>5 process, and I think everyone here knows that over</p> <p>6 the last year, they have not diminished at all in</p> <p>7 the attention of stakeholders and the public, and</p> <p>8 their importance.</p> <p>9 Second, the agency and the program heard the</p> <p>10 message, and that has continued to work faster,</p> <p>11 approve more generics more quickly, and give us a</p> <p>12 more robust generic drug marketplace for the United</p> <p>13 States, however, do not sacrifice quality. The</p> <p>14 public and our healthcare providers depend upon the</p> <p>15 quality of these products and being able to use</p> <p>16 them interchangeably.</p> <p>17 Last, we heard a great deal, which we</p> <p>18 believe we responded to, in terms of making</p> <p>19 adjustments to the program both in its performance</p> <p>20 and in how the program is structured financially</p> <p>21 and how fees are paid.</p> <p>22 So we hope that you will find as you hear</p>

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1 the details today by the agency officials -- who
2 are also joined by some representatives from the
3 generic pharmaceutical industry trade associations.
4 We have David Gaugh from the Generic Pharmaceutical
5 Association; John DiLoreto from the Bulk
6 Pharmaceuticals Task Force; and Gil Roth from the
7 Pharma and BioPharma Outsourcing Association.
8 I'm not sure if our colleague from the
9 European group is actually here to join us today,
10 but we were fortunate to have a really good robust
11 negotiating team, and I think we ended up with a
12 good agreement. They will be joining our FDA
13 officials up here for different panels.
14 I'd also like to point out to you, if you
15 are interested in the full text of the commitment
16 letter that is available online on our website. So
17 you may study that, but we believe today will give
18 you some very important context and some detail for
19 how we arrived at the agreement.
20 After the presentations, there will be an
21 open public comment period in the afternoon. We
22 welcome all of your comments. If you did not have

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1 the opportunity to register in advance to speak, we
2 will accommodate as many speakers as time allows.
3 Written comments may also be submitted to the
4 docket, which was originally available only up
5 until I believe the beginning of November, and that
6 has been extended.
7 There is a new Federal Register notice that
8 is on display today and will be published formally
9 on Monday that extends the docket until
10 November 16th. And after all comments are
11 received, the agency will consider those and
12 finalize the proposed agreement, which will be then
13 transmitted to Congress by the due date, which is
14 January 15th of 2017.
15 If you have any media inquiries or any other
16 questions, we ask you to take those to Kris
17 Baumgartner and Sandy Walsh, our FDA communications
18 staff who are here. I believe the trade press
19 representatives are here, and you're familiar with
20 them, and will take any questions.
21 I'd like to turn now to our first speaker of
22 the day, Dr. Cook Uhl, who is the director of the

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1 Office of Generic Drugs here at FDA, who's going to
2 give you some opening comments.
3 Opening Remarks - Kathleen Uhl
4 DR. UHL: Good morning. Let me echo Mary
5 Beth's welcome, and thank you, Mary Beth, for those
6 very nice opening comments.
7 First of all, I want to thank everyone who
8 is here, whether you're here in person or on the
9 WebEx, but thank you for your participation here
10 today. I also want to sincerely thank everyone
11 involved in the development of the GDUFA II
12 recommendations. These recommendations reflect
13 nearly a full year of negotiations with a lot of
14 late nights, and long weekends, and extreme hard
15 work for FDA and the industry staff that have been
16 involved in these negotiations. I thank also the
17 patient and consumer groups who have stayed engaged
18 throughout the long process.
19 I have just a few opening comments. First,
20 in terms of the big picture context, the Generic
21 Drug Program has been, and continues to be, an
22 extraordinary public health success story,

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1 absolutely. According to the IMS Institute of
2 Healthcare Informatics, generic drugs saved the
3 U.S. healthcare system \$1.6 trillion between 2005
4 and 2014. So let me say that again, 1.6 trillion,
5 with a T, a big T, trillion dollars over a 10-year
6 period.
7 Nearly 90 percent of the prescriptions
8 dispensed in the United States in 2014 were filled
9 with generics, and I understand the most recent IMS
10 report, that's now on GPhA's website, is 89 percent
11 of prescriptions dispensed in this country are
12 generic.
13 So these numbers speak for themselves. And
14 if you can't put two and two together to understand
15 how they speak for themselves, I will just say
16 these numbers demonstrate the huge success of
17 Hatch-Waxman and GDUFA I.
18 Second, I am extremely proud of FDA's
19 Generic Drug Program staff. OGD, the Office of
20 Generic Drugs, is really the center of the wheel.
21 We are the principal public face of the program.
22 But my office is just one part of that picture.

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1 The program includes many other offices across CDER
 2 and across the agency, including the Office of
 3 Pharmaceutical Quality, OPQ in CDER; many other
 4 parts of CDER; the Office of Regulatory Affairs;
 5 the chief counsel's office; and many other parts of
 6 the agency.

7 I salute the whole team, FDA's team and
 8 industry's team, for getting the job done. About a
 9 year and a half ago, I started telling everyone, as
 10 I've been reporting on progress of GDUFA I, that we
 11 built a machine, and now we're cranking it up, and
 12 our approvals are going to increase.

13 Most of the listeners noted my conviction,
 14 however, they were many times skeptical. And as a
 15 matter of fact, I think most people thought I was
 16 crazy. Well, we just finished fiscal year '16,
 17 FY16. We had approximately 835 tentative approvals
 18 and full approvals in FY16. This substantially
 19 exceeds our prior record of 619 combined approvals
 20 in fiscal year 2012.

21 So this 835 approvals and tentative
 22 approvals is the highest number of approvals and

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1 tentative approvals ever in the history of the
 2 Generic Drug Program at the FDA. And in the last
 3 four years alone -- so basically, the last four
 4 years have all been under GDUFA I -- we have
 5 approved over 2,000 ANDAs, and that's nearly
 6 20 percent of all currently approved ANDAs.

7 On the other hand, the program has some
 8 persistent challenges. In particular, there are
 9 multiple review cycles for original applications.
 10 Historically, it takes on average 3.8 review cycles
 11 for an ANDA to be approved. So there's definitely
 12 more to be done.

13 Over the past four fiscal years, the agency
 14 has issued more than 5,400 complete response
 15 letters. This is a lot of first and second review
 16 cycles that have already been completed. We issue
 17 these complete response letters to industry to
 18 provide information to them about what deficiencies
 19 exist in those applications, and that industry can
 20 correct those deficiencies and hopefully lead to an
 21 approval.

22 So as we move deeper and deeper into these

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1 third and additional review cycles for this large
 2 bolus of ANDAs that are still not approved, the
 3 wave will crest, and our approvals will grow.

4 At the same time, it would be much better if
 5 we didn't have to review each ANDA multiple times
 6 to get it approved. The process is inefficient,
 7 and it's frustrating for FDA and for industry
 8 alike. It's not good for public health. Reducing
 9 the number of review cycles would be a highly
 10 impactful game changer. Thus, improving submission
 11 completeness and reducing the number of review
 12 cycles is the main objective of the GDUFA II
 13 program and the GDUFA II program enhancements.

14 FDA and the regulated industry are strongly
 15 aligned on this shared objective. Ted Sherwood and
 16 Rob Lionberger, who are up here, will walk you
 17 through the main program enhancements later this
 18 morning. The purpose of this meeting is to give
 19 the public an opportunity to present its views on
 20 the proposed recommendations, so we look forward to
 21 your comments today. In addition, the docket will
 22 be open until November 16th.

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1 So again, let me say one more time, thank
 2 you for your attendance today. We appreciate your
 3 engagement, and we welcome your input. Thank you.

4 Presentation - Keith Flanagan

5 MR. FLANAGAN: Good morning. I'm just going
 6 to provide a little background concerning GDUFA II
 7 and the reauthorization process. We're going to
 8 walk through why do we have a GDUFA I in the first
 9 place; what is an UFA; the result of GDUFA I; the
 10 statutory process for reauthorizing the program;
 11 why the proposed GDUFA II is very important; the
 12 main features of the proposed GDUFA II; and four
 13 major lessons learned and corresponding GDUFA II
 14 recommendations.

15 So first, why is there a GDUFA I? As
 16 Dr. Uhl noted moments ago, the Hatch-Waxman program
 17 has been an amazing success, approximately
 18 \$1.68 trillion saved over the past 10 years and
 19 approximately 9 in 10 prescriptions are filled with
 20 generics, so huge successful law.

21 At the same time, the Generic Drug Program
 22 was chronically underresourced and could not keep

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1 pace with the growth of submissions. This became
2 commercially unsustainable, and GDUFA I was enacted
3 as Title III of FDASIA. This was the first ever
4 human generic drug user fee agreement,
5 approximately \$1.5 billion in user fees over five
6 years, and FDA's commitments were phased in over
7 five years.

8 This is may be remedial for many people in
9 the room, but just concerning the very, very
10 basics, user fee agreements are negotiated by FDA
11 and industry, then authorized in law by Congress
12 and the President. And pursuant to the user fee
13 agreement, industry pays agreed-upon fees, and in
14 exchange, FDA fulfills the negotiated commitments.

15 At the first public meeting, about a year
16 and a half ago, a year and a quarter ago -- we went
17 into the details here. But basically, what GDUFA I
18 enabled FDA to do was to execute a deep
19 foundational restructuring of FDA's Generic Drug
20 Program. I'm not going to repeat the entire
21 presentation from last June. You can see it at our
22 website, and the documentation is there.

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1 GDUFA I contained metric goals to improve
2 the speed and predictability of review. We are
3 currently achieving record levels of output, which
4 we expect to continue to increase. As Cook
5 mentioned, we had about 835 TAs and approvals in
6 fiscal year '16, which dramatically exceeds our
7 earlier record, and we think output will continue
8 to increase.

9 We're confident output will continue to
10 increase, improving access to quality, affordable
11 generic medicines. Not to hop up and down about
12 it, but it's worth noting that FDA has met or
13 exceeded all of its negotiated GDUFA I commitments.

14 So there is a procedure prescribed in FDASIA
15 for reauthorizing the program. Pursuant to
16 sections 744C(d) of the Federal Food, Drug, and
17 Cosmetic Act, the first thing we have to do is have
18 consultation with shareholders [sic –
19 stakeholders]. We've checked that. We did that.
20 Second is the statute requires prior public input.
21 So as noted, we conducted a public meeting last
22 June 2015. Third, we're required to post minutes

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1 of the negotiating meetings on the website, which
2 we did. And fourth, we conducted periodic
3 consultations with patient and consumer advocacy
4 groups throughout the negotiations.

5 So item 5 is public review of the
6 recommendations. That's today's meeting. We walk
7 you through the commitment letter, which has been
8 noticed. The FR notice was also very detailed and
9 explanatory, and we are soliciting your feedback.

10 FDA's sorry to repeat this because it's a little
11 tiresome maybe for you, but we want to stress the
12 docket remains open through November 16th, and we
13 welcome your comments. And finally, the
14 recommendations are transmitted to Congress by the
15 statutory deadline.

16 Why is GDUFA II very important? Because if
17 we don't timely reauthorize, there are bad
18 consequences, and if we do timely reauthorize,
19 there will be good consequences. So the bad
20 consequence if we don't have timely reauthorization
21 is the user program pursuant to statute expires.
22 This would create severe disruption in the Generic

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1 Drug Program. There would be staff layoffs
2 affecting reviewers and our field investigators,
3 and it would dramatically reduce program
4 performance.

5 On the other hand, if the program is timely
6 reauthorized, we would have a more efficient and
7 effective review program; as Dr. Uhl mentioned, and
8 Mary Beth as well I think, reduced cycles to
9 approval, increased rate of approval, and we would
10 be able to maintain and grow consumer access to
11 generics.

12 The main features of GDUFA II, many of which
13 other panelists will walk through in the rest of
14 the day -- this is kind of a high-level
15 overview -- ANDA review goals; ANDA review program
16 enhancements; DMF review program enhancements; an
17 enhanced pre-ANDA process for complex products;
18 facility assessment enhancements; enhanced
19 accountability and reporting; a program size
20 commensurate with our workload; modifications to
21 the user fee structure; and some small business
22 considerations.

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1 So I'm going to walk you through four big
2 lessons learned in GDUFA II and how the proposed
3 GDUFA II agreement addresses that. Here's
4 important lesson learned number 1.
5 In GDUFA I, our ANDA review goals were
6 extremely complex and arcane. There was widely
7 differential treatment of different cohorts and
8 tiers of submissions, and in addition, adding
9 another layer of complexity, because, pursuant to
10 GDUFA I, ANDAs submitted prior to fiscal year '15,
11 year 3 of the program, fiscal year '15, did not
12 receive goal dates.
13 Industry sought additional clarity
14 concerning when we might act on those submissions
15 and some predictability so that they could do
16 launch planning and conduct other types of
17 important business planning. So even though the
18 GDUFA I commitment letter didn't require or
19 contemplate it, we assigned informal target action
20 dates to thousands of submissions.
21 The long story short is that got us here.
22 It created some kind of taxonomy over the entire

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1 large workload and charted a feasible path to our
2 current state, where we're achieving record levels
3 of output. On the other hand, it was very
4 difficult to operationalize. And in addition, one
5 result was a significant gap -- one result of the
6 GDUFA I goals as negotiated was there was a
7 significant gap between the formal negotiated
8 review goal commitments on the one hand, and
9 stakeholder expectations on the other.
10 For GDUFA II, we proposed that all ANDAs and
11 ANDA amendments would fall within a single
12 consolidated review goals scheme. This would
13 simplify and streamline program administration and
14 dramatically improve review efficiency. It would
15 enable us to focus more on reviewing ANDAs and less
16 on administering a very complex scheme. It would
17 also reduce that gap between our formal goals on
18 the one hand and stakeholder expectations on the
19 other.
20 So my colleague, Ted Sherwood, will present
21 some of these more detailed recommendations on
22 panel 1.

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1 The next big lesson learned concerned the
2 ANDA review process itself. The GDUFA I commitment
3 letter described the ANDA review process at a high
4 level of generality. The GDUFA I ANDA review
5 procedures, when first operationalized by FDA, did
6 not meet industry's expectations and were
7 reportedly commercially disruptive.
8 There might be some -- I'm kind of
9 understating the magnitude of that, and there are
10 some smirks from industry in the audience. So we
11 had a lot of work to do, and FDA made some
12 adjustments. Applicants saw much more
13 communication and much more transparency.
14 For GDUFA II, the proposed ANDA review
15 procedures are much more specific and programmatic
16 than corresponding features of GDUFA I. They
17 refine and enhance each stage of the ANDA review
18 process from start to finish.
19 There is much more communication and
20 transparency in general and at key points in the
21 process. Roles and responsibilities, sequencing
22 and timing, are prescribed in detail, and there are

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1 more opportunities for applicants to address
2 deficiencies within the current review cycle.
3 That's a big deal. That is intended to reduce the
4 number of cycles to approval. And again,
5 Mr. Sherwood will produce the details on panel 1.
6 The third big lesson learned from GDUFA I is
7 complex products pose distinct scientific and
8 regulatory challenges. Applicants sometimes don't
9 know what FDA expects at the front end, so it is
10 harder for them to develop approvable ANDAs for
11 submission. Then what happens is because of that,
12 after submission, there are often a lot of review
13 cycles for complex product ANDAs, and a huge amount
14 of back and forth between FDA and applicants. This
15 is highly inefficient.
16 So for GDUFA II, we propose an enhanced
17 pre-ANDA process for complex products. The
18 big-picture concept is we want to frontload work so
19 that the ANDA can be right the first time when it's
20 submitted.
21 FDA will issue a guidance concerning this.
22 We want to target this program so it will be sure

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1 to improve review efficiency. We want to mitigate
2 operational risk. And what that means is we still
3 have a lot of ANDAs in house, and our review staff
4 needs to spend a lot of time reviewing those ANDAs
5 so we can get products out. If we're swamped by a
6 high volume of low-impact meetings, that takes time
7 away from review activities.

8 The third thing the guidance will need to do
9 is manage stakeholder expectations. FDA and
10 industry both definitely and strongly want to do
11 this, but I want to clarify that this is targeted.
12 It is not a broad, open-end invitation to consult
13 with FDA, although there are some features in there
14 like control correspondence and other such
15 features, so there are other consult opportunities,
16 and the applicant still has the primary
17 responsibility for developing the ANDA. And
18 Dr. Lionberger will present some of the more
19 detailed recommendations on panel 1.

20 Complex products are a relatively small part
21 of our overall workload but can consume a
22 disproportionate share of resources, so we think it

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1 is going to impact review efficiency a lot.

2 Fourth lesson learned from GDUFA I, in
3 GDUFA I, FDA and industry projected that FDA would
4 receive approximately 750 ANDAs a year, and the
5 agency planned and budgeted accordingly. We
6 actually received approximately a thousand ANDAs a
7 year, and if you look at fiscal years '12 through
8 '15, we got the equivalent of an extra year and a
9 half of work.

10 In addition, as I mentioned before with
11 respect to the target action dates, thousands of
12 pre-year 3 submissions had either no or very modest
13 GDUFA I goals and resources, but FDA still needed
14 to review them, and it usually involved multiple
15 cycles. So there was a pretty significant gap
16 between FDA's resources on the one hand, and our
17 workload, stakeholder expectations, and public
18 health needs on the other.

19 So for GDUFA II, we proposed that the
20 program should have resources commensurate with our
21 overall workload. And Mary Beth Clarke will
22 present the details on panel 2. And that is it for

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1 me. Thank you.

2 Presentation - Robert Berlin

3 MR. BERLIN: Great. Thank you very much.

4 My name is Rob Berlin. I'm a senior policy advisor
5 in the Office of Policy within the Office of the
6 Commissioner. I'm going to walk through a broad
7 overview of the landscape of the generic drug
8 industry, and in particular looking at small
9 business and possible small business relief from
10 fees.

11 The small business group was formed to
12 provide a forum to discuss the characteristics of
13 small businesses and included representatives from
14 each of the trade groups, along with CDER and the
15 Office of Commissioner for FDA. We were formed to
16 address both congressional concerns reflected in
17 congressional reports asking that within GDUFA II,
18 we consider relief for small generic drug
19 manufacturers.

20 In addition, the group was formed to reflect
21 concerns that both FDA and industry had with regard
22 to the fairness and appropriateness of the fee

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1 structure as regards to small business.

2 The group considered approaches, first off,
3 to get a sense of the shape and size of the
4 industry to defining small business, looking at the
5 potential, to look at the number of ANDAs approved
6 either for an applicant or at a facility. We
7 looked at revenue, and we looked at employee
8 numbers.

9 This work was greatly helped by work from
10 our economists who had looked both at submission
11 information to FDA in terms of facility payments
12 and application numbers, and also match that
13 through internet searches, Dun & Bradstreet
14 research, to try to understand affiliate
15 relationships between different entities.

16 In considering approaches to fee relief,
17 industry suggested several ways we might look at
18 this. For instance, we looked at small business
19 relief in the form of a discount or waiver on the
20 fee for the first application that a small business
21 would submit as an ANDA. In addition, we looked at
22 an issue that we've sort of termed payment while

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1 pending, so the idea that entities would be paying
2 a facility fee before there were any approved ANDAs
3 produced at that facility.
4 So working through a variety of these
5 possible options and different ways to approach it,
6 we discussed the practical impact of the proposals,
7 an obvious being any relief provided to small
8 businesses is going to distribute cost to others.
9 Likewise, if you have a process for people to
10 request waivers or to seek relief in some form from
11 fees, you have a burden on the applicants to
12 produce information to support that, and likewise,
13 you have a burden on FDA to administer that program
14 and review information that would come in.
15 At the same time we were talking about these
16 issues, there were two very significant fee issues
17 that fell outside of the small business group's
18 work, and the group intentionally put these issues
19 to the side while acknowledging the discussions in
20 the group would affect our review of these issues
21 and vice versa. And those issues were the overall
22 program cost and the split of the fees between

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1 applications and facilities; and within facilities,
2 between different players, applicants who also have
3 ANDAs, contract manufacturing organizations that
4 were making finished dosage forms, and API
5 manufacturers.
6 So starting with looking at the
7 characteristics of the ANDA sponsors, what we found
8 is most ANDAs are from large firms. Approximately
9 two-thirds of ANDAs come from companies whose
10 parents have revenue of over \$100 million.
11 Likewise, for the sponsor facility, so applicants
12 who have facilities themselves, most applications
13 come from entities who have over a hundred approved
14 ANDAs already.
15 By contrast, when you look at sponsor-only
16 firms that are smaller and more likely to be
17 domestic, often they would have under \$10 million
18 of revenue. So these are entities that don't have
19 any facilities. They have under \$10 million of
20 revenue, and often less than 10 approved ANDAs in
21 their portfolio. And notably, there is a shift
22 over time towards consolidation and movement

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1 outside of the U.S., but what you get as a picture
2 is kind of two poles.
3 You have a lot of applicants where you have
4 many applicants forming your lower end of it, your
5 lower revenue, lower approved ANDA numbers, and
6 then you have a lot of very big parties with a
7 decent size middle, but you have these significant
8 poles.
9 Additionally, we looked at the
10 characteristics of facilities. You see most API
11 and FDF facilities are part of large parent
12 companies, most having over \$100 million in revenue
13 with a small portion under 10 million. But when
14 you break it down, what you see is most API
15 facilities are larger, sponsor facilities are
16 larger, but facility-only operations are small to
17 mid-size, with most having revenue under
18 \$100 million and many having revenue under
19 \$10 million.
20 So as we worked to think about how we would
21 implement any program and how we would consider any
22 relief that might be appropriate, the first

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1 challenge we really wrestled with is how do you
2 define small business, and the number of employees,
3 the revenue, and number of ANDAs. And even within
4 some of these categories, you look at revenue, for
5 instance, we found is it appropriate to be looking
6 at revenue that a company has or is it appropriate
7 to be looking at the resources that a company has,
8 so what support they might have for any work.
9 Some of them you'll find -- some companies
10 would be small under all of these definitions. For
11 instance, a start-up could be small under all three
12 criteria, but at the same time, they may have a lot
13 of support behind them in terms of venture capital
14 that could be introduced and perhaps a plan to get
15 applications approved and move on in a different
16 way from there, you're selling applications,
17 et cetera.
18 By contrast, you also have entities who are
19 small under some criteria but not under others.
20 You might imagine a large company that's new to the
21 generic space will have many employees, significant
22 revenue, but at the same time will have a very

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1 limited number of ANDAs. Likewise, you have some
2 contract facilities that have limited employee
3 numbers, limited revenue, but have quite a
4 significant number of ANDAs at their site, but
5 they're not actually producing as much because they
6 may be listed in applications but not being the
7 primary facility used.
8 So overall, you get a picture, as I
9 suggested, of a substantial number of large firms,
10 but at the same time, a very significant component
11 that's small, which makes it very hard to think
12 about exactly where one would draw the line between
13 small business and larger entities.
14 This becomes particularly challenging as we
15 looked at the API and finished dosage form
16 manufacturers who are non-sponsors. And there you
17 see there's a significant amount of uncertainty
18 about the size of the industry, so you have a lot
19 of entities that are private. You have a lot of
20 entities that are overseas. And with those, it
21 becomes very hard to both know the size of the
22 entity and to know what its affiliation status is.

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1 So as we were working through the data, you
2 end up with a significant portion that you can't
3 fully predict, and it makes it hard to think of how
4 you would appropriately set numbers.
5 Likewise, if you're thinking about how
6 you're going to administer that program, it's very
7 challenging to think about what sort of information
8 would you expect to see from industry in support of
9 an application for relief, perhaps looking at their
10 financials, et cetera.
11 It's a significant burden on FDA as well to
12 look at that information and either provide -- if
13 we have a very high amount of scrutiny on these
14 applications, it's going to take a lot of
15 resources. On the other hand, if you don't, you
16 may have inequity between the different groups as
17 to how they're treated.
18 After looking through a lot of this
19 information, we really concluded that a lot of the
20 traditional models of small business fee relief
21 didn't make a lot of sense here. They would have
22 very high administrative burdens and may not get

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1 relief to the behaviors you're trying to drive and
2 trying to ensure that people are able to
3 participate in the market.
4 So ultimately, the fee structure that will
5 be discussed later this morning by Mary Beth
6 reflects a lot of the work we've done and an
7 understanding of industry that comes from that, and
8 really as an effort to match the program fees and
9 costs to the activities that FDA engages in to
10 respond to industry demand and needs. And while
11 we'll talk through these quite a bit more, if you
12 look, issues like tiered program fees to get at the
13 burdens from different applicants, the ability to
14 pay, and how much applications are putting into the
15 agency was one approach.
16 We looked at the fact that CMOs tended to be
17 smaller businesses and often were in more need of
18 relief. We looked at that in terms of the total
19 fee that the CMOs would be paying as compared to
20 ANDA holders. Likewise, one of the issues that we
21 did raise that will be discussed further and is in
22 the fee structure as now considered is to have no

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1 payment while pending. And that's the idea, again,
2 that while an applicant is waiting for an approval,
3 or for the company with which they're working to
4 gain an approval, they won't be paying a facility
5 fee during that time.
6 So with that, I'll turn to any questions
7 people might have.
8 (No response.)
9 MR. BERLIN: I'll introduce next Rob
10 Lionberger and Ted Sherwood from FDA, and David
11 Gaugh from GPhA as well. Thank you very much.
12 Panel 1
13 MR. SHERWOOD: All right. Good morning,
14 everyone. My name's Ted Sherwood. I'm with the
15 Office of Generic Drugs on the operations side.
16 This is one of these key moments in the life of an
17 operations person, where you're both excited and
18 scared as you go through and look at some of these
19 things. I think a lot of people in FDA would
20 probably have the same sentiments.
21 We'll break this off into two sections. The
22 first one is looking at the performance goals.

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1 This is what gets people excited and certainly
2 makes a lot of the public postings that we see
3 about FDA. Since this is the transition, we're
4 going from GDUFA I into GDUFA II, we're keeping
5 those key metrics.
6 It's a mature program, so we're working at
7 90 percent. We're going to carry that into
8 GDUFA II. For many of the metrics we're going to
9 be talking about and certainly when we look at the
10 application performance, that's a very standard
11 metric that we see with healthy user-fee programs
12 across the entire agency.
13 When we look at the specific goals, we're
14 going to continue to work on the 10-month clock
15 that's new to this year, and that will really push
16 FDA to hit its maximum efficiency in terms of
17 working on both the review parts of the application
18 and the facility assessments. And the facility
19 assessments is the key to the next part.
20 For priority applications -- and here we're
21 carrying over the same definition now, public
22 health, drug shortage, first generic, sole source,

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1 those kind of things. These are more important
2 products. We want to get those out on the
3 marketplace. We want to provide that to the
4 public. We are now going to take one of these
5 scary moments and allow the companies to submit the
6 facility information in advance of the actual
7 formal ANDA. This is to allow us to get a head
8 start on making the assessments and even working
9 the potential steps to get an inspection executed,
10 if that's necessary.
11 Then the actual application will come in a
12 couple months later, and we'll start the more
13 traditional review. And then we'll have to merge
14 those two separate entities into one FDA decision.
15 So this is certainly an area where you see a lot
16 more information from the agency as we move forward
17 and pull all these pieces together.
18 But this is an exciting opportunity. We now
19 have the ability to bring these important products
20 out to the market sooner, so we're looking forward
21 to getting these high-quality applications into
22 this specific priority program.

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1 Then we have the amendments. For the
2 applications that don't get approved under one
3 cycle, which is a common occurrence and one that
4 we'll certainly work with industry to try to
5 mitigate as much as possible, we need to have
6 something in place.
7 So here's the structure. And again, what
8 you'll see is faster times for the priority
9 applications and really highlighting the fact that
10 all the way through the life of that priority
11 application, it is going to go to the express line
12 within the agency. So we're going to give it a
13 thorough review, but it is not going to be waiting
14 and held up at different spots. We will grab it
15 and work on it as it comes in.
16 Then we have the minor amendments, and this
17 is sort of a reflection of what's going on today,
18 where we've worked to hit the sweet spot; what's
19 the best we can do in terms of getting an
20 application amendment into the program, getting it
21 triaged uploaded into the platform, into the
22 reviewer's hands, hopefully ready to go and make

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1 that approval decision, where there are all sorts
2 of administrative efforts that get added on to that
3 package as it moves in for the final stamp of
4 approval.
5 Then we get into the supplements. Right?
6 You have that approval. Companies are going to go
7 out there and make changes and hopefully advance
8 their product. We've broken this off very similar
9 to what we've done in GDUFA I, ten months if we
10 need the inspection; six months if we don't.
11 Now for the priority applications, we've
12 added again that eight months fast track if the
13 company can put forward a successful pre-facility
14 communication. Let us know what the key sites are
15 just as you did on the original applications.
16 We'll start that process rolling in advance of that
17 formal supplement coming in.
18 Then for amendments, same thing, carrying
19 over many of the goals from GDUFA I, but again now
20 putting extra effort and attention on the priority
21 products and moving those through. So we're going
22 to get those changes. If it's an essential

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1 product, we will do whatever it takes to get that
2 change executed so the companies can go to market
3 based on that change.
4 Then again, for the majors and minors,
5 finish the major, get into the minor stage. We're
6 going to fast-track all of those through the
7 system. These are cases where very small changes
8 are needed by the company to hit the standard.
9 We're going to take that and work it through as
10 quickly as possible.
11 Then there's a section on unsolicited
12 amendments. Much of this is carried over. The
13 key, as in GDUFA I, the latter of the dates of the
14 type of change and the type of submission that's
15 being submitted to the agency will determine the
16 appropriate goal for that amendment.
17 Drug master files, we're going to continue
18 the success of GDUFA I and really highlighting this
19 as a separate very special review element in its
20 early stages and then as it gets linked into the
21 final ANDA decision. So in the early stages, the
22 complete and initial assessment is going to be made

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1 for 90 percent of these, so certainly a lot of work
2 to make sure all the pieces are in place for those
3 applications when they are finally submitted to the
4 agency.
5 Controlled correspondence, often times is
6 part of the R&D process for the companies. We're
7 going to work the standard ones through, 60 days,
8 as we're doing now. For complex products, this is
9 actually a slight extension, from 90 days to 120
10 days, to allow the agency more time to provide a
11 more substantial meaningful response to the
12 inquiries. So this is designed to help companies
13 understand the target where there isn't specific
14 guidance and regulation, things like that, already
15 in place.
16 New to this program is allowing formally now
17 the companies to call in and say, hey, we've
18 received your answer. It was on time. Great.
19 However, I still have a question. Section 2, I
20 don't understand this little nuance. Can you
21 explain it or here's what I was getting to with my
22 question. We will entertain those. We will take

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1 those through. It's in both of our best interests
2 to make sure there is a clear understanding of the
3 target for this potential product.
4 Then bridging. As Keith Flanagan indicated,
5 there's a lot of work already here or a lot with
6 the companies that could come back into the agency
7 before GDUFA II is kicked off. We are going to
8 manage those. The dates that we put in place for
9 those correspondences, the amendments, originals,
10 things of that nature, those are going to be
11 honored by us as we cross the bridge into GDUFA II.
12 Then any new submission sent to the agency,
13 starting day 1 of GDUFA II, gets the GDUFA II date.
14 It fits that scheme we talked about, whether it's a
15 two-year-old application or a 20-year-old
16 application that's still struggling through to the
17 finish line, if you make a submission after
18 October 1st of next year, you are going to get the
19 GDUFA II full-court press.
20 Switching sections now, looking at some
21 enhancements to the program -- and this is really
22 more than just review; it's all the efforts and

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1 communications that go along with it -- it starts
2 with the application received. We know that.
3 That's a key first step: defining the bar, helping
4 companies hit that bar, and then screening to make
5 sure that the applications do have all the right
6 pieces.
7 We're going to strive to make those
8 decisions within 60 days so that we can turn that
9 work over to the review programs. We're going to
10 have now a formalized information request process
11 built in there.
12 So if the company has minor issues, or we
13 think the data may be in the application, it's just
14 not presented in the way that we're connecting
15 with, we're having trouble finding it, we see
16 summaries, they must have had the data, it's a
17 significant application, they got certain points,
18 the other points must be buried in there somewhere,
19 then we will work with the company to try to find
20 those, make sure everything is in fact within that
21 application, and allow that hopefully to move
22 forward into the review teams.

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1 Then we're going to be notifying the
2 applicant, at the time we make the decision to
3 accept your application, whether or not, you are
4 standard or priority review. You will know that.
5 That will help then to define the goals, and it
6 will be an indicator to you when you can start to
7 expect to receive further review communications
8 from the agency.
9 We're going to issue the IRs. In fact, many
10 people are familiar with those. We're going to
11 expand and take one of the successes off of the new
12 drug program, the discipline review letter, and
13 apply that now into the generic program. This is
14 very important. This is again one of these
15 exciting and scary features.
16 We are committing to providing a mid-point
17 response to the applicant. We've done our work.
18 We've gone through the application. We've
19 collected information from all the disciplines.
20 Here's a preliminary finding by the agency.
21 This is a big game changer. We're going to
22 continue to issue IRs and these DRLs throughout the

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1 life of that cycle. So if we give the company a
2 dot-the-I, cross-the-T type of change at the
3 mid-point, and they quickly turn that around, we
4 will keep reviewing. And if there's time, we'll
5 even do another round; here's one more I that has
6 to be dotted before we get to that final stamp of
7 approval. We will work with the companies as much
8 as the schedule -- and this is where it works with
9 both the review and industry timelines, feeding
10 together to make this successful.
11 Some of the other new features are we will
12 work through the goal. We will miss the goal -- we
13 own that -- if we can take an important product and
14 bring that imminent approval. So if the company is
15 on the edge, one quick little update and you're
16 ready for approval, we will work with you. We will
17 miss that goal to get the good products out on the
18 market whenever they can.
19 So we're certainly watching and very
20 conscientious of when we think the first commercial
21 marketing date will be. We will drive our program
22 to try to hit that. And of course, as we do now,

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1 we will continue to send the responses when we have
2 them. If we're done early, we will provide the
3 response early. When we're done, we will send it
4 out.
5 We're going to pass on different signals
6 from the regulatory project managers. So if we get
7 information from one of the review disciplines that
8 something substantial has gone wrong or is missing,
9 we're going to communicate that right then and
10 there. "Hey, regulatory affairs colleague, I'm not
11 sure how all this is going to play out, but I was
12 talking to the discipline; they have some big
13 issues. They're going to be providing very
14 specific information soon, but I wanted to let you
15 know as soon as I did that this application has
16 some additional hurdles before it's going to be
17 ready." We want the companies to understand that
18 and use that to help in their planning for this
19 product or other products that they may be working
20 on.
21 If we realize we may miss a goal -- maybe
22 it's a good reason we're missing it, to try to turn

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1 it into an approval, are there some other complex
2 issues associated with it -- we're going to inform
3 the applicant, here's what's going on, here's the
4 status to date, here's why we think we're going to
5 miss that goal, here's when we think we're going to
6 be able to communicate to you.
7 We will allow the companies to contact us,
8 periodically. We don't want phone calls every day,
9 but we will allow them at key decision points
10 within the company to say, hey, one of these
11 cruxes, we need to figure out whether they're going
12 left or right with this product; what's the status?
13 We will go in there discipline by discipline, this
14 one's ready; this one's on the verge of being
15 completed; this one hasn't been started yet.
16 That's the kind of information we will do to help
17 the companies navigate this process.
18 We're going to include, any time we make a
19 decision, to change the priority status of an
20 application. The issue's been resolved. Maybe
21 it's no longer priority, or we've gotten word that
22 there is a potential issue emerging, potentially a

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1 drug shortage or something like that that could
2 change during the life of that application. We
3 will work to make sure companies understand that.
4 When we issue major deficiencies, we will
5 explain them. We will explain why we think they're
6 major. We understand that's going to have
7 significant impact and obviously lengthen the time
8 of the response from the agency. So we'll explain,
9 these are the five things that are wrong. Here is
10 why we think this is going to be a major effort for
11 us to review the additional data. We're going to
12 have to go back nearly to step 1, so on and so
13 forth.
14 We're going to allow companies to continue
15 to send in requests for complete-response telephone
16 conversations. "You've issued those five
17 deficiencies to me. I'm not sure what number 4
18 means. I want to sit down and talk with you." We
19 will allow a face-to-face discussion of those. So
20 the companies can work through the process, and we
21 will arrange to get the right people at that phone
22 call to explain, here's what we're seeing, or in

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1 some cases what we're not seeing. Here's what's
2 needed. Here's what we think would help close that
3 gap. Again, make sure everybody understands the
4 target that will help the applications flow through
5 much faster. So the hope is, after this telephone
6 conversation, the responding amendment comes in and
7 can be moved very successfully towards approval.
8 We talked about changes. One of the key
9 things that we will do when we change the status of
10 an application, which is rare but certainly a big
11 event for the companies, we will allow them the
12 opportunity to come back and sort of question the
13 decision. "Here's why we made that request, FDA.
14 Here's what we think is going on and why it
15 supports our request." And we at the agency, then,
16 will respond. "Here's our information or here's
17 the interpretation of the regulation. This is why
18 we said you're in this lane versus the other lane."
19 So this is going to help companies have a
20 better understanding of what it means to be
21 standard versus priority review.
22 Then of course, as we said before, we are

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1 going to champion the applications. We want them
2 to be approved. We need them to be approved.
3 That's what helps us fulfill our mission, getting
4 the drugs out to the public. So we will work to
5 get the good applications approved hopefully at a
6 higher rate within that first cycle.
7 Having those mid-point touch points is going
8 to be very important to this; tell you the
9 information in the middle of that review process,
10 give you the expectations, and give you an
11 opportunity to provide that, get those last pieces
12 of those puzzles in place so we can make an
13 approval at the end of that first cycle. That's
14 the goal that we're working towards.
15 Obviously, for the important products that
16 have those key dates -- and I think the companies
17 are very aware of those -- we are going to do
18 whatever it takes on our end to make sure that we
19 can hit those dates. So companies that submit
20 their applications in a timely manner, have the
21 right pieces in place, they're going to get
22 championed to hit that date. And that same logic

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1 applies to the tentative approvals. We understand
2 that that's a very important metric for the
3 companies, and it sets them up for success and
4 hopefully soon to get on the marketplace.
5 We have a new program on dispute resolution.
6 We have it now. It's informal. We're going to
7 make it formal. We are going to take the existing
8 successful program under PDUFA, on the new drug
9 side, and bring that into the generic program. And
10 one of the steps to that is an informal dispute
11 request. We are now designating a position within
12 the Office of Generic Drugs to help the companies
13 navigate that. They will help explain the process,
14 link the applicant in to the right area to get that
15 potential dispute resolved.
16 We have goals on this; new program. We're
17 going to slowly build this into place, but we are
18 committed to working with the companies so at least
19 they understand the environment, they understand
20 the rules of engagement, and they know how to put
21 together a successful dispute.
22 Then we're going to continue to advance the

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1 program. Even if it's not outlined in these goals,
2 what some of our colleagues are going to be talking
3 about, we are continuing to move the program
4 forward. As we see ways to do better business, to
5 communicate more efficiently, we are going to take
6 advantage of that.

7 So it's a tremendous amount going on to have
8 all of this come together, but we're excited. This
9 really gives us the opportunity to get the products
10 out there. And one of the keys to this, into
11 making all this a success, is getting the right
12 target out there, and Rob Lionberger is going to
13 talk about that. Thank you.

14 DR. LIONBERGER: Good morning, everyone.
15 I'm going to talk about our pre-ANDA program and
16 specifically its impact on complex products.
17 Before we do that, we have to define what we mean
18 by complex products. There's a formal definition
19 of complex products in the GDUFA II commitment
20 letter. It talks about products with complex
21 active ingredients, formulations, routes of
22 deliveries or dosage forms, complex drug device

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1 combinations, or other products where there's
2 unexpected complexity or uncertainty.

3 So this definition is really intended to
4 exclude from complex products solid oral tablets
5 and capsules, oral solutions, and simple solution
6 injectable products. Those products are the vast
7 majority of our workload. Those are what we
8 consider standard products.

9 The complex products include things like
10 complex mixtures, locally-acting drugs, novel
11 dosage forms. The complex drug-device combinations
12 are products like metered-dose inhalers, in
13 addition to being a drug and device, but also have
14 significant patient use issues that require
15 additional discussion around those products.

16 So we think that we focus the attention for
17 complex products on the ones that have scientific
18 challenges that are harder to develop, that need
19 more attention through the pre-application review
20 process.

21 Under GDUFA II, there's a proposed pre-ANDA
22 program that goes beyond complex products. So the

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1 things we'll talk about here are not just limited
2 to complex products, but there's a special focus on
3 making sure that they meet the needs for complex
4 products. But now under the proposed GDUFA II, we
5 have an integrated pre-ANDA program that includes
6 meetings, product-specific guidances, regulatory
7 science components, the control correspondence
8 process, and inactive ingredient database
9 improvements that should broadly accelerate and
10 clarify requirements for application submission.

11 In GDUFA I, we were doing a lot of these
12 things, but there weren't commitments around all of
13 them. Now, in the GDUFA II commitment letter,
14 there are commitments in all of these different
15 categories, so we have an integrated program in the
16 pre-ANDA space that I think will give companies
17 clarity on where to go to get the answer for
18 specific types of questions.

19 Now, one of the things that's completely new
20 in the commitment letter are the meetings. The
21 meetings are specifically focused for complex
22 products. There are three types of meetings that

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1 are described in the GDUFA II commitment letter.
2 If we go sequentially through the product
3 development life cycle, the earliest type of
4 meeting is what we call a product development
5 meeting. These are meetings when you're developing
6 a complex product, you're trying to identify what
7 are the appropriate bioequivalent standards for
8 this product, what are the challenges in
9 development. These products are difficult because
10 there are complex scientific issues.

11 So these meetings are focused on the
12 scientific exchange, on specific issues with the
13 expectation that there's work and preparation from
14 the potential ANDA applicant before they come in,
15 and then that allows FDA to provide appropriate
16 feedback to advance that development program early
17 in the process.

18 As you proceed through product development,
19 there's an opportunity also for what we call
20 pre-submission meetings. So these are when you
21 have your application all put together, it's a
22 complex product. So it may be things that FDA ANDA

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1 reviewers don't normally see in an application.
2 The pre-submission meeting is an
3 opportunity, some time approximately a year before
4 a submission, to really walk through the review
5 team about what's going to be in the application,
6 what's going to be new, what are the types of data
7 that you're going to see. It's not a substantive
8 pre-review, but it gives opportunity for FDA to
9 point out, these are things you might need to
10 clarify to make the review go faster.
11 The pre-submission meetings also are the
12 opportunity where FDA's review staff will align the
13 scientific staff that have been talking to you in
14 the product development meetings with the people
15 that will be reviewing your ANDA process. So it
16 will be a transmission of information also
17 internally to make these product submission
18 meetings a linkage between the earlier discussions
19 and the ANDA review process for the complex
20 products.
21 Finally, even when you're in the review
22 process for complex products, there's an additional

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1 aspect of a mid-cycle review meeting for the
2 complex products that have had these pre-ANDA
3 meetings where you'll get the opportunity for a
4 teleconference with the review team after that
5 initial set of discipline review letters, where the
6 initial issues have been identified. And this is
7 an additional opportunity to accelerate the
8 development and review of complex products.
9 So to explain how this system will work, we
10 will be issuing a guidance on the meetings, which
11 will describe how these different meetings work;
12 how they're integrated; what the expectations for
13 the data packages are; where you send the packages;
14 what types of requests you'll get back from FDA
15 with respect to the meeting granted; how we'll
16 schedule them; what we'll do in the lead up to the
17 meeting; and how we'll provide the minutes and the
18 conclusions from the meetings to you.
19 One aspect that's in the commitment letter
20 is what we call an integrated meeting track. For a
21 complex product development program, once you're
22 granted that product development meeting early in

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1 the process, then you'll be eligible for the
2 pre-submission meeting before your application
3 comes in and for the mid-cycle review meeting. So
4 there's a real integrated track that links those
5 meetings together once you've entered into that
6 type of interaction with FDA. And I think this
7 will really link through the pre-application
8 discussions into the review process in a very
9 effective and efficient way.
10 In the commitment letter, there are goals
11 for the meetings. You're going to be guaranteed a
12 meeting decision in a timely manner. In all cases,
13 there's a phase-in. In the first two years, we'll
14 get you a meeting decision within 30 days, and then
15 after that, within 14 days you'll get a decision
16 whether the meeting is granted. And then the
17 meetings will be conducted within 120 days from
18 those decisions. There's no limit to the number of
19 meetings; I'll talk a little bit about that on the
20 next slide as we move into the product-specific
21 guidances.
22 In the product-specific guidances, I think

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1 many of you are familiar that the product-specific
2 guidances identify primarily bioequivalence
3 methodologies but often times for complex products,
4 additional information. There are approximately
5 1600 of these guidances on our web page now.
6 They're a critical part of the current review
7 process. They're one of the big reasons why the
8 first cycle acceptable rates for our bioequivalence
9 reviews are very high, because we're very clear
10 about what the bioequivalence expectations are.
11 So now in the GDUFA II commitment letter,
12 there are goals related to the product-specific
13 guidances for non-complex new chemical entities, we
14 have a commitment to have those guidances available
15 two years before the earliest lawful filing date.
16 So you can get the guidances before you start
17 conducting the studies for those products.
18 For the complex products, there's no
19 commitment on the guidances. We're going to
20 provide guidances as soon as the scientific
21 recommendations are available. But in the
22 negotiations, there's an incentive process for us

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1 to get those complex guidances available. In the
2 meeting process, if there isn't a guidance
3 available, we will guarantee that we will meet with
4 you if you have an acceptable meeting package. So
5 for places where there's a complex product and we
6 haven't yet put out a guidance, those will be
7 prioritized for product development meetings.
8 It's in FDA's incentive to provide timely
9 guidances, but if we're not able to do that, that
10 is where you'll have the opportunities to discuss
11 an individual development program with FDA through
12 the meeting process.
13 The meeting process also prioritizes for
14 complex products, cases where FDA puts out a
15 guidance, but you think there's a scientifically
16 sound alternative approach that may be more
17 efficient that may lead to faster access to generic
18 products. Those types of meetings are also
19 prioritized under GDUFA II, and we will grant those
20 meetings as well.
21 So even if we have a guidance, but you think
22 there's an alternative approach, those two types of

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1 meetings are the ones that will be granted when
2 there's an acceptable meeting package. Other
3 meetings will be granted based on the workload
4 availability and the value to the review process.
5 For other product-specific guidances, we'll
6 continue our current practice. Through the generic
7 drug mailbox, the industry can request guidances.
8 This makes us aware of products where we may not
9 know that there's an interest in generic drug
10 development, and so we can factor that into our
11 planning and make those guidances available to
12 facilitate drug development.
13 We will also in our internal process
14 prioritize public health priorities. If we know
15 there's a drug shortage, we'll try to ensure that
16 there's a product-specific guidance available so
17 that the requirements for generic products are as
18 clear as possible in that space.
19 There are multiple other aspects of the
20 pre-ANDA process that are described in the GDUFA II
21 commitment letter. Ted mentioned the goals for
22 controlled correspondence add a separate category

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1 for complex controls. This also allows us to
2 expand the scope of questions that we will answer
3 through the control process. So the complex
4 control process in the commitment letter talks
5 about questions of the clinical impact, but it also
6 talks about places where there might be a
7 product-specific guidance, and you might be
8 proposing an alternative approach.
9 For example, a product-specific guidance
10 talks about having a parallel pharmacokinetic
11 bioequivalence study, and you think for this drug a
12 cross-over study would be appropriate, that would
13 become a complex control correspondence that gives
14 us enough time to do the detailed scientific
15 analysis to give you an answer for those questions.
16 The complex control correspondence is also
17 the place that you will go for bioequivalence
18 protocols that are related to products that have
19 REMS with elements for safe use that lead into the
20 safety determination process, you'll have a
21 commitment on the timeline for those protocol
22 reviews.

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1 The commitment letter also has regulatory
2 science enhancements. It has improved commitments
3 about linking the outcomes of our regulatory
4 science activities to guidance development. It has
5 a new process for gaining industry input into
6 regulatory science priorities through formation of
7 industry working groups that will be able to meet
8 with FDA multiple times during each year to make
9 sure that industry input is clearly provided to
10 FDA, and it allows us an opportunity to explain
11 what we're doing in each priority area.
12 The inactive ingredient database
13 enhancements are in the commitment letter. These
14 will provide new information on what we think is a
15 critical pain point for industry in terms of the
16 maximum daily exposure for each excipient, not just
17 the amount that's in approved products. This is a
18 big gap in the current inactive ingredient database
19 that's a pain point for industry, and we have a
20 commitment to address that and provide much better
21 information in that case.
22 The safety determination letter, once the

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1 protocol is reviewed through the complex
2 correspondence process, there are specific
3 timelines for getting a safety determination letter
4 that may help access to products that are difficult
5 to acquire in the marketplace.
6 Finally, if we look at the pre-ANDA program
7 as a whole, the intention is that it's going to
8 clarify expectations for prospective applicants
9 early in product development. For complex
10 products, you'll have specific access to meetings
11 and a meeting track that should provide the
12 necessary direct interaction on those more complex
13 products.
14 All of these aspects of the program will
15 help applicants develop more complete submissions:
16 the inactive ingredient database, control process,
17 timely availability of product-specific guidances,
18 all are linked to better submissions. Better
19 submissions and having this information decided up
20 ahead should lead to an effective review process.
21 We don't want a situation where a complex
22 application comes in, and it's on the 10-month

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1 clock, and we have to decide what to do in those
2 10 months.
3 Through these pre-ANDA processes for those
4 complex products, we have our scientific, our
5 regulatory staff, all of the internal FDA
6 stakeholders aligned before the application comes
7 in, and then the application review process can
8 focus on reviewing the data that comes in and not
9 deciding what's acceptable just at the time the
10 application comes in.
11 When you put all of these together, they
12 should be reducing the number of review cycles,
13 especially for the complex products, where we've
14 seen some products go into double-digit review
15 cycles because we're figuring out what we have to
16 do while the application is under review. The goal
17 of the pre-ANDA program is to figure out all of
18 those requirements before the application is
19 submitted.
20 Thank you very much, and I think this is the
21 time for questions, not just for me, but also for
22 Ted as well, and David.

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1 (No response.)
2 MS. CLARKE: Hearing no questions, we will
3 take a break. We are running a little ahead of
4 schedule, so we'll just make it a little bit
5 longer. If folks could come back by 20 minutes of
6 11, I think that will give everybody an adequate
7 period for a break, check email, whatever we need
8 to do. We'll resume then.
9 (Whereupon, at 10:19 a.m., a recess was
10 taken.)
11 Panel 2
12 MS. CLARKE: So we'll go ahead and get
13 started now with our second panel on the proposed
14 new fee structure. I'd like to acknowledge we have
15 a few other people who have joined us now here,
16 Donal Parks from CDER's Office of Management, and
17 we're joined with three of our trade association
18 representatives, John DiLoreto, David Gaugh, and
19 Gil Roth.
20 I think it's particularly important for us
21 to have them up here for this portion because at
22 this point, we're really not just representing the

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1 agency's portion of the program, but really this is
2 the heart of the negotiated agreement. And I
3 think, as most people will readily understand, it's
4 one thing to talk about what's in an agreement and
5 what we want programmatically. It's a whole other
6 conversation to talk about how much to pay for that
7 and who gets to pay what, which is about the fee
8 portion. So we're going to try to enlighten you on
9 those things.
10 The commitment letter that we've referred to
11 several times and posted on our website does not
12 have the detail on the new fee structure. That's
13 actually in a separate summary. That's just
14 generally -- I would do that because the other
15 details of that are in the statute, not in the
16 commitment letter. So right now, the summary is
17 what is available.
18 The first thing I'd like to talk about are a
19 few -- I'm going to talk a little about the things
20 that we had to grapple with in terms of
21 establishing the overall program size, and then
22 we're going to get into more fee specifics as we

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1 move through this. And we're going to end up at
2 the end of this session also talking about some
3 pieces of the agency's financial management of the
4 program and how we go about doing our work
5 analyzing the need for our resources and how we
6 assign those.

7 So first of all, it's been mentioned a few
8 times, GDUFA I assumed that FDA would receive
9 approximately 750 ANDAs per year. Those of you all
10 who are insiders or have been with the program for
11 a while may find that surprising because before
12 GDUFA I launched, the number actually was at a
13 thousand. But there was a thought on the part of
14 both the agency and I think industry that the
15 introduction of the new fees might actually result
16 in a decrease in the number of generic drug
17 applications; certainly not something the agency or
18 the industry hoped for, and in fact turned out not
19 to be the case. If anything, the number of
20 applications coming into the program continued to
21 increase.

22 But that was the number that was used for

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1 the baseline budget projections, and so it's an
2 important thing to note that that number continued
3 to go up. It is our baseline workload. So an
4 important feature of GDUFA II is that we've sort of
5 resized the program commensurate with the volume of
6 work that is coming in.

7 Also, we recognized, in trying to determine
8 the overall size of the program, the ANDA itself is
9 the best indication of the workload as a driver.

10 There are many other activities, some that you've
11 already heard about, that Ted Sherwood detailed;
12 some that you'll hear about when they talk about
13 facilities that go on in the program that are
14 beyond or not linked just to the ANDA itself, but
15 it really is a program that the ANDA itself is the
16 best indication and the driver of overall workload.

17 So at this point in the program and
18 separately from the negotiations, there have been
19 some coverage about the number of resources FDA is
20 currently utilizing on behalf of the program. In
21 the first two years of the program, we were
22 building up that program and hiring new staff.

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1 There were over 1,000 staff hired during GDUFA I.
2 It takes some time with federal hiring to get all
3 of those new staff on board and even a little bit
4 more for them to be productive.

5 In FY15 -- and this is in the GDUFA
6 financial report for that fiscal year -- you can
7 see that the program passes kind of a tipping
8 point, where it begins to spend even more than it's
9 collecting in one year. That's a common occurrence
10 that happens in new federal programs. And
11 currently, we are on track to spend over
12 \$400 million at our current work rate. And that is
13 not an overspend per se, but it is a spend that is
14 commensurate with the workload that we have and
15 with the desire to continue to work through that
16 pre-GDUFA backlog that we started GDUFA I with.

17 As has been mentioned earlier, we have met
18 and exceeded those goals, and we have met the
19 original backlog goal of making one touch, but the
20 agency and the program are really committed to
21 working through that and getting really those
22 applications not just the one touch that they need,

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1 but all of the review work to get them approved and
2 out on the market. So all of those factors
3 informed our current sizing for GDUFA II, as well
4 as the new negotiated commitments that you've heard
5 about.

6 The final price tag that we arrived at is
7 493.6 million. That is a substantial increase over
8 GDUFA I, which with, I believe, the collections we
9 started at 299 million. But they're higher of
10 course because of inflation, but that is still a
11 substantial increase. But that is an increase
12 based upon both the new program enhancements that
13 we are putting into the program, but more
14 importantly, it's really for the volume of the
15 ANDAs that are coming into the agency. And in many
16 ways, the best way to view that is a problem of
17 success. The U.S. healthcare market needs a robust
18 generic drug industry, and the ANDAs are the
19 expression of that.

20 During the course of this, with this
21 increase amount of funds, the agency probably will
22 not be hiring significant new staff, but we will be

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1 working with staff that we have very hard. You
2 will see over the next couple of years as we move
3 into GDUFA II that output, as Ted Sherwood noted,
4 is going to continue to increase, and we hope
5 fervently that the number of review cycles to
6 approval are going to decrease.

7 So let's talk a little bit about some of the
8 most important modifications to the user-fee
9 structure and how we arrived at this. One of the
10 most important things in administering a user fee
11 on behalf of the agency is to have some stability
12 for the revenue stream, And to do that, you need to
13 find a balance between application fees and some
14 other type of fee.

15 In GDUFA I, that was the facility fee, which
16 really was the one annualized fee. So facilities
17 paid that fee every single year, whereas
18 application fees are when a sponsor was following
19 that application. And really to be stable, you
20 want something that is more predictable. And the
21 concept of a program fee, which is now being used
22 in other user-fee programs as well, was considered

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1 and then adopted for GDUFA II for the proposal.

2 The application volume of course can
3 fluctuate. We've seen it go up. But it has varied
4 fairly dramatically, and this can pose challenges
5 for the fees that are collected and for even
6 setting and calculating those fees. So to better
7 align with the program -- because the work does not
8 stop in the generic's program just with the
9 approval of an ANDA; that continues.

10 An ANDA really should be seen, especially
11 when it's actively being marketed, as a live thing
12 that may have updates and other things,
13 inspections; surveillance inspections continue on
14 manufacturing sites. So this is a new concept that
15 really we think better reflects the program itself.

16 A few other things, we introduced, in
17 addition -- the important thing on this annualized
18 fee is now not only will facilities pay this
19 annualized fee, but ANDA holders, so the sponsors
20 themselves will pay an annualized fee because in
21 the generic drug marketplace, it's often the case
22 that not every individual approved ANDA is actually

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1 marketed or may not be marketed on a continual
2 basis by that sponsor.

3 You'll see as we go through this that ANDA
4 sponsors will be grouped into tiers based upon the
5 size of their entire portfolio as opposed to a per
6 ANDA fee assessed, which would have been one way to
7 do this. There are multiple different ways of
8 doing this, and in our negotiations with industry,
9 we reached an agreement that the best possible way
10 to do this is to think about it as an ANDA
11 sponsor's total portfolio size. And I'll talk
12 about this a little bit more in a moment.

13 As soon as a new ANDA holder has even one
14 approved ANDA in their portfolio, they will move
15 into this category of paying a program fee. If
16 they do not have -- if it's a new ANDA holder who
17 is new to the generic drug space, they will not
18 begin paying this fee until that time. So all they
19 would pay is actually the filing fee with ANDA.

20 A few other important changes to the fee
21 structure. First of all, facility fees. The
22 facilities will continue, both API and finished

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1 dosage form, to pay an annualized fee just as they
2 did under GDUFA I. Percentages do change here. In
3 the facilities, however, a couple of important
4 changes are, one, facilities that do both
5 operations -- this is not the majority of
6 facilities, but there are an important number of
7 facilities that do both of those -- will only pay
8 one fee, and they'll pay the finished dosage form
9 fee. So they won't be hit twice.

10 Another important change here is that
11 contract manufacturing organizations, or CMOs, will
12 pay one-third of the total of the FDF fee. This
13 was an important change noted because contract
14 manufacturers, which are defined in the statute,
15 are those manufacturers who are also not the ANDA
16 holder.

17 The generic drug industry, as Rob Berlin
18 mentioned in his overview that we did for the
19 negotiation, this is a very complex industry with a
20 lot of different business models. You have some
21 firms that are only ANDA holders, some firms that
22 are only in the manufacturing space, and some that

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1 do a mix of both. So some of the changes to the
2 fee structure are designed to more mimic the wide
3 variety that we see in this industry.
4 A few other things that we decided to do,
5 some of these mapped to the fact that we went with
6 a program fee for ANDA holders. We've eliminated
7 the supplement fees. Previously, industry was
8 paying a separate fee for every time a prior
9 approval supplement was sent into the agency. This
10 meant a lot of very small fees coming in. This too
11 can vary quite a bit, and really, it should be
12 considered as part of the ongoing maintenance and
13 life cycle of an approved ANDA.
14 This is also important, we feel, for
15 purposes of encouraging updates by the industry.
16 If industry does not have to pay every individual
17 time that they want to make a small change, either
18 for labeling, about other important safety updates,
19 and some of those changes may even be requested by
20 the agency itself, then we are much more likely to
21 be able to facilitate that if they're not actually
22 having to pay each individual time and it's more

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1 rolled in, at least conceptually, with the ANDA
2 holder fee.
3 So we've talked a little bit about small
4 business considerations, and a few important things
5 that we have done to build into what was billed as
6 a small business consideration, but in fact really
7 was a much broader conversation based in the
8 research work that was done and really from the
9 conversations that we had with industry, and
10 designing a system that more accurately reflected
11 this industry, its complexity, and their ability,
12 and really what they gain as value and benefit from
13 the program.
14 The first thing that's important to note, no
15 facility or an ANDA sponsor is charged this
16 annualized fee until an ANDA in which it's listed
17 has actually been approved. We think this is
18 important not only because the approved ANDA is an
19 important marker of their value and the revenue
20 that they're going to be able to gain and the
21 benefits that they see from the program, it's also
22 important because, we believe, that by not doing

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1 this, we have removed at least a perceived, if not
2 actual, barrier of entry into the generic drug
3 marketplace.
4 Previously, if a manufacturer wanted to
5 enter this space and was new into the space and
6 listed in an ANDA, they might find themselves
7 paying the facility fee for however long it took
8 for that ANDA to actually be approved. With this
9 change under GDUFA II, that will no longer be the
10 case.
11 The annual program fee for the ANDA holder
12 in the proposal has three separate tiers that is
13 also designed to reflect new entrance into the
14 generic drug space, and then to reflect the wide
15 variety in size of firms that are engaged in this,
16 so that we have a small tier for ANDA holders who
17 have 1 to 5, a medium size for those once they
18 reach 6 approved ANDAs up to 19, and then a large
19 at 20-plus ANDAs.
20 There are a large number of ANDA holders,
21 and Donal Parks is going to talk a little bit more
22 about our initial thinking and some steps we're

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1 going to take to get our arms around this. But we
2 reached these cut-off points with a lot of business
3 intelligence and really driven primarily by our
4 industry colleagues who know their own industry far
5 better than we do by combining our resources and
6 intelligence there. And I've already mentioned the
7 CMO change in there. But CMOs are often smaller
8 businesses than the individual facilities that
9 might be owned by a much larger company.
10 Donal, I'm going to let you come up. Donal
11 Parks from our Office of Management is going to
12 talk a little bit about the ANDA holder fee, which
13 is probably the most complex of our new fees.
14 MR. PARKS: Thanks, Mary Beth.
15 So as Mary Beth mentioned, we're going to
16 have this new fee, so we've been thinking through
17 how we're going to operationalize this. And it's
18 important to note that companies may have
19 affiliates and they may have approved ANDAs under
20 different names in our system, and it wouldn't
21 really be right to charge separate fees to all of
22 them. We'd be fine with that, but you all probably

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1 wouldn't like it.

2 So what we're going to do is a clean-up

3 effort so that we know who is related to whom, who

4 should be showing up as one entity instead of

5 several, and to do some data clean-up as well

6 because in some cases, we have a company showing up

7 with a comma LLC, and some with no comma LLC, and

8 things like that.

9 So what we're going to do is go through a

10 process of cleaning up, or allowing you to help us

11 clean up, the data so that when the fees become due

12 in October of 2017, it's seen as a reasonable

13 approach.

14 Working through the timeline here, we have

15 to publish the fees for FY18 in August of 2017.

16 That's about two months before the fiscal year. So

17 in order to do that, we're going to be posting

18 information on our website and accepting feedback

19 from folks who have an interest in it.

20 So starting around December, early December,

21 we're going to publish a list of what our systems

22 reflect as approved ANDAs. And what that list is

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1 going to show is the name of the owner of record,

2 according to our system, the approved ANDA number,

3 and the drug substance that it relates to.

4 That information will be available from our

5 website on or around early December of 2016. And

6 then that will give folks who are on that list an

7 opportunity to check it out, and you'll be able to

8 see if we're showing you as different entities, or

9 you may have some sort of a corporate family that

10 you want to reflect under one group.

11 What you'd be able to do is tell us, hey, I

12 want to combine all of these under one. These are

13 the ANDAs I'm claiming for my family. And then

14 we'll take that information and clean up our

15 database, and then we'll republish the list

16 somewhere around March, early March or mid March,

17 then that will hopefully show fairly well what

18 those changes have been.

19 There will be changes. There will be

20 mistakes. People can continue to send information

21 back into us. And then around June, we will use

22 the information we have at that point to help us

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1 establish the fees. We'll create the denominators,

2 or calculate the denominators, send that off to the

3 Office of Financial Management. They'll do the

4 math. They'll publish the FR notice. In early

5 August, we'll have the numbers.

6 Just as a summary to compare GDUFA I to

7 GDUFA II, the column on the left shows the types of

8 fees; the middle column, GDUFA I; the last column

9 on the right, GDUFA II. You'll see that the

10 percentage for the ANDA application fee is going

11 from 24 percent to 33. The DMF is dropping from

12 the 6 percent that was under GDUFA I to 5 percent

13 under GDUFA II. Then for the annual fees

14 themselves, the API and FDF facilities are going

15 from 14 percent to 7 percent, and 56 percent to

16 20 percent, respectively.

17 The CMO facility that Mary Beth talked about

18 is kicking in. That wasn't a differentiating

19 factor in GDUFA I, but in GDUFA II, they will pay

20 one-third of the FDF facility. So it will be

21 one-third of the facility fee for either domestic

22 or foreign. So foreign firms will still have the

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1 \$15,000 foreign facility fee differential, so the

2 CMOs would pay their one-third fee plus that as

3 well.

4 The holders did not have a separate fee

5 under GDUFA I, but under GDUFA II we will, and that

6 will account for 35 percent of the total target

7 revenue every year, and it will be spread out as

8 follows. The small group, the 1 to 5 ANDA holders,

9 will pay one-tenth of the large fee; the medium,

10 those with 6 to 19 approved ANDAs, will pay

11 four-tenths or 40 percent of that large fee; and

12 then the large, the 20-plus holders, will pay the

13 full fee. When we set the fees in August of 2017,

14 you'll see what the fees are.

15 I'm going to turn it back to Mary Beth for

16 this other stuff that I don't understand.

17 MS. CLARKE: You've heard quite a bit about

18 GDUFA I transforming the generics program and this

19 deep foundational restructuring. And that deep

20 foundational restructuring really goes beyond just

21 the ANDA review process. We want to talk just a

22 few minutes about some important enhancements,

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1 which are proposed accountability in reporting
2 enhancements that go in.
3 These are all part of moving the generics
4 program into what I'll call its final phase of
5 really being managed, measured, and reported out as
6 a program much more similar to the new drugs or any
7 of our other user-fee programs. We have built in
8 some things into the commitment letter that provide
9 a much more robust internal capacity development
10 here within the agency, which will allow for
11 regular performance monitoring and reporting out.
12 So there will be a much more frequent regular
13 assessment of the progress towards the goals.
14 The original statute called for annual
15 reporting, and that has been already transformed
16 and is done more frequently. But there are quite a
17 number of things within the commitment letter that
18 outline additional reporting responsibilities, and
19 there are resources going to a much more robust
20 capacity and workload analysis that we'll be doing,
21 much more consistent methodologies, which include
22 the reporting of all of the metrics and about the

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1 use of the resources and the administration of the
2 program overall. And this will be on a very
3 similar basis and platform with the other user-fee
4 programs that the agency is administering,
5 particularly those in the drugs area.
6 We also have built in third-party
7 evaluations that we'll be doing. We really will
8 work on a series of activities to have a much more,
9 as I mentioned, robust resource management planning
10 and modernized time reporting system that will more
11 accurately reflect, in a much more detailed level,
12 all the different component parts of the program
13 and what the resource utilization is to achieve the
14 performance goals that have been negotiated.
15 It also involves an independent third-party
16 evaluation of the program, so not all of this will
17 be in-house. We'll have an ongoing in-house
18 effort, but we will have an outside assessor doing
19 that as well. And we will have a formal public
20 report, which will be published upon then, with
21 recommendations no doubt because there always are.
22 So the agency, not only in GDUFA but in the

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1 other programs, but most importantly for this
2 program now, is really committed to the financial
3 administration of the program and to enhancing its
4 overall fiscal responsibility in the program. This
5 is particularly important for us because we have
6 multiple user-fee programs, as many of you all
7 know, right now.
8 So we are managing multiple streams of
9 money, and all of them come with very specific
10 performance goals. So this is a commitment that
11 really -- GDUFA is part of a larger strategy on
12 behalf of the agency to make sure that this is
13 managed at an appropriate level.
14 Some of the reporting that you can look for
15 under GDUFA II -- you will see some monthly
16 reporting on performance, additional quarterly
17 reporting that will be ongoing, and of course the
18 annual report, which currently exists. This is
19 going to allow industry and other
20 stakeholders -- and we certainly have seen, during
21 the course of GDUFA I and through this negotiation
22 process, that we have a lot more stakeholders

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1 beyond industry itself: the public, consumer and
2 patient organizations, and Congress itself. So
3 this will give all stakeholders more regular
4 information about how the program is progressing.
5 I'd like to stop now. We haven't had too
6 many questions, and we do have the open comment
7 period at the end. But fees have a tendency to
8 generate a lot of questions, so I'd like to open up
9 the floor in case there are some questions because
10 this we understand is a bit of a fast and
11 high-level overview.
12 (No response.)
13 MS. CLARKE: Any comments from anybody else
14 that I missed?
15 (No response.)
16 MS. CLARKE: No? All right. Well, that's
17 really good.
18 We are then at a break. We are ahead of our
19 schedule. It is now 11:00. Some of our panelists
20 for the third and final panel are in other meeting
21 obligations right now. So I think what we are
22 going to do is take an early break for lunch, and

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1 then try to reconvene shortly after 12 noon. If I
2 could ask folks to be back at 12:15, which is a
3 little ahead of our start on the agenda. There is
4 the small cafe here in the lobby, which is
5 available for folks if they want to have lunch in
6 that interim time period. Thank you.
7 (Whereupon, at 11:06 a.m., a lunch recess
8 was taken.)
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1 AFTERNOON SESSION
2 (12:46 p.m.)
3 Panel 3
4 MS. CLARKE: If I can ask folks to take
5 their seats, we're going to resume with our third
6 panel, focusing on facilities. We have our same,
7 three industry trade representatives here, and for
8 FDA, we have Ashley Boam and Ann Marie Montemurro.
9 Ashley, are you starting off?
10 MS. BOAM: Yes. Thank you, Mary Beth.
11 An important part of the proposed agreement
12 has to do with certain enhancements in the area of
13 facilities. Just as a little bit of background,
14 FDASIA, which was promulgated into law in 2012,
15 changed how FDA was instructed to do our
16 surveillance inspections. And in particular, the
17 law eliminated a prior requirement to do
18 inspections, surveillance inspections, on a certain
19 frequency. Instead, the law directed FDA to do our
20 drug inspections across the globe on the basis of
21 risk.
22 However, the transition to this new

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1 paradigm, we heard from our industry counterparts,
2 has been commercially disruptive, in part because
3 those prior expectations and requirements for
4 certain frequency-based timing of inspections had
5 provided certain predictability for the industry.
6 So while we recognize a facility assessment
7 is not limited to the ANDA program and to GDUFA, we
8 did include in GDUFA II a number of facility
9 related enhancements to try to address some of the
10 challenges raised specifically by the generic drug
11 industry.
12 In particular, the enhancements to address
13 concerns raised by some of our U.S. API
14 manufacturers, to mitigate certain export related
15 challenges that were identified by this group, in
16 the proposed commitment letter, FDA would issue a
17 guidance to explain our new risk-based site
18 selection model that we have been using since the
19 Act directed us to in 2012; how that works, how we
20 use that to prioritize facilities for surveillance
21 inspections.
22 We would also undertake certain outreach

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1 activities to foreign regulators to help them
2 understand how FDA operates its site selection
3 model, and then to support the export of safe and
4 effective pharmaceutical products by the U.S. based
5 pharmaceutical industry in several ways, including
6 communications to provide the current compliant
7 status of U.S. facilities to our foreign regulator
8 counterparts.
9 On the ANDA side, the application holder
10 side, to address some of the concerns that we heard
11 about -- transparency and the speed of facility
12 assessment and the potential impact of that
13 facility assessment in a surveillance mode against
14 an application that happened to be in-house, and
15 the potential impact on approvability and product
16 launch -- FDA would communicate to an applicant
17 when we've identified facility issues from an
18 inspection that could impact the approvability of
19 the ANDA or an associated post-approval supplement.
20 We would communicate that through an IR,
21 which is an information request, a discipline
22 review letter, or a complete response letter, as

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1 appropriate, given some of the other circumstances
 2 with the application.
 3 We would also communicate to the facility
 4 owner final inspection classifications that do not
 5 negatively impact approvability of any pending
 6 application within 90 days of the end of the
 7 inspection. So if FDA has reviewed all the
 8 information from the inspection and new follow-up
 9 information from the facility, and has determined
 10 that there are not issues that would hold up
 11 approvability of any associated application, that
 12 would be made clearly known within 90 days or the
 13 end of that inspection.
 14 As we go forward, we'll also provide updates
 15 to the industry and seek stakeholder feedback on
 16 how this process is running and to make sure that
 17 we're addressing some of the concerns that arose in
 18 GDUFA I as we move forward with GDUFA II.
 19 In addition to providing enhanced
 20 transparency about the compliance status of GDUFA
 21 self-identified facilities and sites, we would
 22 update our existing publicly available database on

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1 would issue a first-adequate letter. Once the DMF
 2 has undergone a complete review and the ANDA
 3 referencing it has also been approved, or
 4 tentatively approved, FDA would issue a no further
 5 comment letter, meaning there are no additional
 6 questions to that DMF.
 7 By fiscal year 2019, FDA would issue a
 8 guidance on post-approval changes to a type 2 DMF,
 9 as well as to address the appropriate submission
 10 mechanisms for any ANDAs that reference that DMF
 11 for which post-approval changes are occurring.
 12 That concludes my review of facilities and
 13 DMF enhancements, and I'm happy to entertain any
 14 questions.
 15 (No response.)
 16 MS. BOAM: Thank you.
 17 Open Public Comment
 18 MS. CLARKE: We are ready to begin now our
 19 open public comment period, and we have one
 20 registered speaker I know of, who I will introduce
 21 and ask to come forward, which is Paul Brown with
 22 the National Center for Health Research. If you

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1 a more routine basis, and include not just
 2 manufacturing facilities but sites that are
 3 involved in the conduct or analysis of
 4 bioanalytical or clinical bioequivalence or
 5 bioavailability studies.
 6 The proposed commitment letter also includes
 7 certain enhancements related to the Drug Master
 8 File program, so there are a number of targeted
 9 improvements to the DMF review process. To begin,
 10 DMF review comments that were sent to the DMF
 11 holder would be issued at least in parallel with
 12 the issuance of review comments related to the DMF
 13 for the ANDA.
 14 We would also outline procedures and
 15 timelines for telecons or email exchange as desired
 16 by the DMF holder to clarify first-cycle review
 17 deficiencies identified by the agency in the hopes
 18 that clarifying how these exchanges can occur will
 19 get us to an acceptable DMF status more quickly.
 20 Then once we have done a complete review for
 21 the DMF and there are no open issues related to
 22 that DMF for the ANDA that references that DMF, FDA

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1 can come forward to the microphone.
 2 MR. BROWN: Good afternoon. I'm Paul Brown.
 3 I'm the government relations manager for the
 4 National Center for Health Research. Thank you for
 5 the opportunity to speak on the commitment letter.
 6 Our center is a think tank in Washington, D.C. We
 7 conduct and scrutinize research on the safety and
 8 effectiveness of medical products. We do not
 9 accept funding from pharmaceutical companies. We
 10 do not have any conflicts of interest.
 11 We respect the FDA, and we're committed to
 12 ensuring that it has the resources it needs to make
 13 sure that our medical products are safe and
 14 effective. Given the inadequate appropriations
 15 provided to the FDA, we strongly support increasing
 16 GDUFA and other user fees to improve FDA's
 17 resources in order to enable the agency to fulfill
 18 its public health mission.
 19 Our center has attended all of the GDUFA II
 20 meetings, either in person or by phone. We agree
 21 with GDUFA's intent, which is to provide additional
 22 revenues so that FDA can hire more staff to improve

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1 the generic drug review process that will lead to
2 increased access to generic drugs, which is, as
3 mentioned earlier today by several people, saving
4 trillions, nearly \$1.7 trillion or less. We also
5 support the commitment letter's streamlining of the
6 user-fee structure, which will provide a more
7 stable resource of funding and give small companies
8 a financial break on user fees.

9 We support the GDUFA II agreement because it
10 increases user fees by nearly \$1 billion over five
11 years. Increased fees are needed because the
12 number of abbreviated new drug applications was
13 underestimated previously, as was already
14 mentioned. However, we are concerned that if the
15 applications go up more than estimated in GDUFA II,
16 then even the increased user-fee amounts will not
17 be enough to cover the needed FDA staff.

18 We're also concerned that fees may not have
19 increased enough to offset the increased workload
20 that the performance goals require FDA to meet.
21 The performance goals are resource-intensive and
22 include tight timelines for review of original

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1 ANDAs and ANDA amendments, PAS's and PAS
2 amendments. They also include short timelines
3 regarding the review of drug master files,
4 controlled correspondence, pre-submission meetings,
5 safety determination letters, teleconferences, or
6 T-cons as you've been referring to them today, and
7 many other deadlines.

8 Some of the performance goals in the
9 commitment letter seem a little unrealistic. For
10 example, a commitment letter states that FDA will
11 meet 90 percent of most performance goals by
12 certain dates, including six months for priority
13 major ANDA amendments. That sounds like a New
14 Year's resolution to me; I will lose 90 percent of
15 my body fat by June. It's a nice goal, but I'm not
16 sure it's actually doable.

17 As public health advocates, we need more
18 information on how much time and staff it currently
19 takes the FDA to review these applications, then we
20 can better estimate how much additional staff and
21 funding it will take to reach these goals.

22 I'm just going to talk briefly on a couple

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1 of things that aren't in the commitment letter.

2 Safety. FDA monitors the adverse events
3 reports for generic drugs. This is important. It
4 is not unusual for side effects from drugs to show
5 up years after the drugs have been on the market
6 when the generic drug is dominating the market or
7 perhaps the only drug on the market. That is why
8 GDUFA fees should be used for enhanced safety
9 reviews.

10 Conflicts of interest. FDA's primary
11 mission is to protect the public health. GDUFA and
12 other user fees should fund an independent review
13 not just of performance goals, but of how the
14 program, the user-fee programs, have affected
15 overall public health. Have user fees changed
16 FDA's priorities? Is FDA now treating industry as
17 a customer that needs to please instead of acting
18 as a regulator to ensure the public health?

19 I just want to spend a couple seconds on
20 process issues. Let's start with the positive. We
21 greatly appreciated the GDUFA II fee structure
22 summary. It was concise and easy to read. Thank

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1 you very much for putting that together.

2 Regarding the commitment letter itself, it
3 could use some improvement. The current letter
4 uses too much jargon. Too many abbreviations are
5 not defined making the commitment letter a chore to
6 read. I would suggest next time around when you're
7 doing the outline, actually spell out what the
8 abbreviation is like A, B, and C, and then start
9 using the abbreviations.

10 Regarding the meetings themselves, FDA needs
11 to somehow improve its outreach efforts. It was
12 disappointing that few consumer, patient, and
13 public health advocates attended the GDUFA
14 stakeholder meetings.

15 For GDUFA III, we recommend that you hold
16 some of the meetings in Washington, D.C. at the HHS
17 building. It is actually very difficult for some
18 folks to get out here to the White Oak campus.
19 Metro is not very accessible for here. So I would
20 suggest not having all the meetings there, but
21 maybe every other meeting, or maybe every third
22 meeting, in Washington, D.C.

1 Conclusions. We strongly support increasing
2 GDUFA and other user fees to improve FDA's
3 resources in order to enable the agency to fulfill
4 its public health mission. We strongly support the
5 increased resources for hiring review staff,
6 however, we have not seen enough data in the
7 commitment letter to convince us that the GDUFA
8 user fees are adequate to cover the increased
9 workload.
10 Patients, consumers, and public health
11 advocates should have a greater role in the
12 discussion of how user fees are spent. We do not
13 pay the fees, but we do pay for the medications.
14 We pay directly when we use our own money to buy
15 the products. We pay for the insurance. We pay
16 for public health programs. And we pay for health
17 problems that may result when medicines don't work
18 well. And as taxpayers, we pay for the
19 appropriations that are still supporting major
20 portions of FDA resources. We should be at the
21 table, or at least in the room, when negotiations
22 take place for user fees.

1 we would really appreciate that. The link to the
2 docket is directly in the Federal Register notice,
3 which is displaying today.
4 If we have no further either statements for
5 the record or any other questions, then we are
6 adjourned for today. Thank you very much for your
7 input and for your interest. We look forward to
8 hearing more from you before November 16th. Thank
9 you.

10 (Whereupon, at 12:34 p.m., the meeting was
11 adjourned.)

1 Thanks for the opportunity to speak, and I
2 want to thank -- this is my last day at my current
3 job. I've been doing this for eight years. I want
4 to thank Mary Beth and Keith and others at the
5 meetings. You've always held professional
6 meetings, and I found them informative. Thank you.
7 Closing Remarks
8 MS. CLARKE: Thank you for your really
9 comprehensive comments, which we will take under
10 advisement, definitely. You covered quite a bit
11 about the agreement, as well as the process, and we
12 appreciate that.
13 Do we have anybody else here in the audience
14 who would like to make a statement on behalf of the
15 public?
16 (No response.)
17 MS. CLARKE: For those of you all who are
18 watching or joining us remotely, we don't have an
19 ability to have you ask questions right now or make
20 comments live, but we do welcome your comments in
21 written form to the docket, which is open, as we've
22 said a few times, until November 16th. So please,

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