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THE UNITED STATES DEPARTMENT OF
HEALTH AND HUMAN SERVICES
Food and Drug Administration

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Reauthorization of the : Docket No.
Biosimilar User Fee Act : FDA-2015-N-3326
(BsUFA) :
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PUBLIC MEETING

DATE: Tuesday, November 2, 2021
TIME: 9:00 a.m.
BEFORE: Tasha Ray, Meeting Moderator
LOCATION: Webcast via Zoom
JOB No.: 4839269

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1 APPEARANCES	1 PUBLIC COMMENTORS:
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20 STEVEN KOZLOWSKI, DIRECTOR	20
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<p style="text-align: right;">Page 6</p> <p>1 M E E T I N G</p> <p>2 MS. RAY: Good morning. We'll go ahead and</p> <p>3 get started. Welcome to the U.S. Food and Drug</p> <p>4 Administration's public meeting on the reauthorization</p> <p>5 of the Biosimilar User Fee Act referred to as BsUFA.</p> <p>6 My name is Tasha Ray. I work in the office of Program</p> <p>7 and Strategic Analysis in FDA's Center for Drug</p> <p>8 Evaluation and Research, or CDER. I will serve as</p> <p>9 today's moderator. BsUFA is the legislation that</p> <p>10 authorizes FDA to collect user fees to support the</p> <p>11 process for the review of biosimilar biological</p> <p>12 products. The current authorization of the program,</p> <p>13 BsUFA II, expires in September 2022. Activities are</p> <p>14 therefore under way to reauthorize the program for</p> <p>15 fiscal years 2023 through 2027. Today's meeting is an</p> <p>16 important step in engaging with public stakeholders on</p> <p>17 the BsUFA program.</p> <p>18 The purpose of today's meeting as outlined in</p> <p>19 the federal Food, Drug and Cosmetic Act is to gather</p> <p>20 input from the public on the proposed recommendations</p> <p>21 for the reauthorization of BsUFA. The full text of</p> <p>22 the proposed BsUFA III commitment letter can be found</p>	<p style="text-align: right;">Page 8</p> <p>1 speakers please adhere to the list and timeframes in</p> <p>2 the agenda. I'll also let you know if you're running</p> <p>3 over. Given our virtual format, this meeting will not</p> <p>4 include questions from FDA to any of the speakers nor</p> <p>5 will FDA be able to take any questions during the</p> <p>6 meeting. Although you cannot see us in person, please</p> <p>7 know that my colleagues who are leading and</p> <p>8 participating in the reauthorization process are</p> <p>9 listening, and we very much value your important</p> <p>10 perspective.</p> <p>11 Today's meeting is not the only chance to</p> <p>12 gather public input. The public docket mentioned</p> <p>13 previously is open until December 2nd, and we</p> <p>14 encourage the public to submit comments. We will</p> <p>15 periodically be sending out the docket link throughout</p> <p>16 today's meeting. A recording and transcript of this</p> <p>17 meeting will also be made available online.</p> <p>18 A few last housekeeping items. If you</p> <p>19 experience technical issues during the webcast, please</p> <p>20 contact us through the Q&A box at the bottom of the</p> <p>21 screen, and we'll do our best to assist you. You can</p> <p>22 also email us at emily.ewing@fda.hhs.gov. We'll have</p>
<p style="text-align: right;">Page 7</p> <p>1 on the Agency's webpage. We have also opened a public</p> <p>2 docket for those who wish to submit written comments.</p> <p>3 After the public meeting and the close of the</p> <p>4 public docket, we will revise the recommendations as</p> <p>5 appropriate and present our proposed recommendations</p> <p>6 to congressional committees. We will cover several</p> <p>7 topics in our meeting today.</p> <p>8 We will begin with Dr. Patrizia Cavazzoni,</p> <p>9 Center Director of CDER, who will provide opening</p> <p>10 remarks. Andrew Kish, Director of CDER's Office of</p> <p>11 Program and Strategic Analysis, will follow with the</p> <p>12 background on BsUFA and the reauthorization process.</p> <p>13 We will then have a series of presentations from FDA</p> <p>14 covering a proposed BsUFA enhancement.</p> <p>15 Following these presentations, we'll take a</p> <p>16 20-minute break. And then we'll continue the meeting</p> <p>17 with remarks from industry association representatives</p> <p>18 who participated in the negotiation process. Finally,</p> <p>19 there will be a public comment session for those</p> <p>20 members of the public who submitted an online request</p> <p>21 to provide comments.</p> <p>22 As we do have a full agenda, we ask that</p>	<p style="text-align: right;">Page 9</p> <p>1 a 20-minute break around 10:00 a.m. If schedule</p> <p>2 modifications are needed, we'll send a notification in</p> <p>3 the top. With that, we look forward to beginning this</p> <p>4 important conversation. I'll now turn it over to Dr.</p> <p>5 Cavazzoni for your opening remarks.</p> <p>6 DR. CAVAZZONI: Good morning. I want to</p> <p>7 welcome everyone to today's public meeting to discuss</p> <p>8 the proposed enhancements to the BsUFA program.</p> <p>9 Providing a transparency in opportunity for public</p> <p>10 engagement are a vital piece of the BsUFA process.</p> <p>11 Last November, we requested public input on priorities</p> <p>12 for BsUFA negotiations. And over the course of</p> <p>13 negotiations, we posted meeting in its, to FDA's</p> <p>14 websites (indiscernible) the BsUFA discussions.</p> <p>15 Today, we will present the proposed</p> <p>16 enhancements to you. We look forward to your feedback</p> <p>17 and consideration in this step of the reauthorization.</p> <p>18 The public meeting is one of the final steps in the</p> <p>19 reauthorization process. The proposed enhancements</p> <p>20 for the third authorization of BsUFA provide funding</p> <p>21 for continued maturation of, of the biosimilar repeat</p> <p>22 program. This funding will help the Agency address</p>

<p style="text-align: right;">Page 10</p> <p>1 current and future needs. The BsUFA III agreement 2 provides support for the establishment of new 3 supplement categories, timelines, and performance 4 goals along with other enhancements through the review 5 process. 6 Additionally, the agreement includes a 7 focused effort to support the development of 8 interchangeable products. This effort includes 9 stakeholder input on key priorities for 10 interchangeable development. BsUFA III also, also 11 introduces a new BsUFA regulatory science pilot 12 program. The pilot program will support research to 13 advance the development of interchangeable products 14 and improve the efficiency of biosimilar product 15 development. Public input will also be critical to 16 reviewing project progress and identify, identifying 17 future regulatory science research that are needed for 18 biosimilars. Importantly, the agreement provides 19 continued sound financial footing for the biosimilar 20 program. BsUFA III will build on the financial 21 enhancements introduced in BsUFA II including maturing 22 the capacity planning function, which is critical to</p>	<p style="text-align: right;">Page 12</p> <p>1 background on the BsUFA program, where we were, are at 2 in the reauthorization process and a quick overview of 3 the proposed enhancements. 4 DR. KISH: Okay. Thank you. Good morning, 5 everyone, and thank you for joining the meeting. All 6 right. So I'll -- I'm going to give a brief 7 background on biosimilars, particularly the, the UFAs, 8 and then also, also a brief overview of the 9 reauthorization process and where we are today. We 10 can go to the next slide. 11 So a little bit on just the user fee 12 construct for those who have joined the, the meeting 13 back in November or any of the other UFA meetings. 14 This probably looks familiar but just as as reminder. 15 So what, what are user fees? So Congress instructs 16 FDA to establish a user fee program for the process of 17 the review of the biosimilar biological product 18 applications, and fee funds are added to new, to non- 19 fee appropriated funds. They are intended to increase 20 the staffing resources, the speed, and enhance the 21 review process. A key distinction with user fees is 22 that they pay for services that directly benefit the</p>
<p style="text-align: right;">Page 11</p> <p>1 ensuring FDA has the ability to keep pace with 2 sustained increases in workload. 3 I am pleased that even as our centers 4 continue to work hard on our COVID-19 response, our 5 staff have been able to come to an agreement that 6 addresses some current critical needs while looking 7 towards the future. Of course, the success of BsUFA 8 is not the result of FDA's work alone. Your 9 participation is a crucial element. So, please, don't 10 forget to provide comments and feedback to the public 11 docket after this meeting. We look forward to 12 continuing to work closely with you and to support you 13 as we fulfill our mission to deliver on the promise of 14 science with data-driven results and rigorous 15 scientific analysis to protect the health of the 16 American public. 17 Thank you again for attending today's virtual 18 meeting and special thanks to all of the speakers on 19 today's program. We look forward to a productive 20 meeting. 21 MS. RAY: Thank you very much, Dr. Cavazzoni. 22 I would now like to invite Andrew Kish to provide</p>	<p style="text-align: right;">Page 13</p> <p>1 payers. This is what distinguishes it from a tax. 2 So what do we discuss in these technical 3 negotiations? They are around desired enhancements of 4 the specific activities related to the process, the 5 review process. So that can include what new or 6 enhanced process the FDA or industry will seek during 7 this five, five-year timeframe. We discuss what is 8 technically feasible to do and what are the resources 9 required to implement and sustain those enhancements. 10 The important distinction is that we do not discuss 11 policy content. You may see in the agreement that 12 there is agreement around issuing guidances. However, 13 there is no discussion in these technical negotiations 14 what the FDA's position will be in those guidances. 15 Discussions also include mechanics of the user fee 16 program. So into the nut and bolt of how fees are 17 collected, the types and products are covered by each 18 fee, and as you're probably aware, everyone in the, in 19 the audience, the medical product industry programs 20 must be reauthorized every five years. Going to the 21 next slide. 22 BsUFA is still a relatively new program --</p>

<p style="text-align: right;">Page 14</p> <p>1 not our, not our newest, but close to it. It came 2 about in the BPCIA Act of 2009 where FDA was directed 3 to develop recommendations for a user fee program. 4 Something that's interesting at that point in time -- 5 I know I mentioned this in the, the kick-off meeting 6 back in November -- is there -- at that time when we 7 had the conflict BsUFA for a specific user fee 8 agreement, there were no market applications for 9 products on the market.</p> <p>10 There wasn't an established drug development 11 process where history related to biosimilar biological 12 products in the U.S. at that time. So after 13 consultation with regulated industry and public 14 stakeholders, FDA did come up with a BsUFA I 15 arrangement in agreement as transmitted to Congress, 16 and it was passed (indiscernible). But BsUFA is at 17 its 9th year and as a point of comparison, BsUFA is is 18 at it's 28th. BsUFA, since it's creation, has 19 facilitated the approval of 31 biosimilar biological 20 products for the American public.</p> <p>21 Really brief overview of BsUFA I and BsUFA II 22 and the key highlights of what was in those</p>	<p style="text-align: right;">Page 16</p> <p>1 structure based on program costs. So we no longer 2 reference PDUFA. We also implemented the review 3 program to promote the efficiency and effectiveness 4 for the first cycle review of biosimilar applications 5 and submit the minimized number of recycles necessary 6 for each biosimilar approval. It also added 7 commitments to assess the program and clarify the 8 regulatory pathway that hits that capacity. Moving to 9 the next slide.</p> <p>10 So where are we today? I -- as Tasha and 11 Patrizia already mentioned, this is a critical step in 12 the reauthorization process. This is language from, 13 from the statute. You might be familiar with it. So 14 we go through a, a full process and around 15 consultation. And then we move into the second step 16 there, which is public review of recommendations. And 17 the highlighted section is where we are today, and 18 that's publishing the recommendations to Federal 19 Register providing the public 30 days, at least 30 20 days to provide written comments to that docket and to 21 hold this meeting today to get your feedback. After 22 this meeting, the next step is then to review all the</p>
<p style="text-align: right;">Page 15</p> <p>1 agreements, BsUFA I, as previously mentioned, really 2 was just creating a user fee program really when there 3 wasn't much experience, or really any experience with 4 the process. So at that point in time, industry and 5 FDA and other stakeholders agreed let's, let's go 6 forward with referencing PDUFA fee amounts at, at the 7 start of BsUFA.</p> <p>8 So we -- we referenced the fee amounts and 9 the fee types and added a new fee type for products in 10 the development phase in order to generate revenue, 11 support FDA's review work during the, the development 12 IND stage and to, to enable sponsors to have meetings 13 with FDA early in development. BsUFA I also 14 introduced predictable timelines and review process 15 performance goals. Again, primarily modeled on the 16 BsUFA construct.</p> <p>17 So as we transition to BsUFA II, we had 18 several years of experience with, with the, the new 19 pathway at that time when we were discussing BsUFA II. 20 We also had some insight into program costs now that 21 the program was off the ground. So BsUFA II, we were 22 able to establish an independent efficient user fee</p>	<p style="text-align: right;">Page 17</p> <p>1 feedback that we receive through the public docket 2 making the assessments if anything in the package 3 needs to change and then transmit the recommendations 4 to Congress no later than January 15th next year.</p> <p>5 On the next slide is the, a graphical and 6 review if you're not a fan of reading statute, like 7 myself. A sense of a timeline for the BsUFA III 8 reauthorization. If we start with the public 9 announcement, a class in October of last year, we held 10 negotiations with industry from March to July. We 11 were going through a clearance process through the 12 administration, and we are at the public meeting 13 today.</p> <p>14 And as -- as mentioned previously, we 15 transmit the package to Congress no later than January 16 15th. And then it is with Congress to reauthorize 17 BsUFA III. And the current specific agreements, sun 18 sets on September 30th, 2022. And just a little bit 19 on the BsUFA III agreement overview of my colleagues 20 from FDA will do a deeper dive on each section. Go to 21 the next slide.</p> <p>22 This is around 10 enhancement areas that</p>

<p style="text-align: right;">Page 18</p> <p>1 we're going to highlight today that are new changes 2 going into BsUFA III. One is around supplements, a 3 meeting management, best practices in application 4 review, URRRA human factors' timelines, sections as Dr. 5 Cavazzoni mentioned, interchangeable products and 6 regulatory science, expense and finance, hiring 7 retention, and information technology. 8 So I would now like to turn it over to my 9 colleague, Sarah Yim, who is the Director of the 10 Office of Therapeutic Biologics and Biosimilars, who 11 is going to give you more information on some of these 12 enhancements. 13 DR. YIM: Thanks, Andy. Next slide, please. 14 So I'm going to summarize for you the proposed BsUFA 15 III enhancements for the first four areas that Andy 16 mentioned. Starting with supplements, the changes 17 introduce new supplement categories and timelines to 18 expedite the review of supplements. This includes 19 faster review timelines for safety labeling updates 20 and labeling updates to add or remove an indication 21 where FDA does not need to review efficacy data. Also 22 depending on the content of this submission, the new</p>	<p style="text-align: right;">Page 20</p> <p>1 within 4 months of receipt of the supplement. 2 Category D Supplements are those seeking licensure for 3 an additional indication when the submission contains 4 new datasets, except for the types of datasets 5 described in Category E and F Supplements also if the 6 supplement does not contain an up-to-date agreed upon 7 IPS fee. This category has an action goal date of 8 within 6 months of receipt of the supplement. 9 Category E and F Supplements both have an action goal 10 date of within 10 months of receipt. Category E 11 supplements are those seeking licensure for an 12 additional indication where the supplement contains 13 efficacy datasets. And Category F Supplements are 14 those seeking an initial determination of 15 interchangeability. Next slide, please. 16 So this slide summarizes the performance 17 goals for a regional applications and supplements. 18 There is no change to the timelines or goals for 19 original biosimilar biological product applications or 20 resubmitted original applications. Although not noted 21 on this slide, there is also no change to the 22 timelines for manufacturing supplements. For A</p>
<p style="text-align: right;">Page 19</p> <p>1 timelines are 3 months, 4 months, 6 months, or 10 2 months from the supplement receipt date. Next slide, 3 please. 4 Category A Supplements are supplements 5 seeking to update the labeling with regards to safety 6 information that has been updated in the referenced 7 product labeling. This category has an action goal 8 date of within three months of receipt of the 9 supplement. Category B Supplements are supplements 10 seeking licensure for an additional indication, when 11 the submission does not include new datasets with the 12 exceptions listed in the parentheses here, and the 13 supplement also does not seek a new route of 14 administration, dosage form, dosage strength, 15 formulation or presentation, and the supplement has an 16 up, up-to-date agreed upon initial pediatric study 17 plan. This category has an action goal date of within 18 4 months of receipt of the supplement. Next slide, 19 please. 20 Category C Supplements are supplements 21 seeking to remove an approved indication. This 22 category also has an action date, action goal date of</p>	<p style="text-align: right;">Page 21</p> <p>1 through D Category Supplements, the performance goals 2 start at 70 percent in 2023, go to 80 percent in 2024, 3 and then 90 percent for years 2025 through 2027. For 4 Category E and F Supplements, the performance goals 5 are 90 percent within 10 months of receipt for 6 original supplements and 90 percent within 6 months of 7 receipt for resubmitted supplements. Next slide, 8 please. 9 Moving on to meeting management enhancements, 10 the enhancements include modifying the operation, 11 operationalization of BIA meetings so that preliminary 12 comparative analytical data is no longer expected in 13 order to meet with FDA. The biggest change is the 14 introduction of a new biosimilar product development 15 meeting type called Type 2a. This meeting is intended 16 to focus on a narrow set of issues requiring input 17 from no more than three disciplines or review 18 divisions. In order to facilitate a reduced meeting 19 scheduling or written response time down to 60 20 calendar days. This is compared to the historical 21 Type 2 meetings under BsUFA II, which are now called 22 Type 2b meetings and still have a meeting scheduling</p>

<p style="text-align: right;">Page 22</p> <p>1 or a response time of 90 calendar days. BPD Type 4 2 meeting requests have been modified to allow for the 3 background package to be submitted up to 14 days after 4 FDA receipt of the meeting requests instead of the BPD 5 standard expectation of having the background package 6 submitted with the meeting request. Finally, 7 consistent with PDUFA VII, there will be a new follow- 8 up opportunity for sponsors to submit clarifying 9 questions after meetings or written response only 10 responses. And, of course, we're going to be updating 11 meetings, guidances, maps, and SOPs accordingly. Next 12 slide, please. 13 Building on the lessons learned during BsUFA 14 II, FDA will update relevant guidances, maps, and SOPs 15 to reflect best practices in communication during 16 application review. Next slide, please. 17 And, finally, consistent with PDUFA VII, 18 there will be final performance goals for the review 19 of use-related risk analyses and human factor study 20 protocols. FDA will also provide guidance on 21 considerations related to combination products. 22 Now, I'll turn the podium over to Dr. Laurie</p>	<p style="text-align: right;">Page 24</p> <p>1 any time during the review cycle regardless of whether 2 or not we have communicated the intent to inspect to 3 the sponsor. 4 The next statement I want to talk about with 5 regards to facilities is about the use of alternative 6 tools. So during the COVID-19 public health emergency 7 where FDA has been limited in the inspections that we 8 can conduct due to travel restrictions, we have really 9 enhanced our use of alternative tools to evaluate 10 facilities. So we recognize there is a lot of 11 interest in how FDA will continue to use these 12 alternative tools once travel restrictions are lifted. 13 Our intention then is to look at how we have used 14 these tools during the pandemic, what's worked, what 15 hasn't worked, what changes do we have to make, and 16 then to sort of determine how best to use these tools 17 moving forward after the public health emergency. 18 So our commitment there shown in the second 19 bullet is to, to commit to a guidance that will talk 20 about our thinking on the use of alternative tools to 21 assess manufacturing facilities named in pending 22 applications beyond the COVID-19 pandemic. So when</p>
<p style="text-align: right;">Page 23</p> <p>1 Graham to discuss the next set of enhancements. Thank 2 you. 3 DR. GRAHAM: Thanks, Sarah. So I'm going to 4 start today by talking about a couple of commitments 5 around facilities. So can we go to the next slide, 6 please? 7 Okay. So these, these commitments around 8 facilities are also part of PDUFA VII. So the first 9 commitment has to do with communications around pre- 10 license inspections. So consistent with current 11 practice, FDA notifies sponsors of pre-license 12 inspections when we need to, for example, see the drug 13 substance or drug product that is the subject of the 14 BLA in manufacturing during the inspection. However, 15 we want to ensure predictability, predictability 16 around these notifications. So our commitment there 17 is shown in this first bullet that we will notify 18 sponsors at least 60 days in advance and no later than 19 the midcycle of a pre-license inspection for 20 applications not including supplements where FDA needs 21 to see the product being manufactured. And, of 22 course, we reserve the right to conduct inspections at</p>	<p style="text-align: right;">Page 25</p> <p>1 I'm talking about alternative tools, I'm talking about 2 things like requesting existing inspection reports 3 from sort of trusted regulatory partners through 4 mutual recognition agreements or confidentiality 5 agreements, requesting information from applicants, 6 requesting records and other information directly from 7 facilities and other inspected entities and, as 8 appropriate, utilizing new or existing technology 9 platforms to assess manufacturing facilities. Next 10 slide, please. 11 So now I want to switch gears, and I want to 12 talk about that focused area in BsUFA III about 13 interchangeable products. So as you've already heard, 14 there is a focused effort to further advance the 15 development of safe and effective interchangeable 16 biosimilar biological products, and this focused 17 effort is multi-pronged. 18 So the first part of it is the research 19 component, which is really about leveraging the 20 regulatory science program that my colleague in OPQ, 21 Steve Kozlowski, is going to be talking about in a 22 couple of minutes. Our intent is to leverage the</p>

<p style="text-align: right;">Page 26</p> <p>1 regulatory science program to advance product 2 development, assist in a regulatory decision making, 3 and support guidance development.</p> <p>4 The next prong in our focused effort is 5 stakeholder engagement. So we really do want to have 6 a dialogue with industry. We want to talk about sort 7 of challenges and, and how we can further develop 8 interchangeable products. So we have committed to 9 holding a scientific workshop on the development of 10 interchangeable biosimilar biological products to help 11 sort of identify future needs. This can include 12 future guidance needs, future research needs. But we 13 intend to have this workshop on or before October 14 31st, 2025.</p> <p>15 Within 12 months following the public 16 workshop, we intend to draft a strategy document for 17 public comment. This strategy document will outline 18 the actions the Agency will take to facilitate the 19 development of interchangeable biosimilar biological 20 products. The strategy document can identify sort of 21 activities and deliverables including updating or 22 creating new guidances, maps, SOPPs, guidances, and</p>	<p style="text-align: right;">Page 28</p> <p>1 to support post-approval manufacturing changes to 2 support biosimilar and interchangeable biosimilar 3 biological products. And I want to point out that in 4 addition to sort of committing to certain dates by -- 5 by which we have the draft guidances up, we have also 6 committed that within 18 months after the close of the 7 public comment period on the draft guidance, we will 8 either publish a revised draft or a final guidance.</p> <p>9 And now I'm going to turn it over to my 10 colleague in OPQ, Steve Kozlowski.</p> <p>11 DR. KOZLOWSKI: Thank you. So I'm going to 12 talk about the regulatory science program, if we could 13 advance the slide.</p> <p>14 So in demonstrating biosimilarity, a 15 manufacturer generates an area of data that compares 16 the proposed product to the approved reference 17 product. Similarly, in interchangeability, which we 18 have heard again about the, the focused effort to 19 enhance those, there are data and information that are 20 needed to support that, some of which are currently 21 included in guidance.</p> <p>22 In both of these areas, there are potential</p>
<p style="text-align: right;">Page 27</p> <p>1 other changes to FDA programs. The strategy document 2 will also include proposed timeframes for the specific 3 actions outlined in the document. Our intent then is 4 within 9 months of the closing of the comment period, 5 we will publish a final strategy document. Next 6 slide, please.</p> <p>7 And the next and final piece of our multi- 8 pronged focused effort is on guidance. We have 9 committed to producing four foundational guidance 10 documents. The first has to do with describing 11 considerations for developing presentations, container 12 closure systems, and device constituent parts for 13 proposed interchangeable biosimilar biological 14 products. The second guidance is a guidance on 15 labeling for interchangeable biosimilar biological 16 products. The third guidance is on promotional 17 labeling and advertising considerations for 18 interchangeable biosimilar biological products.</p> <p>19 And, finally, the fourth guidance is a CMC 20 guidance on post-approval changes. And this guidance 21 will describe the nature and type of information for 22 different recorded categories of sponsorship provided</p>	<p style="text-align: right;">Page 29</p> <p>1 opportunities to better leverage data and information. 2 Both provide a similarity and interchangeability. FDA 3 is committed to enhancing regulatory decision making 4 and in facilitating the best science-based 5 recommendation in these areas, which are foundational 6 to bias in work development. In doing this, we are 7 piloting two demonstration products.</p> <p>8 The first is advancing the development of 9 interchangeable products, which, again, ties to the 10 focused effort on interchangeable products. And that 11 will involve evaluating the data and information, 12 specifically calling out real world evidence, needed 13 to meet the standards in determining 14 interchangeability. That effort can include looking 15 at differences in presentations and container closure 16 systems on, and how the impact of those changes would 17 be evaluated and also methodologies to predict 18 immunogenicity, which can also really facilitate 19 development of these products. The second effort is 20 in improving the overall efficiency of biosimilar 21 product development. And that will involve 22 considering latest scientific knowledge in advances</p>

<p style="text-align: right;">Page 30</p> <p>1 and our collective experience with biosimilars, which 2 is a large dataset now. And so specifics in that will 3 be streamlining through considering advance 4 technologies in both analytical and pharmacological 5 assessment. And similar to demonstration products on 6 interchangeability, predicting immunogenicity is a key 7 factor in enabling development, and that will be 8 evaluated in the context of both of these 9 demonstration products. If we could move to the next 10 slide.</p> <p>11 So how will these be communicated on the 12 outcome of these two regulatory demonstration 13 products? So in terms of interaction with 14 stakeholders, there will be a midpoint public meeting 15 to look at the progress of these projects and to 16 solicit input on future priorities. Preceding that 17 engagement will be an interim report on where the 18 projects are on. And there will also be a final 19 summary report on the outcomes of the research project 20 within the pilot.</p> <p>21 Now there will be a distinct strategy 22 document separate from the report on the research</p>	<p style="text-align: right;">Page 32</p> <p>1 the financial enhancements, building on the financial 2 enhancements in BsUFA II to advance the sustainability 3 of the program resources and to further enhance the 4 operational agility of the program. Topics in the 5 financial area include resource capacity planning, 6 enhancing financial transparency, and updates to the 7 fee setting process.</p> <p>8 So starting first with capacity planning, 9 resource capacity planning is a capability designed to 10 use data and analysis to help reform resource needs. 11 BsUFA II included commitments to establish the RCT, or 12 resource capacity planning, or RCT capability to 13 modernize our time recording approach and to establish 14 a new methodology to address review workload needs 15 called the capacity planning adjustment. BsUFA III 16 negotiated commitments are largely focused on 17 continuing to ensure the RCT capability. As we 18 collect more data on resource needs and refine 19 methodologies for forecast and review workload, the 20 RCT capacity will continue, continually mature. In 21 addition, we will be working to further integrate RCT 22 analytics in the Agency's resource and operational</p>
<p style="text-align: right;">Page 31</p> <p>1 pilot outcome that will really take what we have 2 learned from the program and use it in developing a 3 comprehensive strategy document. That will be a year 4 after the projects are completed. And that project 5 will include potentially updated maps, guidances, or 6 other steps to leverage the information that we have 7 gained and also timeframes for these actions. Thank 8 you. We can move to the next.</p> <p>9 So Joshua Barton is now going to talk about 10 some of the financial parts of this resource capacity 11 planning. So thank you.</p> <p>12 DR. BARTON: Okay. Good morning. Thank you, 13 Steve. My name is Josh Barton. I'm the Director of 14 our Resource Capacity Planning Staff in CDER, and this 15 morning I'll be speaking to you the financial topics 16 as well a hiring and IT within BsUFA III. These three 17 areas are foundational to ensuring the continued 18 success of the BsUFA program and providing the 19 resources, expertise, and technology to implement the 20 BsUFA III enhancements describes by my colleagues 21 earlier today. Next slide, please.</p> <p>22 The financial topics were focused on building</p>	<p style="text-align: right;">Page 33</p> <p>1 decision-making processes.</p> <p>2 Specific commitments in this area include the 3 publication of an implementation plan, which will 4 outline the continual improvement approach for the 5 capacity-planning adjustment and how it will integrate 6 resource capacity planning analytics in the Agency's 7 resource and operational decision-making processes for 8 within BsUFA III. We'll provide annual updates on 9 progress to that implementation plan and, and document 10 how the CPA funds are being used within the BsUFA 11 program in the annual financial report.</p> <p>12 There will also be a third-party evaluation 13 of the resource capacity planning capability, which 14 will be published in fiscal year 2025. And these 15 commitments are also designed to be consistent with 16 PDUFA, PDUFA VII to build on economies of scale across 17 the programs. The next slide, please.</p> <p>18 Around financial transparency, this is 19 largely a continuation of existing commitments within 20 BsUFA II, whereby we will publish a five-year 21 financial plan and hold a public meeting to discuss 22 the plan. And that financial plan will be updated</p>

<p style="text-align: right;">Page 34</p> <p>1 each year with the corresponding public meeting each 2 year. There are a couple of commitments to, specific 3 commitments to include certain information in the 5, 4 5-year financial plan including reporting on personnel 5 compensation and benefits costs that exceed the funds 6 provided by the personnel costs and benefit portion of 7 the inflation adjustment. This is related to the new 8 strategic hiring and retention adjustment, which I 9 will speak to you briefly in the next slide. We'll 10 speak to how we -- within the five-year financial plan 11 how we plan on managing costs related to personnel 12 beyond BsUFA III. And we'll provide updates on 13 progress towards implementing the plans to reduce the 14 carryover balance as committed to in BsUFA II and as, 15 as we'll outline in FY '22 financial report. The next 16 slide will also have some additional details on that. 17 Next slide.</p> <p>18 In terms of modifications or updates to the 19 fee adjustment, the fee-setting process, the fee- 20 adjustment process each year, the BsUFA III agreement 21 includes modifications to the capacity planning 22 adjustment to clarify the scope of the inputs of use</p>	<p style="text-align: right;">Page 36</p> <p>1 today is, of course, our ability to hire and retain 2 the necessary scientific and technical expertise to 3 deliver on the program. In recognition of this under 4 BsUFA III, FDA will continue reporting the hiring 5 goals on the FDA website.</p> <p>6 And there will also be a targeted assessment 7 of hiring and retention to be conducted by independent 8 contract or with expertise in HR operations and to be 9 overseen by the directors of CDER and CBER. This 10 assessment will build on the findings of previous 11 evaluations conducted under both PDUFA VI and BsUFA 12 III and will focus on, on improvement -- focusing 13 improvements on, on remaining challenges. The 14 assessment will be published in 2025 and will be 15 followed by a public meeting to discuss its findings 16 and the Agency's plan to address any recommendations 17 coming out of this report. And this also is designed 18 to be consistent with the PDUFA VII agreement to build 19 on (indiscernible) scale across the programs. Next 20 slide.</p> <p>21 But shifting gears to the IT-related goals. 22 As you may be aware, the FDA has published its vision</p>
<p style="text-align: right;">Page 35</p> <p>1 in the methodology. It includes a new strategic 2 hiring and retention adjustment to provide funds to 3 cover costs for retaining high, retaining and hiring 4 highly qualified scientific and technical staff for 5 the BsUFA program. And it includes enhancements to 6 the operating reserve adjustment to, to manage 7 financial risks to the program by establishing a 8 minimum amount and maximum amount of available 9 operating reserves to be maintained each year.</p> <p>10 The defined minimum amount is, is 10 weeks, 11 or the equivalent of 10 weeks of operations. And the 12 defined maximum is, is phased into 21 weeks. It's 13 phased in over the first couple years of BsUFA III, as 14 outlined in the slide. So 33 weeks in FY '23, the 15 equivalent of 27 weeks in FY '24, and the equivalent 16 of 21 weeks in FY '25 and, and subsequent years 17 remaining at a maximum of 21 weeks. Next slide.</p> <p>18 So that's, that's -- that concludes the, the 19 financial topics, and I'll speak to the hiring as 20 well. Hiring is critical to the, the continued 21 success of the BsUFA program and the implementation of 22 the enhancements discussed earlier in the meeting</p>	<p style="text-align: right;">Page 37</p> <p>1 for a modernized technology and data environment in 2 its, in its, via its T map and, and D map, the 3 technology and modernization action plan and the data 4 modernization action plan. These commitments are the 5 next step establishing and executing on a data and 6 technology modernization strategy that reflects the 7 vision in those preceding plans providing strategic 8 direction and for the future state of, of these data- 9 driven initiatives.</p> <p>10 It's intended to increase transparency and 11 support FDA to progress in key areas of focus such as 12 leverage and (indiscernible) technologies for 13 regulatory activities and, and enabling enterprise 14 approaches where feasible. FDA will share progress in 15 any needed adjustments to the strategy annually. Part 16 of the modernization effort is the transition and 17 enhancement of the Electronic Submission Gateway, or 18 ESD, shifting from an on-premise implementation to a 19 cloud-based solution with an improved architecture 20 that supports expanded data submission bandwidth and 21 storage all while continuing to ensure its stable 22 continued operations.</p>

<p style="text-align: right;">Page 38</p> <p>1 This modernized cloud-based ESG will include 2 an enterprise identify and access management solution. 3 It will streamline the registration and access of ESG. 4 FDA will continue to provide, provide ESG performance 5 metrics as well as periodic progress updates on this 6 transition. And, again, these, these commitments are 7 designed to be consistent the with PDUFA VII 8 commitments as well. 9 And with that, I have completed my three 10 sections, and we'll hand this back to our moderators. 11 Thank you. 12 MS. RAY: Thank you, Josh, and thank you to 13 all of our presenters. This concludes our overview of 14 the proposed enhancements. So we will now take a 15 break. As we're running a bit early, the meeting will 16 resume at 10:05. Our session following the break will 17 be industry comments, and I'll ask that the speakers 18 of that session to make sure you're back a few minutes 19 early. Thank you. 20 AUTOMATED VOICE: Recording stopped. 21 (Off the record.) 22 (Back on the record.)</p>	<p style="text-align: right;">Page 40</p> <p>1 As all of us attending this matter today can 2 agree, biologic medicines represent one of the great 3 medical breakthroughs, breakthroughs of our time 4 treating cancer, rheumatoid arthritis, Crohn's 5 Disease, and many other previously untreated, or 6 poorly treated conditions. Biosimilars hold the 7 promise of making important medicines more accessible 8 to patients. Through science that carefully, 9 intricately characterizes the underlying protein, 10 biosimilar sponsors are able to develop products that 11 have no clinically meaningful differences in safety, 12 priority, or potency as compared to their 13 corresponding originator biologics. Biosimilars are 14 projected to save Americans tens of billions of 15 dollars over the next decade but only if patients can 16 access, access them. 17 Since 2010, FDA has approved 31 biosimilars, 18 and the pipeline is growing because of, because of 19 upcoming patent expirations and investments in R&D by 20 biosimilar developments, developers. The programmatic 21 enhancements industry and FDA negotiated in BsUFA III 22 will support timelier patient access to biosimilars</p>
<p style="text-align: right;">Page 39</p> <p>1 MS. RAY: Welcome back from our break. And 2 now let's move into the next session for industry 3 comments. We invited three representatives who were 4 actively throughout the negotiation process, and these 5 four agreed to participate. They are Cory Wohlbach 6 from the Association for Accessible Medicines, Camelia 7 Thompson from the Biotechnology Innovation 8 Organization, Lucy Vereshchagina from the 9 Pharmaceutical Research and Manufacturers of American, 10 and Meaghan Smith from the Biosimilars Forum. Each 11 speaker will have a maximum of 10 minutes. Cory, you 12 are first and may start us off when you're ready. 13 MR. WOHLBACH: All right. Good morning, 14 everyone. Good afternoon. My name is Cory Wohlbach. 15 I'm a Global Vice President for Biosimilar Regulatory 16 Affairs at Teva Pharmaceuticals, and today I'm 17 speaking on behalf of the Association for Accessible 18 Medicines, biosimilar's counsel. I was a BsUFA III 19 negotiator sitting with the counsel, and I appreciated 20 the opportunity to provide the AM perspective on BsUFA 21 III enhancements that are described in the commitment 22 letter.</p>	<p style="text-align: right;">Page 41</p> <p>1 helping translate scientific advancements into 2 affordable medicines for American patients. AM is 3 proud to represent companies that play a leading role 4 in this effort. BsUFA has been a successful user fee 5 program. 6 It has helped increase the rate of first 7 cycle approvals for biosimilars, and there is clear 8 and predictable pathway to market with a substantial 9 body of guidance for industry and well-developed 10 meeting structure ensuring sponsors get early and 11 meaningful feedback from the FDA on development 12 programs. BsUFA III builds, builds on that foundation 13 of the existing BsUFA program and will help bring more 14 biosimilars to market more quickly by investing in 15 regulatory science, further enhancing communication 16 between FDA and sponsors, and improving supplement 17 review times, among other changes. 18 AM is pleased that the BsUFA III program will 19 include a regulatory science program. Investing in 20 regulatory science will lead to improvements in how 21 FDA assess, assess the safety, efficacy, and quality 22 of biosimilars. The two newly created pilot programs</p>

<p style="text-align: right;">Page 42</p> <p>1 will investigate opportunities to streamline 2 biosimilar development and will review the cited 3 requirements to meet the regulatory standard of 4 interchangeability. Importantly, there is ample 5 opportunity for increasing transparency and 6 communication by way of public feedback regarding the 7 regulatory science projects that FDA will undertake. 8 Another significant improvement is to the meeting 9 process, which will enable earlier interaction between 10 biosimilar sponsors and FDA without the need for 11 preliminary analytical data.</p> <p>12 Additionally, a new BPD Type 2a meeting will 13 help better inform product development by allowing FDA 14 to meet with sponsors on a rapid timeline to discuss 15 very specific questions about biosimilar development 16 plan. These rapid, targeted meetings will ultimately 17 save resources, minimize, minimizing the need for 18 lengthier meeting requests. The negotiating 19 enhancements also include a provision to allow 20 biosimilar sponsors to request that FDA clarify any 21 items following a meeting. Again, to minimize the 22 need to conduct another meeting to increase</p>	<p style="text-align: right;">Page 44</p> <p>1 guidances, guidance documents through the public 2 comment process.</p> <p>3 In conclusion, the negotiated BsUFA III 4 agreement includes significant improvements to advance 5 biosimilar development and, ultimately, to improve 6 patient access to high quality, safe, and effective 7 biosimilars. The AM Biosimilar Council strongly 8 encourage the administration in Congress to support 9 the negotiated agreement and to enact it as well.</p> <p>10 Thank you.</p> <p>11 MS. RAY: Thank you, Cory. We'll now move to 12 Camelia Thompson from the Biotechnology Innovation 13 Organization.</p> <p>14 DR. THOMPSON: Good morning, everyone. I am 15 Camelia Thompson, Senior Director in the Science and 16 Regulatory Team at the Biotechnology Innovation 17 Organization. Bio is the world's largest trade 18 association representing biotechnology companies, 19 academic institutions, state biotechnology centers, 20 and related organizations across the United States and 21 in more than 30 other nations. Bio's members develop 22 medical products and technologies to treat patients</p>
<p style="text-align: right;">Page 43</p> <p>1 efficiencies. These process improvements will go a 2 long way toward bringing biosimilars to market faster 3 and ensuring the biosimilar sponsors submit complete 4 applications to FDA.</p> <p>5 The BsUFA III agreement will also bring more 6 predictability and efficiency to supplement reviews. 7 Now that more biosimilars have been approved, there is 8 a need to streamline the process by which supplements 9 are approved. The new commitments address this need 10 by establishing different review metrics for different 11 types of supplement, supplemental BLAs.</p> <p>12 Finally, FDA has recently approved the first 13 two interchangeable biosimilars, a milestone 14 achievement for the biosimilars community. Still, 15 more work needs to be done to provide additional 16 clarity when seeking this regulatory designation. 17 That is why it is important that the BsUFA III 18 agreement includes commitments for FDA to publish 19 multiple guidance documents related to 20 interchangeability on topics including labeling and 21 post-approval manufacturing changes. We look forward 22 to participating in the development of these</p>	<p style="text-align: right;">Page 45</p> <p>1 afflicted with serious diseases, to delay the onset of 2 these diseases, or to prevent them in the first place.</p> <p>3 Bio and their member companies strongly 4 supported the establishment of a pathway for the 5 approval of biosimilars because we recognize that 6 market entry of safe and effective biosimilars may 7 provide increased choices for patients and physicians. 8 We remain committed to ensuring the success of the 9 emerging biosimilars market through our engagement and 10 ongoing policy developments related to biosimilars, 11 including our recent participation in the technical 12 negotiations for the reauthorization of BsUFA.</p> <p>13 In regards to supplements, BsUFA III will 14 establish new performance goals and timelines for 15 review and action on original supplements to add or 16 remove an indication based on the content of the 17 supplement. For example, the supplement may include 18 efficacy-related datasets. Will also establish new 19 performance goals and timelines for review and action 20 on original supplements seeking to update the labeling 21 for a licensed biosimilar or interchangeable product 22 with regards to applicable safety information that has</p>

<p style="text-align: right;">Page 46</p> <p>1 been updated in the referenced product labeling. 2 Industry's focus here was predictability, and these 3 commitments will provide enhanced efficiency, 4 consistency, and predictability for sponsors regarding 5 specific review timelines, and, ultimately, enhance 6 patient access to biosimilars.</p> <p>7 In regards to labeling, in order to help 8 ensure patient safety, it is important that 9 manufacturers of biosimilar and interchangeable 10 products have a timely, clear, and transparent process 11 for adding important risk information to their labels 12 when that risk information is the same risk 13 information included in the label of the referenced 14 product. BsUFA III will facilitate prompt updates to 15 safety information by establishing a review timeline 16 for safety labeling updates for the biosimilar with 17 regards to safety that has been updated in the 18 reference product labeling.</p> <p>19 In regards to meeting management, the BsUFA 20 III commitments enhance the current formal BPD meeting 21 types to better guide industry during the early 22 development phase to minimize numerous meeting</p>	<p style="text-align: right;">Page 48</p> <p>1 interactive communication with sponsors during drug 2 application review. FDA and industry will discuss 3 best practices for communication during application 4 review and potential mechanisms to operationalize 5 these best practices. Industry will be able to gain 6 insight from FDA on preparing for the most productive 7 meetings gained in BsUFA III.</p> <p>8 In regards to human factors protocols and 9 use-related risk analysis for combination products, 10 the demand for Agency review and feedback of proposed 11 human factors studies and or user risk-related 12 analyses exceeds current staffing. And in contrast to 13 PDUFA, there are no specific review goals agreed up on 14 under BsUFA. BsUFA III will establish predictable 15 timeframes for when to expect Agency feedback for the 16 review of URRA and human factors study protocols.</p> <p>17 This will have a significant impact on 18 program development and application submission for 19 drug device combination products. BsUFA also provides 20 funding for additional FTEs based on the new review 21 timelines. Guidance is also forthcoming regarding how 22 a URRA along with other information can be used to</p>
<p style="text-align: right;">Page 47</p> <p>1 requests to the FDA due to early and effective 2 collaboration and more efficiently support ongoing 3 development programs. The BIA meeting description 4 will be modified to enable sponsors to attain early 5 FDA advice on overall development design including, 6 but not limited to, novel study designs or endpoints 7 or specific statistical approaches.</p> <p>8 This can enable sponsors to discuss the 9 feasibility of 351(k) licensure for their product 10 earlier in development. A new meeting type will focus 11 on a narrow set of issues and is subject to a 60-day 12 goal to allow for rapid, targeted feedback. This will 13 speed the process of obtaining input on focused 14 targeted questions. The clarification of FDA feedback 15 and comments will ensure a sponsor's understanding of 16 FDA feedback and comments made during an FDA sponsor 17 meeting or in a WRO would support efficient product 18 development.</p> <p>19 In regards to best practices, best practices 20 for communications during biosimilar application 21 review are the responsibility of both industry and 22 FDA. This initiative will continue to enhance timely</p>	<p style="text-align: right;">Page 49</p> <p>1 inform when the results from a human factors 2 validation study may need to be submitted to a 3 marketing application.</p> <p>4 On behalf of Bio, we look forward to working 5 with all of you. This concludes my remarks, and thank 6 you for your time.</p> <p>7 MS. RAY: Thank you, Camelia. We'll now move 8 to Lucy Vereshchagina from Pharmaceutical Research and 9 Manufacturers of America.</p> <p>10 DR. VERESHCHAGINA: Thank you and good 11 morning, everyone. I'm Lucy Vereshchagina, Vice 12 President of Science and Regulatory Advocacy at the 13 Pharmaceutical Research and Manufacturers of America, 14 or PhRMA.</p> <p>15 PhRMA is a trade association that represents 16 America's leading innovative biopharmaceutical 17 research companies, which are devoted to discovering 18 and developing medicines that enable patients to live 19 longer, healthier, and more productive lives. PhRMA's 20 membership includes mainly leading biopharmaceutical 21 companies actively developing biosimilar medicines, 22 and we appreciate the opportunity to participate in</p>

<p style="text-align: right;">Page 50</p> <p>1 today's public stakeholder meeting and would like to 2 thank the FDA and our fellow negotiators for 3 developing important and impactful BsUFA III 4 performance goals (indiscernible). 5 As many speakers before me mentioned, 6 biosimilars are playing an increasingly critical role 7 in bringing new options to patients and increasing 8 competition. As previously mentioned, there is 31 FDA 9 approved biosimilar products currently, including two 10 interchangeable biosimilars as well as nearly a 11 hundred programs in the FDA's biosimilar program. And 12 while the U.S. has not had the biosimilar market in 13 place as long as the EU, the U.S. market has 14 significantly walked over the (indiscernible). 15 And, in fact, the U.S. has approved more 16 biosimilar products than the EU have in a comparable 17 period of time. And this is largely due to the 18 regularity predictability and efficiencies that have 19 been provided by the FDA's successful implementation 20 of the abbreviated approval pathway for biosimilars 21 and the resources provided to BsUFA. 22 As a result of growing competition,</p>	<p style="text-align: right;">Page 52</p> <p>1 interchangeable biosimilar products. BsUFA III will 2 also inform us of strategic development of guidance, 3 best practices, and procedures, specifically that they 4 will issue guidance on topics conditional for the 5 development of interchangeable biosimilar products, 6 hold a scientific workshop, and develop a strategy 7 document on the development of interchangeable 8 products. And they will also file a, a regulatory 9 science program, which clearly outlines demonstration 10 projects and deliverables focused on advancing the 11 development of interchangeable biosimilar products and 12 improving the efficiency of biosimilar product 13 development. 14 BsUFA III will also enhance manufacturing, 15 inspection, (indiscernible) communications, and 16 modernize facility assessment of (indiscernible), 17 which is based on (indiscernible). Specifically, 18 BsUFA III will promote timely FDA communication 19 responses regarding manufacturing facility inspections 20 and provide guidance on the use of (indiscernible) of 21 tools to assess manufacturing facilities' names, named 22 in pending applications.</p>
<p style="text-align: right;">Page 51</p> <p>1 annualized savings due to biosimilars reached \$6.5 2 billion dollars in 2020 and potential savings 3 estimated to exceed \$100 billion dollars in the 4 aggregate between 2020 and 2024. Many innovative 5 medicines are now competing with multiple biosimilar 6 versions with some brand biologics currently facing 7 competition from four to five biosimilars. And in 8 2021, average sale prices of biosimilars were as much 9 as 45 percent less than the originator's price of the 10 initial biosimilars (indiscernible). 11 PhRMA has been a strong supporter of and 12 participant in BsUFA since its inception in 2012. And 13 through the target of improvements outlined in the 14 BsUFA III performance goals whether BsUFA III will 15 build on the success of the program and help increase 16 timely access to safe and effective biosimilar and 17 interchangeable biosimilar products for patients. 18 I will highlight (indiscernible) provisions 19 in the performance goals so (inaudible) specifically 20 BsUFA III will advance development of interchangeable 21 biosimilar products by providing information and 22 guidance to sponsors for development of biosimilar and</p>	<p style="text-align: right;">Page 53</p> <p>1 BsUFA III will also modernize (indiscernible) 2 infrastructure and support adoption of (indiscernible) 3 technologies and to modernize of this data and 4 (indiscernible) capabilities in allowing 5 (indiscernible) efforts, BsUFA III will support 6 (indiscernible)-based modernization of the Electronic 7 Submission Gateway with an improved architecture that 8 supports expanding data submission, bandwidth, and 9 storage. 10 BsUFA III will also enact, enhance 11 accountability and transparency in (indiscernible) 12 activities and with organization plans by establishing 13 a strategy on data-driven regulatory initiatives. 14 BsUFA III will also enhance of this hiring, 15 retention, and financial management and will build on 16 the foundational works started in BsUFA II to 17 modernize financial and staff resource management, 18 accountability, and transparency, including clear 19 hiring goals and progress reporting. The additional 20 staff will help ensure that the new BsUFA III 21 initiative are implementable and that the Agency has 22 supportive resources in place.</p>

<p style="text-align: right;">Page 54</p> <p>1 BsUFA III also includes other important 2 commitments covered in details by Dr. Thompson before 3 me and other speakers earlier today such as specific 4 timelines for review of certain applications documents 5 including those seeking to update safety labeling to 6 effect changes to the referenced product labeling, 7 identification to existing meeting types, and 8 establishment of when your meeting type for rapid 9 targeted feedback to enable timely corrections between 10 sponsors and their biosimilar drug development and 11 review.</p> <p>12 In conclusion, BsUFA III will play a critical 13 role in improving the predictable, timely, and 14 efficient development and regulatory review of 15 biosimilar and interchangeable biosimilar products. 16 And PhRMA fully supports both the proposed BsUFA 17 performance goals as well as the timely legislative 18 reauthorization of BsUFA. PhRMA looks forward to 19 working with FDA, Congress, patient, and medical 20 provider groups, and other stakeholders to ensure 21 timely authorization of this important program and to 22 make sure that there are no disruption to their daily</p>	<p style="text-align: right;">Page 56</p> <p>1 licensure is critical to ensuring patient access to 2 many life-saving or life-altering medications. The 3 Biosimilars Forum believes that the improvements to 4 the biosimilar review program under BsUFA III 5 represents FDA's dedication to bringing biosimilars to 6 the market as efficiently as possible.</p> <p>7 We applaud FDA's willingness to engage 8 sponsors early in the development process and provide 9 targeted feedback. We are glad to see that the 10 commitment letter codifies the timeliness the Agency 11 had agreed to for labeling supplement reviews, 12 improves upon those safety labeling supplements, and 13 includes supplements to add an indication without 14 additional data. These commitments will go a long way 15 toward improving the efficiency of the biosimilar 16 review process.</p> <p>17 The Forum was and is very supportive of FDA's 18 inclusion of a regulatory science program under BsUFA 19 III. We very much agree with FDA that regulatory 20 science is key to bringing more biosimilars to market 21 and perhaps, eventually, streamlining the pathway to 22 market for certain biosimilar applications. Better</p>
<p style="text-align: right;">Page 55</p> <p>1 activities. Thank you, and thank you for your time.</p> <p>2 MS. RAY: Thank you, Lucy. We'll now move to 3 Meaghan Smith from the Biosimilar Forum.</p> <p>4 MS. SMITH: Thanks so much. Good morning, 5 everyone. I'm Meaghan Smith. I'm an Executive 6 Director of the Biosimilars Forum. On behalf of our 7 members, I am pleased to participate in today's public 8 meeting on the reauthorization of the Biosimilar User 9 Fee Act. The Forum is a nonprofit trade association 10 whose mission is to educate stakeholders on the value 11 of biosimilars and to improve access to biosimilars in 12 the United States. We thank FDA for your 13 collaboration and hard work in negotiating the BsUFA 14 III commitment letter.</p> <p>15 Biosimilars are a key contributor to 16 healthcare savings in the U.S. Although biologic 17 drugs represent only two percent of medicines 18 prescribed to patients in the U.S., the cost of these 19 drugs represent approximately 40 percent of total 20 prescription drug spending. Biosimilars provide the 21 necessary competition to allow Americans access to 22 lower-cost biologic alternatives, and their timely</p>	<p style="text-align: right;">Page 57</p> <p>1 regulatory science will both, both stir the Agency's 2 understanding of analytical similarity, which, in 3 turn, may reduce the need for confirmatory clinical 4 studies in certain cases thereby enabling biosimilars 5 to be made available to patients sooner.</p> <p>6 FDA's focus on interchangeability through the 7 regulatory science program should help to bring much 8 needed clarity and guidance just as more 9 interchangeable products reach the market. We are 10 excited the FDA licensed the first interchangeable 11 products this year, and we anticipate that by the end 12 of BsUFA III, FDA will have even more experience with 13 the development and approval of interchangeable 14 biological products.</p> <p>15 While these changes are laudable, the Forum 16 does want to call attention to the impact of the 17 current inspectional backlog on FDA's ability to meet 18 its BsUFA III commitments. The COVID-related 19 inspectional backlog has disproportionately affected 20 biosimilars. The percentage of on-time actions for 21 original biosimilar product applications, including 22 resubmissions, plunged from 100 percent during Q3 of</p>

<p style="text-align: right;">Page 58</p> <p>1 FY 2020 to 75 percent during Q4 and further dropped to 2 67 percent during Q1 of FY 2021.</p> <p>3 This trend for biosimilar applications is 4 markedly worse than for other user fee programs and 5 suggests that biosimilars have been more adversely 6 affected by pandemic-related inspectional issues. For 7 the BsUFA III commitment letter to be a success and 8 for FDA to continue to meet its goals of first cycle 9 licensure of biosimilar and interchangeable products, 10 the inspectional backlog must be addressed.</p> <p>11 As, as we head into BsUFA III, we look 12 forward with the Agency to implement the commitment 13 letter to the mutual benefit of biosimilar sponsors 14 and FDA. We are excited by the fact that there is now 15 a robust enough biosimilar industry with enough 16 development experience to help BsUFA mature over the 17 next five years. We are at a critical inflection 18 point for the industry, and we believe that the 19 commitments FDA has made to biosimilar review will be 20 critically important to sustaining and submitting the 21 biosimilar pathway for years to come.</p> <p>22 Thank you for the opportunity to speak today.</p>	<p style="text-align: right;">Page 60</p> <p>1 announce when your time is nearly up and then again 2 shortly after the 10-minute mark if necessary. We 3 will hear today from Cate Lockhart from the Biologic 4 and Biosimilars Collective Intelligence Consortium and 5 Radia Hocini from El Kendi Pharmaceutical.</p> <p>6 We also had signed up Geetanjali Saini from 7 Abhilashi College of Pharmacy and Andrew Siegel from 8 the Global Colon Cancer Association, but they were not 9 able to log in today. When I call your name, please 10 unmute yourself and begin your comment. If you are 11 having technical issues, please let us know and we can 12 move onto the next person and come back to you once 13 they're resolved. First up, we have Kate Lockhart.</p> <p>14 DR. LOCKHART: Good morning, and thank you to 15 the FDA for the opportunity to provide public comment. 16 My name is Cate Lockhart, and I am the Executive 17 Director of the Biologics and Biosimilars Collective 18 Intelligence Consortium, or BBCIC. My organization 19 resides under the umbrella of AMCP, the Academy of 20 Managed Care Pharmacy. BBCIC is the only nonprofit 21 research consortium dedicated to evaluating the real- 22 world safety and effectiveness of biologics, including</p>
<p style="text-align: right;">Page 59</p> <p>1 The Forum strongly supports FDA's ongoing efforts to 2 advance a robust biosimilars program. We are happy to 3 offer our members time and expertise towards ensuring 4 the continued success of the BsUFA program. Thank 5 you.</p> <p>6 MS. RAY: Thank you, Meaghan. We'll now move 7 into the final session of today's meeting, the Open 8 Public Comment. This is another important mechanism 9 to engage the public in a conversation. Please keep 10 in mind that FDA will not be responding to your 11 comments, but they will be transcribed and be part of 12 the public record. To facilitate a transparent 13 process, we encourage you to note any financial 14 interests that you have that are related to your 15 comment.</p> <p>16 If you do not have such interests, you may 17 state that for the record. And if you prefer not to 18 provide this information, you can still provide your 19 comment. We collect an online request for comment as 20 part of the meeting registration process. We have 4 21 people signed up. Each speaker will have 10 minutes 22 to speak. As I stated previously, I'll verbally</p>	<p style="text-align: right;">Page 61</p> <p>1 biosimilars, through a transparent science-driven 2 approach to using real world data.</p> <p>3 Our mission is to generate reliable real- 4 world evidence that examines the safety and 5 effectiveness of biologics in order to, to improve 6 public health. BBCIC is a public service initiative 7 that draws on de-identified healthcare data covering 8 over 90 million patient lives in the BBCIC distributed 9 research network that leverages some of the 10 infrastructure and tools developed by the FDA for 11 their sentinel system.</p> <p>12 As a true consortium, BBCIC includes 13 participants from stakeholder groups across the 14 healthcare system including pharmaceutical 15 manufacturers, health plans or insurance companies, 16 pharmacy benefit managers, patient advocates, 17 clinician experts, and academic scientists who all 18 come to the table with the shared goal of producing 19 rigorous unbiased research to build the evidence base 20 around biologics including biosimilars.</p> <p>21 My comments address FDA's commitment to 22 enhancing regulatory decision-making and facilitating</p>

<p style="text-align: right;">Page 62</p> <p>1 science-based recommendations through the regulatory 2 science pilot program and its two demonstrated 3 projects. BBCIC supports FDA's commitment to 4 investigate and evaluate the data and information, 5 including real-world evidence, or RWE, to meet 6 evidence standards for determining interchangeability. 7 BBCIC also supports FDA's goal to improve the 8 efficiency of biosimilar product development, 9 especially through the enhancement of regulatory 10 decision-making based on the latest scientific 11 knowledge.</p> <p>12 While BBCIC encourages FDA's continued 13 adoption of RWE as part of the regulatory process, we 14 also recommend FDA identify and utilize additional 15 sources of RWE like those from BBCIC that focus 16 explicitly on biologics to foster efficiency and 17 consistency by more broadly leveraging the evidence 18 base of RWE.</p> <p>19 For instance, BBCIC routinely conducts 20 longitudinal and utilization analyses for products 21 with available biosimilars to describe real-world 22 product use and treatment patterns, patient</p>	<p style="text-align: right;">Page 64</p> <p>1 patient outcomes and other effects of real-world 2 product switching or confirmatory studies for 3 regulatory decisions.</p> <p>4 In conclusion, I would like to thank today's 5 attendees for their attention and to FDA for the 6 opportunity to provide public comment and for their 7 consideration of BBCIC's perspective. Thank you very 8 much for your time.</p> <p>9 MS. RAY: Thank you, Cate. We will now move 10 onto Radia. Radia, if you could please unmute 11 yourself and turn on your video, and you can begin 12 your comment. You should see a mute or unmute button 13 in the bottom right corner of your screen. We can 14 hear you.</p> <p>15 DR. HOCINI: (Indiscernible.) 16 AUTOMATED VOICE: Recording stopped. 17 AUTOMATED VOICE: Recording in progress. 18 MS. RAY: Thank you, Radia. It sounds like 19 we're having some trouble hearing. So that will 20 conclude our meeting. Thank you to all of the public 21 commenters. Like I said, this concludes our public 22 meeting on the proposed BsUFA reauthorization. FDA</p>
<p style="text-align: right;">Page 63</p> <p>1 characteristics, and clinical outcomes. Currently, we 2 are conducting a large-scale retrospective real-world 3 comparative safety and effectiveness study of all GSF 4 products, both filgrastim and pegfilgrastim referenced 5 products, and biosimilars. This is an ambitious 6 study. It's the first study of its kind and scale. 7 We are also studying medication switching patterns and 8 outcomes in patients with rheumatoid arthritis treated 9 with immunomodulating therapies, including tumor 10 necrosis factor inhibitors and janus kinase 11 inhibitors. Additionally, we're driving the state of 12 real-world research through ongoing methods and 13 infrastructure development initiatives.</p> <p>14 Finally, BBCIC believes the use of RWE also 15 supports FDA's goal to promote transparency in 16 regulatory decisions by expanding the use of well- 17 designed real-world studies as supplemental 18 information beyond randomized clinical -- randomized 19 controlled trials to better capture the diversity of a 20 real patient population. Real-world studies offer a 21 means to efficiently evaluate questions that are 22 pertinent to all healthcare stakeholders such as</p>	<p style="text-align: right;">Page 65</p> <p>1 values all of the input that's been generated from 2 today's discussion, and we look, look forward to 3 receiving further comments to our public document. 4 Anyone from the public is welcome to contribute 5 through the public docket. The recording for this 6 meeting and the transcript will also be posted to 7 FDA's BsUFA III webpage.</p> <p>8 (Whereupon, at 10:41 a.m., the proceeding was 9 concluded.) 10 11 12 13 14 15 16 17 18 19 20 21 22</p>

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9 which this was taken; and, further, that I am not a
10 relative or employee of any counsel or attorney
11 employed by the parties hereto, nor financially or
12 otherwise interested in the outcome of this action.

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Sarah E. Cobetto
SARAH E. COBETTO

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