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U.S. FOOD AND DRUG ADMINISTRATION

PUBLIC MEETING ON THE RECOMMENDATIONS FOR
PRESCRIPTION DRUG USER FEE ACT (PDUFA) REAUTHORIZATION

OPENING REMARKS

JANET WOODCOCK,
FDA ACTING COMMISSIONER OF FOOD AND DRUGS

Tuesday, September 28, 2021

9:00 a.m.

JOB No. : 4808420

<p style="text-align: right;">Page 2</p> <p style="text-align: center;">A P P E A R A N C E S</p> <p>DR. JANET WOODCOCK FDA Acting Commissioner of Food And Drugs</p>	<p style="text-align: right;">Page 4</p> <p>1 essence of this process that involves plenty of public 2 input. 3 Indeed, one of the most critical aspects of 4 the user fee process is to provide transparency and 5 opportunities for public engagement. To support this 6 goal, throughout the course of the negotiations, we've 7 posted over 100 meeting minutes to FDA's website, 8 summarizing our ongoing discussions. For each month 9 that negotiations were underway, we also held meetings 10 with our public stakeholders to make sure we understand 11 their important perspectives and priorities. 12 This public meeting, one of the final steps in 13 the process, is an essential part of the FDA's 14 commitment to transparency, to public engagement, and 15 our ability to meet future public health needs. Today, 16 after many months of negotiations, we look forward to 17 presenting to you the proposed enhancements that we 18 have developed and we look forward to your feedback and 19 consideration in this next step in the process. 20 I want to point out that our staff has been 21 working full steam on this proposal even as our entire 22 agency has really been consumed in our response to 23 COVID-19. The proposed enhancements in this latest 24 round of PDUFA negotiations provide funding for the 25 Agency to address some important needs of today, while</p>
<p style="text-align: right;">Page 3</p> <p style="text-align: center;">P R O C E E D I N G S</p> <p>DR. WOODCOCK: I want to welcome everyone to today's public meeting to discuss the proposed enhancement to the PDUFA program. I want to thank you for your participation, and also thank the presenters on today's program. We all understand the key role that the Prescription Drug User Fee program plays in reinforcing the FDA's work. Since Congress passed this law in 1992, user fees have helped expedite the drug approval process, and provide support to the work we do in many other ways. For example, in safety, we have really tried to strengthen our regulatory resources, including enhancing and modernizing our drug safety initiatives and programs and improving the safe use of medicine. This has included, for instance, continued development of the Sentinel System, which has become an integral component of FDA's routine regulatory and safety review program, with an ongoing scientific training program and clear evidence of regulatory impact. So, over the course of six iterations of the PDUFA law, we have seen a number of changes and improvements, of which the focus on drug safety, including post-market, has been one. That is the</p>	<p style="text-align: right;">Page 5</p> <p>1 also looking forward and creating opportunities to 2 foster drug development for the future. 3 For example, the proposed agreement provides 4 critical support to the Agency to manage the increase 5 in advanced biological therapies such as cell and gene 6 therapies. As we expect more of these programs to 7 mature, PDUFA VII should help support the necessary 8 staff capacity and capability to ensure the timely 9 development and review of these products. 10 The support provided by PDUFA also helps 11 ensure that our science-based agency is able to apply 12 the best available science and most rigorous data to 13 the decisions we make throughout the entire medical 14 product lifecycle, from the earliest stages of product 15 development to post-market safety. That's why PDUFA 16 VII will continue advancing regulatory evidence 17 generation and drug development tools in areas like 18 real-world evidence, rare disease endpoint development, 19 and complex innovative trial design. 20 And it's why the proposed enhancements of this 21 agreement will help ensure not only a focus on 22 producing quality reviews, but also in concepts like 23 advanced manufacturing, which help support the timely 24 development and availability of new and innovative 25 products for patients. Similarly, this proposal seeks</p>

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1 to keep up with the advances and use of modern
 2 technology in the pharmaceutical sector, by providing
 3 the FDA with the support to modernize its data and IT
 4 capacity and capabilities.
 5 This includes the use of cloud-based
 6 technology in the PDUFA program, along with enhanced
 7 ability to evaluate digital health technologies that
 8 support drug development and review. Another important
 9 proposed enhancement in PDUFA VII is how it builds on
 10 the successes of the FDA's patient-focused drug
 11 development efforts to enhance the incorporation, the
 12 patient's voice in drug development and decision-
 13 making.
 14 Many treatments increasingly rely on the input
 15 and the voice of patients, with therapies targeted and
 16 tailored to the patient's specific characteristics and
 17 needs. And we hope this trend will continue. We
 18 believe these proposed commitments offer even greater
 19 opportunity and promise. Our success, both in the past
 20 and the future, depends on collaboration and
 21 communication. That's why your participation and input
 22 are crucial, and why I want to thank you again for your
 23 engagement in today's virtual meeting.
 24 It's extremely important that we get your
 25 feedback, so please don't forget to provide comments to

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1 the public docket after this meeting. We are eager to
 2 continue to work closely with you as we fulfill our
 3 mission to deliver on the promise of science, with
 4 data-driven results and rigorous scientific research
 5 and analyses to protect and promote the health of
 6 Americans.
 7 We look forward to a productive meeting.
 8 Thank you.
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1 CERTIFICATE OF NOTARY PUBLIC
 2 I, EMMANUEL PEZOA, the officer before whom the
 3 foregoing proceedings were taken, do hereby certify
 4 that any witness(es) in the foregoing proceedings,
 5 prior to testifying, were duly sworn; that the
 6 proceedings were recorded by me and thereafter reduced
 7 to typewriting by a qualified transcriptionist; that
 8 said digital audio recording of said proceedings are a
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 12 action in which this was taken; and, further, that I am
 13 not a relative or employee of any party to the action;
 14 employed by the party in the action;
 15 otherwise interested in the outcome of the action.
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 17 EMMANUEL PEZOA
 18 Notary Public
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 9 this was taken; and, further, that I am not a relative
 10 or employee of any counsel or attorney employed by the
 11 parties hereto, or otherwise interested in the outcome
 12 of the proceeding.
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