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

Page 2

A P P E A R A N C E S

DR. JANET WOODCOCK
FDA Acting Commissioner of Food And Drugs

Page 3

P R O C E E D I N G S

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 essence of this process that involves plenty of public input.

Page 4

Indeed, one of the most critical aspects of the user fee process is to provide transparency and opportunities for public engagement. To support this goal, throughout the course of the negotiations, we've posted over 100 meeting minutes to FDA's website, summarizing our ongoing discussions. For each month that negotiations were underway, we also held meetings with our public stakeholders to make sure we understand their important perspectives and priorities.

This public meeting, one of the final steps in the process, is an essential part of the FDA's commitment to transparency, to public engagement, and our ability to meet future public health needs. Today, after many months of negotiations, we look forward to presenting to you the proposed enhancements that we have developed and we look forward to your feedback and consideration in this next step in the process.

I want to point out that our staff has been working full steam on this proposal even as our entire agency has really been consumed in our response to COVID-19. The proposed enhancements in this latest round of PDUFA negotiations provide funding for the Agency to address some important needs of today, while

Page 5

also looking forward and creating opportunities to foster drug development for the future.

For example, the proposed agreement provides critical support to the Agency to manage the increase in advanced biological therapies such as cell and gene therapies. As we expect more of these programs to mature, PDUFA VII should help support the necessary staff capacity and capability to ensure the timely development and review of these products.

The support provided by PDUFA also helps ensure that our science-based agency is able to apply the best available science and most rigorous data to the decisions we make throughout the entire medical product lifecycle, from the earliest stages of product development to post-market safety. That's why PDUFA VII will continue advancing regulatory evidence generation and drug development tools in areas like real-world evidence, rare disease endpoint development, and complex innovative trial design.

And it's why the proposed enhancements of this agreement will help ensure not only a focus on producing quality reviews, but also in concepts like advanced manufacturing, which help support the timely development and availability of new and innovative products for patients. Similarly, this proposal seeks

Page 6

to keep up with the advances and use of modern technology in the pharmaceutical sector, by providing the FDA with the support to modernize its data and IT capacity and capabilities.

This includes the use of cloud-based technology in the PDUFA program, along with enhanced ability to evaluate digital health technologies that support drug development and review. Another important proposed enhancement in PDUFA VII is how it builds on the successes of the FDA's patient-focused drug development efforts to enhance the incorporation, the patient's voice in drug development and decision-making.

Many treatments increasingly rely on the input and the voice of patients, with therapies targeted and tailored to the patient's specific characteristics and needs. And we hope this trend will continue. We believe these proposed commitments offer even greater opportunity and promise. Our success, both in the past and the future, depends on collaboration and communication. That's why your participation and input are crucial, and why I want to thank you again for your engagement in today's virtual meeting.

It's extremely important that we get your feedback, so please don't forget to provide comments to

Page 7

the public docket after this meeting. We are eager to continue to work closely with you as we fulfill our mission to deliver on the promise of science, with data-driven results and rigorous scientific research and analyses to protect and promote the health of Americans.

We look forward to a productive meeting.

Thank you.

Page 8

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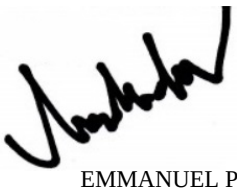

EMMANUEL PEZOA

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Page 9

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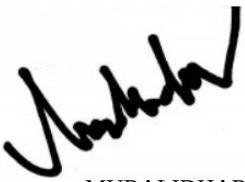

MURALIDHAREN K.V.