From: CDER Trade Press <CDERTradePress@fda.hhs.gov>
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Subject: Message from Janet Woodcock, M.D., director of FDA's Center for Drug Evaluation and Research

CDER Staff:

As we embark on a new year, I'd like to thank you for all the great work accomplished last year and highlight our strategic goals for several topics that cross multiple CDER offices.

Making progress in these priority areas advances our mission to ensure that safe, effective, high-quality drugs are available for the American public.

Postmarket safety initiatives: Maintaining our robust postmarket surveillance and risk evaluation programs is critical for identifying new adverse events that did not appear during the product development process and for learning more about known adverse events. Through a risk-based approach, we take into account the nature of the drug, its potential adverse events, the intended population, the potential for serious outcomes, as well as the impact on individuals and the overall potential impact on public health. We will enhance postmarket safety practices through increased coordination so that we can rapidly analyze and resolve drug safety problems when they arise. For example, we continue to investigate the presence of genotoxic impurities, called nitrosamines, found in some types of drugs.

New Drugs Regulatory Program Modernization: We will work toward full implementation of a streamlined, interdisciplinary review process and template to support the integrated review for assessing new drug applications and biologic license applications. Other aspects of modernization include implementing standardized and consistent approaches for managing IND applications and post-market drug safety. Because of staff commitment to this multi-phase initiative, we are operationalizing a new organizational structure across the Office of New Drugs, the Office of Translational Sciences, the Office of Surveillance and Epidemiology, and the Office of Pharmaceutical Quality. The reorganization will enable greater efficiency among staff in New Drugs Regulatory Program offices and enhance alignment of interrelated disease areas.

User fee programs: This year, we'll begin our next round of negotiations on these critical programs. CDER's three user fee programs will need to be reauthorized for 2022: Prescription Drug User Fee Act (PDUFA), the Generic Drug User Fee Amendments (GDUFA), and the Biosimilar User Fee Act (BsUFA). User fee programs help us fulfill our mission of protecting the public health and accelerating innovation in industry.

Sunscreens: We issued a highly-anticipated proposed rule last year highlighting our commitment to update our regulatory approach in light of increased sunscreen use. When finalized, the proposed rule will put into effect final monograph regulations for OTC sunscreens, as required by the Sunscreen Innovation Act (SIA).

Drug compounding: Through our compounding regulatory program, we protect the public from contaminated products through ongoing inspections, warning letters, and risk alerts. We will continue developing novel approaches to engage outsourcing facilities and help them produce the highest quality products. The Compounding Quality Center of Excellence is a new initiative designed to enhance collaboration among and provide educational programs for outsourcing facilities aimed at improving the overall quality of compounded medicines.

Opioid abuse: Addressing the opioid crisis remains one of CDER's top public health priorities. While it is encouraging to see that total drug overdose deaths in the United States dropped for the first time in decades, we still have much work to do as deaths from drug overdoses remain at historically high levels. We remain committed to addressing this national crisis on all fronts, with a continued focus on decreasing exposure to opioids and preventing new addiction; supporting the treatment of those with opioid use disorder and expanding access to naloxone; fostering the development of novel pain treatment therapies; improving enforcement of diverted opioids and illegal drugs; and accessing the benefit/risk framework that evaluates not only the outcomes of opioids when used a prescribed, but also the public health effects of inappropriate use of these drugs. In addition, we will continue to implement the SUPPORT Act to build upon our efforts and adapt our responses to confront the changing nature of the opioid crisis.

Drug shortages: This critical health care issue reduces treatment options, limits access to medications, and threatens the well-being of patients in need of important therapies. Meaningful solutions to drug shortages will require collaboration and cooperation among all stakeholders. We are committed to working with legislators, industry, health care professionals, other agencies, purchasers and purchasing organizations, academia, patients and many others to prevent and mitigate drug shortages.

To help us achieve our goals, we will work to further improve internal processes for our center's governance structure, information technology, and hiring. We continue to dedicate resources and energy to streamline the interview and selection process.

In 2020, you'll hear more about diversity, inclusion, and civility as we implement programs and initiatives to foster a safe and respectful work environment in CDER. Each of you is key to accomplishing what we do for the public, and I appreciate the dedication you display every day to your work, your colleagues, and CDER's mission.

I look forward to another exciting year!

Janet Woodcock