U.S. FOOD & DRUG ADMINISTRATION

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Brazilian Health Regulatory Agency Meets with FDA to Discuss Medical Product Issues

Today, the FDA Principal Deputy Commissioner Janet Woodcock, M.D., and other FDA officials met with a delegation from the Brazilian Health Regulatory Agency (ANVISA) led by Director-President Antonio Barra, M.D., to discuss issues of mutual interest related to drugs, biologics, and medical devices.

Agência Nacional de Vigilância Sanitária (Anvisa) is the most mature regulatory system in Latin America. It issues market authorizations for medical devices and pharmaceuticals; exercises post-marketing surveillance to ensure manufacturers comply with Brazilian requirements and is an active participant in international regulatory convergence initiatives.

The FDA maintains a close collaborative relationship with ANVISA, which was only heightened over the past two years during the coronavirus pandemic, Dr. Woodcock told the Brazilian delegation.

The FDA and ANVISA have a signed Statement of Cooperation and a Confidentiality Commitment in place that allow the two agencies to exchange inspection reports and discuss drug applications. Throughout the pandemic, these arrangements allowed the two regulators to share regulatory approaches to decision-making regarding medical products used to treat and prevent COVID-19.

ANVISA is also one of the seven regulatory agencies that participate with the FDA in Project Orbis, which provides the agencies a framework for concurrent submission and review of oncology drugs.

At today's meeting, officials discussed strategies to address drug shortages and the medical product supply chain, the potential for future collaboration related to drugs for rare diseases, plans for the exchange of non-public information, monitoring medical products sold on the internet, and Brazil's progress in developing a Unique Device Identification System for medical devices.

The meeting was facilitated in a hybrid fashion, with some participating in person at the FDA's headquarters in White Oak, Maryland, and others participating virtually.

Joining Dr. Woodcock from the FDA were Mark Abdoo, associate commissioner for global policy and strategy; Dr. Peter Marks, director of the Center for Biologics Evaluation and Research; Theresa Mullin, associate director for strategic initiatives in

the Center for Drug Evaluation and Research; and Melissa Torres, associate director for international affairs in the Center for Devices and Radiological Health. Joining Dr. Barra were Leonardo Dutra, head of Anvisa's International Affairs Office; Karin Mendes, head of the Anvisa Cabinet; Renato Stancato, head of the Science and Technology Section of the Brazilian Embassy in Washington; and Samia Melo, advisor to Dr. Barra.