U.S. FOOD & DRUG ADMINISTRATION

Office of Global Policy and Strategy

OGPS STATEMENT

January 12, 2023

Today, the FDA signed the Agreement on Mutual Recognition between the Swiss Confederation and the United States of America Relating to Pharmaceutical Good Manufacturing Practice.

By signing such an agreement, with the Swiss Confederation (Switzerland), the FDA and the Swiss Agency for Therapeutic Products (SwissMedic) will be able to utilize each other's good manufacturing practice inspections of pharmaceutical manufacturing facilities, avoiding the need for duplicate inspections.

The Food and Drug Administration Safety and Innovation Act, enacted in 2012, permitted the FDA to enter into agreements to recognize drug inspections conducted by foreign regulatory authorities determined to be capable of conducting inspections that meet U.S. requirements.

The FDA already has a Mutual Recognition Agreement (MRA) in place with the European Union and one with the United Kingdom. In addition to covering good manufacturing practice inspections of facilities making human drugs, the MRA with SwissMedic also includes veterinary drugs.

The FDA's Office of Global Policy and Strategy has been negotiating the U.S.-Switzerland MRA since 2021. Before the MRA enters into force, the FDA must determine whether SwissMedic is capable of conducting inspections that meet U.S. requirements, and SwissMedic must make a similar determination with respect to the FDA meeting Swiss requirements.

"In today's global pharmaceutical market, MRAs offer a way for the FDA to work more efficiently and maximize its resources," said Andi Lipstein Fristedt, FDA Deputy Commissioner for Policy, Legislation, and International Affairs, who signed the agreement on behalf of the FDA. "Once the MRA enters into force, the FDA will be able to rely on the factual findings of SwissMedic experts in many cases, thus avoiding duplicate inspections and allowing the FDA to expand its inspectional reach.