U.S. FOOD & DRUG ADMINISTRATION

Office of Global Policy and Strategy

OGPS STATEMENT

April 12, 2023

Xinjiang Uyghur Autonomous Region of the People's Republic of China

The FDA remains concerned about the human rights abuses occurring in the Xinjiang Uyghur Autonomous Region of the People's Republic of China. Given these concerns, we would like to reiterate that the Federal Food, Drug, and Cosmetic Act requires clinical trials to obtain the legally effective, informed consent of human subjects as described in the Act and the FDA's implementing regulations. For more information on the FDA's human subject protection and good clinical practice requirements, please see, for example, 21 CFR Parts 312 (312.60 and 312.120) and 314 (314.125(b)(16) and 314.150(b)(8)), 601 (601.2(a)), 812 (812.28(a)(1), 812.30(b)(4), and 812.100), 814 (814.45(a)(5), 814.46(a)(4), and 814.118(a)(7)), and 860 (860.260(c)(9)). These regulations are intended to protect the rights, safety, and welfare of human subjects and help ensure the integrity of clinical data that support marketing authorizations.

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