

June 10, 2022

Dear Colleagues:

The Food and Drug Administration's (FDA's) Office of Regulatory Affairs (ORA), Office of Enforcement and Import Operations (OEIO) 90-day pilot project to conduct drug entry admissibility reviews on a national basis and expanded staffing to 24/7shift coverage will conclude on June 11, 2022.

The Nationalized Drug Entry Review Pilot has been running since March 13, 2022, during which time we conducted entry admissibility reviews on a national basis versus the current port-by-port entry review approach. We also utilized entry review staff over multiple time zones allowing us to expand our drug entry review coverage times.

FDA will be assessing data from the pilot to determine any benefits gained from a national drug entry review approach; the potential to automate portions of the entry review process; allowing entry reviewers more time to focus on potentially higher violation products; and efficiencies gained from timely receipt of associated documentation.

The contact information established for this pilot will be shut down, including the ERPilot@fda.hhs.gov email, and phone numbers 833-312-3237 and 301-796-2249.

For drug import questions, please contact the OEIO divisions (see [Import Offices and Ports of Entry | FDA](#)).

Data, information, and lessons learned from the pilot will be reviewed and analyzed to determine improvements in the entry review program.

Sincerely,

Dan R. Solis

Assistant Commissioner for Import Operations