



March 4, 2022

Dear Colleagues:

The volume of imported FDA regulated commodities continues to increase, driven in part by e-Commerce, trade volume and supply chain complexities which require ORA to assess our approach to import entry review.

The Food and Drug Administration's Office of Regulatory Affairs' Office of Enforcement and Import Operations (OEIO) is looking at several new ways to increase efficiency and effectiveness in our operational work. As part of this effort, OEIO has developed a 90-day pilot project to maximize our entry review staff at the periods of highest volume drug entries.

The Nationalized Drug Entry Review Pilot will run from March 13, 2022 through June 13, 2022. We will conduct entry admissibility reviews on a national basis versus the current port-by-port entry review approach. The pilot, which is being managed by OEIO's Division of Food Defense Targeting, will utilize entry review staff over multiple time zones allowing us to expand our drug entry review coverage times to twenty-four-hour coverage per day, with 7 days per week staffing. We will cover all 336 ports of entry and this expanded coverage should allow for increased response time of drug entries. The pilot will also examine the potential to automate portions of the entry review process, allowing entry reviewers to focus more of their time on potentially higher violation products.

During the period of the Nationalized Drug Entry Review Pilot, FDA would also like to determine if efficiencies can be gained by receiving associated documentation at the time the entry is made rather than waiting for regular Documents Requested communications. We are calling this, *The More We Know, The Faster You Go*.

Our expectation is that the results and critical feedback from the pilot will provide OEIO with data to support potential changes to our entry review process.

We are excited about the prospects of this pilot and look forward to communicating more information on our results once the pilot has concluded. If you have any questions, please contact the new Nationalized Drug Entry Review Pilot at ERPilot@fda.hhs.gov or by phone (toll free) 833-312-3237 or 301-796-2249.

Sincerely,

Dan R. Solis
Assistant Commissioner for Import Operations