FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS

September 19, 2022

Dear Colleagues:

Customs and Border Protection's (CBP) Office of Field Operations (OFO) and the Food and Drug Administration (FDA) Office of Enforcement and Import Operations (OEIO) and Office of Information Systems Management (OISM) will implement a streamlined notification process between both agencies effective October 1, 2022. The process will allow for the timely issuance of the demand for redelivery of goods refused by the FDA.

CBP and FDA initiated a pilot to streamline the communication between both agencies for FDA refused entries. The pilot commenced in early 2021 and was initially limited to the service ports of Laredo, San Francisco, and Baltimore which represented the various ports of lading (land, sea, and air.) The pilot has since been expanded to include all ports in Detroit and New York as well as multiple ports in Atlanta.

The new approach is largely seamless to the trade but provides CBP, FDA, and the trade with an efficient means of receiving notification of FDA refusals across the nation as well as CBP's subsequent issuance of the CBP Form 4647 Demand for Redelivery. The new process establishes clear lines of communication and predictable results. It should be noted that the CBP's Centers of Excellence and Expertise (CEE) role is limited to the issuance and final close out of the CBP Form 4647; importer of record (importer) and/or broker will need to coordinate the redelivery to export or destroy the refused FDA regulated goods with their local FDA office as well as the cargo office at the CBP port where the cargo will be redelivered

In addition to the benefits of a streamlined process the new FDA refusal notification process brings CBP processes into conformance with the updated regulations in 19 CFR 141.113 by specifying that Centers of Excellence and Expertise will receive post-release FDA refusal notifications and will issue the CBP Form 4647 to the importer on an account basis.

As part of the new FDA Refusal notification process, CBP will leverage the new ACE forms application for the issuance of the CBP Form 4647 Demand for Redelivery which will then be sent via the ACE portal (or mailed to the importer if the importer has not opted to receive forms electronically through the portal). A copy of the CBP form 4647 will also be emailed to FDA and the Customhouse Broker (broker) if the importer has not designated the broker to receive it via the ACE portal. The issuance of the CBP form 4647 Demand for Redelivery via the ACE forms module will provide consistency and will allow trade users to view, respond and manage electronic versions of the forms. Please see CSMS #51707590 for additional information on the new ACE form module and a link to a Quick Reference Guide.

As we move into the new process across the nation, the FDA will issue the FDA Notice of Refusal and CBP will then subsequently issue the CBP Form 4647 Demand for Redelivery. It should be noted that all locations will use the new process for all FDA refusals effective October 1, 2022; this includes locations where the FDA and CBP were previously issuing a joint notice of refusal and demand for redelivery.

We are excited to have a uniform process across all FDA and CBP offices and we look forward to future collaboration between both agencies.

Sincerely,

Dan R. Solis
Assistant Commissioner for Import Operations