Latest Developments of FDA's Weekly Entry Filing Procedure for Foreign Trade Zones

"A Deep Dive into FDA WEF for FTZs"

The U.S. Food and Drug Administration's ("FDA") Weekly Entry Filing ("WEF") procedure for Foreign Trade Zones ("FTZs") was instituted in the mid-1990s to provide a vehicle to "expedite entry of repetitive shipments of 'low risk' merchandise from FTZs in the United States." Participants in FDA WEF must have prior approval from FDA, U.S. Customs and Border Protection ("CBP") and any other government agency involved, and must submit entry data electronically via the Automated Broker Interface ("ABI"). Under this procedure, the FTZ operator/user files a weekly estimated entry on its CBPF 3461 (or "cargo release") only for merchandise previously vetted and approved for WEF filing by FDA and the filer should receive an automatic FDA "may proceed" for each line estimate. Expedited release from FTZs of previously FDA-vetted and approved merchandise helps improve the participant's supply chain while freeing up limited CBP and FDA resources to focus on "high risk" shipments in a continuously changing import environment.

This certainly has been the case in the past two years, since President Obama's Executive Order ("EO") 13659, Streamlining the Export/Import Process for America's Businesses was signed on February 19, 2014. Pursuant to the EO, a deadline of December 31, 2016 was established for participating Federal agencies to have the necessary capabilities, agreements, and other requirements in place to utilize the International Trade Data System ("ITDS") and supporting systems (such as the Automated Commercial Environment or "ACE"), as the primary means of collecting the standard set of data and other relevant documentation required for the release of imported cargo and clearance of cargo for export.

On May 16, 2016, CBP published a Federal Register Notice ("FRN"), 81 FR 30320, announcing that effective June 15, 2016 ACE would become the sole CBP-authorized electronic data interchange ("EDI") system for processing certain electronic entry and entry summary filings (including Type 06 FTZ entry type) accompanied by FDA data. CBP also published via Cargo Systems Messaging Service ("CSMS") #16-0000431 the "Entry Types by PGA" chart. In the chart, CBP distinguishes between "regular" (or individual) and "weekly estimate" Type 06 consumption entry for FTZs. For FTZs, any required FDA data must always be filed at the "time of ACE Cargo Release/entry, regardless of whether it is a weekly estimate or regular Type 06".

Subsequently, FDA published a new web page on June 6, 2016 titled "Foreign Trade Zones/Weekly Entry Filing" that includes useful information on FTZs and the FDA WEF process, including instructions on FDA's current application and review process for the FDA WEF program:

http://www.fda.gov/ForIndustry/ImportProgram/ImportBasics/ucm505817.htm

The distinction between "regular"/individual and "weekly estimate" Type 06 FTZ entry is crucial since only merchandise previously approved for FDA WEF can be included on a weekly estimate. According to FDA's "Foreign Trade Zones/Weekly Entry Filing" website, "If the request for FDA WEF processing is not granted, future FTZ withdrawal entries (entry Type 06) will be processed the same as other entries. This means that those entries will require submission of entry data **at the time of actual withdrawal**, and may be subject to document review, field examination and/or sample collection," (emphasis added.)

The FDA FTZ/WEF web page referenced above is packed with detailed information and we strongly encourage any FTZ participant with FDA-regulated products to become familiar with the web page

content and also make a proactive determination as to whether FDA has previously approved WEF for all products included on Type 06 weekly estimates. The website provides valuable insight as to which FDA-regulated products are amenable for WEF processing (a.k.a. "low risk") in general, as well as commodity-specific information. For example, FDA's Center for Devices and Radiological Health ("CDRH") has determined that medical devices/in-vitro diagnostic products are not amenable for WEF processing, while some radiological health/electronic products subject to a performance standard may be allowed depending on their product codes.

There are some intricacies, however, that the FDA FTZ/WEF web page does not address but that have been revealed in our dealings with the various FDA district offices. For example:

- With the move to ACE, FDA is focusing on the name and address of the manufacturer and is "cleaning up" Manufacturer IDs ("MIDs") and Foreign Establishment Identifiers ("FEIs"); this means that exact matches must occur on the name and address approved for FDA WEF and the name and address transmitted on the Cargo Release/weekly estimate.
- FDA's screening criteria appear to be Manufacturer FEI, Shipper FEI, Importer FEI, FDA Product Code, Port of Entry.
- FDA encourages filers to include FEI numbers on entry transactions; however, FEIs are not made available to the filer at the time of entry and there is currently no independent mechanism for obtaining this information. A formal request can be filed with FDA to obtain the FEIs and FDA has also begun providing FEIs back to the WEF applicant at the time of the WEF approval.

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It is an exciting and busy time in ACE with the many Partner Government Agencies coming on board. December 31st is knocking at our door and the "single window" concept is becoming more of a reality. As ACE moves toward full implementation, companies should ensure that they have access to the "ACE Portal" and understand how to use it effectively to not only help with monitoring and entry reporting but also with leveraging the available information for research and analysis.