Automated Commercial Environment / International Trade Data System (ACE/ITDS) Frequently Asked Questions

1) What is FDA's role in the import process?

While primary responsibility for administering U.S. laws relating to imports is exercised by CBP, FDA is responsible for determining whether or not an FDA-regulated product is in compliance with the laws enforced by FDA. The discharge of this joint responsibility involves close coordination and cooperation between FDA and CBP for such imports. FDA receives notice from CBP of the arrival at each U.S. port of entry (sea, land, rail, and air) where FDA-regulated products are imported, of each shipment containing an FDA-regulated product. The PGA Message Set in ACE for FDA-regulated products contains the data that assists FDA in determining the admissibility of those products under FDA authorities.

When an FDA-regulated product is offered for import into U.S. commerce, CBP, through an information technology interface, electronically transmits the entry data to FDA. The entry is electronically screened to determine if an automated review is appropriate. If the entry is subject to a manual review, FDA staff review the information submitted in ACE and determine whether a field exam or sampling is necessary, if more information should be requested, or if the entry should be released or subject to refusal. In conjunction with this process, FDA manages a system of import alerts and other guidance to provide direction to field staff in determining whether imported product lines have the appearance of a violation and warrant refusal, unless and until the importer demonstrates that the product is in compliance.

2) What exactly is ACE/ITDS?

The Automated Commercial Environment or ACE is the sole CBP-authorized electronic data interchange (EDI) system for electronic submissions of import entries of FDA-regulated products. ACE replaced the previous CBP-authorized EDI system, the Automated Commercial System, also known as ACS. The purpose of ACE is to streamline business processes, to facilitate growth in trade, to ensure cargo security, to provide better means to combat threats, and to foster participation in global commerce, while ensuring compliance with U.S. laws and regulations.

The International Trade Data System (ITDS), as described in section 405 of the Security and Accountability for Every Port Act of 2006 (SAFE Port Act) (Pub. L. 109-347), was

established to modernize and simplify the way in which partner government agencies (PGAs), including FDA, interact with the trade community by creating a "single window" through which filers submit the data elements required for import or export of cargo. The purpose of ITDS is to eliminate redundant filing requirements, to efficiently regulate the flow of commerce, and to effectively enforce laws and regulations relating to international trade, by establishing a single portal system, operated by CBP, for the collection and distribution of standard electronic import and export data required by all PGAs (19 U.S.C. 1411(d)(1)(B)). CBP designed ACE to provide that "single window" for the electronic filing of import entries.

3) Why is this happening now?

On February 19, 2014, President Obama issued Executive Order 13569 to streamline export and import processes. Among other things, the Executive Order requires the completion of the ACE/ITDS single window by December 2016. Effective July 23, 2016, ACE became the sole CBP-authorized electronic data interchange system for the import of FDA-regulated products.

4) Why is FDA requiring the submission of certain data elements in ACE at the time of entry?

The number of import lines that include FDA-regulated products continues to grow steadily every year and this is posing challenges to the Agency in enforcing the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act. The number of import lines in 2015 that included an FDA-regulated article exceeded 35 million. In ACS, where submission of data elements was optional, the number of voluntary data submissions varied depending on the commodity. Where certain data was missing or inaccurate, entries had to be manually reviewed by FDA staff for an admissibility determination and processing of entries was sometimes significantly delayed. FDA determined that certain data elements may be material to our import admissibility review and, if they were submitted in ACE at the time of entry, this would facilitate automated "May Proceed" determinations by us for low-risk FDA-regulated products. This, in turn, would allow the Agency to focus our limited resources on products that may be associated with a greater public health risk. An automated review to determine whether an article "May Proceed" is much faster and less resource intensive for FDA and the trade community than a manual review by Agency personnel. The rule requires that the FDA-required data elements be submitted in ACE at the time of entry.

5) Are the required data elements the same for all commodities?

FDA regulates a number of different commodities, and the requirements for admissibility of these commodities are not necessarily the same. The required data elements are contained in the rule and further described in the FDA Supplemental Guide to the CATAIR which is available on the CBP website at (https://www.cbp.gov/document/guidance/fda-supplemental-guide-release-16).

6) What happens if an import filer does not submit the required data elements?

If a filer fails to submit the complete and accurate information required by the rule in ACE at the time of entry, the entry may be rejected without FDA performing an admissibility review of the article.