

TSN ITDS Committee
Announcing the Formation of the Food and Drug Administration (FDA)
ACE/ITDS Working Group

Attention, Brokers, Importers, and Software Developers

The International Trade Data System (ITDS) Committee of the Trade Support Network (TSN) needs your input and participation in an upcoming **ACE/ITDS FDA Working Group** under the auspices of the Security and Accountability for Every Port Act (SAFE Port Act) and in accordance with the ITDS protocols for implementing ACE/ITDS in the spirit of the February 2014 Executive Order on Streamlining the Export/Import Process for America's Businesses.

Working Group Purpose

The purpose of the FDA ACE/ITDS Working Group will be to ensure that all stakeholders are invited to participate in a discussion of the technical solution and data elements that will be required by the U.S. Food and Drug Administration (FDA) in the new cargo release and control functionality of ACE/ITDS. Primarily the workgroup will focus on the IT related issues associated with implementing the ACE/ITDS. The working group will consist of members of the international trade community; including trade software developers, that offer [import] commodities into the United States and which are regulated by the FDA. Officials from the FDA and the U.S. Customs and Border Protection (CBP) that are working on the development and deployment of ACE/ITDS will be part of this working group. The engagement in ACE/ITDS will require electronic [entry] submissions of all FDA required import data for cargo admissibility processing, in an XML format under a NEIM standard. Your involvement is needed to ensure that the transition to ACE/ITDS will continue to support efficient and timely cargo releases while in compliance with FDA requirements.

FDA Authority

The FDA is responsible for ensuring that FDA-regulated foods, drugs, cosmetics, medical devices, biologics, tobacco products and radiation-emitting electronic products imported or offered for import into the United States meet the requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act), Fair Packaging and Labeling Act (FPLA), Nutrition Labeling and Education Act (NLEA), Import Milk Act/Filled Milk Act, Federal Caustic Poison Act, and Public Health Service Act (PHSA), Part F, Subpart 1, Biologic Products. For example, Section 801 of the FD&C Act authorizes examination of foods, drugs, cosmetics, devices and tobacco products offered for import into the United States. If among other circumstances, a product appears to be adulterated, misbranded, or an unapproved new drug, based on examination of samples or otherwise, it is subject to refusal of admission into the United States. Section 801 of the FD&C Act also requires that FDA receive notice, in advance of arrival, of food imported or offered for import into the United States. The prior notice information is used by FDA to target and make food establishments/security risk assessment decisions related to imported food.

Working Group Task

The working group is tasked with assuring that all technical and data requirements are transitioned to ACE/ITDS in a seamless, efficient, and timely manner, and in particular, that the ACE data assists the FDA to execute its import processing and review duties. ACE/ITDS will allow more efficient government decision-making associated with goods arriving at the border, reducing the time for clearing goods from many days to, in some cases, seconds. This will dramatically speed the flow of legitimate commerce across our borders. Furthermore, coordinated and automated messaging about these decisions will increase predictability in the private sector and allow them to plan supply chain movements with greater confidence and less cost. ACE/ITDS once deployed will decommission the current system known as Automated Commercial System (ACS). The official “single-window” system of record will be known as ACE. ACE will require that all data related to ACE Cargo Release and Control to be submitted electronically under the Partner Government Agency (PGA) Message Set.

Working Group Commitment

Working Group participants should be prepared to commit to weekly conference calls typically of 2 hour duration over a six to eight-week period. Travel may also be required for on-site meeting(s) if necessary. A more definitive schedule will be determined at the Working Group’s first meeting. The teleconferences will focus on the business process and technical data flows required for the above referenced FDA Message sets in order to define the programming and operational guidelines to be implemented by CBP, FDA, importers, and importer brokers when filing and processing entries for products subject to FDA jurisdiction at US borders. Regulatory and policy issues are outside the scope of this working group.

To participate in the FDA ACE/ITDS Working Group please send your contact information to:

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