

Trade Alert: FDA Issues New Import Data Requirements

Posted on **November 30, 2016** by **FDA Voice**

By: Howard Sklamberg, J.D.

One of FDA's many responsibilities is to review imported products regulated by the agency to determine admissibility. This job has become increasingly challenging with growing volumes of imports of FDA-regulated products each year — from six million import entries in 2002 to 35 million in 2015.



To help meet that challenge in a way that benefits both government and the trade community, import entries of products regulated by FDA are submitted through an electronic system called the [Automated Commercial Environment \(ACE\)](#). A final rule [published on November 29 in the Federal Register](#) specifies certain data that must be submitted in ACE when an FDA-regulated product is offered for import into the United States. The effective date of the rule is December 29, 2016, 30 days from the date of publication.

The trade community helped us pilot ACE, which is operated by U.S. Customs and Border Protection (CBP), from August 2015 to May 2016. In July 2016, ACE became the sole CBP-authorized system for electronic submissions of entries that contain FDA-regulated products.

The rule also includes technical revisions to certain sections of FDA regulations:

- The owner or consignee of an FDA-regulated product is now defined as the importer of record. This brings FDA regulations up to date with previous revisions to customs laws. (21 CFR 1.83 and 21 CFR 1005.2)
- FDA will now directly provide a notice that an FDA-regulated product is to be sampled, rather than having to go through CBP to provide that notice. (21 CFR 1.90)
- FDA may now provide written notices electronically to the importer of record about FDA actions to refuse FDA-regulated products and/or subject certain drug products to administrative destruction. (21 CFR 1.94)
- The rule clarifies that FDA can reject an entry for failure to provide through ACE the complete and accurate information required by the rule.

As a result of the more streamlined import process for FDA-regulated products provided by ACE, the rule is expected to lead to an efficient use of FDA and importer resources, and more effective enforcement of laws and regulations enforced by FDA.

FDA will continue to provide assistance to filers working to properly submit the required data. Some of the

measures we have instituted:

- We are offering telephone meetings with importers, customs brokers, and other stakeholders, in real-time, while they are filing entries in ACE. Request a meeting by emailing ACE_Support@fda.hhs.gov.
- An ACE Support Center is staffed 24/7. Reach FDA staff by email at ACE_Support@fda.hhs.gov or by phone at a domestic toll-free line (877-345-1101) or a local/international line (571-620-7320).
- Upon request, FDA will assist in a filer's first ACE submission, or for filers who import various commodities, FDA will assist with every first submission of a particular commodity.
- Additional assistance for general import operations and policy questions, including FDA product codes and entry requirements, is available via email at FDAImportsInquiry@fda.hhs.gov or by calling 301-796-0356.

ACE replaces the Automated Commercial System, an older electronic submission system. Additionally, ACE provides an efficient single window for importers. Prior to the development of ACE, importers of products regulated by multiple government agencies could in some cases be required to submit information more than once.

ACE has already shown promise in accomplishing the dual goal of protecting public health while also serving the needs of the trade community by facilitating a more efficient review for admissibility of compliant products. FDA processing times for both automated and manual review have already been substantially reduced, by approximately 75% and 93% respectively, compared with the agency's processing times in the previous system.

The ACE system serves to protect public health by allowing FDA to focus its limited resources on those FDA-regulated products being offered for import that may be associated with a greater public health risk.

Howard Sklamberg, J.D., is FDA's Deputy Commissioner for Global Regulatory Operations and Policy

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