From: U.S. Food & Drug Administration (FDA) [mailto:fda@service.govdelivery.com]
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FDA U.S. FOOD & DRUG ADMINISTRATION

New System Speeds FDA Import Decisions

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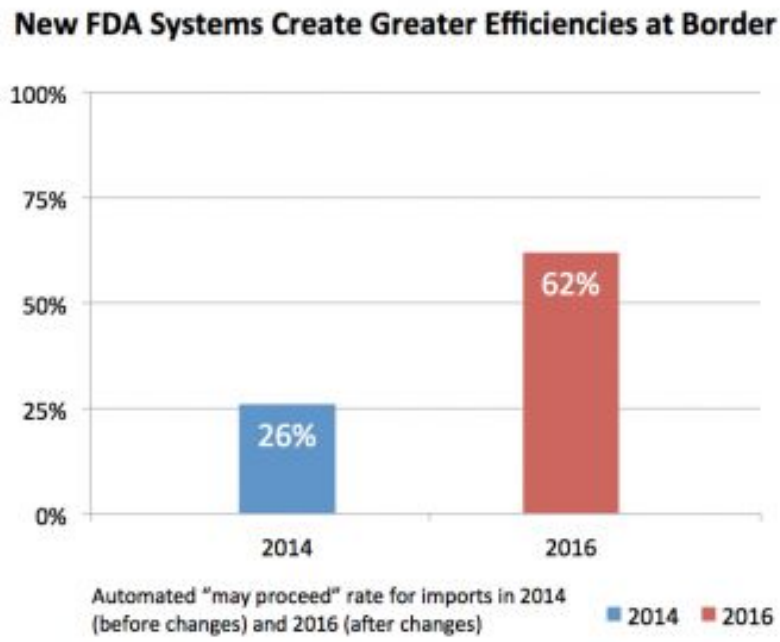

The data is in. A new automated system for determining whether FDA-regulated products can enter the United States is allowing us to make decisions faster and more efficiently.

Quick admissibility decisions are critical to commerce, especially when perishable products are involved. The new system brings better response times while still protecting consumers.

FDA has used an automated system to assist in making decisions about the admissibility of FDA-regulated products since the early 1990s. In 2015, FDA began piloting a new system, the Automated Commercial Environment (ACE). It features modernized infrastructure that can more quickly process larger amounts of data.
Part of the pilot involved the collection of additional shipment information, such as intended use codes, that could assist in automatically making informed admissibility decisions. Results were promising. So in July 2016, the use of ACE and the provision of additional data were required for everyone seeking to import FDA-regulated goods into the U.S.

Products offered for import into the U.S. must comply with the same standards as domestic products. ACE is one of many tools FDA uses to determine the admissibility of imports – tools that also include inspections of manufacturing plants abroad, physical inspection of goods arriving at our ports, and import alerts which flag manufacturers or products which have had previous violations. By better automating the admissibility process with respect to lower-risk products, FDA can focus more resources on higher-risk products.

Improvements under ACE

ACE, coupled with other enhancements to FDA systems, has brought benefits to both government and the import community. Among the benefits:

§ Due to a number of changes in FDA systems, including ACE, automated messages that an import "may proceed" into U.S. commerce without manual review by an FDA employee have increased dramatically since ACE was piloted, from 26 percent of lines to 62 percent. (A line is a single type of product in a shipment. A shipment might include one or more types of products).
§ FDA employees have less need to request additional information from the importers of record for additional documents or information. That means fewer delays in FDA admissibility decisions about shipments. Under ACE, 28,374 fewer lines needed additional documents and information than prior to ACE.
§ Although we don't have an exact count of the average processing time before ACE went into effect, we know that times have improved. Indeed, today, automated "may proceeds" are being processed on average within 1 minute and 36 seconds.

§ We're also seeing improvements for products that require manual processing. Products are receiving "may proceed" within a median of one hour if no additional documentation is required. When additional information or documents are needed, decisions are processed within 72 hours, compared to 96 hours under the previous system.

The import community, which has cooperated in submitting the data needed to optimize ACE, shares the credit for these improvements. Further cooperation, particularly by addressing common errors, will bring even greater benefits.

More Improvements through Compliance – Errors to Avoid

A study of FDA rejections between November 2016 and March 2017 found that the most common problems involved the submission of invalid or canceled food facility registration numbers and invalid FDA product codes, which identify the items in a shipment. When offering an FDA-regulated product for import, those filing the paperwork need to remember to:

§ Submit for all FDA-regulated products the correct company name and address of the importer, the manufacturer, delivered-to party, and shipper. Providing the unique number assigned to the company by Dun & Bradstreet (DUNS) or the FDA Establishment Identifier (FEI) provides additional firm-specific information, which assists in finding the companies in FDA's database.

§ Submit "Intended use" information for FDA-regulated products.

U.S. Customs and Border Protection (CBP), which makes initial decisions before referring shipments to FDA, cites the three most common errors that lead to rejection of entries prior to their being transmitted to FDA:

§ Incorrect syntax or omission of required affirmations of compliance;

§ Missing or invalid entity information, which identifies companies involved in the manufacture and importation of the product; and,

§ Missing or invalid units of measure.

The FDA ACE Error Guide details the messages FDA sends when the agency receives entries with problems that prevent further processing of entries.

FDA is standing by to help. An ACE support center is staffed from 6 a.m. to 10 p.m. EST. Contact the center by e-mail at ACE_Support@fda.hhs.gov or toll free from the U.S. at 877-345-1101. Local and international callers should dial 571-620-7320.

Upon request, FDA will assist those filing an import entry of a particular commodity for the first time. Make the request by emailing the support center.

The Division of Import Operations (DIO) also can be contacted for general import operations and policy questions, including questions surrounding the appropriate FDA product code or

for more information about an entry declaration requirement. Email FDAImportsInquiry@fda.hhs.gov or call 301-796-0356.
Thank you for helping us make import operations efficient and effective as we continue to focus on our mission of protecting public health.

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