FDA Mandatory Transition to ACE System - June 15, 2016

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The Automated Commercial Environment (ACE) has been the sole electronic data interchange (EDI) system authorized by the Commissioner of CBP for processing certain electronic entry and entry summary filings since March 31, 2016. This has required upgrading of software by all partners in the services supply chain, such as airlines, forwarders, customs brokers, container freight stations, etc. KWE has been at the forefront of effecting these changes, with minimal or no impact to our customers' cargo processing needs, as we made the switch to ACE Entry Summary processing a few months back, and to ACE Cargo Release processing for all shipments with APHIS Lacey Act and NHTSA data on the mandatory date of March 31, 2016.

In the Federal Register Notice published on May 16, 2016, U.S. Customs & Border Protection (CBP) announced that ACE would be the sole CBP-authorized Electronic Data Interchange (EDI) system for processing certain electronic entry and entry summary filings accompanied by Food & Drug Administration (FDA) data, effective June 15, 2016.

Therefore, if you are an importer bringing in foodstuff, medical devices, pharmaceuticals, cosmetic ingredients, biologics, radiation-emitting products, etc. , please be aware of the enhanced data requirements specific to each of these industries. Some of you may have already been informed of these upcoming requirements by us. However, we would like to remind you to initiate obtaining and providing all the required additional data requirements in the below links and attached documents to your primary entry filing office so that the transmission of data is smooth and efficient, and we may address any remaining concerns prior to the mandatory filing date going into effect.

Provided are relevant links for the general summary of the FDA's Import Program, Tips for Importing FDA-Regulated Products in ACE, FDA Quantity Codes, and ACE Affirmations of Compliance codes.

For those of you who would prefer to have more information rather than less, please feel free to refer to FDA Supplemental Guidance 2.4.1.

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For pressing inquiries and updates, please reach your local KWE branch for information.