Regulatory Alert: FDA Clearance of Reagents

September 8, 2016

Reagents are usually considered medical devices by the Food and Drug Administration (FDA), unless they have a clear non-medical use such as test kits for chlorine levels in a swimming pool.

Laboratory biologic reagents must be transmitted and cleared by the FDA if they are intended for the prevention, treatment, diagnosis, cure of diseases, injuries or conditions in human beings, (ex. - blood transfusions, antibodies for injection into a human).

Depending upon the intended use of the "reagent" it may or may not require FDA entry transmission. Reagents can be medical devices, requiring both FDA Registration and Listing. Reagents can also be in the research phase of in vitro diagnostic product development, or, for use in basic scientific research for the purpose of knowledge generation. While these “research” types of reagents do not require FDA Registration and Listing, they do require FDA entry transmission.

A shipment containing “reagents” or referencing a reagent tariff number (e.g., heading 3822), requires FDA entry transmission.

Reagents that are clearly not medical devices; not in the research phase of in vitro diagnostic product development; or, not for use in basic scientific research for the purpose of knowledge generation, do not require FDA entry transmission. To avoid FDA review and clearance, the foreign shipper will need to provide clear, cogent, and convincing documentation that the contents of the shipment are not subject to FDA entry. (Ex – “used as a component in airbag systems”).

The current US de minimis of $800, which allows U.S. Customs & Border Protection (CBP) clearance from the manifest details, does NOT apply on FDA medical devices or parts of medical devices with their own product code.

Timeline for Implementation: September 12, 2016

References:

FDA Medical Devices page:
http://www.fda.gov/MedicalDevices/default.htm

Content Intended For FedEx Express Customers Only
FDA Replacement Reagent Guidance Document


FDA In Vitro Diagnostic Document

http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/default.htm