FedEx Regulatory Alerts & Updates

Regulatory Alert: FDA New and End-Dated Product Codes

September 26, 2018

BACKGROUND INFORMATION
The United States Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH) is the branch of the FDA responsible for the premarket approval of all medical devices, as well as overseeing the manufacturing, performance and safety of these devices.

Medical device-related FDA product codes are administered by CDRH.

WHAT HAS CHANGED?
The FDA has announced via U.S. Customs and Border Protection's Cargo Systems Messaging Service (CSMS), message #18-000516, that effective November 5, 2018, there will be changes to a portion of its CDRH product codes. The FDA provided four lists of product code changes within the CSMS message. These lists are comprised of:

1. Product codes that will be end-dated, or retired, and have new codes supplied in their place
2. Product codes that are end-dated due to duplication
3. Product codes that are end-dated with no replacements
4. Six new product codes which are unrelated to any end-dated codes

It is important to note that any entry made utilizing end-dated product codes on or after November 5, 2018, will be rejected by the FDA.

Q&A
<u>One of my commodities currently utilizes a product code that is being end-dated. What should I do?</u>
If it is an end-dated product code for which the FDA has provided a new code, then ensure that beginning on November 5, 2018, your commercial invoices and any supporting documentation are updated appropriately. This is a very important step as any entries submitted to the FDA containing end-dated product codes will be systematically rejected until the correct product code is applied.

<u>One of my commodities currently utilizes a product code that is being end-dated and there is no replacement code provided by the FDA. What should I do?</u>
There are two different scenarios in which this could apply: (1) the FDA has end-dated the product code due to duplication, or (2) the FDA has end-dated the product code without a replacement. If it is the first scenario, then you will need to find the duplicated product code that

the FDA is referring to. If the second scenario applies, then you will need to search for another applicable product code classification.

If you have a question for the FDA concerning these end-dated product codes, they have provided the trade with a contact email address for the Product Code Builder Feedback group: PCBFeedback@fda.hhs.gov.

Is there a FedEx contact who can assist me with FDA consultation?
Yes, the Trade Consulting & Advisory Services (TCAS) team is available to provide a fee-based service for classification assistance and guidance. Their contact information can be found here: http://ftn.fedex.com/us/services/advisory/index.shtml.

General regulatory questions on U.S. import or export issues prior to shipping can be directed to the Regulatory Consulting Group (or RCG). The group email is rcg@fedex.com.

Timeline for Implementation: September 27, 2018

Reference:

CSMS Message #18-000516:
https://csms.cbp.gov/viewmssg.asp?Recid=23724&page=&srch_argv=18-000516&srchtype=all&btype=&sortby=&sby