



# FedEx Regulatory Alerts & Updates

## **Regulatory Alert: FDA Clearance of De Minimis Value Shipments into USA**

July 10, 2017

### **WHAT HAS CHANGED?**

The US Food & Drug Administration (FDA) identified five categories of regulated products which could be released by U.S. Customs & Border Protection (CBP) without notification to the FDA for purposes of determining eligibility, if they are valued at or below the current de minimis level of \$800.00USD.

The official update is provided in the July 4, 2017 Cargo Systems Messaging Service (CSMS) message # 17-000388 cited below. The five specific FDA regulated items identified are:

- Cosmetics
- Dinnerware (including eating or cooking utensils)
- Radiation-emitting non-medical devices (TV's, CD players, etc.)
- Biological samples
- Food, excluding ackees, puffer fish, raw clams, raw oysters, raw mussels, and foods packed in air tight containers intended to be stored at room temperature.

It is important the shipment commercial invoice include a complete and accurate description of the article to insure it is quickly and easily recognized as one of the above five items and the duty free de minimis entry be made on the shipment.

The FDA Prior Notice requirements must continue to be met on all food and feed shipments regardless of value or quantity. Specific exemptions from the prior notice requirements are only permitted for one of the indicated reasons under 21 CFR 1.277(b). All exemptions are listed in the link below entitled "FDA General Enforcement Provisions for the Prior Notice of Imported Food".

## Q&A

### 1) *Can food be imported for non-commercial reasons from a non-commercial shipper to a U.S. recipient and is Prior Notice required for it?*

The FDA and CBP usually forego taking any regulatory action when Prior Notice is not provided for food imported for non-commercial purposes from a non-commercial shipper. Non commercial purposes would include:

- Food purchased by a traveler and shipped to the traveler's U.S. address by the traveler and NOT the commercial establishment
- Gifts purchased at a commercial establishment and shipped by the purchaser and NOT the commercial establishment

Please see the link below entitled "Importing Non Commercial Food to Your Friends and Family" for specific FDA details on this topic.

### 2) *Can various FDA regulated items be combined in a single shipment?*

This is not recommended. Most FDA regulated items – except the de minimis level articles listed above – require very specific FDA clearance information for ACE filing and US import clearance. If a foreign traveler, for example, combined several pairs of sunglasses with non-commercial gift food items with a total value of \$500USD to an individual in the USA, the mandatory FDA clearance of sunglasses takes precedence. The shipment would NOT clear as a de minimis value shipment.

## FDA Support

Questions related to the FDA reporting requirements for de minimis shipments may be submitted to FDA's Division of Import Operations at (301) 796-0356 or [FDImportsInquiry@fda.hhs.gov](mailto:FDImportsInquiry@fda.hhs.gov).

## Timeline for Implementation: Immediate

### References:

Cargo Systems Messaging Service (CSMS) Notice July 4, 2017 regarding FDA and de minimis value import shipments:

[https://apps.cbp.gov/csms/viewmssg.asp?Recid=22791&page=&srch\\_argv=17-000388&srchtype=all&btype=&sortby=&sby](https://apps.cbp.gov/csms/viewmssg.asp?Recid=22791&page=&srch_argv=17-000388&srchtype=all&btype=&sortby=&sby)

FDA General Enforcement Provisions for the Prior Notice of Imported Food:

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=1.277>

FDA Importing Non Commercial Food Items to Friends and Family:

<https://www.fda.gov/Food/GuidanceRegulation/ImportsExports/Importing/ucm086165.htm>