FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS
OEIO DIVISION OF NORTHEAST IMPORTS

FDA DNEI IMPORT CONTACTS/REFERENCES

Updated October 17th, 2018

GENERAL IMPORT INQUIRIES

	I am trying to…	I should go to…
1	Get a general FDA import question answered.	Contact FDA at the Port you intend to use or email FDAImportsInquiry@fda.hhs.gov
2	Find an FDA contact for a specific port	Navigate to the webpage "**FDA Import Offices and Ports of Entry**", click on region of the port you wish to contact, a PDF file opens listing contacts for each Port within the area. https://www.fda.gov/ForIndustry/ImportProgram/ucm435008.htm
3	-Check the status of an entry with FDA -Notify FDA of availability of goods for exam -Upload documents to FDA for review	FDA's Import Trade Auxiliary Communications System: http://Itacs.fda.gov
4	Contact FDA about a specific entry that is under review by FDA, but has not yet been detained	Contact FDA at the Port of entry (see above #2) For Division of Northeast Imports: oraoeioneimpibstatus@fda.hhs.gov
5	Respond to an FDA detention or other Compliance Action for a specific entry	Generally, contact the Compliance Officer listed on your most recent FDA Notice of Action
6	Resolve an issue with **ACE** (Automated Commercial Environment) rejecting entries due to apparent FDA issues.	Refer to the "FDA Supplemental Guide" or "ACE Supplemental Guide" on CBP's website: https://www.cbp.gov/document/guidance/fda-supplemental-guide-release-16 Call: 877-345-1101 (domestic/toll free) or 571-620-7320 (local/international) Email: ACE_Support@fda.hhs.gov Refer to the Federal Register, Final Rule of "Submission of Food and Drug Administration Import Data in the Automated Commercial Environment" https://www.federalregister.gov/documents/2016/11/29/2016-28582/submission-of-food-and-drug-administration-import-data-in-the-automated-commercial-environment
7	Determine an FDA Product Code for an item	Go to FDA's "Product Code Builder" https://www.accessdata.fda.gov/scripts/ora/pcb/index.cfm FDAImportsInquiry@fda.hhs.gov
8	Determine if a specific firm is associated with inspections, recalls, or import alerts.	Search FDA's "Data Dashboard" https://datadashboard.fda.gov/ora/index.htm
9	Find the DUNS number for a firm	FDA DUNS Portal: https://fdadunslookup.com/ Guide: https://www.fda.gov/downloads/ForIndustry/UCM483657.pdf

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COMMODITY OR PROGRAM SPECIFIC RESOURCES	
10	**Center for Biologics Evaluation & Research (CBER)**
	For general import compliance questions related to CBER, Contact: CBERImportinquiry@fda.hhs.gov or call: 800-835-4709 / 240-402-8010
11	**Center for Drug Evaluation & Research (CDER)**
	For general imports compliance questions related to drugs, Contact: CDERImportsExports@fda.hhs.gov
12	**Center for Devices & Radiological Health (CDRH) – Medical Devices & Radiation Emitting Products**
	CDRH at DICE@fda.hhs.gov or phone number: 1-800-638-2041 or 301-796-7100 1.) For Assistance in determining if a product is a device: a. Refer to FDA's webpage, "Is the Product a Medical Device?" b. Go to FDA's "Device – Not a Device" webpage c. Email: DeviceDetermination@fda.hhs.gov 2.) For questions related to Device registration & Listing, refer to FDA's "Device Registration and Listing" webpage: https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ Check R/L Status: reglist@cdrh.fda.gov or 301-796-7400 R/L Policy/detention issues: device.reg@fda.hhs.gov or 301-796-7400
13	**Center for Veterinary Medicine (CVM) – Animal Drugs & Devices**
	For General import compliance questions: CVMImportRequests@fda.hhs.gov or 240-402-7002
14	**Center for Tobacco Products (CTP) – Tobacco Products**
	For General Tobacco Questions: AskCTP@fda.hhs.gov or 1-877-287-1373
15	**Center for Food Safety and Applied Nutrition (CFSAN) – Foods & Cosmetics**
	1.) To learn about general food labeling requirements – Go to FDA's webpage, "Guidance for Industry: Food Labeling Guide" https://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/labelingnutrition/ucm2006828.htm 2.) To see food regulations specific to different types of foods – Go to The "Code of Federal Regulations Title 21" webpage, and search for the appropriate section. *(**note: these are not all inclusive)* https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm Low Acid Canned Foods (LACF): Section 113 — Fish & Fishery Products: Section 123 Acidified Foods: Section 114 — Juice HACCP: Section 120 Food Labeling: Section 101 — Current GMPs/General: Section 117 or 110 FSVP: Section 1 → Subpart L
16	**Foreign Supplier Verification Program (FSVP) – Foods**
	To Learn more about FSVP – Go to FDA's Page "FSMA Final Rule on Foreign Supplier Verification Programs (FSVP) for Human and Animal Food." https://www.fda.gov/food/guidanceregulation/fsma/ucm361902.htm
17	**Voluntary Qualified Importer Program (VQIP) – Foods**
	To learn more about this: a. Go to FDA's webpage, "Guidance for Industry: FDA's Voluntary Qualified Importer Program" b. Check out FDA's Webpage "Workshops, Meetings & Conferences" for updates on the "Voluntary Qualified Importer Program (VQIP)" https://www.fda.gov/food/newsevents/workshopsmeetingsconferences/default.htm