

FDA Detroit District Import Operations

Importation of Biologicals Workshop

November 30, 2016

University of Michigan

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FDA Detroit District Director

Presentation Summary

- Overview of FDA Organization
- Overview of Detroit District Import Operations
- Video – Importing FDA Regulated Biologics

FDA Organization

Office of Commissioner

Specialized Program “Centers” (HQ)

- Center for Food Safety and Applied Nutrition (**CFSAN**)
- Center for Drug Evaluation and Research (**CDER**)
- Center for Biologics Evaluation and Research (**CBER**)
- Center for Devices and Radiological Health (**CDRH**)
- Center for Veterinary Medicine (**CVM**)
- Center for Tobacco Products (**CTP**)

“The Field” (District Offices)

- Office of Regulatory Affairs (**ORA**)

FDA Organization

Role of Specialized Program Centers

- Approve/clear new drugs, medical devices, and biologics.
- Work with ORA to construct inspectional work plan
- Set policies, regulations and guidance documents.
- Collaborate with Districts on Regulatory Actions.
- Provide Subject Matter Experts (SME).
- Provide Policy and Guidance to ORA Field Import Staff.

Role of ORA District Offices (“the field”)

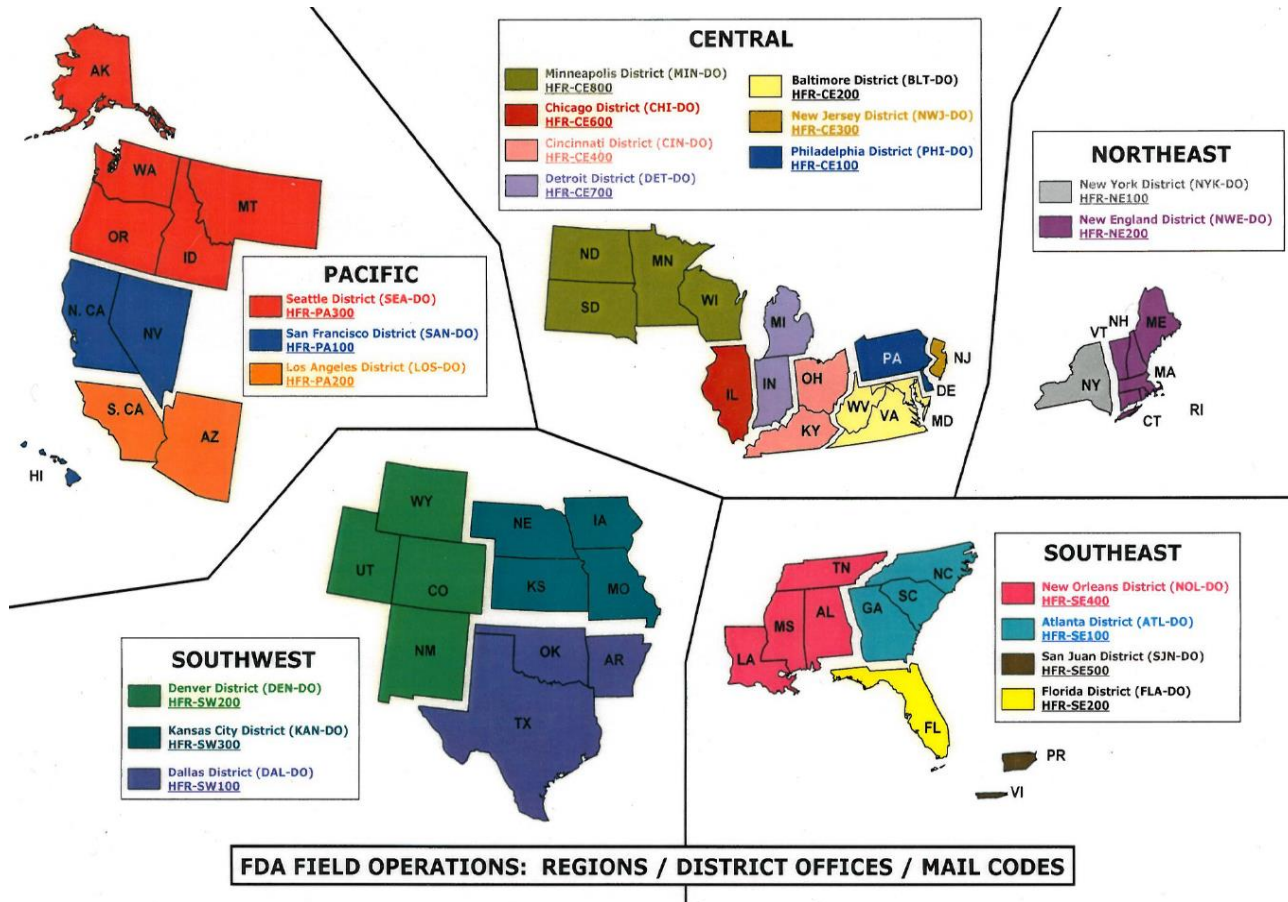
- Implement Policy and Work Directed by Center
- Import examinations, entry review, and sample collections per Workplan
- Conduct inspections – Domestic and Foreign.
- **Office of Enforcement Import Operations.** Agency focal point for Headquarters/field relationships on all import programs operations.



Office of Enforcement Import Operations

- Provides direction, assistance, management, and oversight of field import operations.
- Establishes field uniformity for import activities through adherence to procedural policies and operations automated systems
- Establishes and oversees a field import quality control program.
- Develops and/or reviews Agency import policies, laws & regulations, procedures, programs, and assignments, including the responsibility for issuing import informational directives (Import Alerts, Bulletins, etc.);

ORA Field Organization





FDA Detroit District Import Organization

- Art O. Czabaniuk, District Director
- Keith J. Jasukaitis Director, Investigations Branch (Imports & Domestic)
- **Vacant** - Director, Compliance Branch
- Phenicia Petty, Supervisor - Ambassador Bridge (Detroit, MI)
- Melissa M. Tyrrell, Supervisor - Port Huron, MI

IMPORT STAFF

- 19 Consumer Safety Officers, 1 Consumer Safety Inspector
- 2 Imports Compliance Officers

OEIO- DIVISION OF IMPORT OPERATIONS

(IMPORT OPERATIONS & MAINTENANCE BRANCH)

- Jeff Hilgendorf – Regional Area Manager - District Office

Detroit District Office Locations

- Detroit, Michigan (District Office)
- Ambassador Bridge (Detroit, MI)
- Grand Rapids, MI
- Port Huron, MI
- Kalamazoo, MI
- Indianapolis, IN
- South Bend, IN
- Fort Wayne, IN
- Evansville, IN



FDA Detroit District Major Port Locations

Detroit Ambassador Bridge

- Lines – 1,487,825 = 65%



Port Huron Blue Water Bridge

- Lines – 544,896 = 24%





FDA Detroit District Other Port Locations (Michigan and Indiana)

Michigan

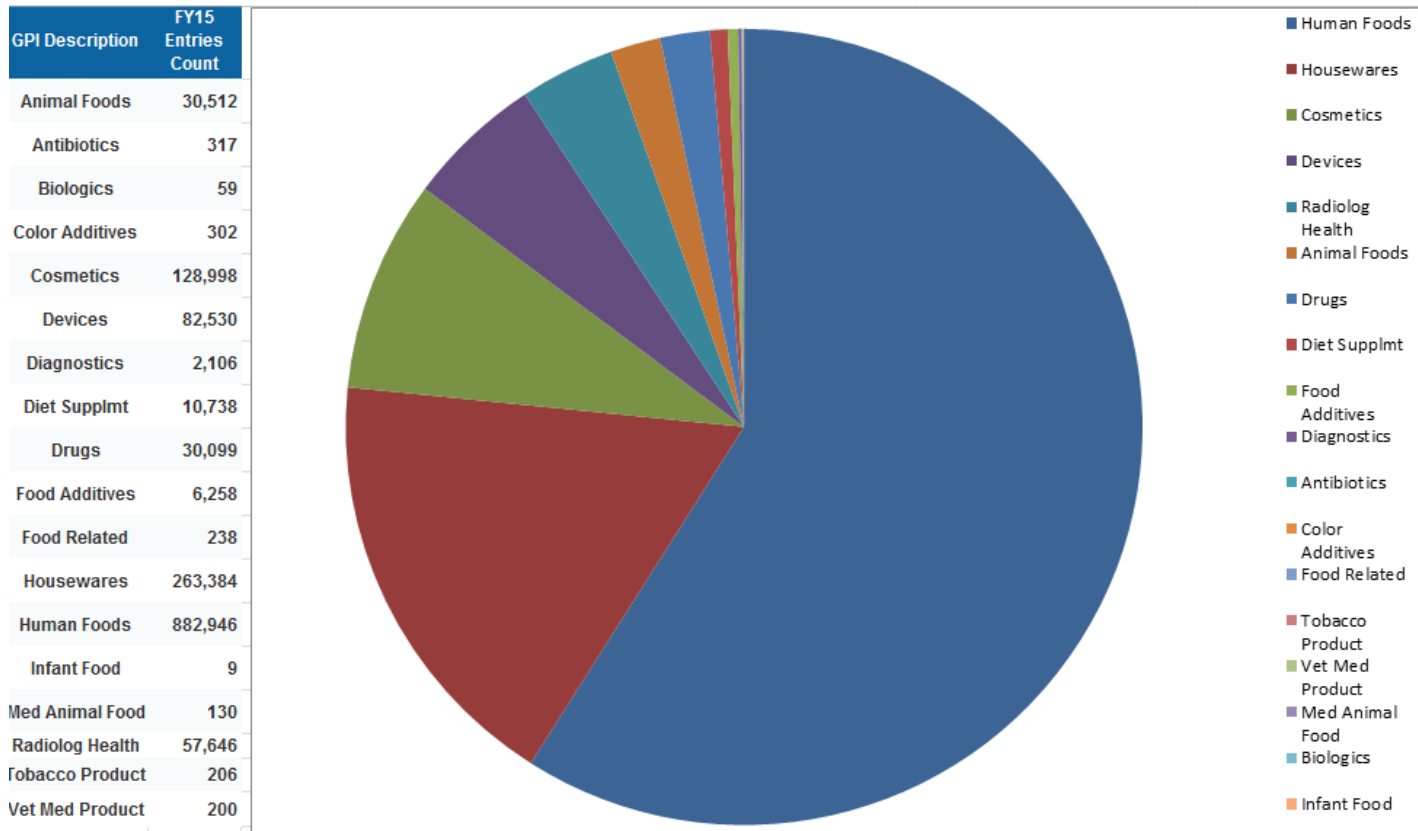
- Detroit Metro Airport (16,438 Entries)
- Sault Ste. Marie – International Bridge (3,198)
- Grand Rapids (1827)
- Battle Creek (261)
- Saginaw/BayCity/Flint (15)

Indiana

- FEDEX Hub – Indianapolis (95,740)
- Indianapolis Airport (10,718)
- Fort Wayne (35)

FDA Detroit District Import Operations

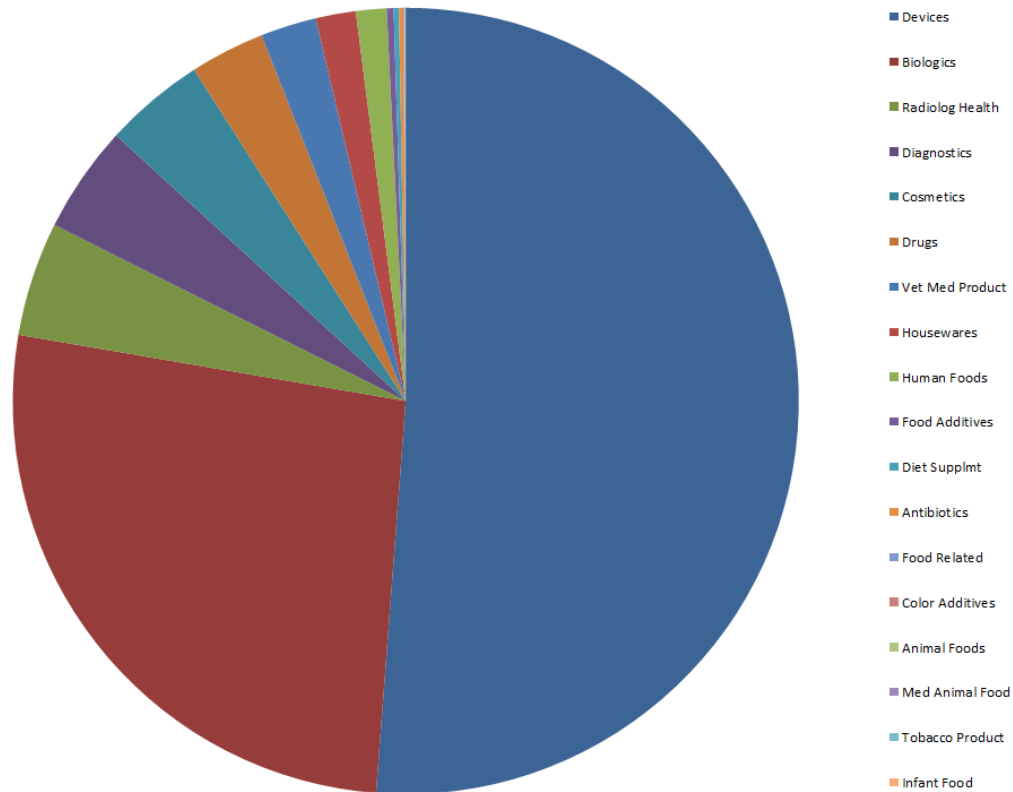
GPI DISTRIBUTION - PORT OF DETROIT



FDA Detroit District Import Operations

GPI Description	FY15 Lines Count
Animal Foods	28
Antibiotics	324
Biologics	47,081
Color Additives	37
Cosmetics	7,353
Devices	91,014
Diagnostics	7,855
Diet Supplmt	386
Drugs	5,464
Food Additives	504
Food Related	72
Housewares	2,932
Human Foods	2,238
Infant Food	3
Med Animal Food	14
Radiolog Health	8,347
Tobacco Product	10
Vet Med Product	4,082

GPI DISTRIBUTION - FEDEX HUB @ INDIANAPOLIS





FDA Detroit District Import Operations Border Locations & Contacts

DETROIT AMBASSADOR BRIDGE

2810 W. Fort Street
Detroit, MI 48207
(313) 226-5249 (P)
(313) 226-2250 (P)
(313) 226-5698 (F)

PORT HURON BLUEWATER BRIDGE

2321 Pine Grove Avenue, Suite 2114
Port Huron, MI 48060
(810) 985-8514 (P)
(810) 985-8513 (P)
(810) 985-8528 (F)

SAULT STE MARIE

900 International Bridge Plaza
Sault Ste Marie, MI 49783
Presently Not Staffed

DAYS & HOURS OF OPERATION

DETROIT AMBASSADOR BRIDGE

Monday – Friday 6:00 am – 6:00 pm
Saturday/Sunday 8:00 am – Noon

PORT HURON BLUEWATER BRIDGE

Monday – Friday 8:00 am – 4:30 pm

SAULT STE MARIE

Presently Not Staffed

DETROIT CROSSING OPERATIONAL ALL HOLIDAYS 8:00 AM – NOON

EXCEPT THE FOLLOWING:

January 1st (New Years Day)
November (Thanksgiving Day)

July 4th (Independence Day)
December 25th (Christmas Day)

AFTER HOURS IMPORT CONTACT ALL CROSSINGS

Melissa Tyrrell, SCSO (313) 434-8477
Phenicia Petty, SCSO (313) 212-9533
Keith Jasukaitis, DIB (313) 617-4464
Art O. Czabaniuk DD (313) 779-5973

