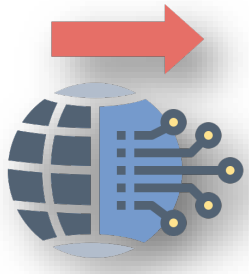
U.S. FOOD & DRUG ADMINISTRATION

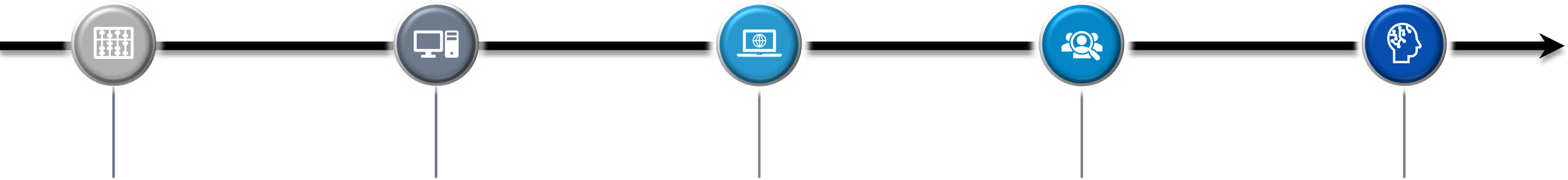
Office of Regulatory Affairs - Office of Import Operations

Digitization of Importation FDA

April 16 - 17, 2024



History of Digitization of Import Process



Pre-digitization

1848
Drug Importation Act

1897
Tea Importation Act

1906
FD&C Act

Discovery

FDA recognized need for electronic submission of data.

FDA determining how sources of data can be submitted electronically.

FDA worked with US Customs to receive imports electronically.

Taking Shape

FDA issues guidance and accepting requirements for imported goods electronically such as registration and listing of drugs and medical devices.

Electronic "entries" allow FDA to more efficiently target products of concern (electronic Import Alerts) while more easily expediting legitimate trade.

Expansion

FDA promotes Transparency initiative including resources to educate public about FDA online and disclosing information about regulated products and firms.

FDA uses PREDICT for targeting which uses automated data mining and pattern discovery and automated queries of center relevant databases.

Electronic receipt and distribution of documents is enhanced with ITACS.

Evolution

FDA expanding use of artificial intelligence and machine learning to improve efficiency and effectiveness.

FDA exploring use of other advanced technologies like digital ledgers and automated assistants.

FDA using technology such as YouTube videos on importation process and interactive data dashboards to better assist the public with how to import products and to have access to FDA data and findings.

Digitization of Aids for Importation

Website	[Importing FDA Regulated Products | FDA] • Includes specifics on every product FDA regulates, what is required at the time of importation, and how FDA verifies it.
Videos	[Videos available on "Importing FDA-Regulated Products: the IMPORT PROCESS" and "Importing FDA-Regulated Products: Human Foods"] • Videos are available in English, Spanish, and Chinese and plans for more commodities in the future.
ITACS	[Import Trade Auxiliary Communications System (ITACS)] • Allows anyone with an entry number to see status and upload availability online. • Allows account management services where firms can receive electronic notices.
ACE Supplemental Guide	[FDA Supplemental Guide | U.S. Customs and Border Protection (cbp.gov)] • Partnering with CBP, this guide provides a blueprint on how to file FDA products electronically through ACE.
Electronic Registration	[FDA industry systems - Accounts management] • Allows firm to electronically register and list products. • Guidance provided for each commodity area for what registration and product listings are required.

Transparency through Digitization

FDA Data Dashboard

FDA data is available in interactive dashboards including, but not limited to:

- Inspectional results
- Compliance actions
- Recall information
- Import Refusals
- Import Summaries and entries
- Firm/Supplier information

Import Alerts Search

Search available for all firm/product combinations on Import Alert by keyword(s), firm name, product.

Also provides guidance on how to be removed from import alert.

FDA-TRACK

Monitors FDA Centers and Offices through key performance measures and projects.

Has dashboards on all products regulated.

Dashboard specific to imported food.