

Public Health Impact of Registration and Listing Data



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Office of Compliance

CDER | US FDA

Oversight Responsibilities

Drug manufacturing facilities

Post-market reporting

Drug registration and listing

Unapproved and misbranded drugs

ClinicalTrials.gov

Bioresearch monitoring

Drug supply chain:
imports and exports

Unsafe online pharmacies

Recalls and incident response

Compounded drugs

Mission

To shield the public from poor quality, unsafe and ineffective drugs through proactive compliance strategies and risk-based enforcement actions.



Accurate Data is Essential to Patient Safety



FDA relies on this information data to protect public health to help:

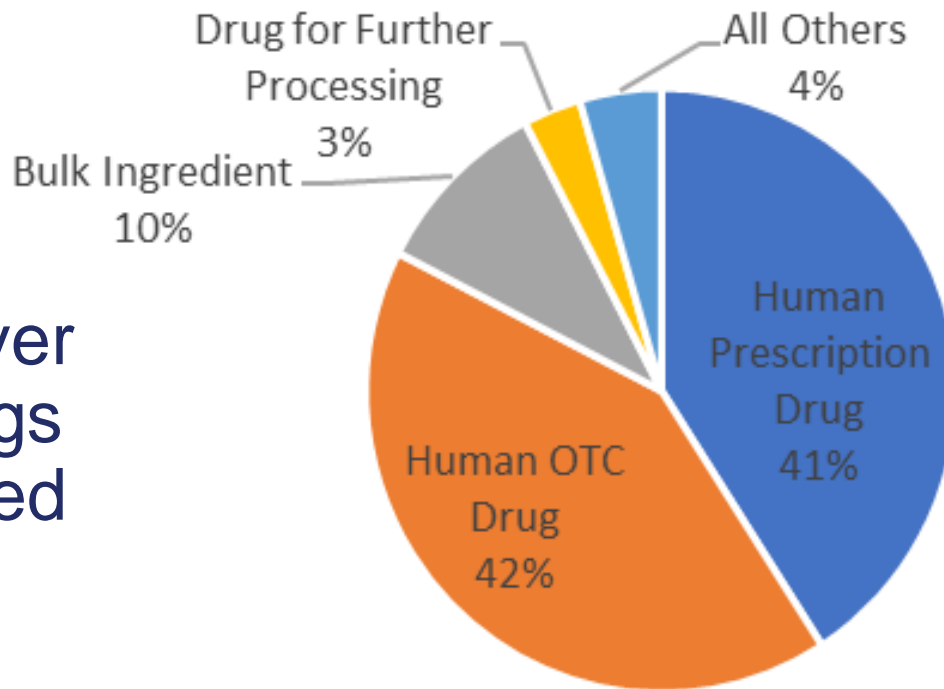
- Drug shortage mitigation efforts
- Inspection planning
- Drug importation review and supply chain oversight
- Recall oversight
- Injury monitoring

DRLS data is **also widely used outside FDA** for electronic prescribing and electronic health records, procurement, and reimbursement.



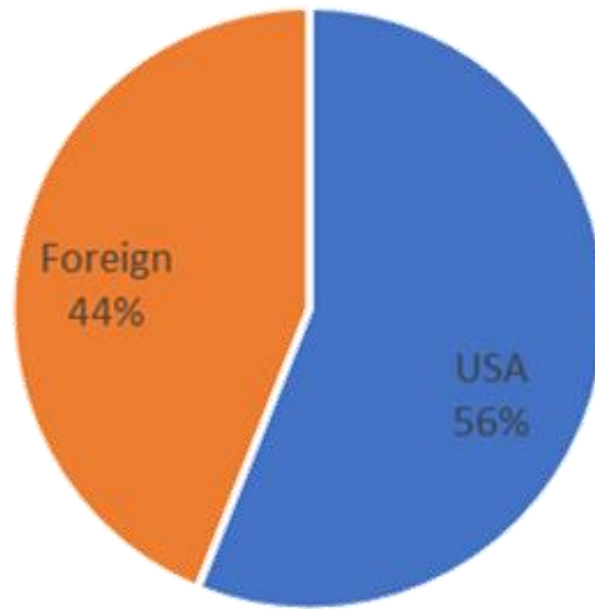
By the Numbers

There are over 148,000 drugs currently listed with FDA.



By the Numbers

There are over 10,500 manufacturing establishments currently registered with FDA.



■ USA ■ Foreign

Registration and Listing Compliance Activities



In Fiscal Year 2024

19,899 drug listings were inactivated due to either not being certified as active or associated with an unregistered manufacturing establishment

208 unused labeler codes were inactivated

141 deficiency letters were issued to firms for inaccurate or incomplete registration and listing data

Warning Letter Excerpt



“Your firm has not fulfilled its listing obligations under section 510(j) of the Federal Food Drug and Cosmetic Act (FD&C Act), 21 U.S.C. 360(j), which is a prohibited act under section 301(p) of the FD&C Act, 21 U.S.C. 331(p).

In addition, the drugs stated above are not properly listed with FDA, causing them to be misbranded drugs under section 502(o) of the FD&C Act, 21 U.S.C. 352(o). Introduction or delivery for introduction of such misbranded drugs into interstate commerce is prohibited under section 301(a) of the FD&C Act, 21 U.S.C. 331(a). These violations are described in more detail below.”

Court case involving inaccurate registration of foreign suppliers



- Company registered foreign suppliers using inaccurate information and without the supplier's knowledge
- After customer rejected an API as potentially harmful (out-of-specification), the company shipped product to different customers without informing them of test results until an FDA inspection
- Finance department oversaw the relationships and transactions with many suppliers rather than its quality personnel

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF FLORIDA
WEST PALM BEACH DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

v.

LGM PHARMA LLC, a limited liability
company,

and

PRASAD RAJE and SHAILESH
VENGURLEKAR, individuals,

Defendants.

CASE NO.: 9:23-cv-80040:

CONSENT DECREE OF PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned attorneys, having filed a Complaint for Permanent Injunction against LGM Pharma LLC, a limited liability company ("Corporate Defendant"), and Prasad Rajee and Shailesh Vengurlekar (who was hired and assumed the position of Senior Vice President of Quality and Regulatory Affairs at Corporate Defendant in 2019), (collectively, "Defendants"), and Defendants having appeared and having consented to the entry of this Consent Decree of Permanent Injunction ("Decree") without contest, without admitting or denying the allegations in the Complaint, and before any testimony has been taken, and the United States of America having consented to this Decree:



Data helps
FDA
investigate
potentially
dangerous
products



FDA

Workshop Topics Ahead




- Registration, labeler code, and listing submission demos
- Regulatory requirements
- OTC drug listing updates and validations
- NDC format proposed rule
- Drug amount reporting

New This Year



Previously known as CDER Direct, FDA Direct now encompasses both **CDER Direct** and **Cosmetics Direct**

**FDA Direct**
CDER Direct & Cosmetics Direct

LOGIN

Username:

Password:

[Forgot your password?](#)

☐ I accept the [Terms of Service](#)

LOGIN

OR

CREATE NEW ACCOUNT

WELCOME TO FDA DIRECT

FDA Direct is U.S. Food and Drug Administration's web-based and free structured product labeling (SPL) authoring tool. Previously CDER Direct, FDA Direct now includes CDER Direct and Cosmetics Direct. Users can create separate accounts, depending on drugs or cosmetics submissions, or a single account that includes both CDER Direct submissions as well as Cosmetics Direct submissions.

CDER Direct

CDER Direct allows users to easily create and submit data directly to the FDA. This system will provide information to FDA/CDER about drug manufacturers and private label distributors, outsourcing facilities, wholesale drug distributors and third-party logistics, and generic drug facilities, along with their drugs in U.S. commercial distribution. CDER Direct has several sections which allows submission of the following data to the FDA: Establishment Registration and Drug Listing, including NDC Labeler Code Requests and NDC Reservations, Outsourcing Facility and Product Reporting, DSCSA Annual Reporting, and Generic Drug Self-Identification.

Cosmetics Direct


On December 29, 2022, the President signed the Consolidated Appropriations Act, 2023 (Pub. L. 117-328) into law, which included the Modernization of Cosmetics Registration Act of 2022 (MoCRA). Among other provisions, MoCRA added section 607 to the Federal Food, Drug, and Cosmetic Act (FD&C Act), establishing requirements for cosmetic product facility registration and cosmetic product listing.

Section 607(a) of the FD&C Act requires every person that owns or operates a facility that engages in the manufacturing or processing of a cosmetic product for distribution in the United States to register each facility with FDA. Section 607(c) of the FD&C Act requires that for each cosmetic product, the responsible person submit to FDA "a cosmetic product listing." Certain small businesses, as defined in section 612 of the FD&C Act, are exempt from the registration and listing requirements. [Click here](#) to learn more about MoCRA.

This free tool allows you to create and submit the following types of data directly to the FDA: Registration of Cosmetic Product Facility and Cosmetic Product Listing. This system will provide information to FDA/Office of Cosmetics and Colors (OCC) about cosmetic product manufacturers/processors and cosmetic products on the market.

New This Year



 **FDA** *Direct*
CDER *Direct* & **Cosmetics** *Direct*

ORGANIZATION TYPE

NOTE: Existing CDER Direct users do not need to create a new account. Existing accounts can be converted to a Combined account, by going to 'EDIT USER PROFILE' after logging to your existing account.

What type of Account are you creating ? ☐ CDER Direct ☐ Cosmetics Direct ☐ Combined (CDER Direct and Cosmetics Direct)

There are three types of account that can be created on FDA Direct: CDER Direct, Cosmetics Direct, and a combined account (CDER Direct & Cosmetics Direct). A combined account is intended for companies that have both drugs and cosmetics submissions. A combined account streamlines both drugs and cosmetics submission requirements and saves time and effort. DUNS number is only a required field if you create a CDER Direct account or a combined account (CDER Direct and Cosmetics Direct). DUNS number is NOT required but requested if you create only a Cosmetics Direct account.

Users can create separate accounts for drug or cosmetic submissions or a single account for both.

For More Information Contact

Drug registration and listing submissions:

eDRLS@fda.hhs.gov

For general questions regarding electronic registration and listing of cosmetic product facilities and products, contact eRLC@fda.hhs.gov

For assistance with accounts activation and validation errors in Cosmetics Direct, contact cosmeticsdirect@fda.hhs.gov

Cosmetics Direct helpdesk:

cosmeticsdirect@fda.hhs.gov



