U.S. FOOD & DRUG ADMINISTRATION

Keynote: Updates to the Drug Registration and Listing Program

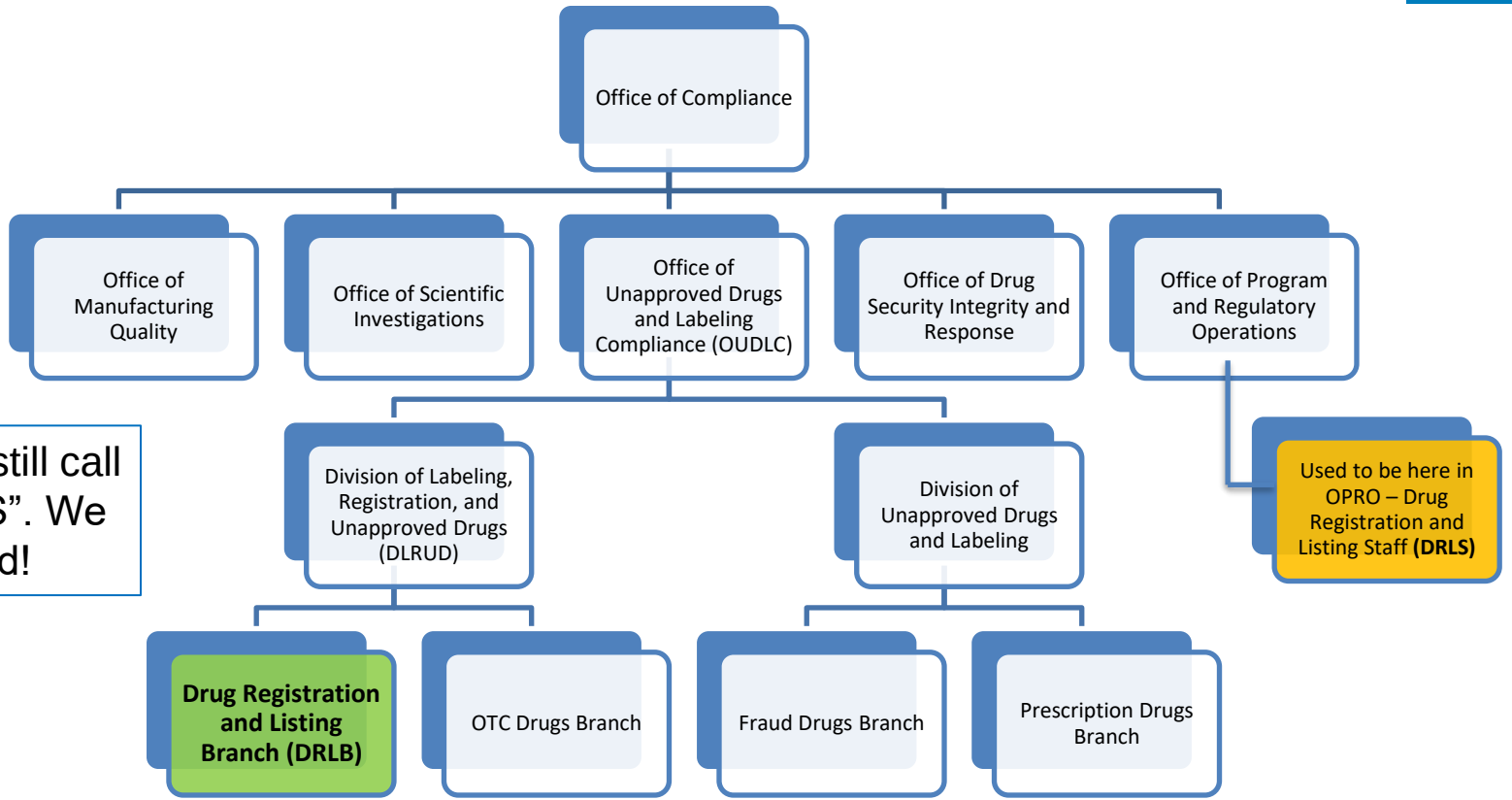
Paul Loebach
Branch Chief, Drug Registration and Listing Branch
Division of Labeling, Registration, and Unapproved Drugs
Office of Unapproved Drugs and Labeling Compliance
Office of Compliance
CDER | US FDA

SBIA eDRLS Using CDER Direct Conference – October 13, 2021

Overview

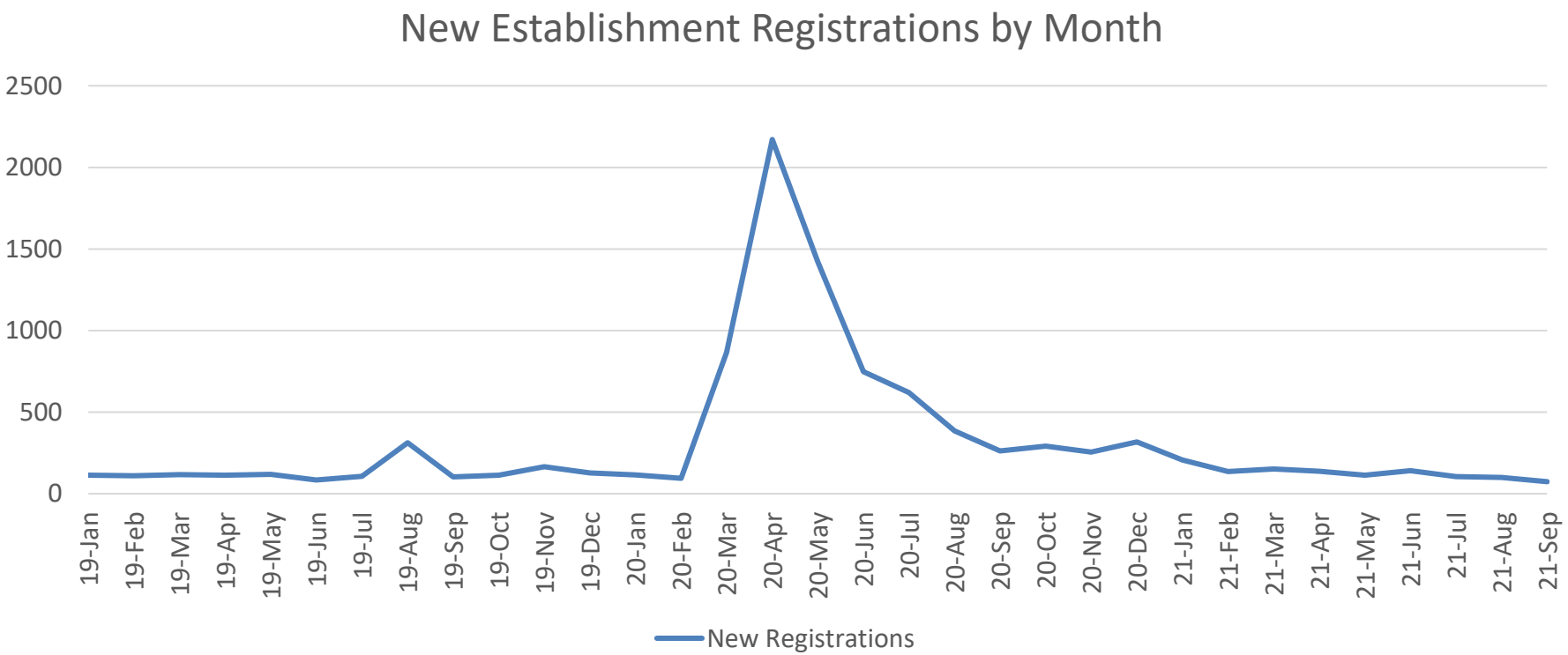
- *Reorganization*
- *Registration and Listing by the Numbers*
- *New Marketing Categories*
- *OMUFA*
- *OTC Monograph Reform*
- *Future of NDC*
- *Today's Agenda Highlights*

A New Home - A (slightly) New Name



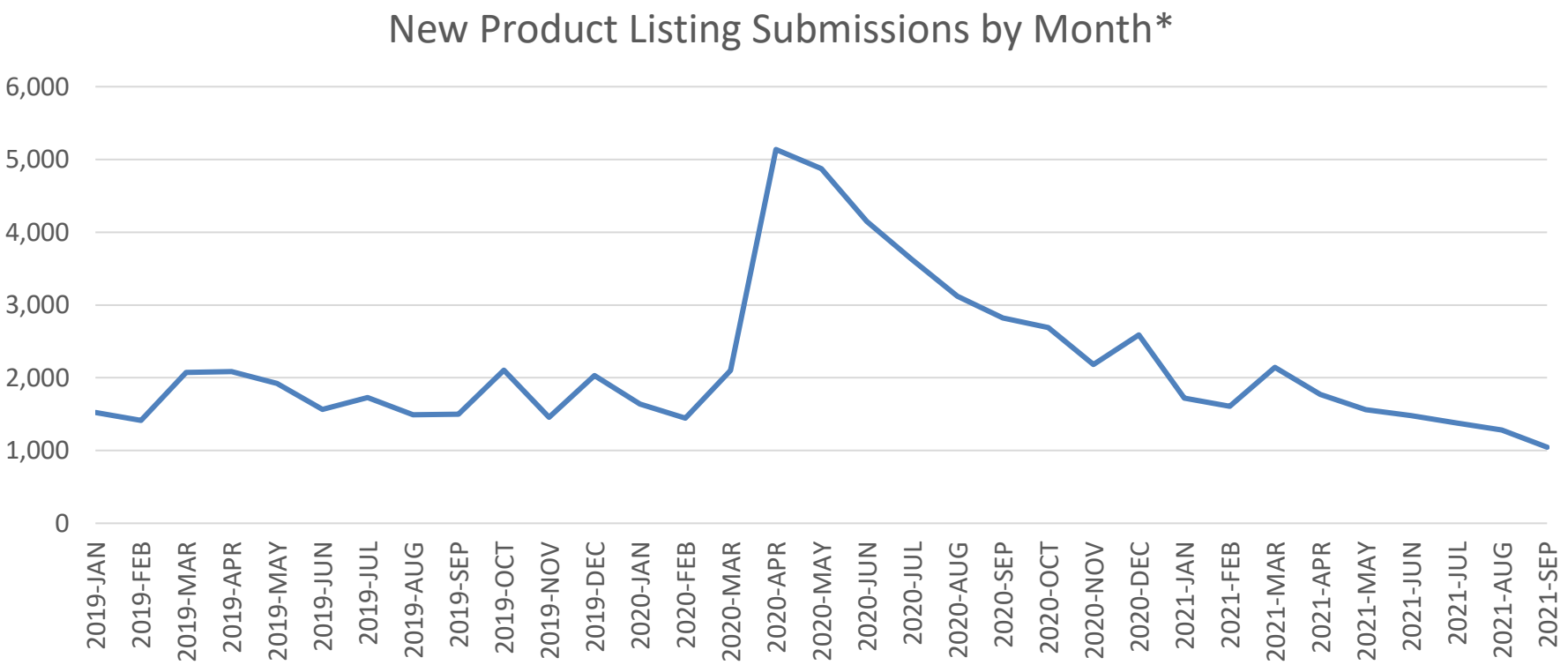
You can still call us "DRLS". We don't mind!

Registration and Listing by the Numbers



Source: eDRLS

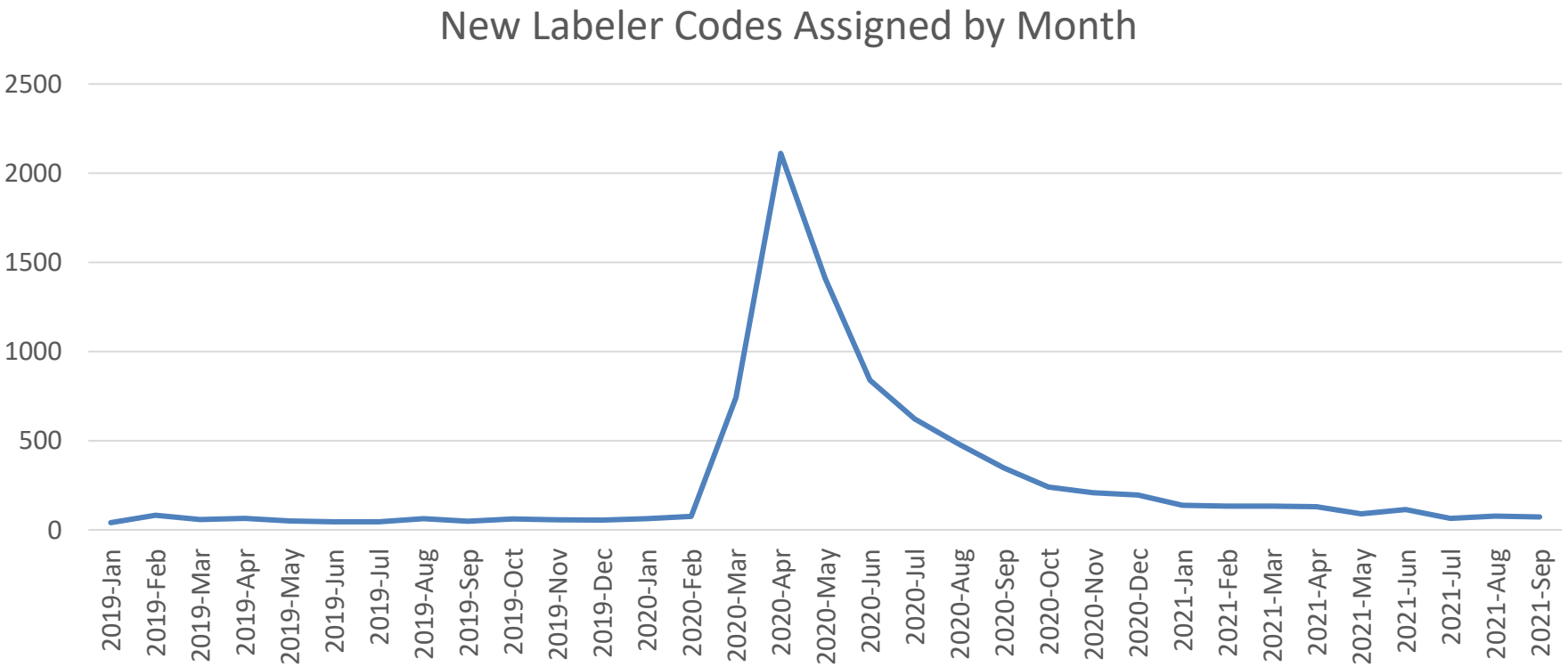
Registration and Listing by the Numbers I



**Measured as version 1 product listing SPLs*

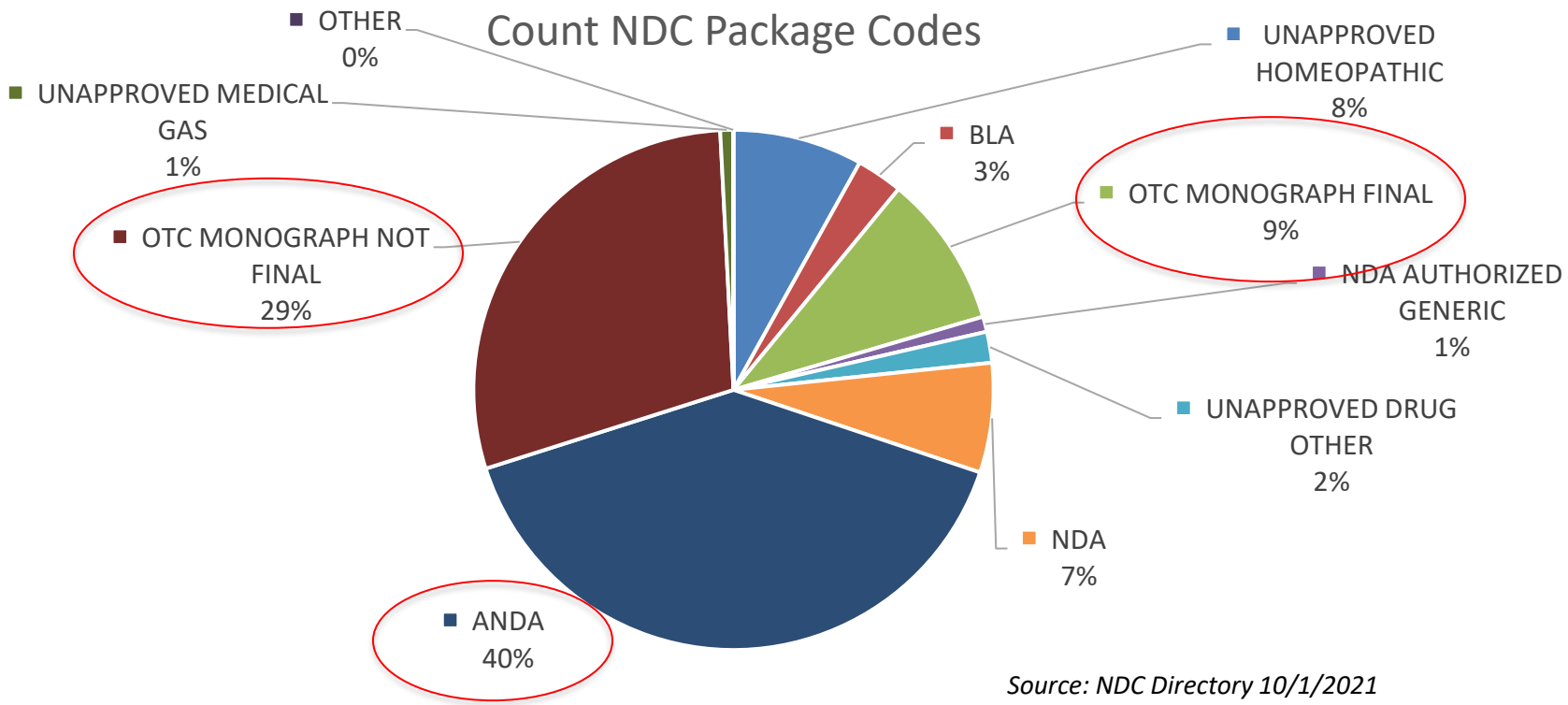
Source: eDRLS

Registration and Listing by the Numbers II



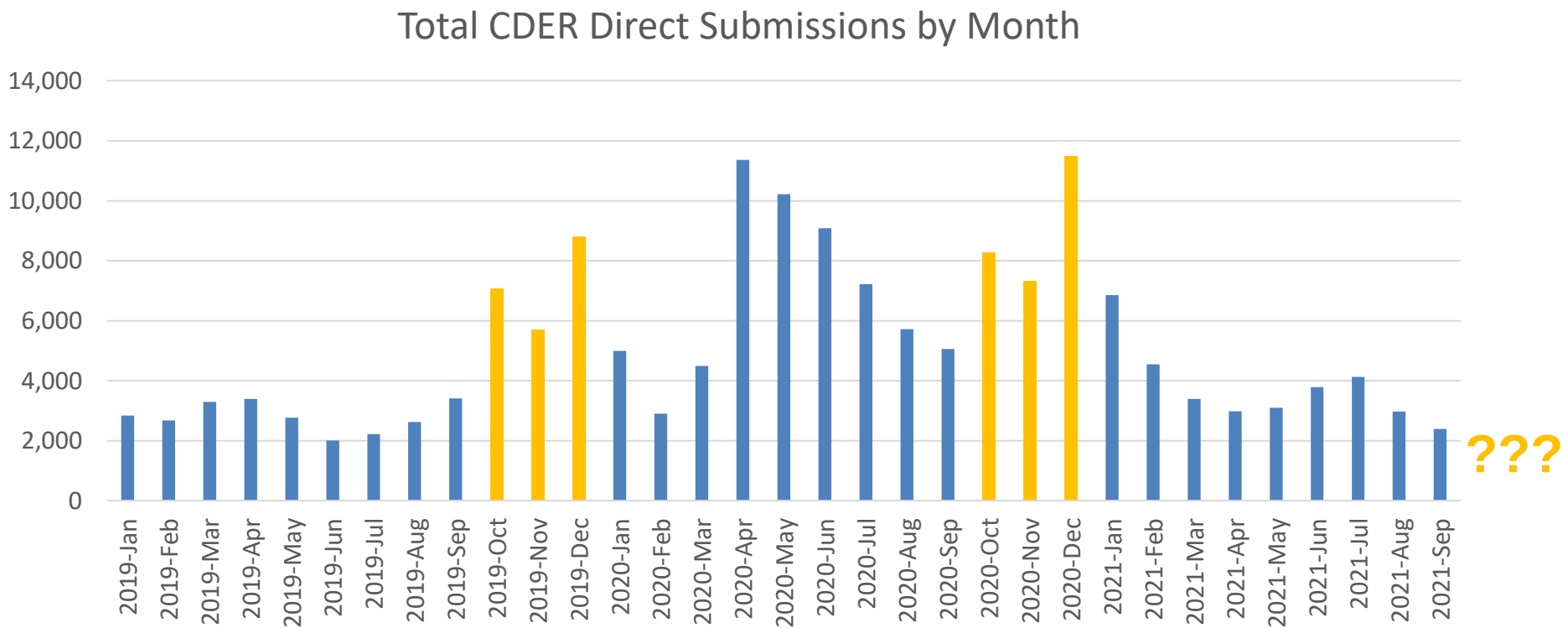
Source: eDRLS

Registration and Listing by the Numbers III



Source: NDC Directory 10/1/2021

Registration and Listing by the Numbers IV



Source: eDRLS

New Marketing Categories

Emergency Use Authorization C96966

- Implemented in Summer of 2021
- Prior to that, drug products under an EUA agreement had to be listed under UNAPPOVED DRUG, OTHER, including vaccines
- Only ***after*** a company has applied for, and been granted, an EUA by FDA can this product be used.

New Marketing Categories Continued

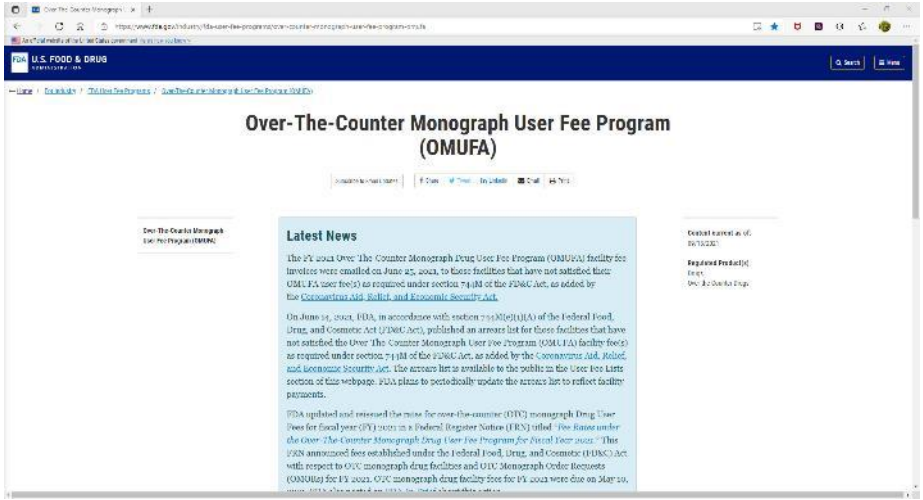
Outsourcing Facility Compounded Human Drug Product C181659
(Exempt From Approval Requirements)

- Implemented in September of 2021 for the current 503B outsourcing facility reporting period and moving forward.
- Prior to that, compounded human drug products had to be reported under UNAPPROVED DRUG, OTHER

Beginning in January 2022, after the completion of the 2021-2 product reporting period, FDA intends to begin including human compounded drugs that are assigned a valid NDC in the NDC Directory

OMUFA

Does your company have a user fee obligation under OMUFA?



CAPT Matthew Brancazio (USPHS) presents on the OMUFA program first thing after the lunch break today!

OTC Monograph Reform

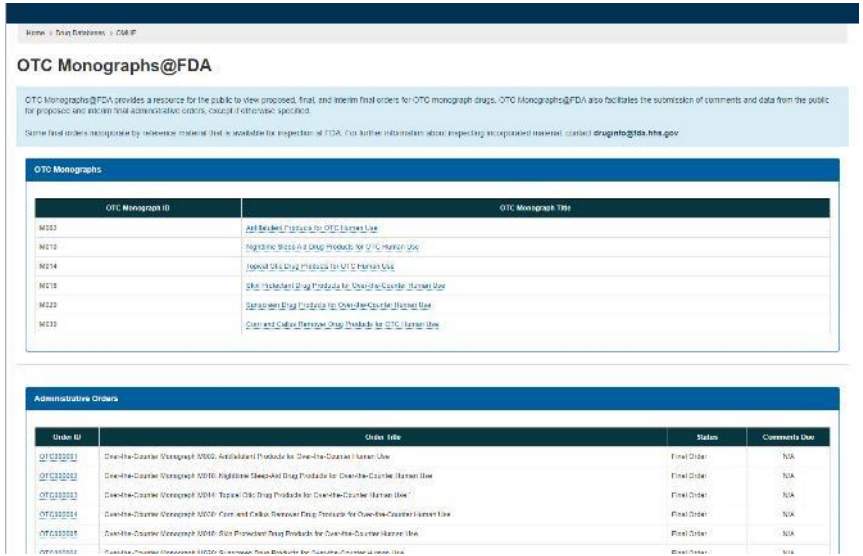
The CARES Act replaces the rulemaking process with an administrative order process for issuing, revising, and amending OTC monographs.

FDA created a new public facing web-portal, **OTC Monographs@FDA**, that provides the public with the ability to view OTC monographs and proposed and final administrative orders that add, remove, or change conditions for an OTC monograph.

OTC Monograph Reform Continued

Displays a current list of OTC Monograph Final Orders.

Shows the list of proposed and final orders and their status



Future of the NDC

You may recall…

- Published a Federal Register Notice in August 2018
- Conducted Public Hearing on November 5, 2018
- Suggested 4 possible options
  - A: Maintaining the current practice and regulation without modification
  - B: Same as option A but transitioning on a specified date in the future to 6 digits labeler codes
  - C: Adopting the 11-digit HIPAA format and transitioning to 12 digits later
  - D: Harmonizing NDC by adopting a 12-digit 6-4-2 format

Future of the NDC

Summary of Stakeholders Comments From the Docket

- There was a vast majority of support for Option D, a single 12-digit standard
    - There were a few individual suggestions for use of alternative code such as GTIN, or to allow the use of alphas.
- Many expressed concern over the timing of the transition:
    - Give plenty of time and notice for industry to plan and implement change (labels, databases, etc). Some requested as much as 10 years.
    - Give formal notification of when less than 10000 labeler codes are left.
    - Allow for a voluntary period to comply.
    - Wait until after DSCSA implementation.

Agenda Highlights I

Wednesday, October 13, 2021

9:15 – 9:25

FDA Website: Resources Available to You

Topics include demonstrations of:

- A walkthrough of the DRLS website including:
  - The National Drug Code (NDC) Directory
  - Drug Establishments Current Registration Site (DECRS)
  - 503B Facilities
  - SPL webpage
- Where to find helpful information without having to send an email

Don Duggan
Team Lead, Helpdesk Operations Team (HOT)
DRLB | DLRUD | OUDLC | CDER

9:25 – 10:05

Drug Registration 101 – The Basics

Topics include demonstrations of:

- How to create and submit various registration and listing submissions using CDER Direct including:
  - Establishment Registration and Updates
  - Establishment Deregistration
  - Labeler Code Request
- ***Q&A session***

Regie Samuel
Technical Information Specialist
HOT | DRLB | DLRUD | OUDLC | CDER

Vikas Arora
Pharmacist
Office of Program and Regulatory Operations (OPRO)
OC | CDER

Puji Huber
Technical Information Specialist
HOT | DRLB | DLRUD | OUDLC | CDER

10:05 – 10:55

Drug Listing 101 – The Basics

Topics include demonstrations of:

- Drug Listing – including content of labeling
- Delisting
- NDC Reservation
- Blanket No Change Certification
- ***Q&A session***

Soo Jin Park
LCDR, USPHS
Regulatory Officer

David Mazyck
Consumer Safety Officer

Troy Cu
Technical Information Specialist

Regie Samuel
Technical Information Specialist

DRLB | DLRUD | OUDLC | CDER

Agenda Highlights II

Wednesday, October 13, 2021

11:10 – 11:30

The National Drug Code (NDC): Rules for Assigning and Changing

Topics include:
- A description on the structure of the NDC
- When to assign a new NDC and which segment to change.
- ***Q&A Session***

Soo Jin Park
LCDR, USPHS
Regulatory Officer
Data Quality and Compliance Team (DQCT)
DRLB | DLRUD | OUDLC | CDER

11:30 – 12:00

503B Human Drug Compounding Outsourcing Facility Registration and Product Reporting 101 – The Basics

Topics include demonstrations of:
- How to create and submit registration and 6-month product report submissions using CDER Direct
- ***Q&A session***

Troy Cu
Technical Information Specialist
HOT | DRLB | DLRUD | OUDLC | CDER

12:00 – 12:30: LUNCH BREAK

12:30 – 12:45

OMUFA Fees for Registered OTC Drug Manufacturers

Topics include:
- An overview of the Over-The-Counter Monograph User Fee Program (OMUFA)
  - Which operations are subject to fees
  - When fees are due
- ***Q&A Session***

Matt Brancazio
CAPT, USPHS
Branch Chief, Policy and Operations Branch
Division of User Fee Management (DUFM)
Office of Management (OM) | CDER

12:45 – 1:30

Tips, Techniques, and Common Mistakes with Submissions

Topics include:
- Quick presentations focusing on common errors and issues with submissions, including:
  - Incorrect strength
  - How to create a kit listing
  - Combination product designation
  - Requesting overrides
- ***Q&A session***

Tasneem Hussain
Pharmacist

Troy Cu
Technical Information Specialist

Paul Loebach
Director

DRLB | DLRUD | OUDLC | CDER

1:30 – 1:45

Compliance Program

Topics include:
- An overview of registration and listing compliance program in addressing inaccurate submissions to the Agency

Leyla Rahjou-Esfandiary
Team Lead
DQCT | DRLB | DLRUD | OUDLC | CDER

Agenda Highlights III

2:00 – 2:15

Registration and Listing Deficiency Letters

Topics include:
- How the move forward with corrections and possible submission errors

Tasneem Hussain
Pharmacist
DQCT | DRLB | DLRUD | OUDLC | CDER

2:15 – 2:30

Current Compliance Projects:
U.S. Agents – Verification Initiative & Listing Inactivation Project

Topics include:
- How FDA is handling foreign establishments with incorrect or out-of-date US agent designations
- Overview of FDA's Drug Listing Inactivation project

Leyla Rahjou-Esfandiary
Team Lead
DQCT | DRLB | DLRUD | OUDLC | CDER

Paul Loebach
Director
DRLB | DLRUD | OUDLC | CDER

2:30 – 3:15

Submission Troubleshooting Exercise

Topics include:
- Hands-on problem solving and trouble-shooting exercises

Julian Chun
Pharmacist
DQCT | DRLB | DLRUD | OUDLC | CDER

3:15 – 3:45

Q&A Panel

All Speakers

3:45 – 4:00

Closing Remarks

Paul Loebach
Branch Chief
DRLB | DLRUD | OUDLC | CDER

Thank You

Thank you for listening to this presentation

Thank you for taking the time out of your day to attend the SBIA eDRLS 2021 Workshop.

Thank you for taking the time to ensure your submissions are complete and accurate.