



**U.S. FOOD & DRUG  
ADMINISTRATION**

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# Next Gen Portal: Controlled Correspondence and Pre-ANDA Meetings

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# FDA Disclaimer



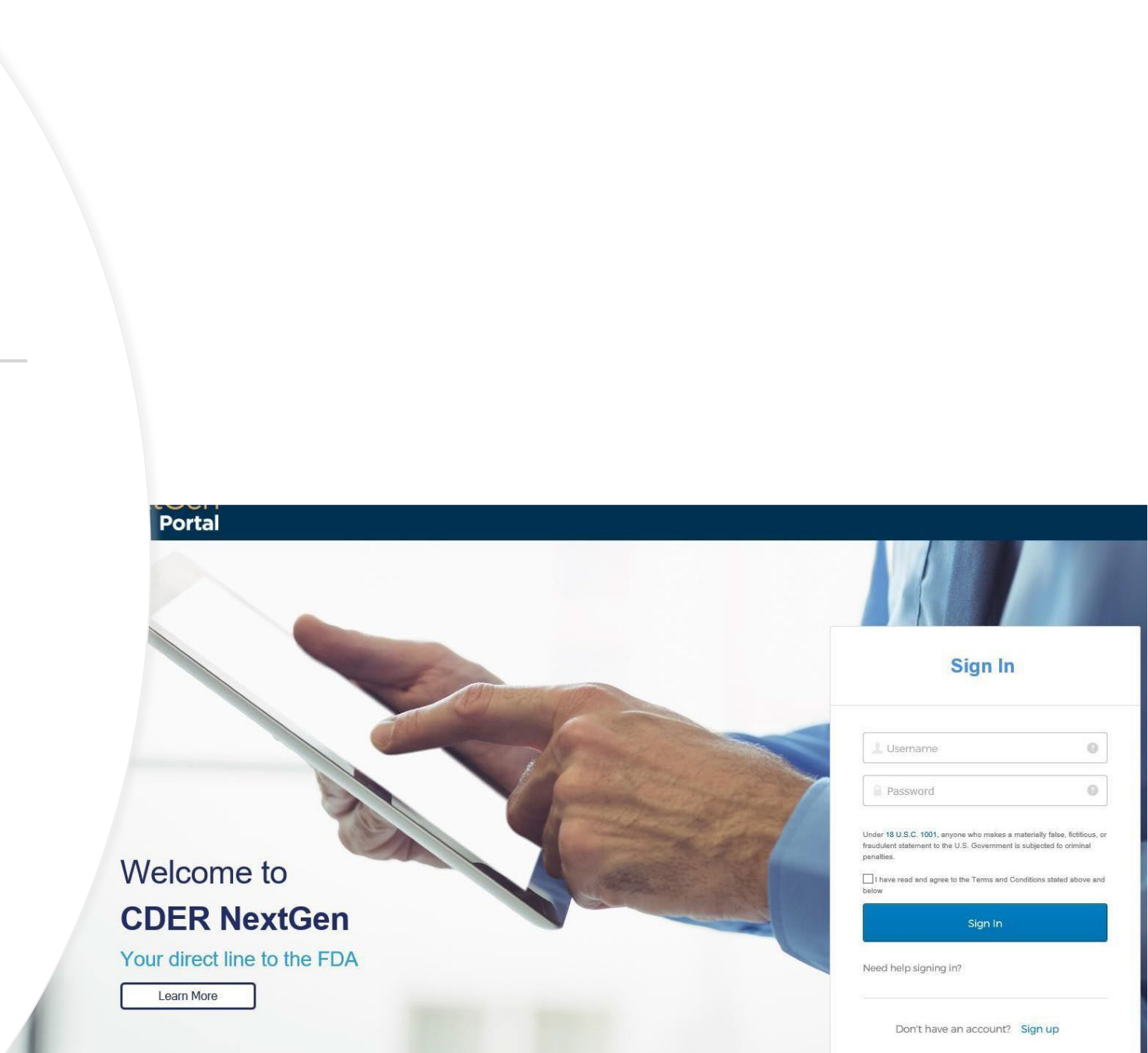
**The views and opinions presented here represent those of the speaker and should not be considered to represent advice or guidance on behalf of the U.S. Food and Drug Administration.**

# Agenda

- What is CDER NextGen Portal?
- Controlled Correspondence
- Pre-ANDA Meeting Request Tips
- How to use CDER NextGen Portal

# What is CDER NextGen Portal?

The CDER NextGen Portal serves as a comprehensive platform for collaboration and reporting, specifically designed to facilitate non-eCTD submissions. The portal allows sponsors to submit notifications, correspondence, and exempt human drug applications efficiently. This collaborative capability consistently reduces regulatory overhead for sponsors, academic institutions, research organizations, and small businesses.



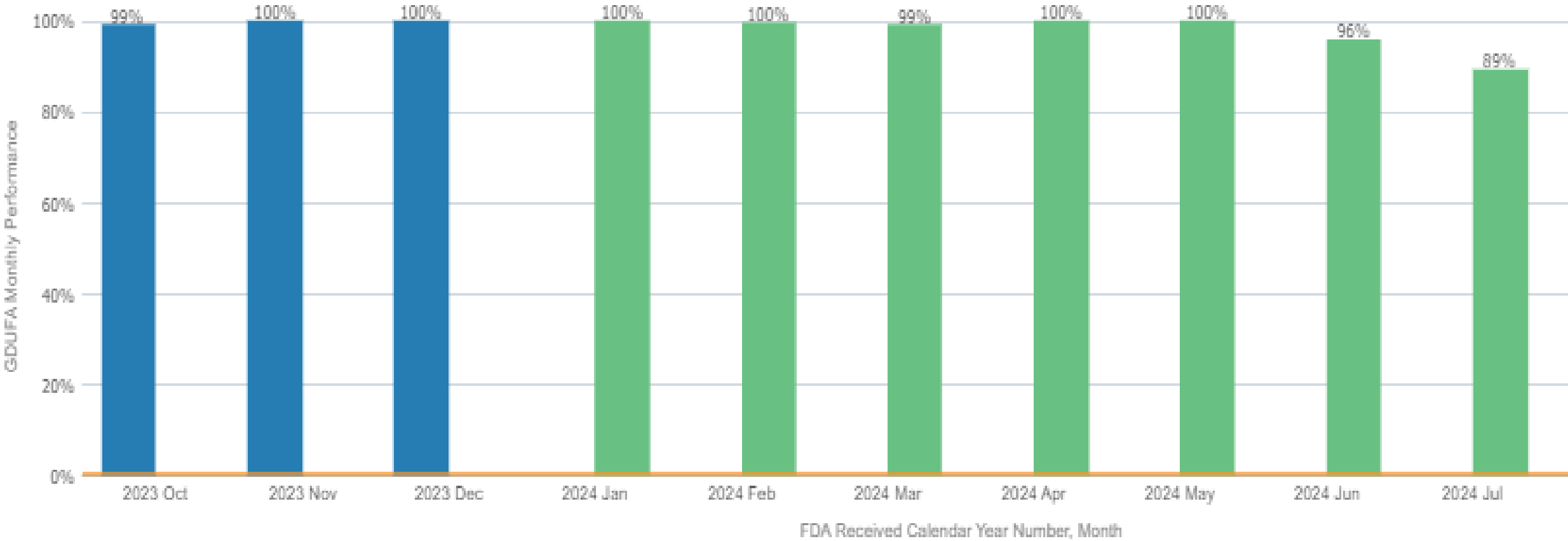
# Controlled Correspondence



# Controlled Correspondence Metrics FY 24

Submissions	Oct 23	Nov 23	Dec 23	Jan 24	Feb 24	Mar 24	Apr 24	May 24	Jun 24	July 24	FY 24
Controlled Correspondence	264	257	213	329	321	260	262	301	278	307	2792
Level 1	235	224	190	282	287	217	236	273	241	270	2455
Level 2	29	33	23	47	34	43	26	28	37	37	337

# Controlled Correspondence Metrics for FY 2024







# CDER NextGen Portal- Controlled Correspondence

## Contact Details for Applicants

### Controlled Correspondence

#### APPLICATION BUILDER

- Contact Details
- Correspondence Info
- Product Details
- Upload Documents

Review & Submit

#### Contact Details

#### Applicant Information

\* Are you submitting as an Applicant or US Agent?

Applicant

US Agent



## Correspondence Information

### Controlled Correspondence

#### APPLICATION BUILDER

- Contact Details
- Correspondence Info
- Product Details
- Upload Documents
- Review & Submit

#### Need Help?

The [Help Center](#) is available to answer questions on creating and submitting a Controlled Correspondence to the FDA.

#### Correspondence Information

##### Request Information

\* Is this related to a previous controlled correspondence that was accepted for substantive review and response?

- Yes
- No

\* Is this request to obtain a Covered Product Authorization for a drug that references a listed drug with REMS/ETASU

- Yes
- No

\* What is the specific type of inquiry for this request?

Select an option..

\* Please provide a brief description highlighting key areas of focus.

# CDER NextGen Portal- Controlled Correspondence



## Product Details

### Controlled Correspondence

#### APPLICATION BUILDER

- Contact Details
- Correspondence Info
- Product Details**
- Upload Documents
- Review & Submit

#### Need Help?

The [Help Center](#) is available to answer questions on creating and submitting a Controlled Correspondence to the FDA.

#### Product Details

##### Product Information ⓘ

\* Is this request related to post-approval submission requirements that are not specific to an ANDA?

- Yes  
 No

\* Is this request related to your previously submitted ANDA or pre-assigned ANDA?

- Yes  
 No

ANDA Number(s)

123131



\* What is the status of the ANDA?

Pending



\* Have you had a Product-Specific Guidance (PSG) teleconference with the FDA?

- Yes  
 No

\* Is this request related to inactive ingredients?

- Yes  
 No



## Upload Document Screen

### Controlled Correspondence

APPLICATION BUILDER

- Contact Details
- Correspondence Info
- Product Details
- Upload Documents**
- Review & Submit

#### Upload Documents

For the following document types, upload files that are 45MB or less of the following file types: pdf, doc, docx, xls, xlsx, ppt, pptx. If the name is longer than 99 characters, it will be shortened automatically.

Document Type	Document Description	File Count
> *Cover Letter ⓘ		Files: 0
> Previous Request(s) and Responses		Files: 0
> Optional Documentation ⓘ		Files: 0

# Pre-ANDA Meeting Requests Tips

# CDER NextGen Portal- Pre-ANDA Meeting Request



## Help Center Screen

### Help Center

To get to the help center use this URL:

<https://cdernextgenportal.fda.gov/s/mrhelpcenterinfo>

Or scan the QR code on the right side.



## Pre-ANDA and CPAM Meeting Request

### FAQs

Common questions and answers about the Pre-ANDA and CPAM Meeting Request process.

### Getting Started

Overview of the Pre-ANDA and CPAM Meeting Request form.

### Reference Guide

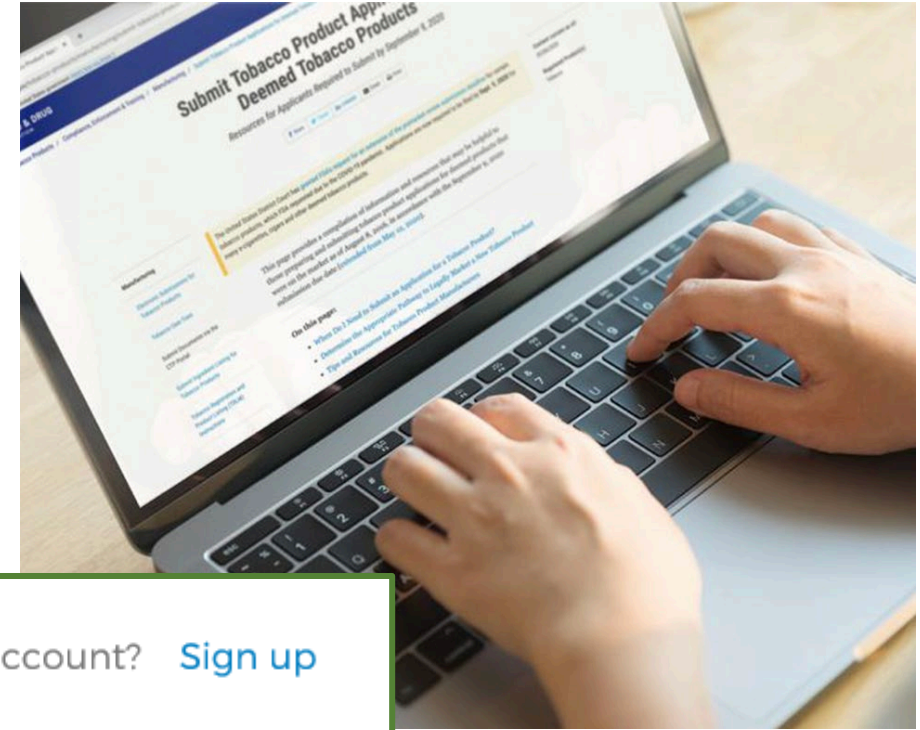
Step-by-step guide for submitting a Meeting Request in the CDER NextGen Portal.

# How to Access NextGen Portal?



- **New Users**

Sign up CDER NextGen Portal, navigate to <https://cdernextgenportal.fda.gov> and follow the signup instructions



Don't have an account? [Sign up](#)

**Thank You**

