

Using the ePortal for Pre-ANDA Meeting Requests

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What is the Portal?

- Also known as CDER Direct NextGen Collaboration Portal
 - Portal for short
- A website where industry can submit information to the FDA
- Has been in use for reporting drug shortages

What Should I Use the Portal For?

- USE for pre-ANDA meeting requests for complex generic drug products
 - Previously through the Generic Drugs email account
- Pre-ANDA product development meetings
- Presubmission meetings
- DO NOT USE for mid-review-cycle meetings
 - FDA will contact you if you are eligible

So You're Ready to Submit a Meeting Request

- First step: Obtain a pre-assigned ANDA number*
 - Apply for a secure email
 - You will need a U.S. agent if you are a non-U.S. applicant
 - You will need to know your RLD
 - Submit an email to cderrappnumrequest@fda.hhs.gov with the required information
 - Issued within three business days

*[Requesting a Pre-Assigned Application number](#)



Create a Login for the Portal*

- Once on the [website](#), click Request a Login
- Choose your “event”
 - Two choices - Drug Shortages or Pre-ANDA Meetings
- Enter the required information
- Once approved, you will receive your username and temporary password
- Login request will not be processed until you verify your email

*<https://edm.fda.gov/>

Login FAQs

- My organization doesn't appear when I search
 - You can enter it manually
- I don't have a DUNS number or I don't know what it is
 - Use the 9-digit code, 999999999
- Contact the EDM support team if needed at EDMSupport@fda.hhs.gov

My Login has been Created – Now What?

- Click “Create New Request”
- Enter required information
 - Pre-assignment number
 - What type of meeting request are you submitting
 - The Reference Listed Drug (RLD)

U.S. Agents

- If you are submitting as a U.S. agent, fill in your applicant information
 - Search for applicant information or enter manually
 - Provide the applicant contact information
- If you are the applicant, with no U.S. agent, proceed to “Attach a Document”
 - Do not enter yourself as a U.S. agent

Adding Your Documents

- You must add a document in order to proceed
- You can add more than one document
 - Cover letter (not required)
 - Meeting package (due at time of request for a meeting)
- Several formats allowed
 - PDF, Microsoft Word, Microsoft Excel, Microsoft PowerPoint, Microsoft Access, SAS, and Text. Macros are not allowed. Files may not exceed 45 MB

Submitting Your Meeting Request

- Before you submit your request
 - You have the option of saving your draft meeting request
 - Come back to it later and continue where you left off
 - FDA cannot see saved meeting requests
- You can delete a meeting request if you have not yet submitted it
- You will be asked to review for accuracy
- Click “Submit to FDA”

What Happens Next?

- You will receive a confirmation message and email
- A letter with the grant or deny decision will be sent to you via email
- A meeting denied letter will complete your project

My Meeting Was Granted

- Granted via a written response or a face-to face meeting
- Information Requests (IR)
 - Sent to the applicant through email
 - Can be sent to the applicant at any time
 - Strive to send early in the process
 - Respond to the IR through the portal

Face-to-Face Meetings

- Preliminary responses for face-to-face meetings received via email approximately five days before your scheduled meeting
- Your opportunity to focus your meeting for clarification
 - Submit presentation materials (not required)
 - Submit a revised agenda
 - Submit these through the portal

After the Meeting

- You can submit post meeting comments
 - Within seven days of the meeting
- FDA will send the final meeting minutes via email
- This completes the meeting request

What's Next in the Portal?

- Two-way communication coming soon to the portal
- Submit and receive documents through the portal with email notification
- All your documents and correspondence in one place

If You Need Help

- There are several help guides and tutorials on the Learn More page for reference
- For portal support, contact EDMSupport@fda.hhs.gov
- For meeting specific help contact PreANDAHelp@fda.hhs.gov

