

FAQs

Frequently Asked Questions

FDA CDER Direct NextGen Collaboration Portal: Pre-ANDA Meeting Requests

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The following questions and answers are those that are most frequently asked and answered by the Center for Drug Evaluation and Research (CDER) Office of Generic Drugs (OGD).

General Questions

1. What is the FDA CDER Direct NextGen Collaboration Portal?

The FDA CDER Direct NextGen Collaboration Portal is a website for Industry to submit information to the FDA.

2. How is the Portal used to request Pre-ANDA meetings with the FDA?

In just a few simple steps, you can initiate your request by uploading your meeting request package. If your meeting has been granted, the portal can also be used to submit other documents related to the Pre-ANDA meeting request, such as meeting presentation materials, responses to information requests (IR) made by FDA, Pre-ANDA Meeting Withdrawal Requests, and post-meeting comments.

3. Why request Pre-ANDA meetings via the Portal? Is it mandatory?

While you can still e-mail Pre-ANDA meeting requests, the online portal benefits you by ensuring FDA has all information needed to review your request and allows you to view your Pre-ANDA meeting request history.

4. What is the difference between the different statuses for my submission?

A meeting request will have a status of **Granted** if the meeting has been approved to be granted face-to-face, by teleconference, or by written response only. A meeting request could be considered **Denied**, if the meeting has been declined based on the submission. A meeting request will have a status of **Pending**, if the meeting has not received a response on whether it is granted or denied. A meeting request will have

a status of **Withdrawn/Cancelled** if the FDA has granted the request to withdraw the meeting request or canceled by the FDA if the meeting has been granted but no longer needs to occur.

5. How do I know if FDA received my request?

Once you submit your Pre-ANDA Meeting Request to the FDA, you should see a pop-up on your screen confirming your submission. You should also receive a confirmation e-mail entitled “FDA CDER Direct NextGen Collaboration Portal - Confirmation of Meeting Request Package - [Event ID: 00000]”. You will receive a 5-digit Event ID to reference throughout all steps of your submission. If you navigate back to the home page, you can view your submitted request under “Open Requests” or “All Requests”. Select your meeting request and click “View Submitted Request”.

Requesting a Login

6. When requesting a login, what phone number should I enter?

For your phone number, put either your individual work cell phone number or direct line and extension. Choose a U.S. phone number you would want the Office of Generic Drugs to call to reach you about the requested meeting.

7. In Organization Information, I cannot find my company name, what should I do?

If your company does not show in the search options, click “Enter Manually” and enter the information required on the Organization Information form. Then, click “Select Organization”.

8. I do not know my DUNS number, what should I do?

If you do not have a DUNS number, you may use the 9-digit code, 999999999.

9. I did not get an email to verify my email address. What should I do?

If you did not receive an e-mail titled “FDA CDER Direct NextGen – Verify Your E-mail Address,” navigate to <https://edm.fda.gov/> to access the FDA CDER Direct NextGen Collaboration Portal within 2 hours, please e-mail technical support (EDMSupport@fda.hhs.gov). **I never got an email with my temporary password.**

Please make sure you received an e-mail titled “Welcome to CDER Direct NextGen”. A temporary password should have been sent within 24 hours of this e-mail. If you did not receive the e-mail titled “FDA CDER Direct NextGen – Temporary Password” within 24 hours, please e-mail technical support (EDMSupport@fda.hhs.gov).

Logging In

10. What is my user name?

Your user name is the e-mail you used when you created your login.

11. How can I update my profile?

Navigate to your Portal homepage, and click “Update Profile”. From there you can update your personal information, as needed. You may also update your profile upon reviewing your information while entering a meeting request.

12. What do I do if I forgot my username?

Check your e-mail and locate the e-mail titled “Welcome to CDER Direct NextGen”. This e-mail contains your username. Your username is usually your work e-mail address. If you cannot find this e-mail and your work e-mail address is not working as your username, please e-mail technical support (EDMSupport@fda.hhs.gov).

13. What do I do if I forgot my password?

Navigate to <https://edm.fda.gov/> to access the FDA CDER Direct NextGen Collaboration Portal. On the login page, click “Forgot Password”. A Forgot Password screen will appear and will request your e-mail address. Once you enter your e-mail and submit, you will receive an e-mail titled “FDA CDER Direct NextGen – Password Reset”. The Password Reset e-mail will have a link to access your security questions. Once you have correctly filled in your security questions, you will be sent a new temporary password.

14. What do I do if I forgot my security question answers to reset my password?

If you do not remember your security question answer for password reset, please e-mail technical support (EDMSupport@fda.hhs.gov).

Attaching Pre-ANDA Meeting Request Documents

15. How do I add a document? Can I upload multiple documents?

You can add documents on the Attach Meeting Request Documents page by navigating to and clicking “Attach Document”. You may upload multiple documents. Please note once you submit your meeting request you cannot add any additional documents to the initial meeting request. If your meeting request is granted, you will be allowed to add documents for the subsequent steps such as meeting presentation materials, responses to information requests (IR) made by FDA, Pre-ANDA Meeting withdrawal requests, and post-meeting comments.

16. What documents will I be required to upload?

The only required document to request a meeting with the FDA is your meeting request package.

17. How do I know what document types are approved to upload?

Allowable Formats: PDF, Microsoft Word, Microsoft Excel, Microsoft PowerPoint, Microsoft Access, SAS, XPT, Text. Macros are not allowed.

18. Can I upload videos?

Videos cannot be uploaded to the Portal at this time.

19. What do I add in Document Description?

The document description box is an optional space to add any additional information you want the FDA to know about your document.

Creating a New Request

20. Do I need a pre-assignment number before creating a new request, and where do I get it?

Yes, a 6-digit ANDA pre-assignment number is required for submitting a meeting request. Before you request a pre-assigned application number, apply for a secure e-mail with the FDA by contacting secureemail@fda.hhs.gov. If using a U.S. Agent to request the number, please be sure that the agent has established a secure e-mail. You can review the process of requesting a pre-assignment number [here](#).

21. What does Submission Type mean?

The Submission Type describes the type of meeting request. Below are the definitions for each Submission Type:

Pre-ANDA Product Development – Discuss new or alternative approaches to demonstrating equivalence early in product development

ANDA Presubmission– Discuss the content and format of unique, novel or complex components of an upcoming ANDA submission

22. What is an RLD Product?

Reference Listed Drug (RLD) is an FDA-approved drug product to which new **generic** versions are compared to show that they are **bioequivalent**. A drug company seeking approval to market a **generic equivalent** must refer to the RLD in its ANDA.

23. What is Response to IR?

Response to Information Request (IR), will apply only when FDA is requesting further information or materials regarding your meeting request. Documents responding to IRs about Pre-ANDA meeting requests are submitted through the Portal.

24. What is the difference between an Applicant and a U.S. Agent?

The difference is by who is submitting the request. Below are the definitions for each:

Applicant – meeting request made directly by the potential ANDA applicant

U.S. Agent – meeting request made on behalf of a potential ANDA applicant or subsidiary

25. Can I save my request, and continue working on it later?

Yes. You may click on “Save as Draft” at any time. From the home page, you can view your saved notification under “Saved Meeting Requests” by selecting your notification and clicking “View Saved Requests”.

26. Can the FDA see saved requests?

No. The FDA cannot see any saved requests. Only information in "Submitted Requests" will be sent and viewed by the FDA.

27. Can I view my submitted meeting requests?

Yes. You may go to “Submitted Meeting Requests” and select “All Requests” You will see your submission history and be able to review any of your submissions by selecting and clicking “View Submitted Request”.

28. I can't find the RLD Product I am searching for, what do I do?

You can report the missing product by clicking the “Report Missing Product” button under “RLD Product Search”.

29. What happens once I submit a request?

Once a meeting request has been submitted, the Industry contact designated in the portal will be notified via e-mail by the assigned project manager as to whether the meeting request has been denied, granted with a face-to-face or teleconference meeting or granted by written response. The project manager will continue to be your point of contact and communicate via the portal with responses in the form of documents.

30. What are the document types that will be sent to me through the portal?

FDA will be sending documentation through the portal to respond to the meeting request. The document types to be sent are the following:

Meeting Grant Letter – documentation approving the meeting request as face-to-face, teleconference, or written response only

Meeting Deny Letter – documentation denying the meeting request

Meeting Scheduled Information Letter – documentation providing the date of the official meeting that was discussed outside the portal

Preliminary Response to Meeting Questions – documentation with responses to questions identified prior to the meeting

Final Written Response – documentation that provides answers to meetings that are categorized as Written Response Only

Information Request – documentation that provides questions that need to be answered by the Applicant or US Agent

Meeting Withdrawn/Cancelled Letter – documentation that provides approval of withdrawal request or reason for cancellation

Meeting Minutes – Final documentation provided in a granted face-to-face or teleconference meeting capturing the items discussed in the meeting

Submitting a Request as an Applicant

31. I normally submit as an applicant, what should I do if I am submitting on behalf of someone else?

When submitting on behalf of someone else, you will choose to submit as a U.S. Agent under “Meeting Request Information”.

32. In login, I cannot find my company name, what should I do?

If your company does not show in the search options, click “Enter Organization Manually” and enter the information required on the Organization Information form. Then, click “Select Organization”.

Submitting a Request as a U.S. Agent

33. I can't find my applicant's information, what should I do?

You may enter your applicant's information manually by choosing “Enter Organization Manually” under Applicant Organization Search.

34. I don't know my applicant's DUNS number, what should I do?

You may use the 9-digit code, 999999999.

35. What phone number should I use for my applicant's information?

Identify the U.S. phone number your applicant would want the CDER Office of Generic Drugs to call.

Contact Information

36. I'm having a technical issue, whom do I contact?

If you are experiencing a technical issue, you may contact support at EDMSupport@fda.hhs.gov.

37. How can I contact the Office of Generic Drugs (OGD)?

Contact the Office of Generic Drugs by e-mail (PreANDAHelp@fda.hhs.gov).