Practical Tips on Using the CDER NextGen Collaboration Portal

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What is the Portal?

- The full name is The CDER Direct NextGen Collaboration Portal or “Portal” for short
- A Website where industry can submit information and requests to the FDA
- Focus today will be on how to use the Portal for pre-ANDA meetings and controlled correspondences

Features of the Portal

- Two-way communication
  - Submit and receive documents through the portal with email notification
- All documents and correspondence in one place
- Multifactor Authentication

Multifactor Authentication

- Beginning in February 2019, the Portal added a second layer of security
- After entering your username and password, you receive a unique code via email
- This code is used for account holder verification
- Questions? Email CDER Platform Support (EDMSupport@fda.hhs.gov)

What Should I Use the Portal For?

- Pre-ANDA meeting requests for complex generic drug products
  - Product development meetings
  - Pre-submission meetings
- Controlled correspondence (New!)
- DO NOT USE for mid-review-cycle meetings
  - FDA will contact you if you are eligible

Using the Portal for Pre-ANDA Meeting Requests

- Obtain a pre-assigned ANDA number*
  - Apply for a secure email
  - Submit an email to cderappnumrequest@fda.hhs.gov with the required information
  - You will need a U.S. agent if you are a non-U.S. applicant
  - Know the reference listed drug (RLD)
  - Pre-assigned ANDA numbers are issued within three business days and do not expire

*Requesting a Pre-Assigned Application number

Create a Login for the Portal*

- Once on the Website, click **Request a Login**
- Choose your “event”
  - Pre-ANDA Meetings, for example
- 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

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

Change of POC/ US Agent

- How do I change my POC or U.S. agent for submitted Pre-ANDA meetings or Controlled correspondence?
  - Submit a new user account request for the Portal via https://edm.fda.gov/
  - Send an email to PreANDAHelp@fda.hhs.gov for Pre-ANDA meetings and GenericDrugs@fda.hhs.gov for Controlled Correspondence with the subject line- Change of POC or US agent request

Cont'd..

Change of POC/ US Agent Cont'd..

The email should include:

- Previous POC Name and Email
- New POC Full Name and Email
- New POC phone #
- List of Meeting IDs Or Control IDs (to be transferred to new account holder)
- Deactivate previous POC account- Yes/ No

Submitting Your Meeting Request

- Click **Create New Request**
- Enter required information
  - Pre-assigned number
  - Type of meeting request are you submitting
  - The RLD
  - U.S. Agent (if applicable)
- You must add a meeting package in order to proceed
  - Multiple documents can be submitted

Adding Your Documents

- 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, Text, Phoenix and Simcyp simulator ".wks" workspace files
  - 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”
- You will receive a confirmation email

What Types of Documents Go Through the Portal?

- Cover letter
- Meeting package
- Information requests
- Preliminary responses for pre-ANDA meetings
- Updated agenda and presentation materials from the applicant
- Written responses
- Post-meeting comments from the applicant
  - Within seven days of the meeting
- Final meeting minutes from the FDA

Submitting Controlled Correspondence

- No pre-assigned number is needed
- Your submission should include:
  - Your question (refer to the Guidance for Industry Controlled *Correspondence Related to Generic Drug Development*)
  - A letter of authorization if you are submitting on behalf of another company

Submitting Controlled Correspondence

- You will need to specify your RLD:
  - Use the RLD per the Orange Book, even if the RLD has been discontinued
  - If there is no RLD, choose the reference standard (RS)
- Post approval changes controls do not need an RLD or RS specified

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

Pre-assigned Application Number requests

- To be released later this year
- Similar to existing request types, will provide:
  - Quick, intuitive data entry with ability to leverage your user profile data and built-in validations
  - All correspondence conveniently available on the Portal
- More updates to follow - stay tuned!


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