

Frequently Asked Questions

CDER NextGen Portal: FDA’s DSCSA Portal

Table of Contents

Contents

General Questions	1
Requesting a Login	2
Logging In	2
Entering Data for Trading Partner Confirmation.....	2
Submitting a Trading Partner Confirmation.....	3
Submitting an Initial Submission.....	3
Searching for a Product.....	4
Entering Lot and Serial Numbers.....	4
Upload Documents.....	4
Contact Information	5

The following questions and answers are those that are most frequently asked and answered by users. For specific questions related to how to complete your submission(s) please refer to the [Reference Guide](#).

General Questions

1. What is the CDER NextGen Portal?

The CDER NextGen Portal is a website for Industry to submit information to the FDA. The CDER NextGen Portal hosts several FDA applications, including the DSCSA Portal.

2. What is the DSCSA Portal?

Within the CDER NextGen Portal, the DSCSA Portal is the mechanism by which Trading Partners will respond to an FDA request for information. The Trading Partner will be prompted to go to the DSCSA Portal and confirm their contact details and will receive a Request for Documentation from the FDA regarding their products, this could include a request for Transaction Information, Transaction Statement, and/or Product Verification.

3. How do you submit DSCSA-related information through the CDER NextGen Portal?

In just a few simple steps, you can submit a DSCS Act by answering pertinent questions and entering or uploading relevant data.

4. How do I know if the FDA received my submission?

Once you submit your DSCSA-related information to the FDA, you should see a confirmation screen, which will display your Event ID number. You should also receive a confirmation e-mail.

Requesting a Login for the CDER NextGen Portal

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

For your phone number, put either your individual direct line and extension or your individual work cell phone number. If you have an international number, please include your country code.

6. What should I do if I cannot find my company name in Organization Information?

If your organization does not appear in the search options, click “Add it here” and enter the information required on the Organization Information form.

7. What should I do if I do not know my DUNS number?

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

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

If you did not receive an e-mail titled “CDER NextGen Portal – Verify Your E-mail Address” within 2 hours, you can send an e-mail to the CDER Support Staff (EDMSupport@fda.hhs.gov).

Logging In

9. What is my username?

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

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

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

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

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

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

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

Entering Data for Trading Partner Confirmation

13. This is my first time submitting a Trading Partner Confirmation to FDA online

using the DSCSA Portal. What do I do?

Navigate to <https://edm.fda.gov> to access the CDER NextGen Portal. Using the Username and Password, login into the Portal. Click “+ Trading Partner Confirmation”. A new screen will display allowing you to enter data about the Trading Partner. Once you are ready to submit to the FDA, click “Submit”.

14. What should I enter for Request ID?

The Request ID will be sent via email from fda-dscsaportal@fda.hhs.gov. Use the same Request ID to validate and submit a Trading Partner Confirmation.

15. I cannot find the facility using the FEI number. How can I enter my facility details?

If the facility is not found when searching by FEI number, an “Add Manually” button will be displayed, and facility details can be added manually. Please note that adding a Facility is optional.

16. Can I save my record and work on it at a later time?

Yes, you may click “Save and Close” at any time and view your saved record on the landing page.

17. Can the FDA see saved records?

No, the FDA cannot see any unsubmitted saved records—only submitted information can be viewed by the FDA.

Submitting a Trading Partner Confirmation

18. After I press submit what happens to my information?

Once you submit your Trading Partner Confirmation to the FDA, you should see a confirmation screen, which will display your Event ID number. You should also receive a confirmation email titled “CDER NextGen Portal – Confirmation of DSCSA Trading Partner Confirmation Submitted to FDA”. If you navigate back to the home page, you can view your submitted record on the landing page. The submitted information is routed directly to the FDA internal workflow for analyzing submissions. If needed, FDA will follow up with questions. The information is not visible to the public.

Submitting DSCSA-related Information to FDA

19. Once FDA has sent a Request for Documentation, how do I begin my Initial Submission?

In the Activity Log page, choose the Initial Submission option in the Actions dropdown. For more details on how to complete your Initial Submission please refer to the [Reference Guide](#).

20. Can I submit Transaction Information and Product Identifier Information at the same time?

Yes, you will be able to select what information you are submitting to FDA.

Searching for a Product

21. I cannot find the product I am searching for. What do I do?

If you cannot locate the product in the Product Search, please enter your drug information manually by selecting “Add Manually”. Be sure to provide the Active Ingredient, Proprietary Name, Strength, Dosage Form, and NDC.

22. Where does the data in the Product Search come from?

The data comes from FDA’s NDC Directory.

23. What is the correct configuration to search by NDC?

Currently, NDCs exist in the following three configurations based on the length of each segment: 4-4-2 (e.g., 1234-1234-12); 5-3-2 (e.g., 12345-123-12); and 5 - 4 - 1 (e . g . , 12345-1234-1). You must Include the dashes (-) in your searches.

24. How do I search for a product with multiple active ingredients?

On the Product Search page under Product Selection, we recommend searching for your product by the NDC, not by the active ingredients.

Entering Lot and Serial Numbers

25. How do I enter Lot and Serial Numbers for my products?

You can upload a CSV (comma-separated values) file using the FDA template and enter all the Lot and Serial Numbers associated with your product. The template is accessible on the Lot Number tab in the product details modal as well as the Help Center.

26. I do not have Lot or Serial numbers for my product.

Select the Check box in the Lot and Serial Number section that states: “Please select the check box if you do not know the Lot Numbers or associated Serial Numbers.”

Upload Documents

27. How do I upload document(s)?

To add a document in response to a request for documentation, select the Upload Document section and add documents for the appropriate Document Type. Users can add multiple documents when uploading files. Note: file names must be under 100 characters.

28. What do I do if I receive an error stating that my document may contain potentially malicious code?

If you have received an error stating that your document may contain malicious code, please remove your document and try uploading it again. If you are still having trouble after multiple attempts, please email CDER Platform Support, EDMSupport@fda.hhs.gov for help.

29. If I have DSCSA-related information in the EPCIS standard, what file formats can I upload when submitting the information?

You can upload XML or JSON format files. For more information on acceptable file formats please visit:

- [PDG](#)
- [GS1](#)

Contact Information

30. I'm having a technical issue, who do I contact?

For all technical support, contact CDER Platform Support at EDMSupport@fda.hhs.gov.

31. I am having issues registering for the CDER NextGen Portal, what do I do?

For guidance on registering for the CDER NextGen Portal, click the Learn More button on the CDER NextGen Portal home page to locate the [User Registration Guide](#) and video and/or contact EDMSupport@fda.hhs.gov.

32. How can I contact the DSCSA Staff?

You can contact the Office of Drug Security, Integrity and Response (FDA-DSCSAportal@fda.hhs.gov).