

Reference Guide: CDER NextGen Portal Account Registration and MFA Enrollment Process

FDA CDER NextGen Portal

Welcome to
CDER NextGen
Your direct line to the FDA
[Learn More](#)

Sign In

Username

Password

Under 48 U.S.C. 1011, anyone who makes a material false, fictitious, or fraudulent statement to the U.S. Government is subjected to criminal penalties.

I have read and agree to the Terms and Conditions listed above and below.

Sign In

[Need help signing in?](#)

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

User Terms and Conditions

- This website browser provides privacy and security notices consistent with applicable federal laws, directives, and other federal guidance for accessing this Government system, which includes (1) the computer network, (2) all computers connected to this network, and (3) all devices and storage media attached to the network or to a computer on the network.
- This system is provided for Government authorized use only.
- Unauthorized or improper use of this system is prohibited and may result in disciplinary action and/or civil and criminal penalties.
- Personal use of social media and networking sites on this system is limited as to not interfere with official work duties and is subject to monitoring.
- By using this system, you understand and consent to the following:
 - The Government may monitor, record, and audit your system usage, including usage of personal devices and email systems for official duties or to conduct HRIS business. Therefore, you have no reasonable expectation of privacy regarding any communication or data transmitted or stored on this system. At any time, and for any lawful Government purpose, the government may monitor, intercept, and search and audit any communication or data transmitted or stored on this system.

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

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Introduction

This guide provides the essential information you need to request an account. The sections described below cover creating and activating an account, as well as enrolling in and using the Multi-Factor Authentication process. For technical support, email CDER Platform Support staff at edmsupport@fda.hhs.gov.


Requesting a Login

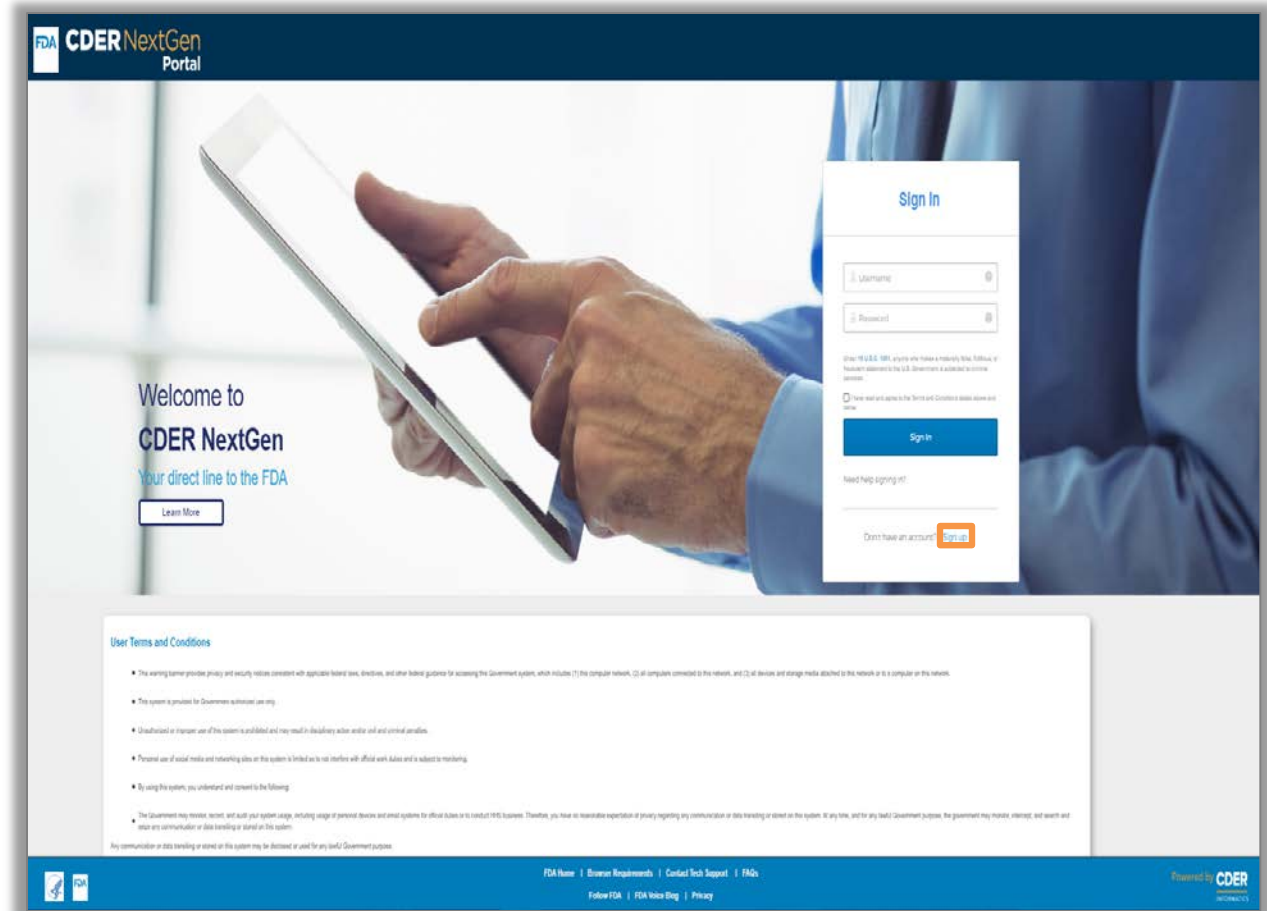
Register to create a Login

This section describes how to complete the first phase in the access request process: submitting a login request.

Step 1. Navigate to CDER NextGen Portal by accessing: <https://edm.fda.gov/>.

Step 2. Click **Sign up**.

 When signing up please ensure you are using one of our supported browsers. These browsers include Google Chrome, and Mozilla Firefox. Please also ensure your browsers allow for the use of third party cookies. If you have any issues enabling third party cookies, please contact your IT Support.



Register to create a Login

Step 3. Enter in your Contact Information: First Name, Last Name, Email Address, Country, Phone Number and extension, if applicable.

Step 4: Search for your Organization Name and/or DUNS by selecting search, indicating that you are not a robot, and picking the appropriate image for verification. If you are unable to find your organization then you can add it manually by selecting “Add it here” and entering Organization Information: Organization Name, Address Line 1, Country, City, State, Zipcode and DUNS Number.

Step 5. Review the Terms and Conditions for the site.

Step 6. Confirm that you agree to the Terms and Conditions by selecting the box next to “I have read and agree to the Terms and Conditions stated above.”

Step 7. Click **Create Account**.

Welcome to the CDER NextGen Portal!

Register for an account below.

*** Contact Information**

* First Name Middle Name * Last Name

* Email * Confirm Email

* Country
Select an Option

* Country Code * Phone Number Extension

*** Organization Information**

Select your organization. To search for your organization, please enter a minimum of three characters into the organization text field prior to clicking search (i.e. "abc" for abc pharmaceutical). If your organization is not found, please manually enter an organization to continue with the registration process.

Organization Name DUNS

Terms and Conditions

Under 18 U.S.C 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.

Under section 11.100, subject C, paragraphs (a), (b), (c) and (2) of Title 21 of the Code of Federal regulations, accepting the terms and conditions will require the verification of a person's identity and will be considered legally binding upon the verification.

I have read and agree to the Terms and Conditions stated above.

Organization Information

* Organization Name

* Address Line 1 Address Line 2

* Country
Select an Option

* City * State

* Zipcode

* DUNS Number

Register to create a Login

Step 8. After clicking Create Account, you will be navigated to a confirmation message stating that your account has been created and that you need to check your email to click on an activation link to complete the registration process.

You have successfully created your profile

Your FDA CDER Next Gen Portal Profile has successfully been created. Please check your email for a confirmation message about your profile. Clicking Continue below will redirect you back to main login screen, where you can login using your newly created profile.

For questions regarding altering profile information, please contact the CDER platform support team (EDMSupport@fda.hhs.gov).

Continue

For questions regarding the registration process, see [this link](#).

Create your Account

Upon clicking the activation link sent to your designated email address, you will be prompted to set up your new password and secure your profile. Keep in mind, this activation link expires within 7 days. If the link has expired, please click the expired activation link and you will be brought to an Okta web page that will prompt you to request a new activation link.

Step 9. You will now be able to Enter your password, Select a Forgot Password question and select a security image.

Step 10. Click **Create My Account**.



If you are not automatically redirected to the CDER NextGen Portal home page, you may navigate there manually by opening your browser and entering <https://edm.fda.gov/>.

Welcome to Department of Health and Human Services - Food and Drug Administration (FDA), sierra!
Create your Department of Health and Human Services - Food and Drug Administration (FDA) account

Enter new password

Enter new password

Password requirements: at least 8 characters, a lowercase letter, an uppercase letter, a number, a symbol, no parts of your username, does not include your first name, does not include your last name. Your password cannot be any of your last 6 passwords.

Repeat new password

Repeat new password

Choose a forgot password question

What is the food you least liked as a child? ▼

Answer

Answer

Click a picture to choose a security image

Your security image gives you additional assurance that you are logging into Okta, and not a fraudulent website.

Grid of 12 images for security selection.

Create My Account

User Login

Logging into the Portal for the First Time

Step 1. Navigate to CDER NextGen Portal by going to: <https://edm.fda.gov/>.

Step 2. Enter your email address as the Username.

Step 3. Enter your new password.

Step 4. Confirm that you agree to the terms and conditions of the site by selecting the checkbox.

Step 5. Click **Sign In**.

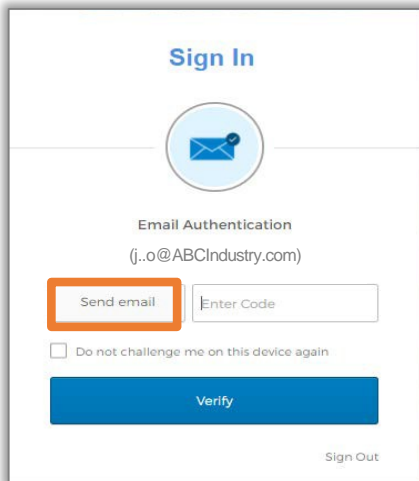
The screenshot displays the CDER NextGen Portal login interface. At the top left, the FDA logo and 'CDER NextGen Portal' are visible. The main banner features a person using a tablet, with the text 'Welcome to CDER NextGen' and 'Your direct line to the FDA' below it, accompanied by a 'Learn More' button. On the right side, a 'Sign In' form is highlighted with an orange border. This form includes a 'Username' field, a 'Password' field, a checkbox for 'I have read and agree to the Terms and Conditions stated above and below', a 'Sign In' button, and a link for 'Need help signing in?'. Below the form, there is a 'User Terms and Conditions' section with a list of terms. The footer contains navigation links: 'FDA Home', 'Browser Requirements', 'Contact Tech Support', and 'FAQs', along with social media icons for Facebook, Twitter, and YouTube. The text 'Powered by CDER INFORMATICS' is located in the bottom right corner.

Multi – Factor Authentication

Step 6. Click **Send Email**.

Step 7. Navigate to your email to receive your authentication code (this email may take a couple of minutes to arrive).

Step 8. You should have received an email similar to the below email.



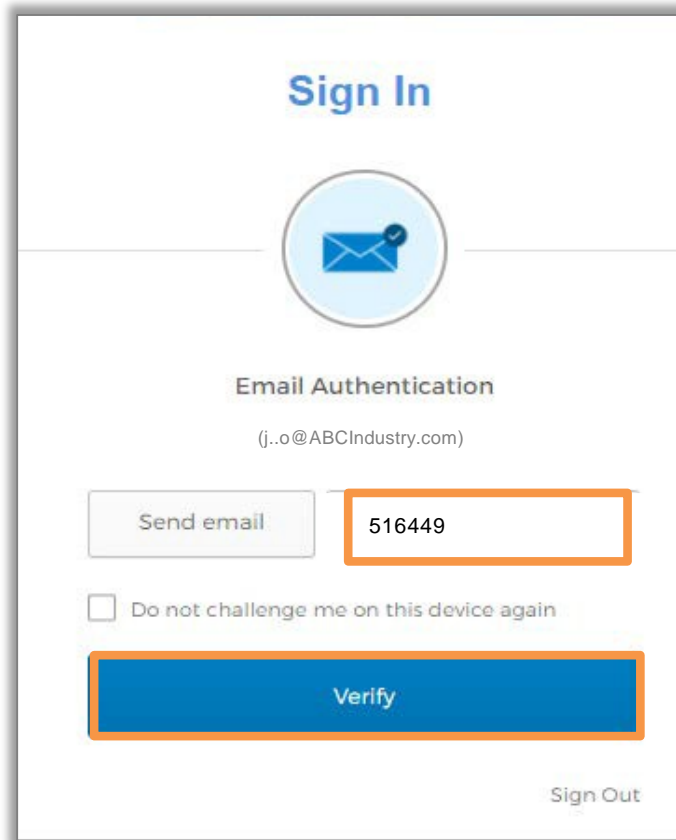
The screenshot shows a 'Sign In' page with a blue header. Below the header is a circular icon of an envelope with a keyhole. The text reads 'Email Authentication (j..o@ABCIndustry.com)'. There are two input fields: 'Send email' (highlighted with an orange border) and 'Enter Code'. Below these is a checkbox labeled 'Do not challenge me on this device again'. At the bottom is a large blue 'Verify' button and a 'Sign Out' link.




Multi – Factor Authentication

Step 9. Enter code. Keep in mind, this code expires within 5 minutes.

Step 10. Click **Verify**.



Sign In



Email Authentication

(j..o@ABCIndustry.com)

Do not challenge me on this device again

[Sign Out](#)

Password Reset

Resetting your Password

Step 1. Navigate to <https://edm.fda.gov/> to access the FDA CDER NextGen Portal.

Step 2. On the login page, click “**Need help signing in**”. The “Need help signing in” link will expand and display the option “Forgot password?”.

Sign In

I have read and agree to the Terms and Conditions stated above and below

Sign In

[Need help signing in?](#)

[Forgot password?](#)

[Help](#)

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

Resetting your Password

Step 3. A “Reset Password” screen will appear requesting your email address. Upon clicking the "**Reset via Email**" button, the screen will display a message that an email has been sent to you. You will receive an email titled “FDA CDER NextGen Portal – Password Reset Request Received”.

Sign In

Reset Password

[Reset via Email](#)

[Back to Sign In](#)

Sign In

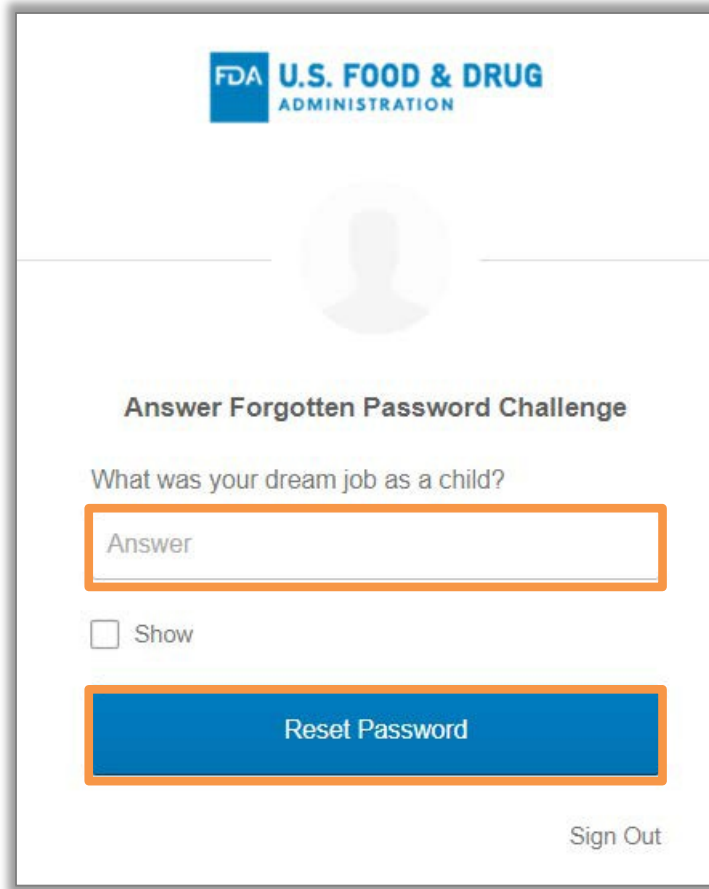
Email sent!

Email has been sent to John.Smith@ABCIndustry.com with instructions on resetting your password.

[Back to Sign In](#)

Resetting your Password

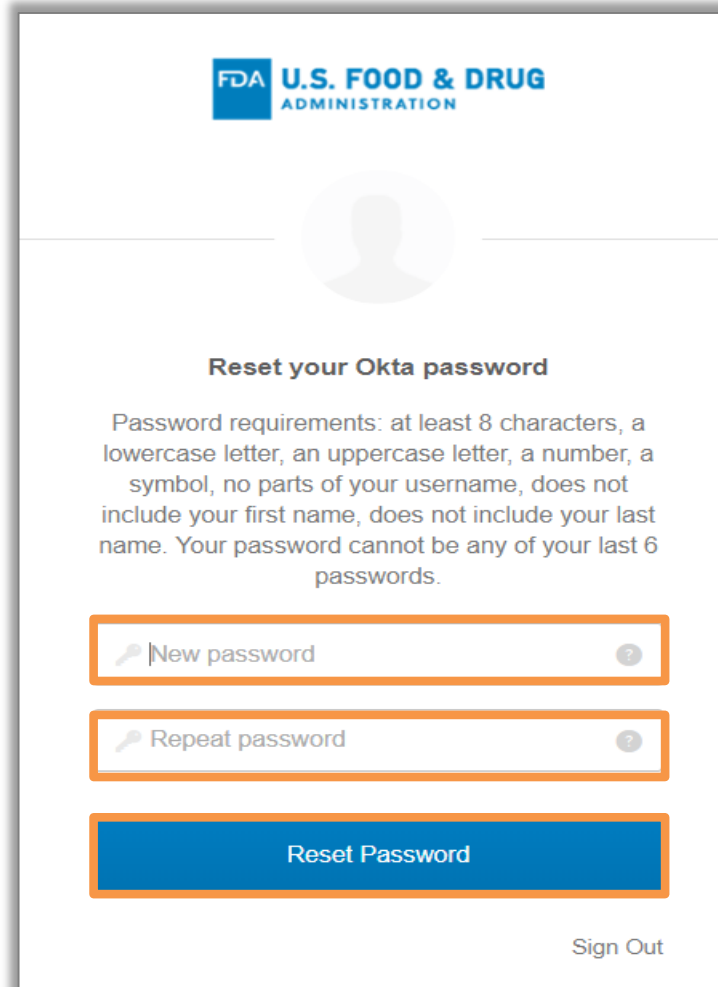
Step 4. The Password Reset email will have a link to access your security questions. Once you click the link, answer the security question then click “**Reset Password**”.



The screenshot shows a web interface for the FDA U.S. Food & Drug Administration. At the top left is the FDA logo, and to its right is the text "U.S. FOOD & DRUG ADMINISTRATION". Below the logo is a circular placeholder for a user's profile picture. The main heading is "Answer Forgotten Password Challenge". Below this is the question "What was your dream job as a child?". There is a text input field with the placeholder text "Answer". Below the input field is a checkbox labeled "Show". At the bottom of the form is a large blue button with the text "Reset Password". In the bottom right corner of the page, there is a link that says "Sign Out".

Resetting your Password

Step 5. Once you have correctly answered your security question, you will be prompted to input a new password. Click **“Reset Password”** when done entering a new password.



The screenshot shows a web page for resetting a password. At the top is the FDA logo and the text "U.S. FOOD & DRUG ADMINISTRATION". Below this is a placeholder for a user profile picture. The main heading is "Reset your Okta password". Underneath, there is a paragraph of password requirements: "Password requirements: at least 8 characters, a lowercase letter, an uppercase letter, a number, a symbol, no parts of your username, does not include your first name, does not include your last name. Your password cannot be any of your last 6 passwords." There are two input fields: "New password" and "Repeat password", both with a question mark icon on the right. Below these is a large blue button labeled "Reset Password". At the bottom right of the page is a link for "Sign Out".

Resetting your Password

Step 6. After resetting your new password, you will be navigated to Portal home page where you will login with your new password.

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[Learn More](#)

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Password

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Technical Support

CDER NextGen Portal Support & Resources

The CDER NextGen Portal (<https://edm.fda.gov>) has many resources for support.

Portal Announcements

Your Portal home page contains **portal announcements** so users are always in the know.



Learn More Information

Everything related to the portal events can be found on the “**Learn More**” link. On the event home page, users can find the “Learn More” link to **user guides and FAQs**.

Technical Support

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

Portal Training Videos

The “**Training Videos**” on the home page contains **1-4 minute video clips** on how to complete submissions for events on the portal.