

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

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Sign In

username@email.com

.....

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

Sign In

Need help signing in?

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2. Unauthorized or improper use of this system may result in disciplinary action, as well as civil and criminal penalties. Authorized use of this system consists of industry submissions of data related to the use cases for which the system is intended.
3. By using this information system, you understand and consent to the following:
 - You have no reasonable expectation of privacy regarding any communication or data transiting or stored on this information system. At any time, and for any lawful Government purpose, the government may monitor, intercept, and search and seize any communication or data transiting or stored on this information system.
 - Any communication or data transiting or stored on this information system may be disclosed or used for any lawful Government purpose.

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

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Introduction

Welcome to CDER NextGen Portal

This guide provides the essential information you need to request an account with CDER NextGen Portal. 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 step 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 Internet Explorer, 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.

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Register to create a Login

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

Step 4. Review the Terms and Conditions for the site.

Step 5. 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 6. Click **Submit**.

Contact Information

First Name *	Middle Name	Last Name *
<input type="text"/>	<input type="text"/>	<input type="text"/>
Email *	Confirm Email *	
<input type="text"/>	<input type="text"/>	
Country *	Phone Number *	Ext.
<input type="text" value="United States"/>	<input type="text" value="(201)555-0123"/>	<input type="text"/>

Fields marked with * are required fields.

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- Under Section 11. 100, sub-part 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.

Register to create a Login

Step 7. After clicking submit, you will be navigated to a confirmation message stating that your account has been created and that you need to check your email to complete the login request process.

**Your account has been successfully created. Please
check your email for the next steps.**

If you do not receive the email or for any questions and support, contact the CDER
Platform Support
[\(\[EDMSupport@fda.hhs.gov\]\(mailto:EDMSupport@fda.hhs.gov\)\)](mailto:EDMSupport@fda.hhs.gov)

OK

Create your Account

Upon clicking the link, you will be prompted to set up your new password and secure your profile.

Step 8. You will now be able to Enter your password, Select a Forgot Password question and select a security image.

Step 9. 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)-Production, sas!
Create your Department of Health and Human Services - Food and Drug Administration (FDA)-Production account

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 8 passwords.

Repeat new password

Choose a forgot password question
What is the food you least liked as a child?

Answer

Click a picture to choose a security image
Your security image gives you additional assurance that you are logging into OIra, and not a fraudulent website.

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**.

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[Learn More](#)

Sign In

username@email.com

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[Sign In](#)

Need help signing in?

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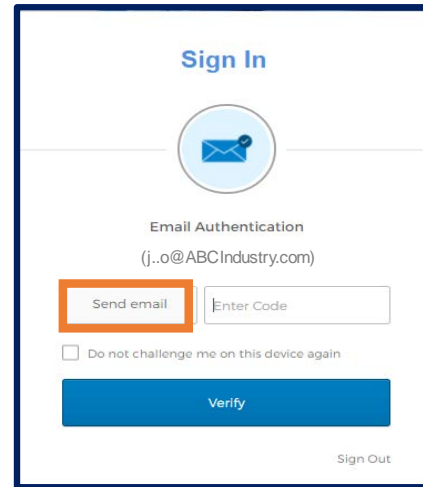
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Multi – Factor Authentication

Step 6. Click **Send Email**.



Sign In

Email Authentication
(j..o@ABCIndustry.com)

Send email Enter Code

Do not challenge me on this device again

Verify

Sign Out

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

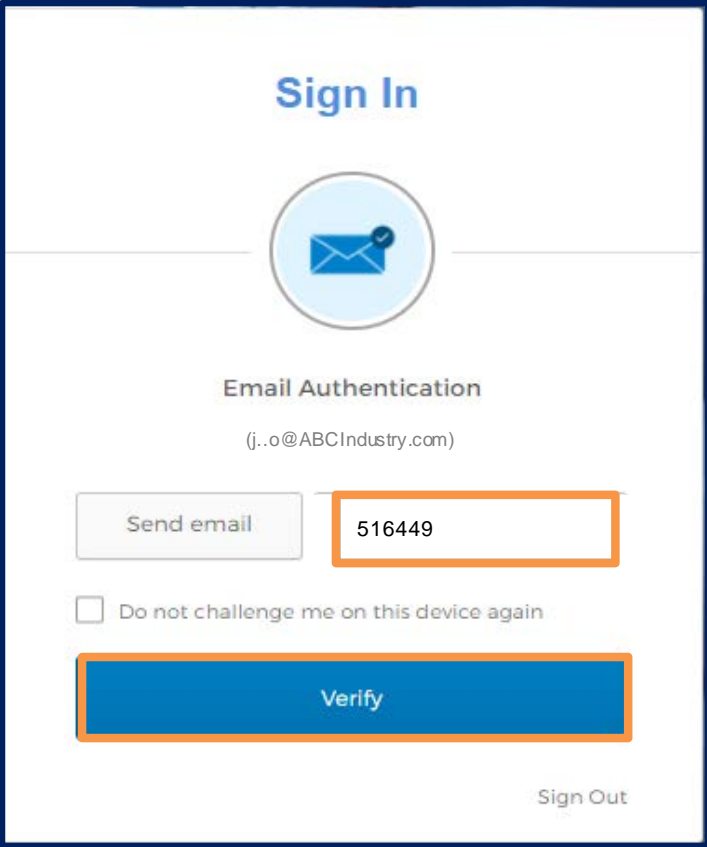
Step 8. You should have received an email similar to the below email.




Multi – Factor Authentication

Step 9. Enter code.

Step 10. Click **Verify**.



Sign In



Email Authentication
(j..o@ABCIndustry.com)

Do not challenge me on this device again

[Sign Out](#)

Profile Management

Review Profile Information and Select Organization

Once you verify your code, you will be directed to the Review Profile Information page. The following steps cover reviewing your profile information.

Step 11. Review that your information is correct, Click **Next**.

Complete Registration

Review Profile Information

Personal Information

To edit Profile Information, please contact FDA CDER Platform Support at [EDM Support](#)

First Name	Middle Name	Last Name	Email	Phone Number	Ext.	Country
John		Smith	John.Smith@ABCIndustry.com	(123) 123-4567	456	United States

NEXT

NOTE

If you would like to make any changes to your profile information, please contact CDER Platform Support (EDMSupport@fda.hhs.gov) for assistance.

Review Profile Information and Select Organization

Step 12. Input either your Company Name or DUNS number in the search bar.

Step 13. Click **Search**.

Complete Registration

Organization Information

Organization Selection

Select the organization you are affiliated with

Company Name: DUNS:

Allowable format: 9 digit numeric code i.e. 123456789.

Step 14. Highlight your Organization.

Step 15. Click **Select Organization**.

Complete Registration

Organization Information

Organization Selection

Select the organization you are affiliated with

Company Name: DUNS:

Allowable format: 9 digit numeric code i.e. 123456789.

Company Name	Company Address	DUNS
ABC Industry	123 DGFH Road, Rockville, MD 20852	0011223344

Review Profile Information and Select Organization

Step 16. Once you have highlighted and selected your Organization, click **Save & Continue**.

Complete Registration

Organization Information

Organization Selection


Select the organization you are affiliated with

Company Name: DUNS:

Allowable format: 9 digit numeric code i.e. 123456789.

Organization Name	Full Address	DUNS
ABC Industry	123 DGFH Road, Rockville, MD 20852	0011223344

Step 17. Once you've selected Save & Continue, you will need to log out and log back in. Please select log out on the top right corner of the screen.

 **CDER** NextGen Portal

John Smith

Your information has been saved successfully. Please log out and then back in to view your updated information.

If you need immediate assistance, please contact CDER Platform Support at EDMSupport@fda.hhs.gov

Review Profile Information and Select Organization

Step 18. Once you log back in, you will land on the portal home page.

The screenshot shows the CDER NextGen portal home page. On the left, a white box contains a personalized greeting: "Hi John, welcome back to CDER NextGen!". Below this, it says "To get started choose an option below" and "Access Your Events". There are two blue buttons: "Program Fee" and "Drug Development Tool". Underneath, it says "Manage Your Profile or Access" and provides contact information for the CDER Platform Support Team at EDMSupport@fda.hhs.gov. On the right, a blue header "Announcements" is followed by a white box stating "No Announcements". The footer is dark blue and contains the FDA logo, navigation links (FDA Home, Browser Requirements, Contact Tech Support, FAQs, A to Z Index, Follow FDA, FDA Voice Blog, Privacy), and the text "Powered by CDER INFORMATICS".


Migrating Your Account

Activate Migrated Account

This section provides guidance for existing portal users on how to activate their migrated account.

Step 1. Once your account has been migrated, you will receive the below activation email.

Step 2. Please click on the activation link in the email or copy and paste it to your browser.



FDA U.S. FOOD & DRUG ADMINISTRATION DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Hi John Smith,

Your login request to the FDA CDER NextGen Portal has been received.

Your username is John.Smith@ABCIndustry.com

Please click the following link below to activate your account.

Note: Third party cookies should be enabled on the browser before clicking the activation link. If you have any issues enabling third party cookies, please contact your IT Support.

[Activation Link](#) (this link expires in 7 days.)

How to Activate my Account

The following instructions outline how to activate your account.

1. When you click on the link above, you will be directed to a page and be asked to enter the password, security question, and select a security image.
2. After you have entered the required information, you will be directed to the FDA CDER NextGen Portal welcome page where you will be asked to log in.
3. Upon signing in, please review your profile information and click Next.
4. Please follow the next instructions below if you are a new user or an existing user.

I am a New User

If you are a new user, please enter your organizational information by searching or selecting then save and continue. You will then be prompted to sign out and sign back in to see your FDA CDER NextGen Portal home page.

I am an Existing User

If you are an existing user, please verify your organizational information then save and continue. You will then be prompted to sign out and sign back in to see your FDA CDER NextGen Portal home page.

Technical Support	EDMSupport@fda.hhs.gov
Documentation	User Guide

NOTE

This email will be sent from noreply@okta.com. If you do not see it in your inbox, please check your spam and junk mail folders for it.

Activate Migrated Account

Step 3. You will now be prompted to do the following;

- Enter your new password
- Select a Forgot Password question
- Select a security image

Step 4. 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)-Production, sas!
Create your Department of Health and Human Services - Food and Drug Administration (FDA)-Production account

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

Choose a forgot password question

What is the food you least liked as a child?

Answer

Click a picture to choose a security image

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

Create My Account

Activate Migrated Account

Step 5. Once you land on the CDER NextGen Portal home page, Enter your email address as the Username.

Step 6. Enter your new password.

Step 7. Confirm that you agree to the terms and conditions of the site by selecting the checkbox.

Step 8. Click **Sign In**.

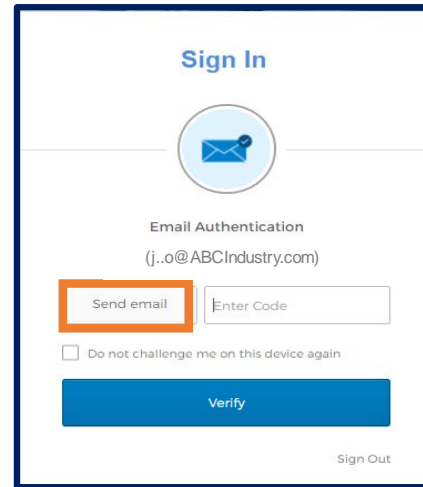
The screenshot displays the CDER NextGen Portal home page. At the top left is the FDA CDER NextGen Portal logo. The main content area features a large image of a hand holding a tablet. Overlaid on the right side of this image is a 'Sign In' form with a blue border. The form includes a 'Sign In' title, a username field (placeholder: 'username@email.com'), a password field (placeholder: '*****'), a checkbox for 'I have read and agree to the Terms and Conditions stated above and below', a blue 'Sign In' button, and a 'Need help signing in?' link. Below the form is a 'Don't have an account? Sign up' link. Below the main image is a white box titled 'Some Things To Keep In Mind | User Terms & Conditions' containing three numbered items: 1. Access to U.S. Government information system; 2. Disciplinary action for unauthorized use; 3. Consent to terms of use, including privacy and data handling. The footer contains navigation links: FDA Home, Browser Requirements, Contact Tech Support, FAQ, A to Z Index, Follow FDA, FDA Voice Blog, Privacy, and a 'Powered by CDER Informatics' logo.

NOTE

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/>

Multi – Factor Authentication

Step 9. Click **Send Email**.



Sign In

Email Authentication
(j..o@ABCIndustry.com)

Send email Enter Code

Do not challenge me on this device again

Verify

Sign Out

Step 10. Navigate to your email to receive your authentication code (this email may take a couple of minutes to arrive).

Step 11. You should have received an email similar to the below email.




Multi – Factor Authentication

Step 12. Enter code.

Step 13. Click **Verify**.

Sign In



Email Authentication

(j..o@ABCIndustry.com)

Do not challenge me on this device again

[Sign Out](#)

Review Profile Information and Select Organization

Once you verify your code, you will be directed to the Review Profile Information page. The following steps cover reviewing your profile information.

Step 14. Review that your information is correct, Click **Next**.

Complete Registration

Review Profile Information

Personal Information

To edit Profile Information, please contact FDA CDER Platform Support at [EDM Support](#)

First Name	Middle Name	Last Name	Email	Phone Number	Ext.	Country
John		Smith	John.Smith@ABCIndustry.com	(123) 123-4567	456	United States

NEXT

NOTE

If you would like to make any changes to your profile information, please contact CDER Platform Support (EDMSupport@fda.hhs.gov) for assistance.

Review Profile Information and Select Organization

Step 15. Verify your organization affiliation and ensure it is correct, click **Save and Continue**.

Complete Registration

Organization Information

Organization Selection

Existing organization you are affiliated with

Company Name	Company Address	DUNS
ABC Industry	123 DGFH Road, Rockville, MD 20852	0011223344

[Save & Continue](#)

Step 16. Once you have verified your information you will be prompted to log out and log back in.

FDA CDER NextGen Portal

John Smith [Log out](#)

Your information has been saved successfully. Please log out and then back in to view your updated information.

If you need immediate assistance, please contact CDER Platform Support at EDMSupport@fda.hhs.gov

Review Profile Information and Select Organization

Step 17. Once you log back in, you will land on the portal home page.

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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

John.Smith@ABCIndustry.com

.....

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

Sign In

[Need help signing in?](#)

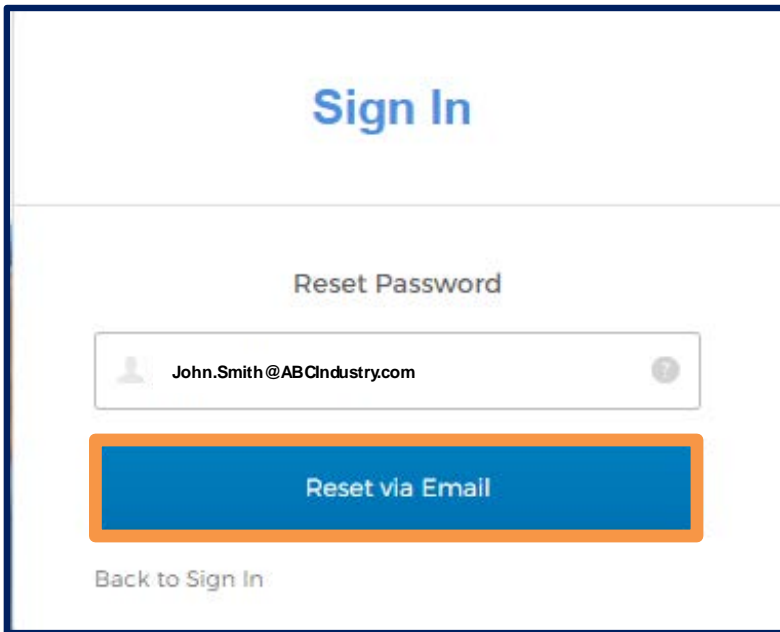
Forgot password?

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”.



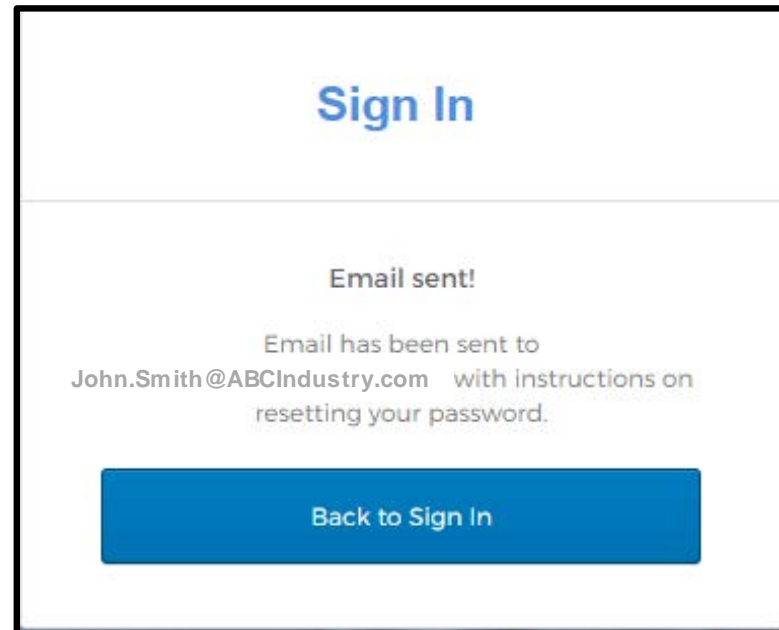
Sign In

Reset Password

John.Smith@ABCIndustry.com

Reset via Email

Back to Sign In



Sign In

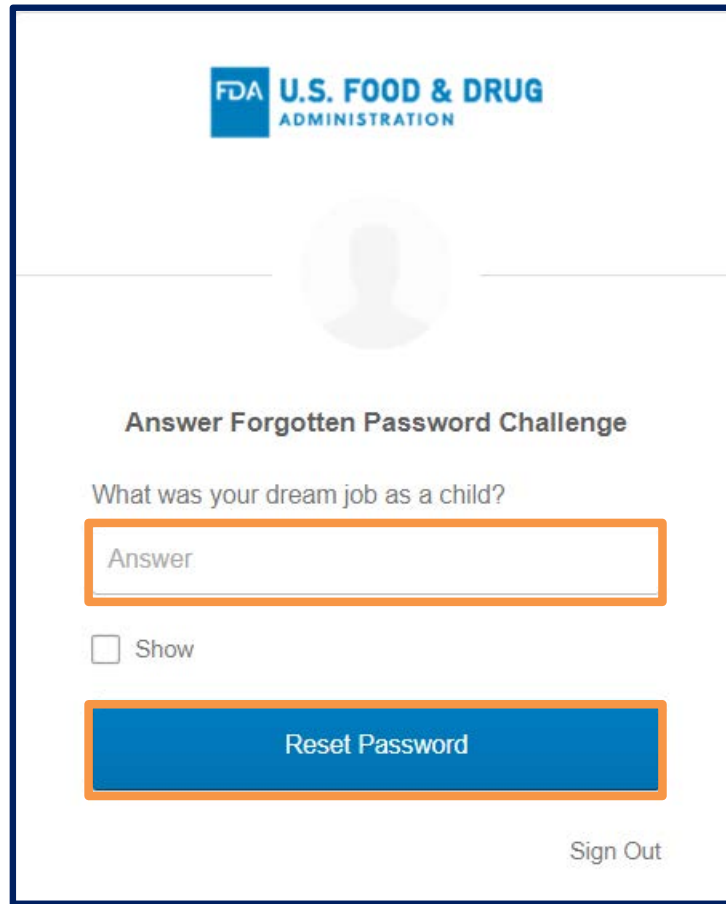
Email sent!

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

Back to Sign In

Resetting your Password

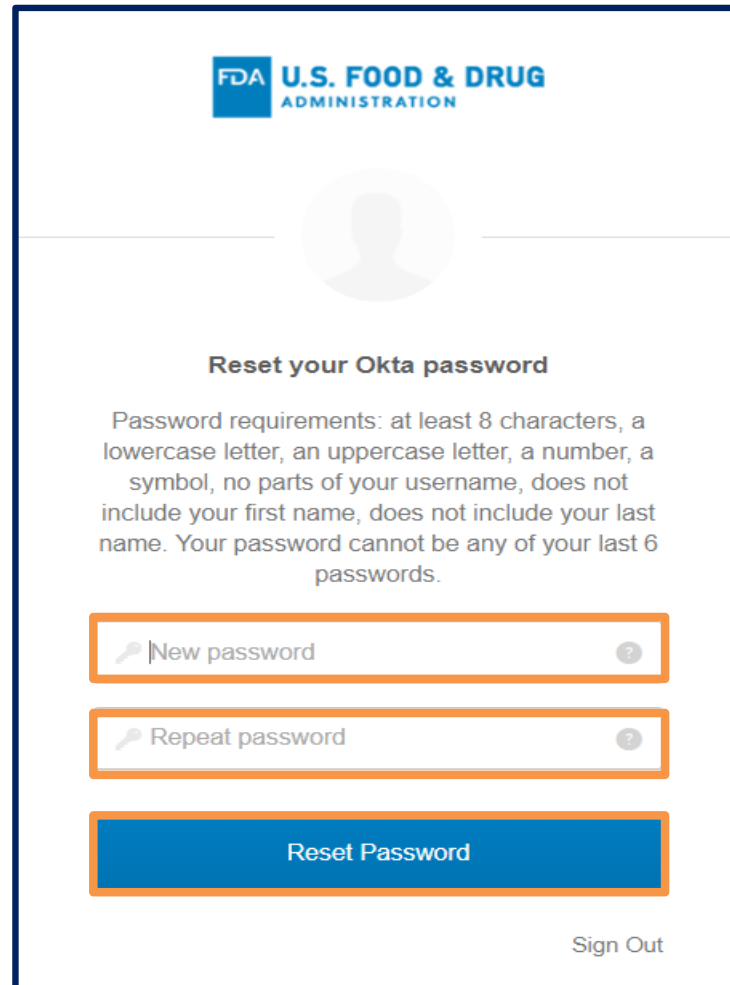
Step 4. The Password Reset email will have a link to access your security questions. Once you click the link, answer the security question then click **“Reset Password”**.



The screenshot shows a web interface for the FDA U.S. Food & Drug Administration. At the top, the logo consists of a blue square with 'FDA' in white, followed by 'U.S. FOOD & DRUG' in blue and 'ADMINISTRATION' in smaller blue text below it. Below the logo is a grey silhouette of a person's head and shoulders. 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 interface for resetting a password. At the top, the FDA logo and "U.S. FOOD & DRUG ADMINISTRATION" are displayed. Below the logo is a placeholder for a user profile picture. The main heading is "Reset your Okta password". Underneath, there is a paragraph detailing 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 fields is a blue button labeled "Reset Password". At the bottom right of the page, there is a "Sign Out" link.

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.

The screenshot displays the CDER NextGen Portal home page. At the top left, the logo reads "FDA CDER NextGen Portal". The main header area features a background image of hands using a tablet, with the text "Welcome to CDER NextGen Your direct line to the FDA" and a "Learn More" button. On the right side, a "Sign In" form is visible, containing fields for "username@email.com" and a password field with masked characters. Below the fields, there is a disclaimer: "Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subjected to criminal penalties." and a checkbox for "I have read and agree to the Terms and Conditions stated above and below". A blue "Sign In" button is positioned below the checkbox. Underneath the button, it says "Need help signing in?". At the bottom of the sign-in area, there is a link: "Don't have an account? Sign up".

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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”** contains **1-4 minute video clips** on how to complete submissions for events on the portal.