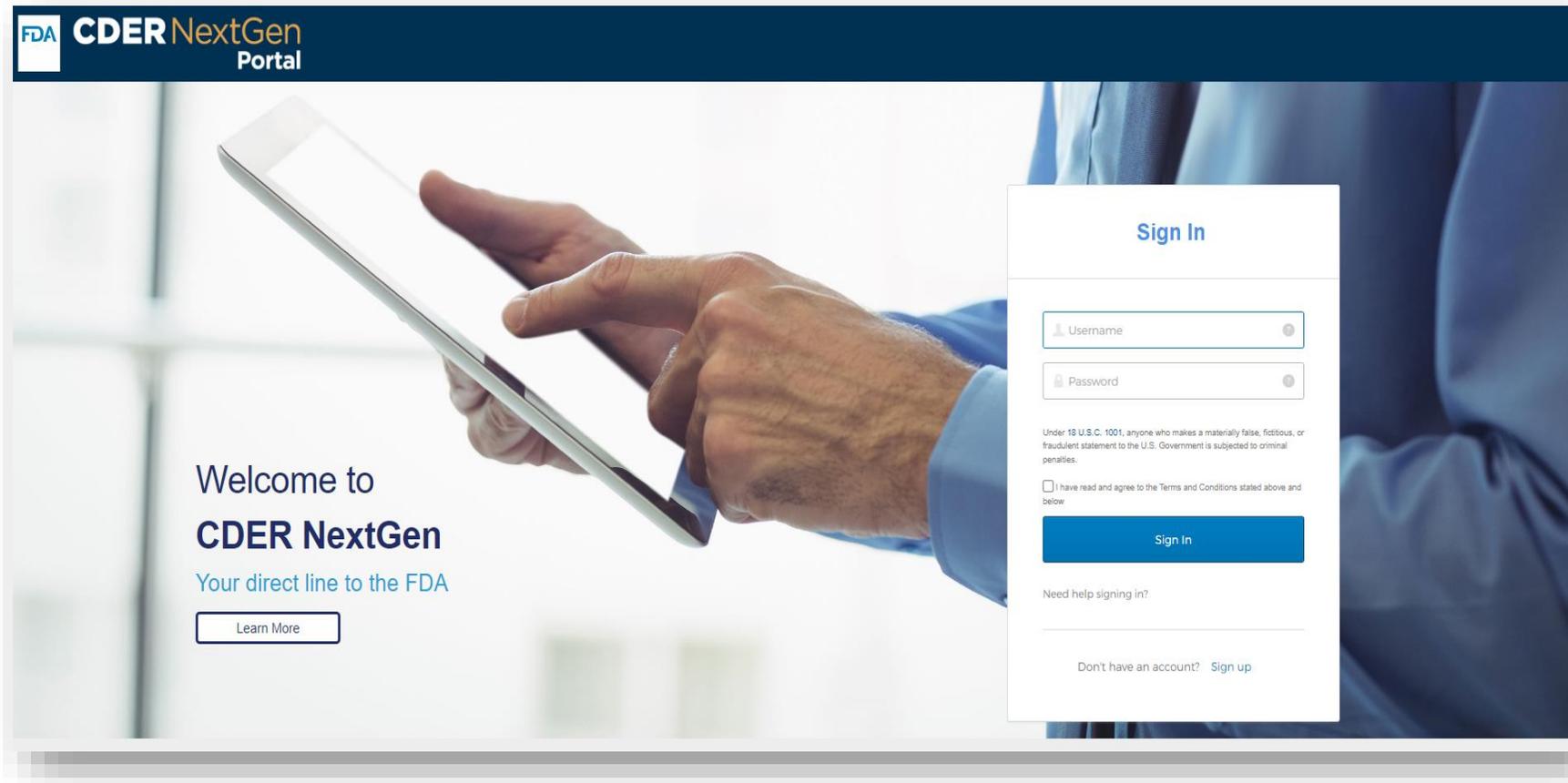


# Reference Guide: CDER NextGen Portal Account Registration

## Welcome to the CDER NextGen Portal

This guide provides the essential information you need to request an account with the CDER NextGen Portal. The sections 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](mailto:edmsupport@fda.hhs.gov).



Click [here](#) to access the CDER NextGen Portal

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User Login	<a href="#"><u>8</u></a>
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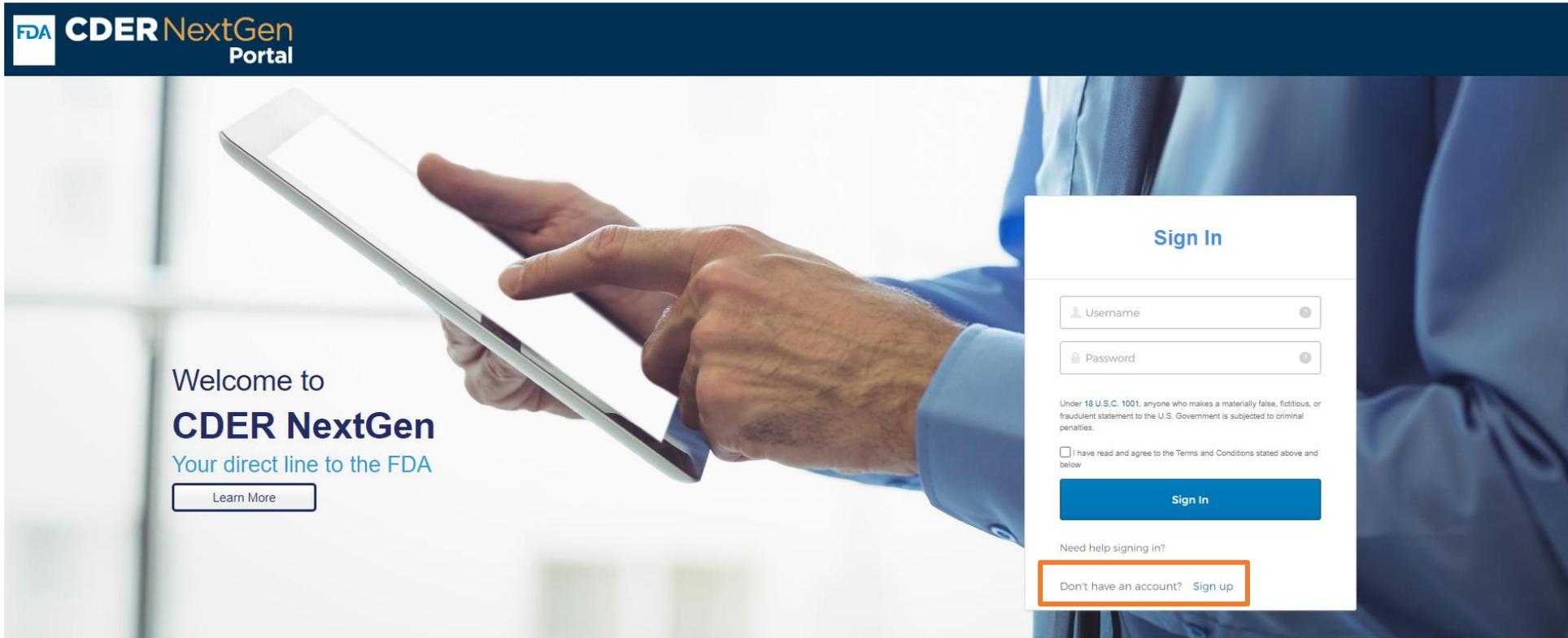
**Requesting a Login**

# 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 browser allows 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 Personal Information: First Name, Last Name, Email Address, Office Phone Number and extension, if applicable.

**Step 4.** Enter your Organization Name and DUNS Number, then click **Search**. **Select** your company from the search.

**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

\* 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 pharmaceuticals). If your organization is not found, please manually enter an organization to continue with the registration process.

Organization Name	Organization Address	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.

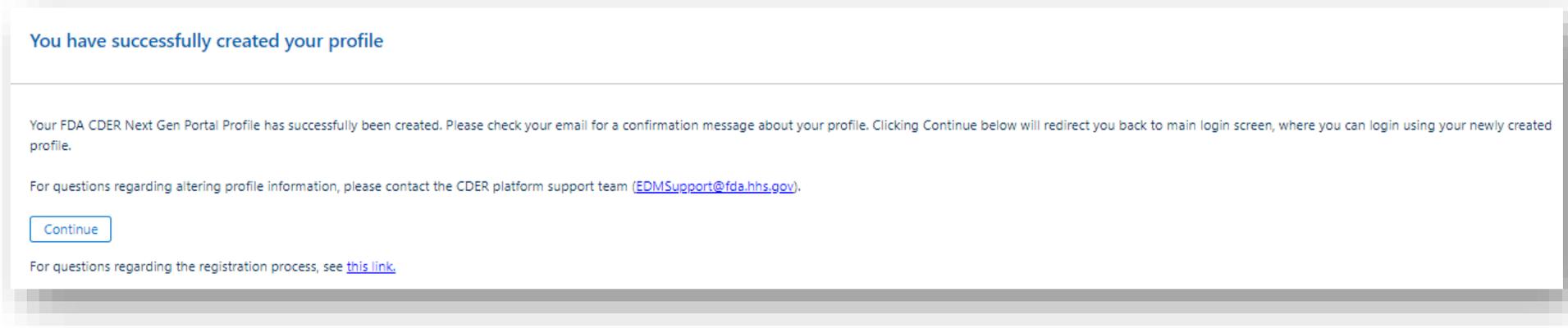
Under section 11, 100, sub-part C, paragraphs (a), (b), (c) and (2) of Title 21 of the Code of Federal regulations, accepting the terms and conditions will require the verification of a person's identity and will be considered legally binding upon the verification.

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

# Register to Create a Login

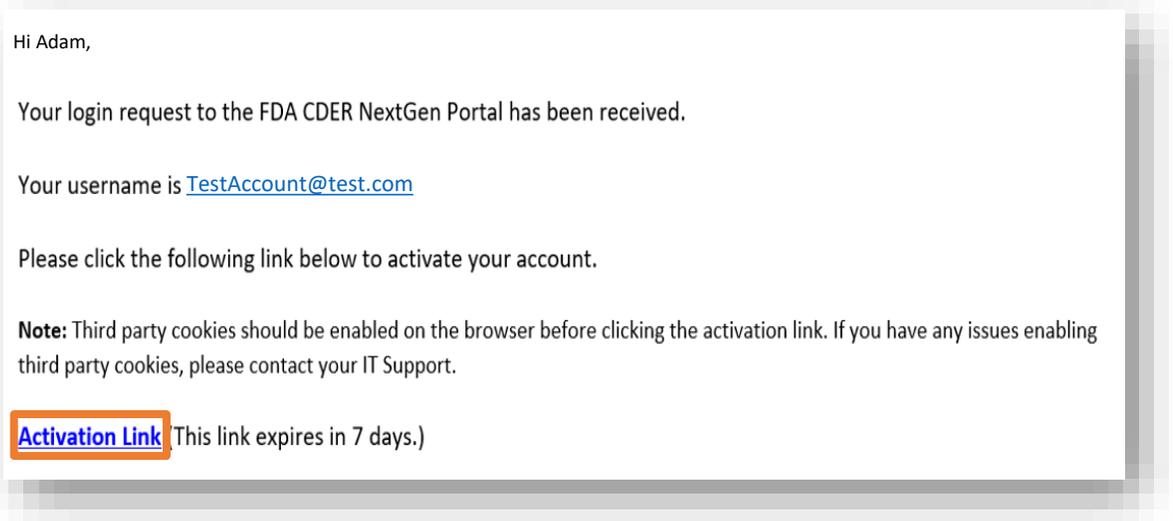
**Step 8.** After clicking Create Account, you will be navigated to a confirmation message stating that your account has been created and that you need to check your email to complete the login request process.

**Step 9.** Once you have received your email, click on the **Activation Link**.



### Multi-Factor Authentication (MFA)

To protect information in your account, the CDER NextGen Portal enforces contextual MFA through your email. Multi-Factor Authentication (MFA) is used as an added layer of security, and you may be prompted for MFA on future login attempts.



# Register to Create a Login

**Step 10.** You will now be able to **Create your Password**, select your **Forgot Password Question** and select a **Security Image**.

Welcome to Department of Health and Human Services - Food and Drug Administration (FDA)  
Create your Department of Health and Human Services - Food and Drug Administration (FDA) 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 Okta, and not a fraudulent website.

**User Login**

# Logging into the CDER NextGen Portal for the First Time

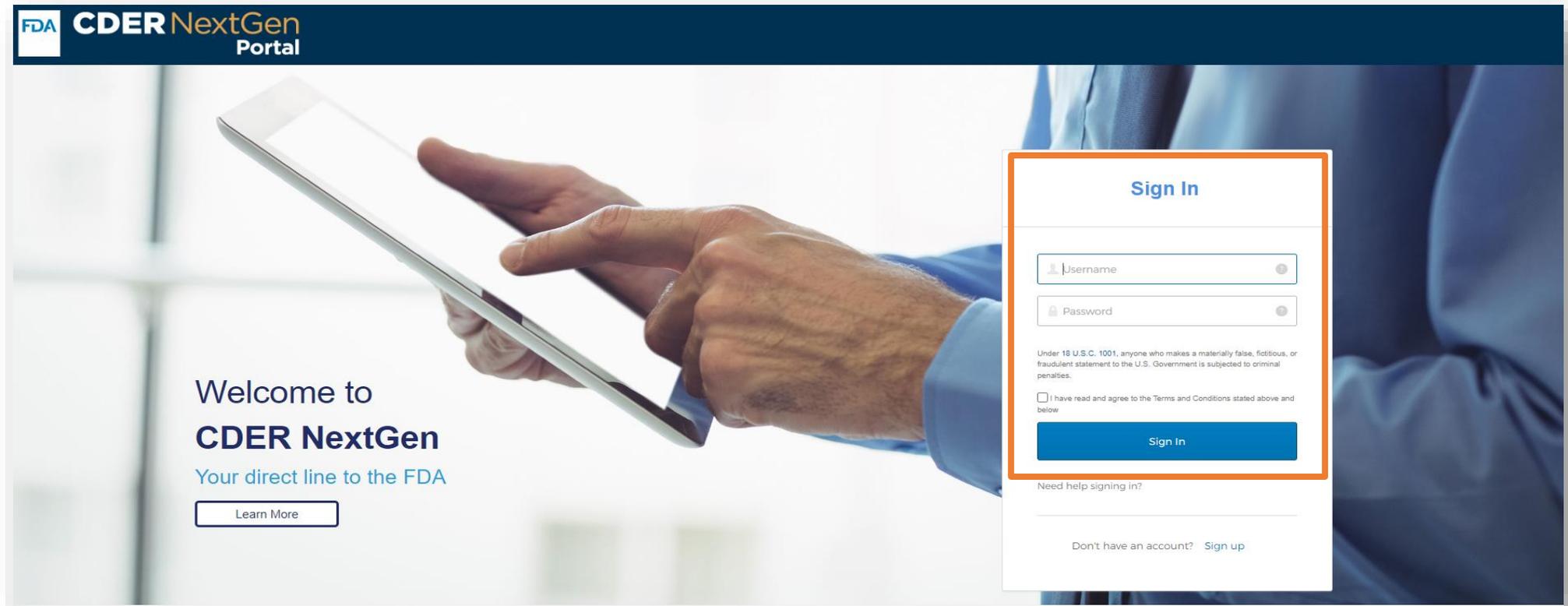
**Step 1.** Navigate to the CDER NextGen Portal by going to: <https://edm.fda.gov>

**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**.



**Step 6.** Once you have logged in, you will land on the CDER NextGen Portal Home Page where you will be able to access use-cases. If you do not see a use-case you're interested in, please contact the specific Office to gain access.

CDER NextGen Portal

Log Out

Welcome, Test!

ALL

**CARES Act Amount Information Reporting**

Submit information on the amount of listed drugs and biological products under section 510(j)(3) of the FD&C Act (as added by Coronavirus Aid, Relief, and Economic Security Act)

**CDER Drug Shortage Potential Impact Outreach**

Submit a response to a potential shortage impact outreach message sent by FDA to support emergency potential shortage notifications (ex: COVID-19 and other public health emergencies)

**Controlled Correspondence**

Submit correspondence to the Agency, requesting information on a specific element of generic drug product development.

**Drug Development Tool**

The Drug Development Tool (DDT) Qualification Program was created to bridge the gap between knowledge and clinical applications. These tools allow sponsors to use DDT in the qualified context and in an IND and NDA/BLA submission without requesting that the relevant CDER review group reconsider and reconfirm the suitability of the tool.

ANNOUNCEMENTS

**CDER NextGen Portal June Comprehensive Code Release**

June 24, 2022 at 05:00 PM

The CDER NextGen Portal will be undergoing maintenance actions in Production starting at 5:00 PM ET (Friday, June 24, 2022) and ending at 11:59 PM ET (Sunday, June 26, 2022). During this time, users will be unable to make submissions in the Portal. If there are any questions, please submit any inquiries to CDER Platform Support team at [edmsupport@fda.hhs.gov](mailto:edmsupport@fda.hhs.gov).

## Password Reset

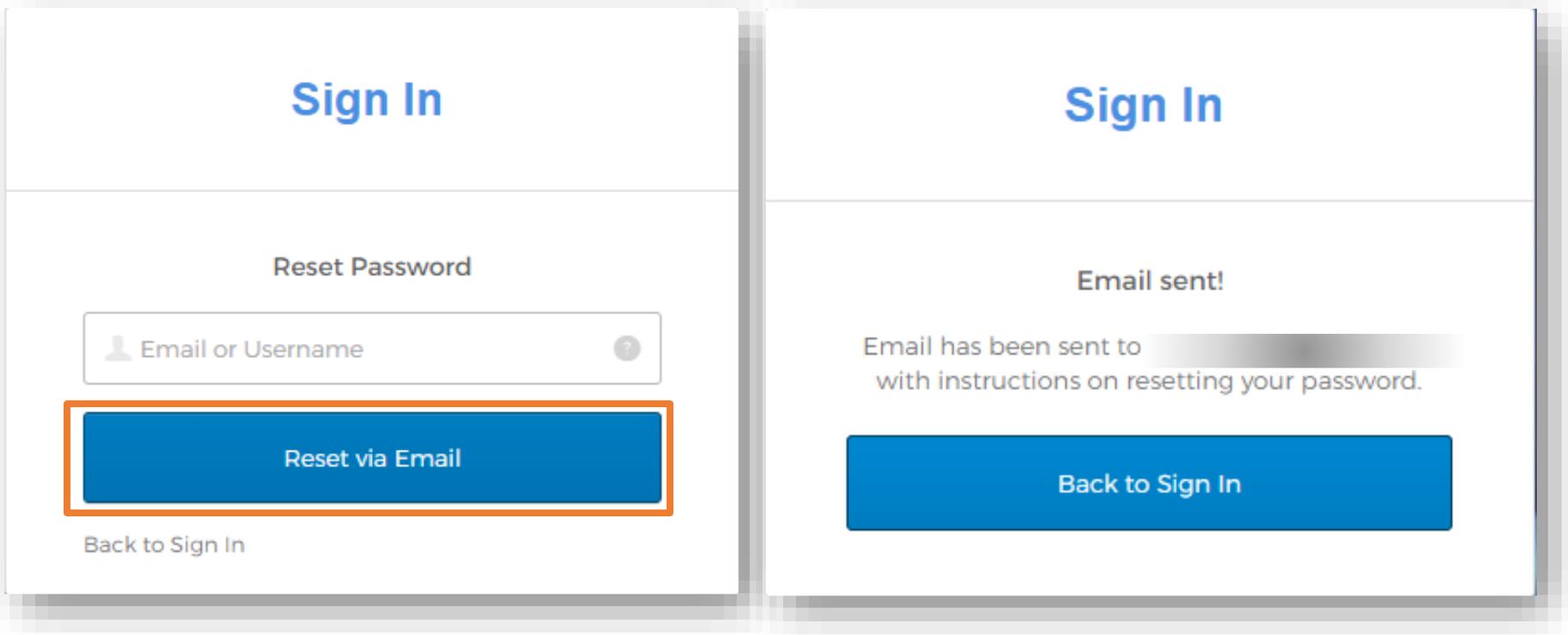
# Resetting your Password

**Step 1.** Navigate to <https://edm.fda.gov> to access the 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?".



**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”.



**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”**.

FDA U.S. FOOD & DRUG ADMINISTRATION

**Answer Forgotten Password Challenge**

What was your dream job as a child?

Show

[Sign Out](#)

**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.

**FDA U.S. FOOD & DRUG ADMINISTRATION**

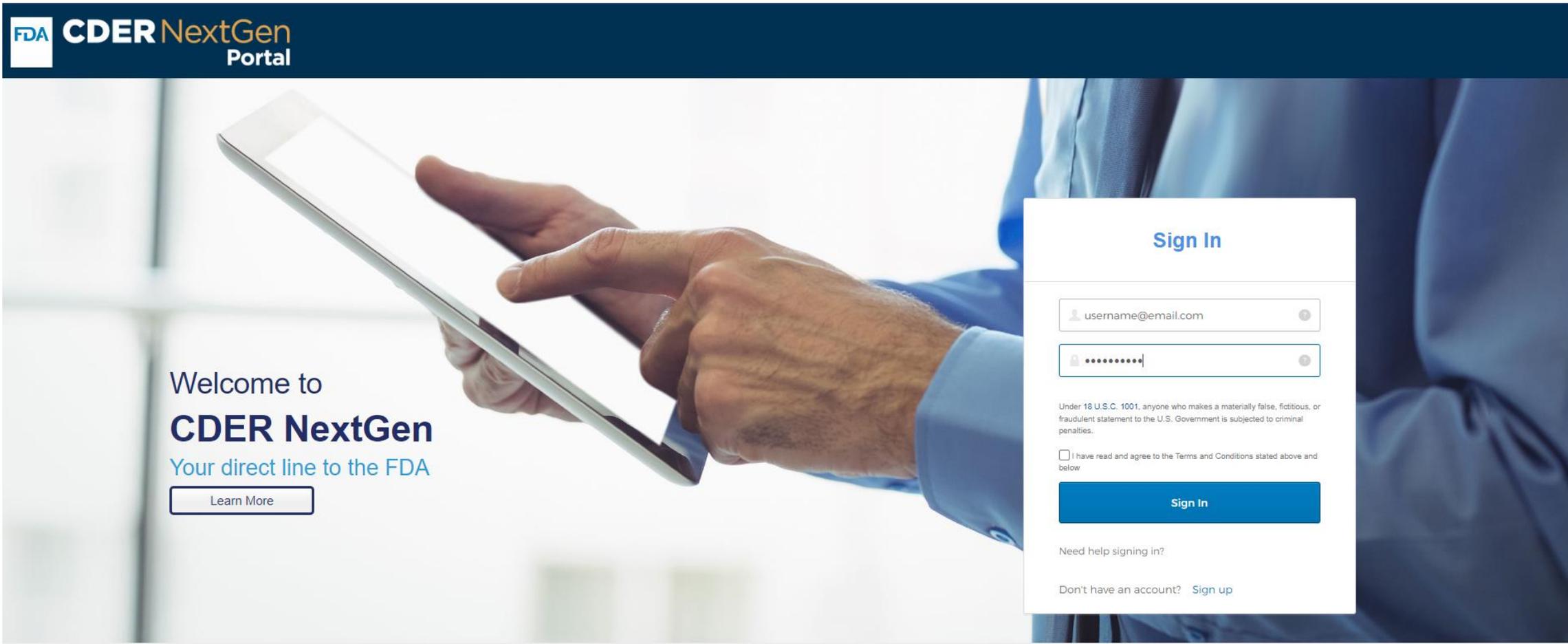
**Reset your Okta password**

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.

**Reset Password**

[Sign Out](#)

**Step 6.** After resetting your new password, you will be navigated to the CDER NextGen Portal Home Page where you will login with your new password.



**Technical Support**

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

### CDER NextGen Portal Announcements

Your CDER NextGen Portal Home Page contains **Portal announcements**, so users are always in the know.



### Learn More Information

Everything related to the CDER NextGen 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](mailto:EDMSupport@fda.hhs.gov).

### CDER NextGen Portal Training Videos

The **“Training Videos”** contains **1-4 minute video clips** on how to complete submissions for events on the CDER NextGen Portal.