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

https://edm.fda.gov/

CDER
INFORMATICS

Table of Contents

CDER
INFORMATICS

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.
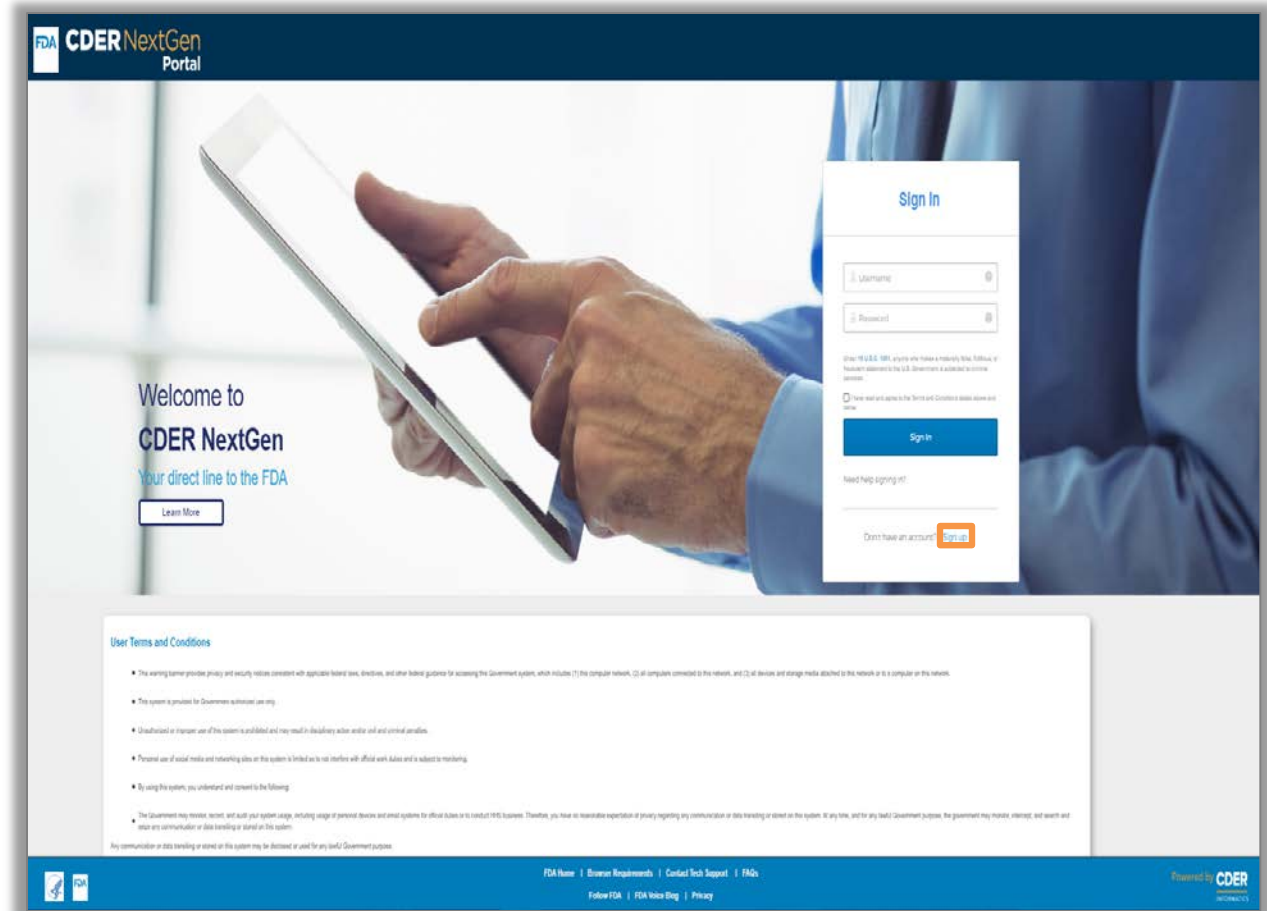
Register to create a Login

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**.

CDER
INFORMATICS

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/.

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.
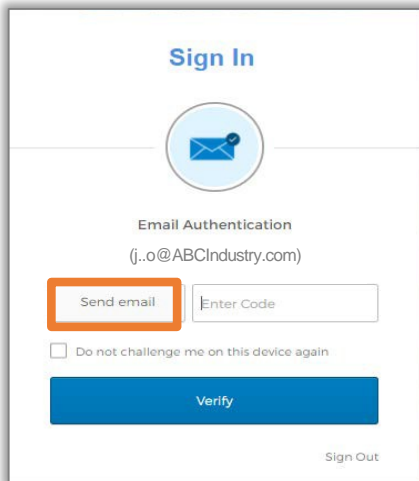
Step 5. Click **Sign In**.

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).

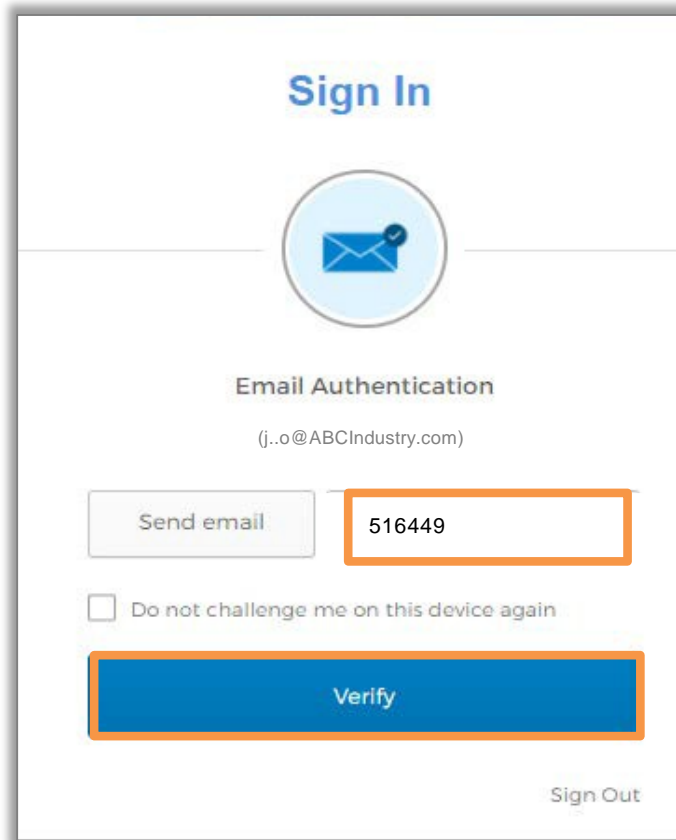**Step 8.** You should have received an email similar to the below email.

Multi – Factor Authentication

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

Step 10. Click **Verify.**

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?".

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".

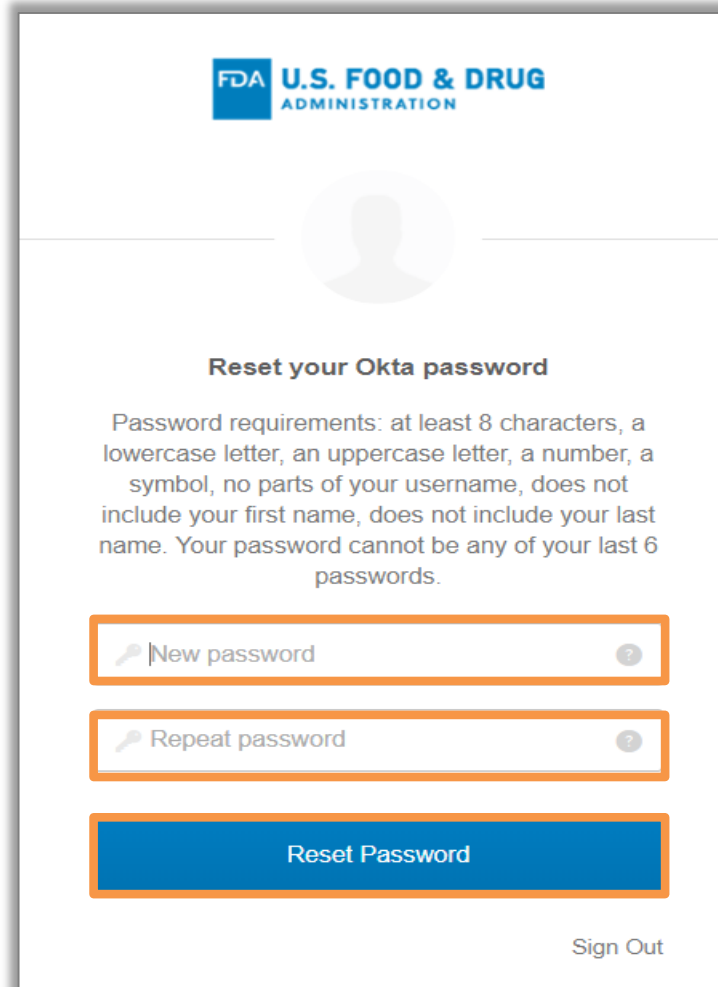# Resetting your Password

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**".

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.

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.

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.

CDER
INFORMATICS