FDA CDER NextGen Portal

NEW: Research IND and Alternate Submission Events

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CDER | US FDA

SBIA Webinar – May 2020

AGENDA

- Electronic Submission Paths to CDER
- Introduction to CDER's NextGen Portal
- What's New?
- How to sign up
- Support
- Demo

ELECTRONIC SUBMISSION PATHS TO CDER

CDER NextGen
(CDER Only except for DDT)

- Drug Shortage Notifications
- Non-eCTD submission to DMF Type III, Research IND
- Non-eCTD submission to application granted eCTD Waiver
- Pre-ANDA Meetings
- GDUFA II Program User Fees
- Controlled Correspondence
- Drug Development Tools (DDT)
- Request an Application Number
- Non-eCTD submission of Medical Gas, Promotional Material, EUA, or Presubmission

ESG (All Centers)

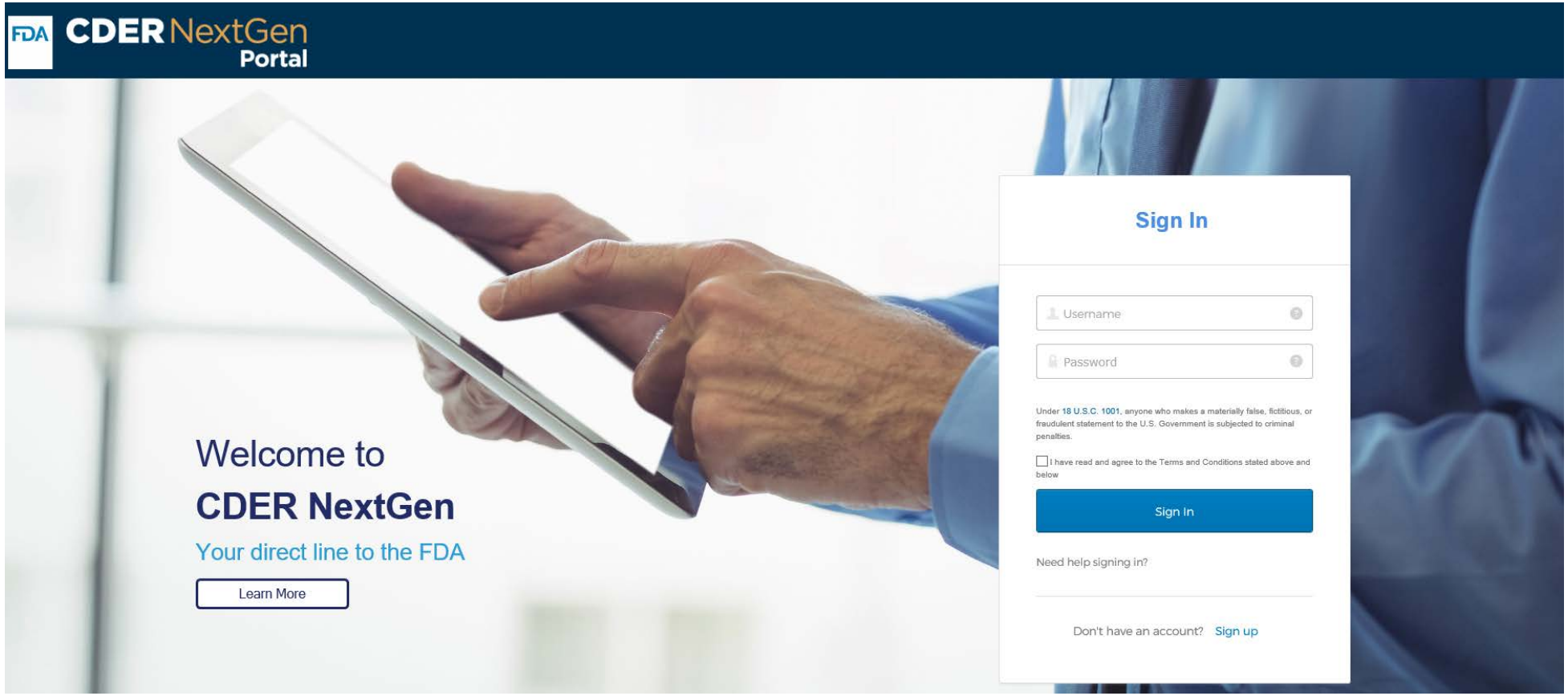
- eCTD submission to NDA, BLA, ANDA, IND, DMF applications
- Non-eCTD submission to DMF Type III, Research IND
- Non-eCTD submission to application granted eCTD Waiver
- E2B Postmarket Safety Reports (submitting to FAERS)
- SPL Submissions

CDER Direct (CDER Only), SPL Submissions

- NDC Labeler Code Requests
- Product Listing and Reporting
- Establishment Registrations and annual updates
- GDUFA Facility Self-ID Product Listing
- 503 Outsourcing Facility – registration and product reporting
- Wholesale Drug Distributors and Third Party Logistic Providers (WDD/3PL)

CDER's NextGen PORTAL

The CDER NextGen **Collaboration Portal** is a **cloud-based** system that has enabled a transformation in the way CDER and industry work together.



WHAT HAVE WE ALREADY DONE, AND WHAT IS NEW?

WHAT IS RESEARCH IND IN CDER NEXTGEN?

What's New: FDA recently added a new event in the CDER NextGen Portal for submission of Research INDs

Target Audience: Sponsors who currently submit Research INDs in paper (non-eCTD)*

Benefits of CDER NextGen:
https://www.fda.gov/media/136301/download

*This is for Research INDs only. Commercial INDs must be in eCTD and may not use the CDER NextGen Portal unless granted an eCTD waiver. See *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications Guidance for Industry* (eCTD Guidance) for more information.

RESEARCH IND SUBMISSION METRICS

CDER has seen an increase in electronic submission of Research INDs via CDER NextGen Portal, resulting in less paper.

	2020			
Research IND counts (standardized)	**March**		**April**	
	Count	% of total	Count	% of total
Paper	969	62%	384	25%
CDER NextGen Portal	225	15%	735	48%
ESG	357	23%	408	27%
Total	**1,551**	**100%**	**1,527**	**100%**

WHAT IS ALTERNATE SUBMISSION IN CDER NEXTGEN?

What's New: FDA recently added a new event in the CDER NextGen Portal for submissions not required in eCTD

Target Audience: Sponsors who currently submit the following in paper (non-eCTD)

- EUAs
- DMF Type III
- Marketing and Advertising
- Pre-submissions (Not for rolling submissions. Submitting content to a drug or biologics license application must follow the eCTD guidance)
- Medical Gas
- Applications which received a waiver from the eCTD Guidance

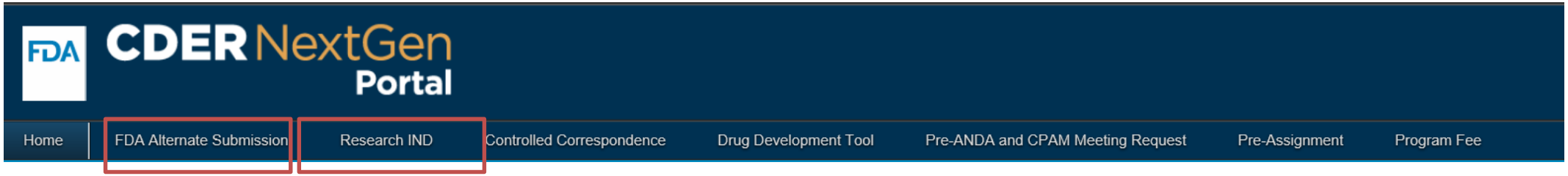
The goal is to provide a way for industry to send submissions (*applies only to submissions not required in eCTD**) without the need for paper or electronic media (i.e. hard drive, DVD).

*FDA eCTD Guidance: https://www.fda.gov/media/135373/download

HOW DO I GAIN ACCESS TO THE PORTAL?

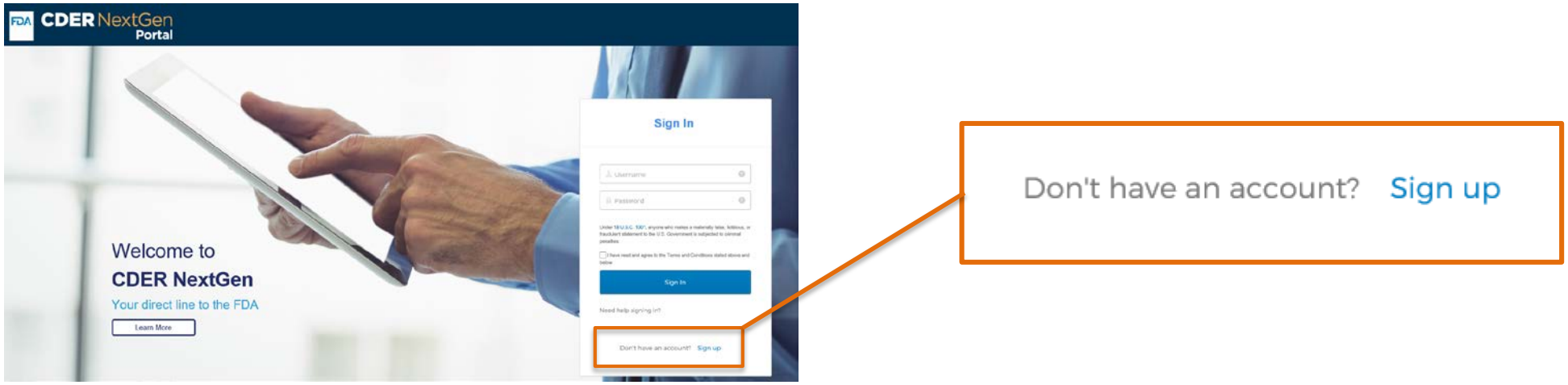
Existing Portal Users

Research IND and Alternate Submission tabs were added to your account automatically – click on it when you are ready to submit



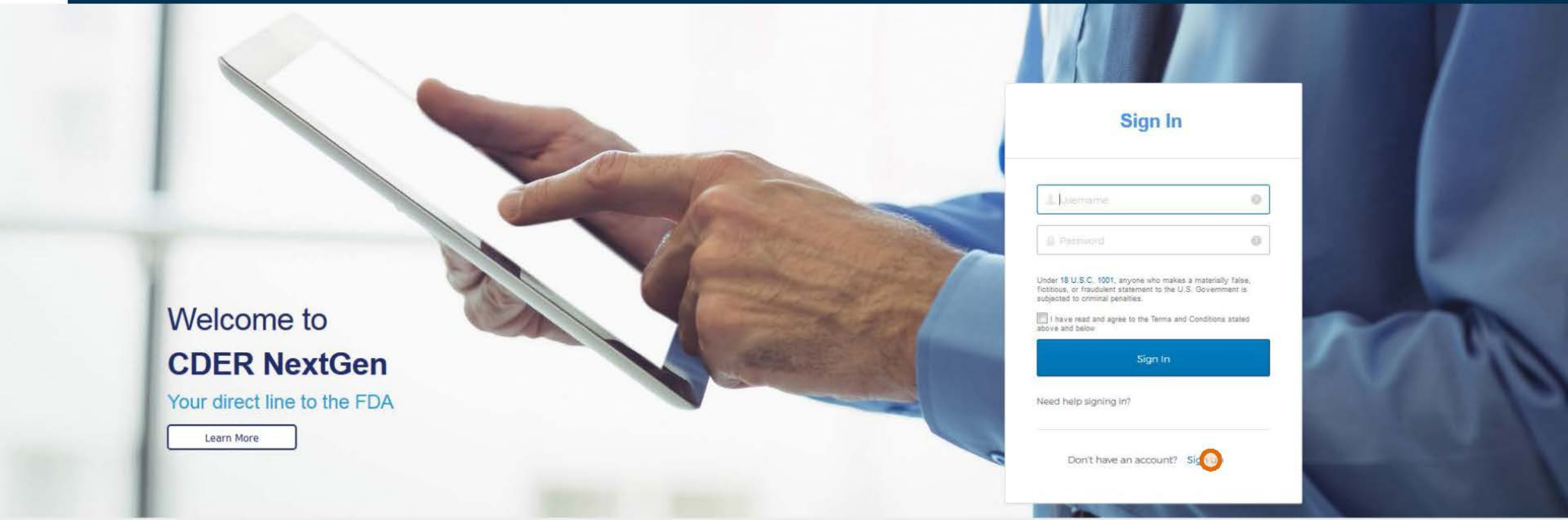
New Users

To register for an account with the CDER NextGen Portal, navigate to https://edm.fda.gov and follow the signup instructions



U.S. FOOD & D UG ADMINISTRATION

User Registration



User Terms and Conditions

1. You are accessing a U.S. Government information system. This information system is provided for U.S. Government-authorized use only.
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.

Contact Information

First Name * John

Middle Name

Last Name * Smith

Email * jsmith@gmail.com

Confirm Email * jsmith@gmail.com

Country * United States

Country Code +1

Phone Number * 1235554567

Ext.

Fields marked with * are required fields.

Terms & 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.**

Cancel Submit

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)

OK

Activation Email

DEPARTMENT OF HEALTH AND HUMAN SERVICES

U.S. FOOD & DRUG ADMINISTRATION

Food and Drug Administration
Silver Spring, MD, 20993

Hi JOHN,

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

Your username is jsmith@gmail.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

** Please do not reply directly to this message. This is an automatically generated email and replies will not be monitored. **

U.S. FOOD & DRUG ADMINISTRATION

Welcome to Department of Health and Human Services - Food and Drug Administration (FDA)-Production, Adarsh!

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 your favorite security question?

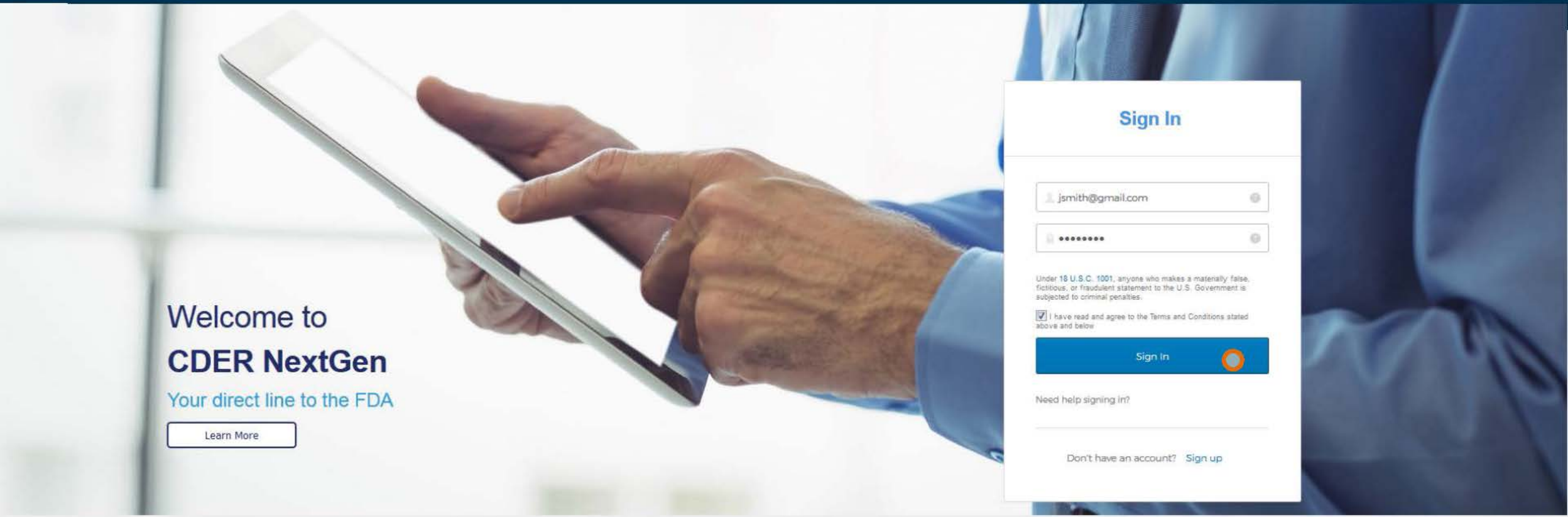
Answer

test

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.

Create My Acco



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   - Any communication or data transiting or stored on this information system may be disclosed or used for any lawful Government purpose.

Authentication Code

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Hi JOHN,

You are receiving this email because a request was made for a one-time authentication code. If you did not make this request, please contact FDA CDER Platform Support immediately.

Please enter the following code for verification.

058136

For technical support, contact the FDA CDER Platform Support Team at EDMSupport@fda.hhs.gov

**** Please do not reply directly to this message. This is an automatically generated email and replies will not be monitored. ****

FDA U.S. FOOD & DRUG ADMINISTRATION

Email Authentication

(a...l@gmail.com)

Enter Code

058136

Sent

Do not challenge me on this device again

Verify

Sign Out

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	JSMITH@GMAIL.COM	1235554567		US

NEXT

Complete Registration

Organization Information

Organization Selection

Select the organization you are affiliated with

Company Name:

Private Firm

DUNS:

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

Search

No Results Found

Enter Organization Manually

Complete Registration

Organization Information

Organization Selection

Select the organization you are affiliated with

Company Name: Private Firm

DUNS:

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

Search

Manually Enter Organization

* Company Name: Private Firm Name

* Country: United States

* State: Maryland

* Address Line 1: 123 Main Street

Address Line 2:

* City: Capitol

* Zip Code/Postal Code: 12345

* DUNS: 999999999

Allowable format: Nine Digit Numeric code (i.e 123456789) if N/A then type 999999999

Add Organization | Cancel

Complete Registration

Organization Information

Organization Selection

Select the organization you are affiliated with

Company Name: Private Firm

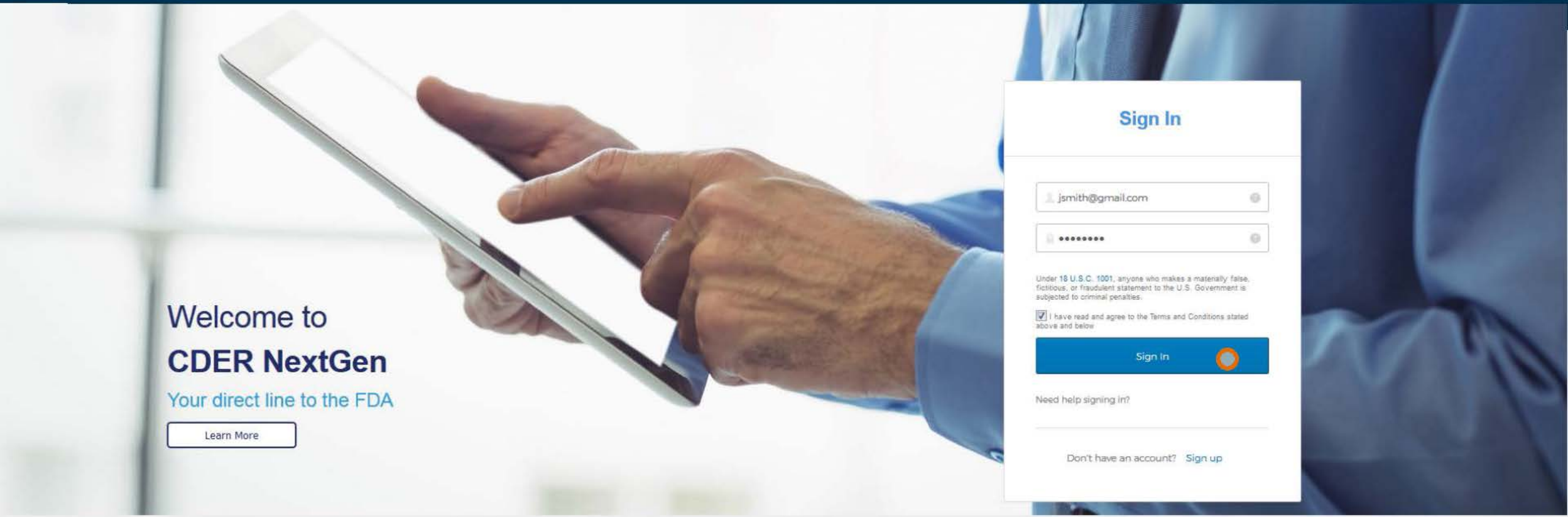
DUNS:

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

Search

Organization Name	Full Address	DUNS
Private Firm Name	123 Main Street, Capitol, MD, US, 12345	999999999

Save & Continue | Remove Organization



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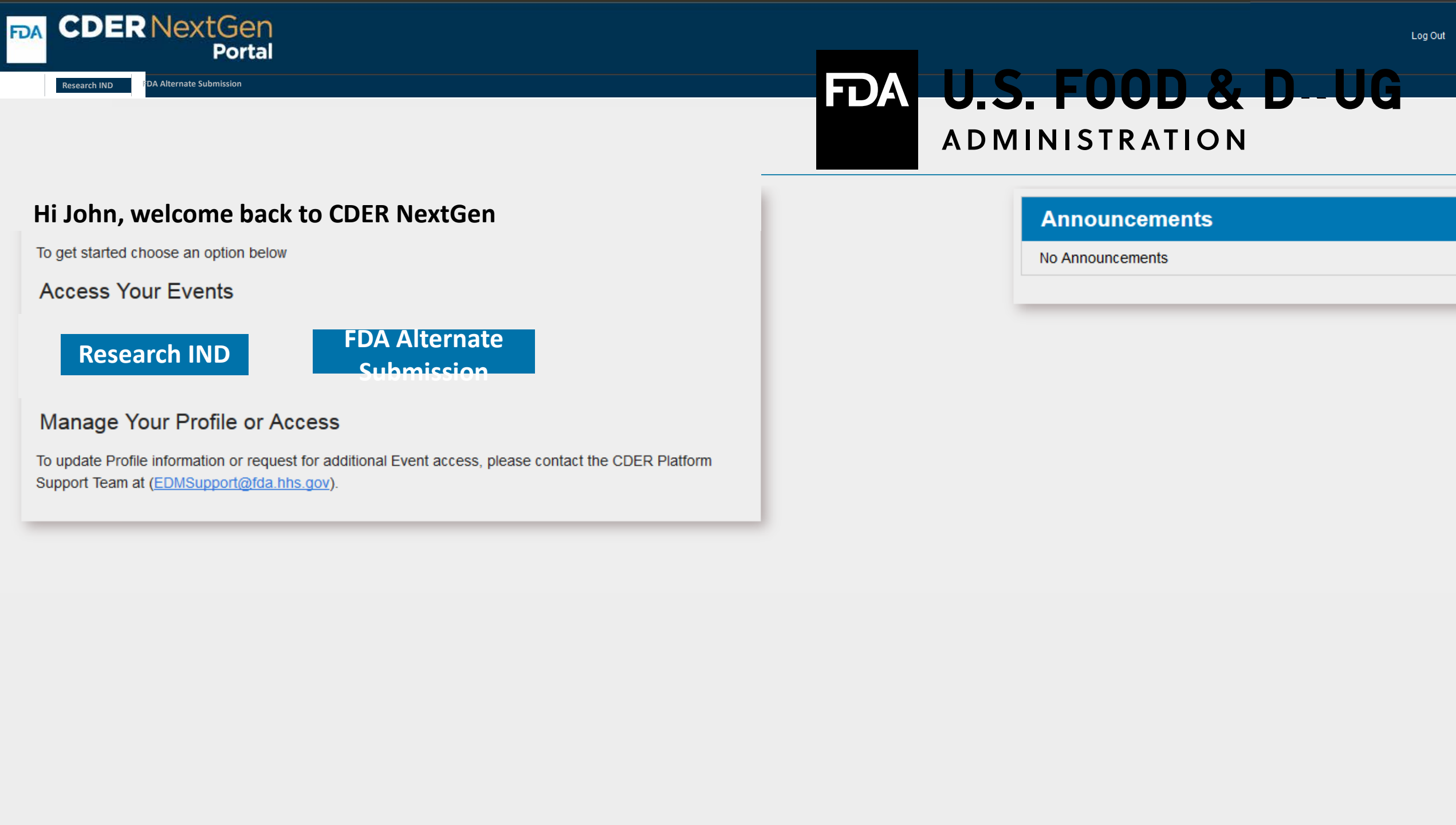
FDA
CDER NextGen Portal
Log Out
Research IND
FDA Alternate Submission
FDA
U.S. FOOD & D--UG
ADMINISTRATION
Hi John, welcome back to CDER NextGen
To get started choose an option below
Access Your Events
Research IND
FDA Alternate Submission
Manage Your Profile or Access
To update Profile information or request for additional Event access, please contact the CDER Platform Support Team at (EDMSupport@fda.hhs.gov).
Announcements
No Announcements

NEED SUPPORT?

- Research IND User Guides (login required)
- Alternate Submission User Guides (login required)
- User Registration Guides
- General FAQs

CDER NextGen Help Desk: edmsupport@fda.hhs.gov

General Questions on CDER Electronic Submissions: esub@fda.hhs.gov