DRUG ENFORCEMENT ADMINISTRATION

3rd Annual Supply Chain Conference

Regulatory Presentation
Orlando, Florida

April 1 – April 3, 2025

Ricardo Quintero, Section Chief, Regulatory (DRG), Presenter

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Persons Required to Register

Law: 21 USC § 822 (a)(1) states:

Every person who manufactures or distributes any controlled substance or List 1(L1) chemical…shall obtain a registration annually.

Why the name 303?

On October 27, 1970, Section 303 was passed into law by Congress and placed in 21 USC § 823

"303" was the number used by Congress to track the legislation; hence the terms:

- **Section 303 Investigations**
- **Section 303 Registrants**
- **Section 303 Applications**

Registrations Specific to the 303 Process

- **Bulk Manufacturers: Only Schedule I and II controlled substances for which "bulk" status is requested**

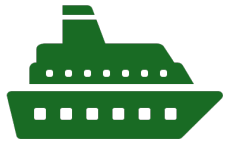
- **Importers: All Schedule I and II controlled substances**

Importers 21 USC § 952 (a)(2)

Registrations

DEA grants Import registrations for the importation of CI & CII controlled substances *to "provide for the medical, scientific, or other legitimate needs of the United States."*

If there is currently a sufficient domestic supply of any given CI or CII controlled substance, requests to import that controlled substance may be denied.



Importation

Importation is authorized only for domestic use in the United States.

An importer may **NOT** import CI or CII controlled substance for the purpose of exporting it.

Bulk Manufacture 21 USC § 802(15)

Definition

Bulk Manufacture: The production, preparation, propagation, compounding, or processing of a drug or other substances, either directly or indirectly or by extraction from substances of natural origin, or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis.

In Plain English

The creation of a controlled substance = Bulk Manufacturing

The created controlled substance is used for the preparation of saleable dosage units.

Synthesize: Produces controlled substance raw materials from basic chemicals

Extract: Derives a drug from an organic source.

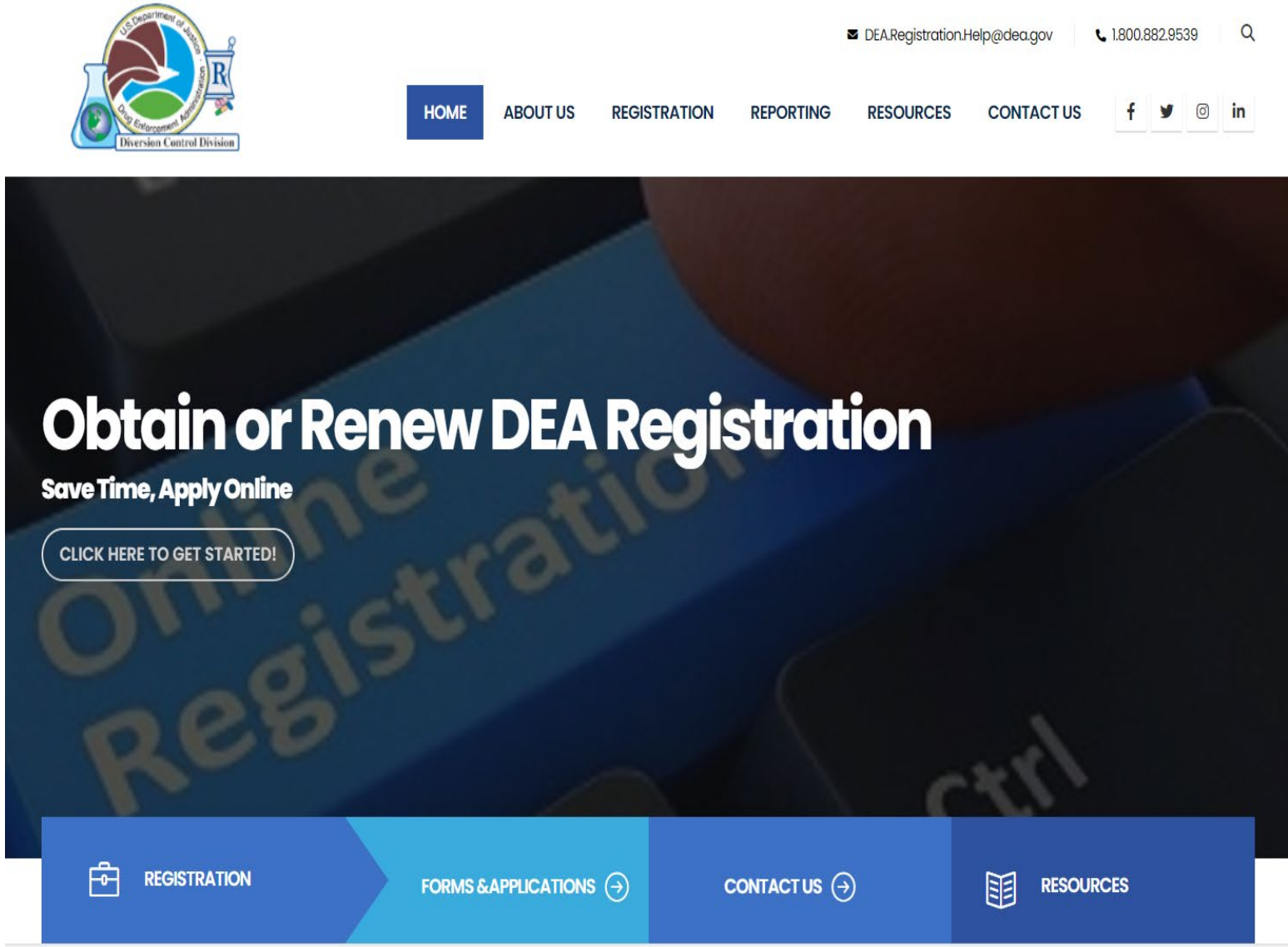
Most *narcotics* are manufactured through extraction. i.e.: Raw opium/cocoa leaves.

The 303 Process: Explained

How is a 303 Initiated?

The 303 Process is initiated upon receipt of the following:

- **New Application for Registration; New Pending**
- **Renewal Application; Renewal Pending**
- **Request to modify a registration; Active Pending (adding of drug codes, updating state license.)**



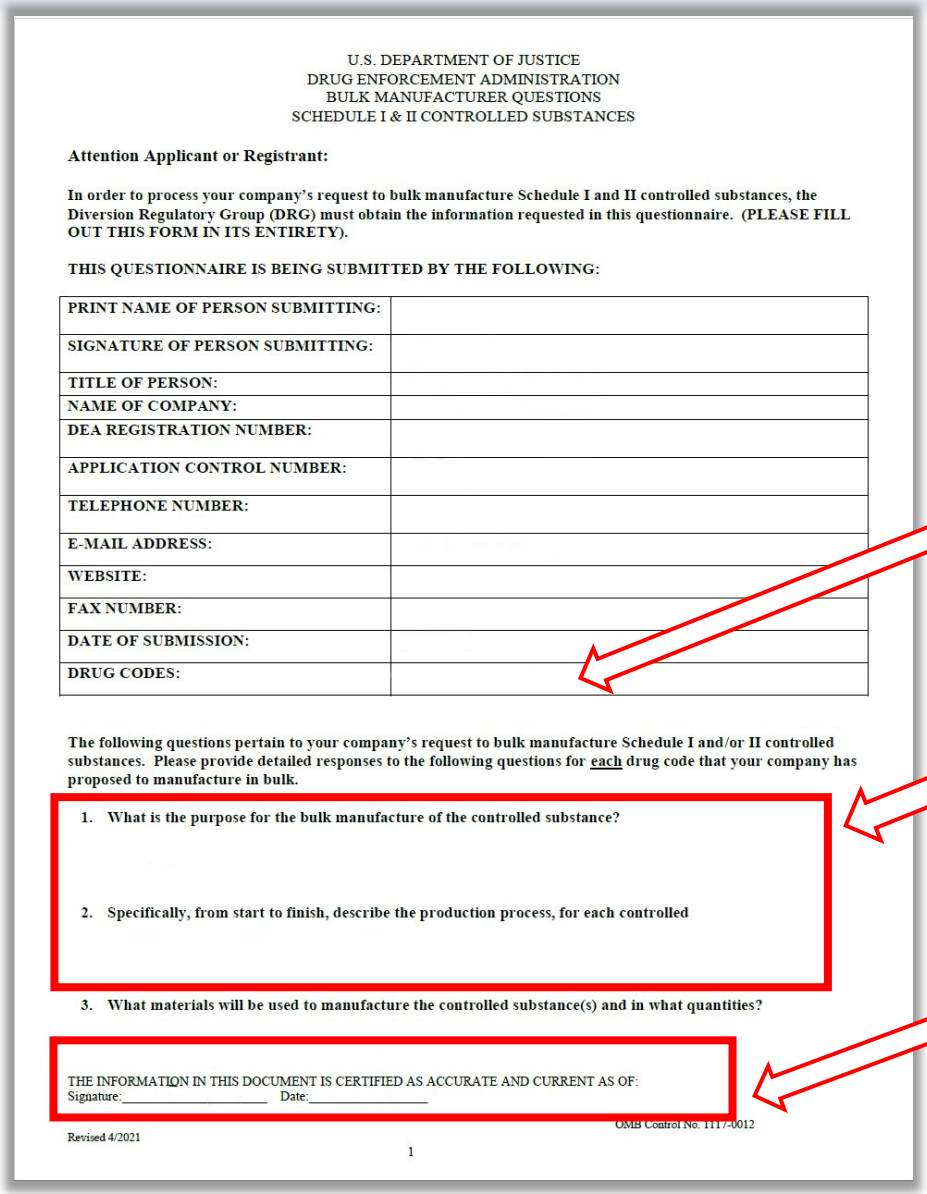
The 303 Process

DRG personnel forward a standardized questionnaire to the applicant to be completed within 10 business days.

Upon receipt of a completed questionnaire, a Notice of Application (NOA) is prepared and forwarded for review and approval by several sections within Diversion Control.

After approval from the Assistant Administrator, the NOA is forwarded to the Federal Register (FR) for publishing.

The 303 Process: The Questionnaire



U.S. DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
BULK MANUFACTURER QUESTIONS
SCHEDULE I & II CONTROLLED SUBSTANCES

Attention Applicant or Registrant:

In order to process your company's request to bulk manufacture Schedule I and II controlled substances, the Diversion Regulatory Group (DRG) must obtain the information requested in this questionnaire. (PLEASE FILL OUT THIS FORM IN ITS ENTIRETY).

THIS QUESTIONNAIRE IS BEING SUBMITTED BY THE FOLLOWING:

PRINT NAME OF PERSON SUBMITTING:	
SIGNATURE OF PERSON SUBMITTING:	
TITLE OF PERSON:	
NAME OF COMPANY:	
DEA REGISTRATION NUMBER:	
APPLICATION CONTROL NUMBER:	
TELEPHONE NUMBER:	
E-MAIL ADDRESS:	
WEBSITE:	
FAX NUMBER:	
DATE OF SUBMISSION:	
DRUG CODES:	

The following questions pertain to your company's request to bulk manufacture Schedule I and/or II controlled substances. Please provide detailed responses to the following questions for each drug code that your company has proposed to manufacture in bulk.

1. **What is the purpose for the bulk manufacture of the controlled substance?**
2. **Specifically, from start to finish, describe the production process, for each controlled**
3. **What materials will be used to manufacture the controlled substance(s) and in what quantities?**

THE INFORMATION IN THIS DOCUMENT IS CERTIFIED AS ACCURATE AND CURRENT AS OF:
Signature:_____ Date:_____

OMB Control No. 1117-0012

Revised 4/2021

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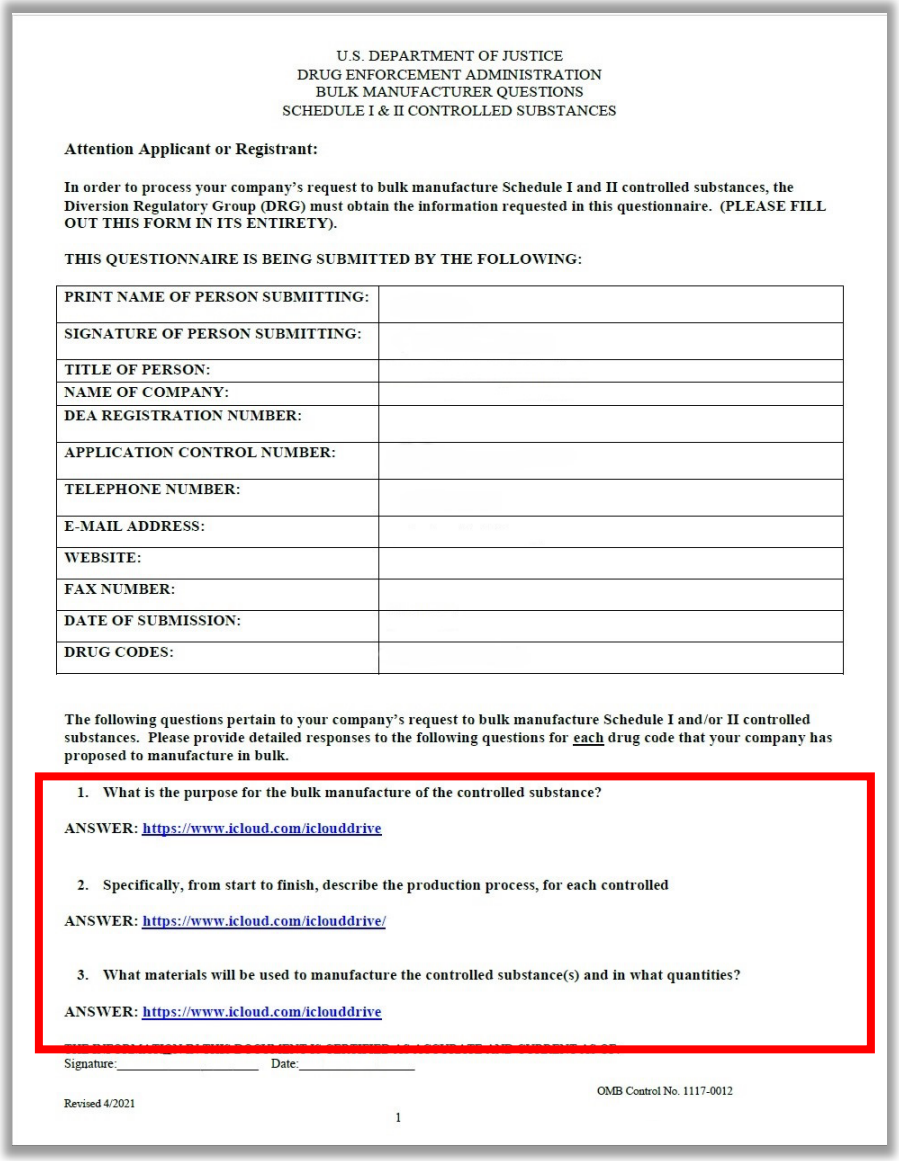
Please complete the questionnaire in its entirety to the best of your ability

- **Schedule I and II drug codes should be listed in the drug codes section preferably, in order by schedule.**
- **These answers impact the verbiage for the NOA drafted by DRG.**
- **Please make sure to sign and date the bottom of each page of the questionnaire.**

The 303 Process: The Questionnaire



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1. **What is the purpose for the bulk manufacture of the controlled substance?**

ANSWER: https://www.icloud.com/iclouddrive

2. **Specifically, from start to finish, describe the production process, for each controlled**

ANSWER: https://www.icloud.com/iclouddrive/

3. **What materials will be used to manufacture the controlled substance(s) and in what quantities?**

ANSWER: https://www.icloud.com/iclouddrive

Signature:_____ Date:_____

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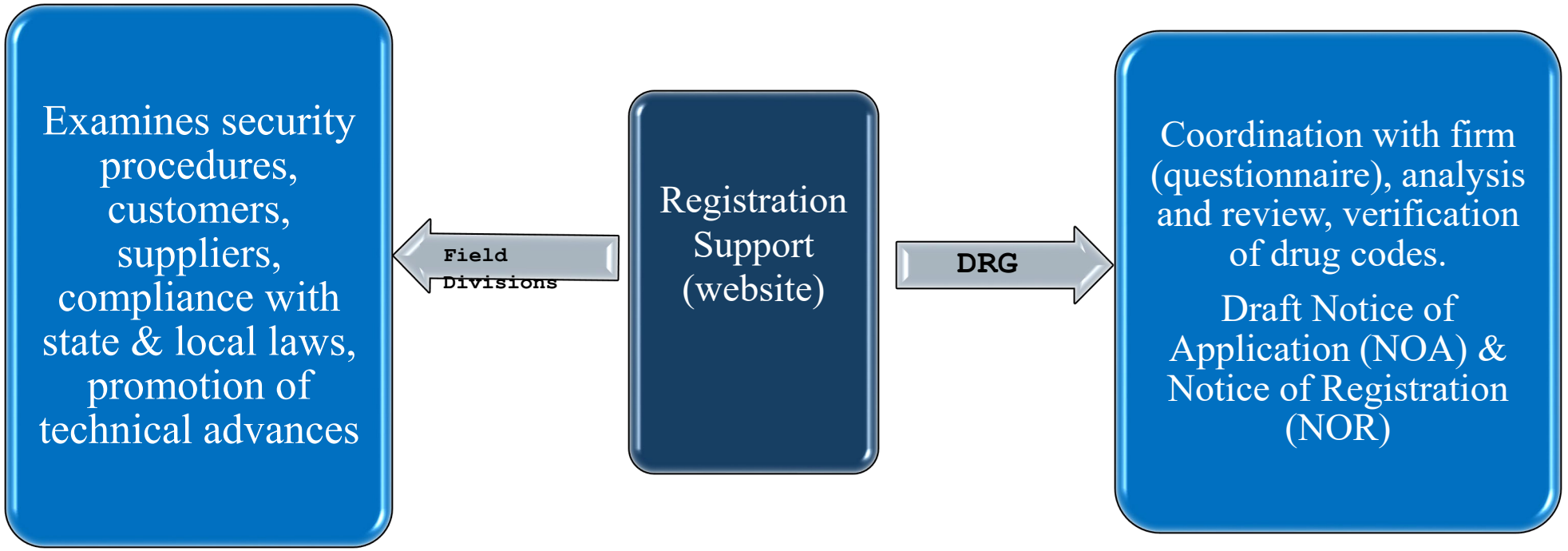
Website links are not permissible answers to questions on the questionnaire.

The 303 Process



Notice of Application (NOA) Workflow

1 Initial Steps

1. Application assigned to PA/SC;
2. Questionnaire emailed to registrant and returned to DRG within 10 days.
3. Once questionnaire is returned to DRG, a NOA is drafted.

Quota (DRQ) Section receives NOA, review, approves and moves to the Regulatory (DRG) Section Chief for review

DRG Section Chief reviews and approves record to send to Document Control Specialist (DCS)

DCS approves record to send to Diversion Executive Assistant

Diversion Executive Assistant approves record to send to Executive Assistant

Executive Assistant approves record to send to Deputy Assistant Administrator (DAA)

Deputy Asst. Administrator approves record to send to Special Assistant

Special Assistant approves to send to Executive Assistant

Executive Assistant approves record forwarded to the Executive Staff Assistant

Executive Staff Assistant provides Asst. Administrator for electronic signature

***If at any point in this cycle a correction, edit, or addition is needed the record will be forwarded back to the assigned staff member in DRG.**

303 Process: Comment Period

The CFR calls for an open comment period during which time other bulk manufacturers or importers of the same basic classes of controlled substances can file comments and objections to the proposed registration.

Open comment period is as follows:

- **Importers: 30 days**
- **Bulk Manufacturers: 60 days**

The comment period starts on the date the NOA is published in the Federal Register (FR).

If there are no comments or objections, we then move to prepare the Notice of Registration (NOR).

Six Public Interests Factors

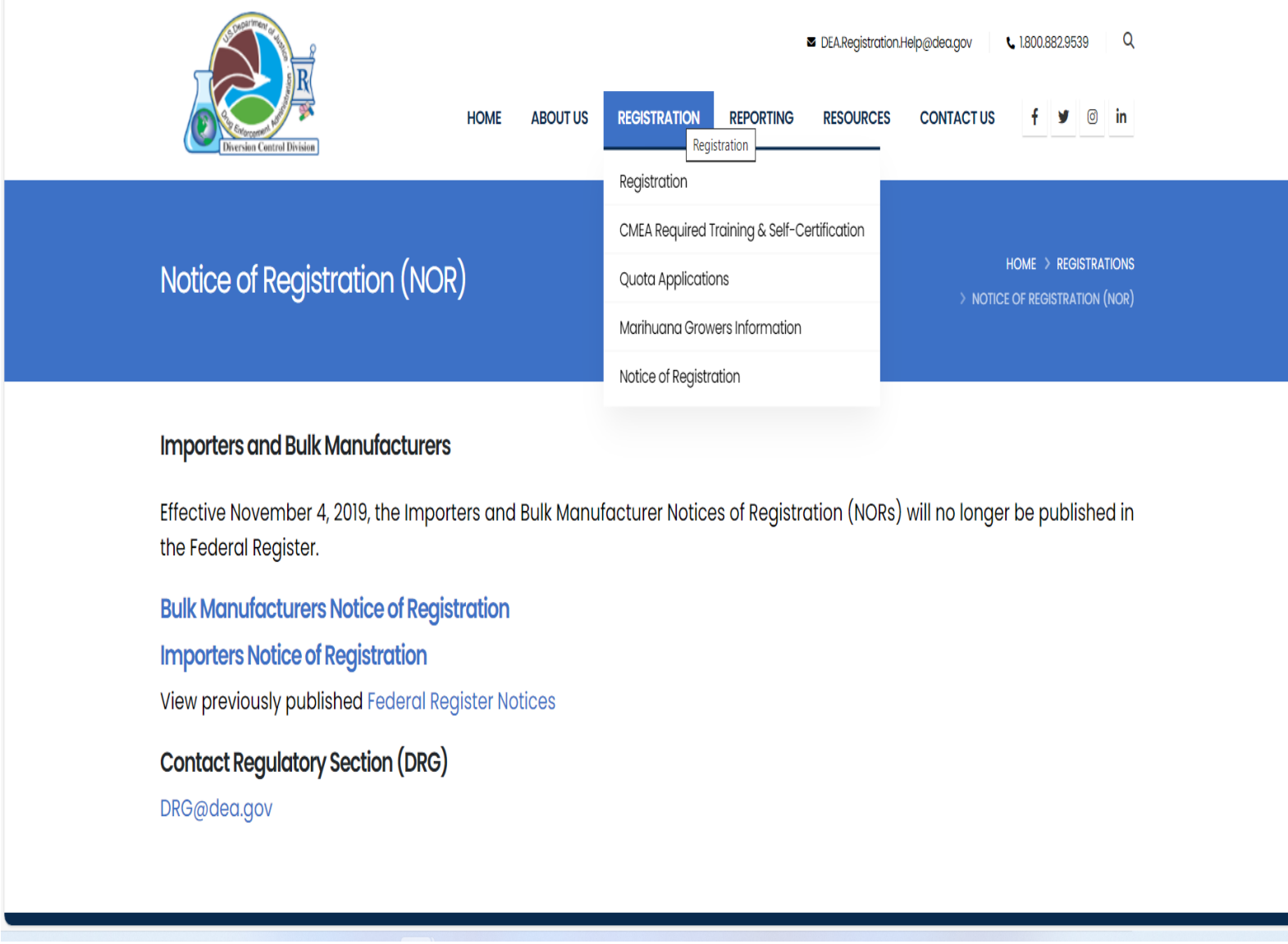
The local DEA field office conducts an on-site investigation of the applicant/registrant which includes the following six public interest factors in 21 USC § 823 (a)(1-6) addressed in their final report.

Six Public Interests Factors

- Maintenance of effective controls against diversion;
- Compliance with applicable State and local laws;
- Promotion of technical advances in the art of manufacturing;
- Prior conviction record of applicant under Federal and State laws;
- Past experience in the manufacture of controlled substances, and the existence in the establishment of effective control against diversion;
- Other factors as may be relevant to and consistent with the public health and safety;

Completion of the 303 Process

Following the publication of the Notice of Registration (NOR), which is posted to our external website, the 303 application is now considered approved or renewed.



Reminders

The 303 process can take 4 - 6 months to complete.

Include **all** Schedule I and II drug codes needed at the time of submitting your application and registration renewal.

Adding Schedule I and II drug codes during the application process will result in a delay.

Be aware of the expiration date(s) on your registrations and submit your renewal applications in a timely manner. If your registration has expired, and you have submitted a renewal application, we will provide you with an extension letter so you may continue operations while we are processing your application.

Bulk manufacturers, please double check drug codes you want in bulk status. Ensuring to place a check mark by the drug codes you intend to manufacture in bulk. If not checked, these codes will not be included on the Federal Register.

A registrant can undergo both a scheduled investigation and a 303 investigation in the same fiscal year.

Questions

Diversion Control Division/Regulatory Section (DRG)

DRG@dea.gov