



The 303 Application Process Diversion Control Division/Regulatory Section (DRG)



Supply Chain Conference

Houston, Texas

May 2-3, 2023

10:00 am – 10:30 am CST

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

Brenda Thomas, Program Analyst, Regulatory (DRG), Presenter



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 an registration annually.



Why the term 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**



How is Section 303 Initiated?

The Section 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.)



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**



303 Process



303 Process

New or renewal applications for registration are submitted via Registration Support from www.deadiversion.usdoj.gov and routed to Regulatory (DRG) for processing.



303 Process

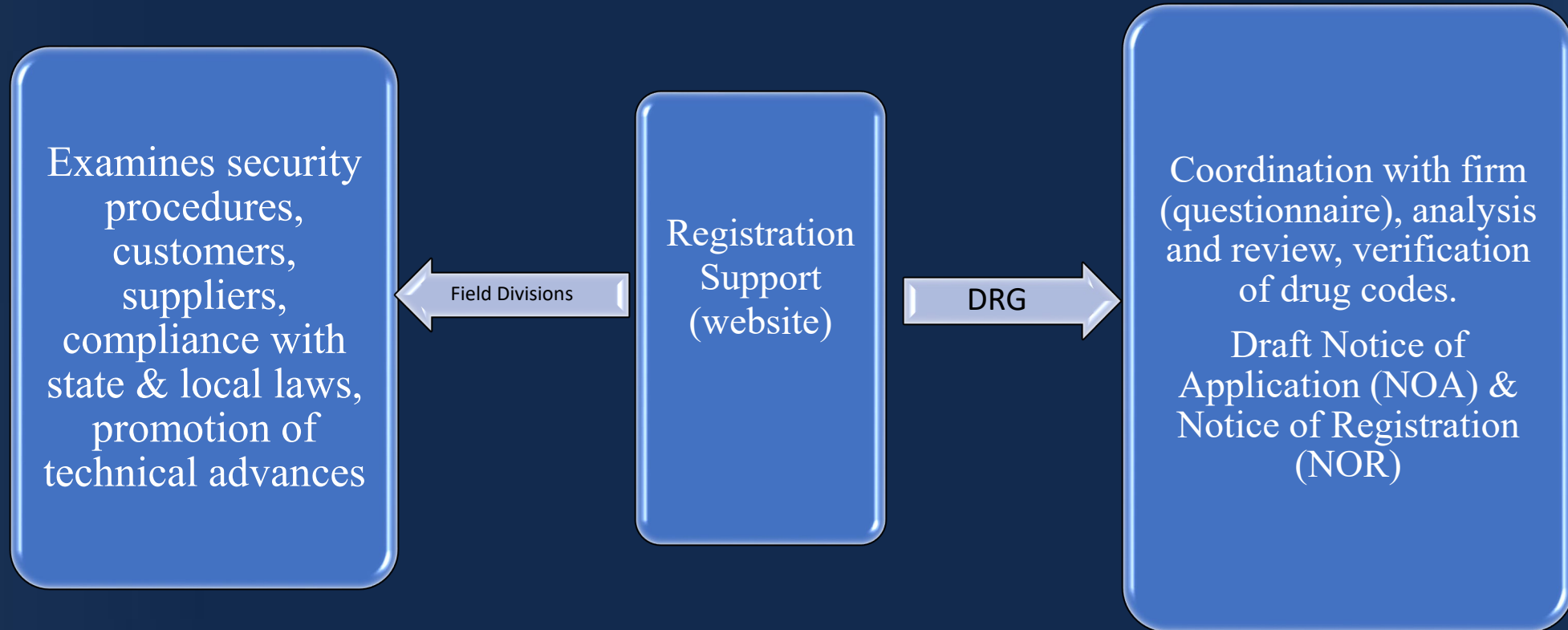
DRG personnel forwards to the applicant, a standardized Importer or Bulk Manufacturer questionnaire to be completed within 10 business days.

Upon receipt of a completed questionnaire, a Notice of Application (NOA) is prepared, 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.



Processing 303 Applications

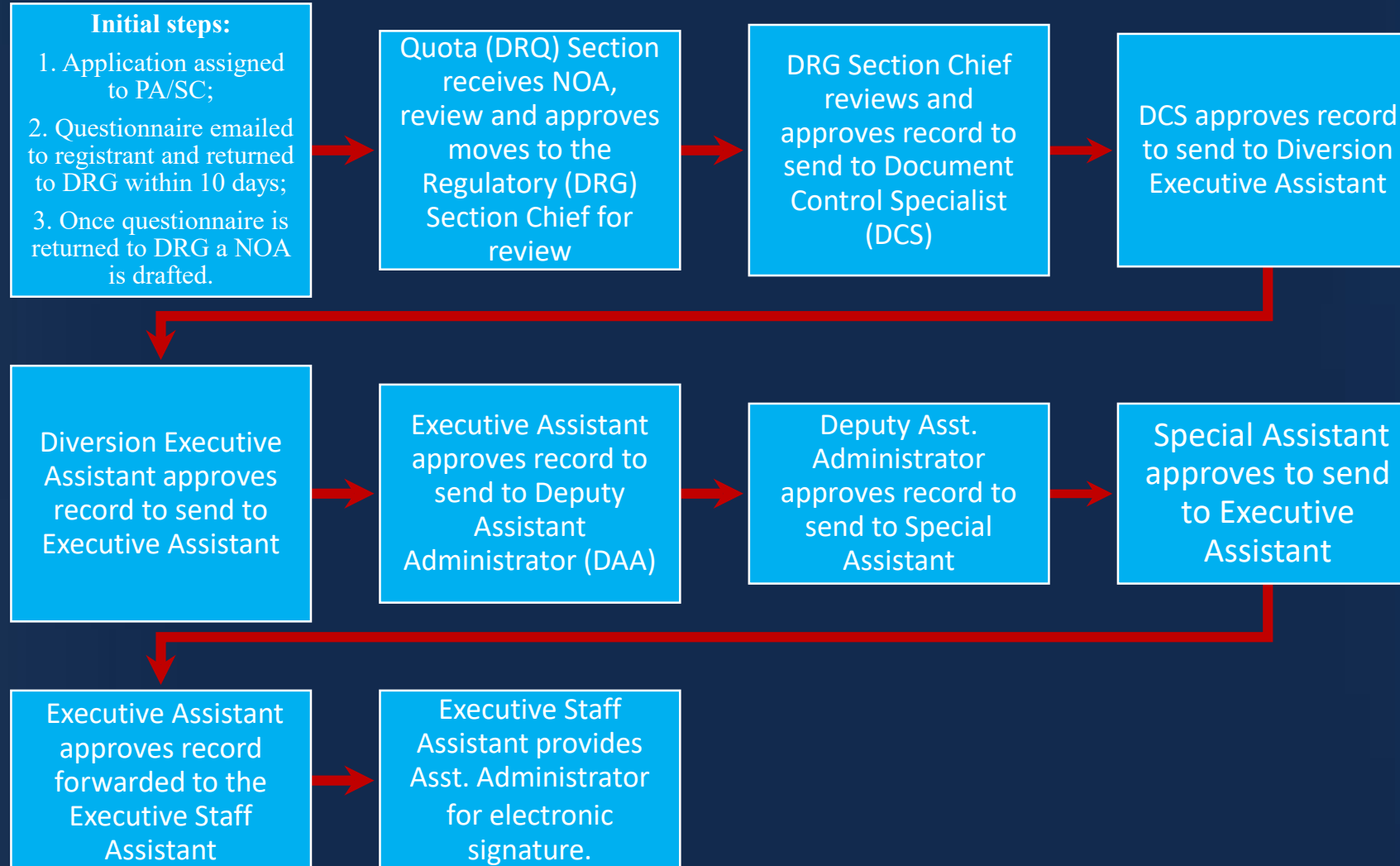
Application received by **Diversion Registration**





Notice of Application (NOA) Flow Chart*

Timeline to complete the application process can take up to 4-6 months



*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 requires 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 commences 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;



303 Process



Following the publication of the Notice of Registration (NOR) on our external website. The 303 application is now considered approved or renewed.

U.S. DEPARTMENT OF JUSTICE ★ DRUG ENFORCEMENT ADMINISTRATION
DIVERSION CONTROL DIVISION

COVID-19 Information Page

HOME REGISTRATION REPORTING RESOURCES ABOUT US

Registration Support
Call: 1-800-882-9539 (8:30 am-5:50 pm ET)
Email: DEA.Registration.Help@dea.gov
Contact Local Registration Specialist

Renewal Applications
New Applications
Check the Status of My Application
Registrant Validation Toolset
Request Copy of DEA Certificate
Request Copy of Last Application/Receipt
Make Changes to My DEA Registration
Order Form Request (DEA Form 222)
Registration for Disposal of Controlled Substances
Search for Year Round Pharmaceutical Disposal Locations

Search for **pharmaceutical**

Cases Against Doctors
Chemical Control Program
CMEA (Combat Meth Epidemic Act)
Controlled Substance Schedules
COVID-19 Information
DATA Waived Physicians
DEA TOX Toxicology Testing Program
Drug Disposal Information
Drug and Chemical Information
E-commerce Initiatives

What's New Get Email Updates:

REGISTRATION

Notice of Registration (NOR) Get Email Updates:

IMPORTERS AND BULK MANUFACTURERS

Effective November 4, 2019, the Importers and Bulk Manufacturer Notices of Registration (NORs) will no longer be published in the Federal Register.

Bulk Manufacturers Notice of Registration

Importers Notice of Registration

[View Previously Published Federal Register Notices](#)

Contact Regulatory Section (DRG)

Phone: 571-362-8137
Email: DRG@dea.gov

Applications
Tools
Resources
CMEA Required Training & Self-Certification
Quota Applications
Marihuana Growers Information
Notice of Registration



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.
- 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