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

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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 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

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 Schedule I or II 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

Definition

The term **Bulk Manufacture** means: 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.

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.

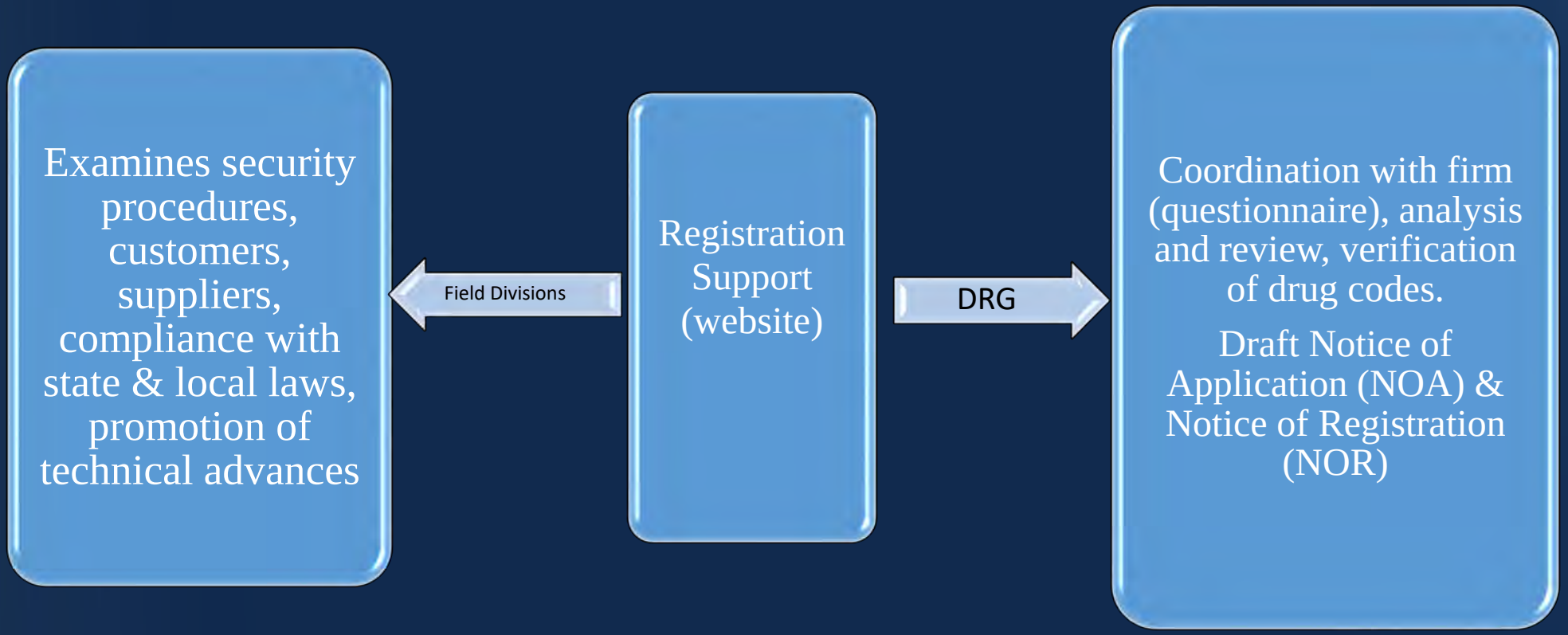
303 Process

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.

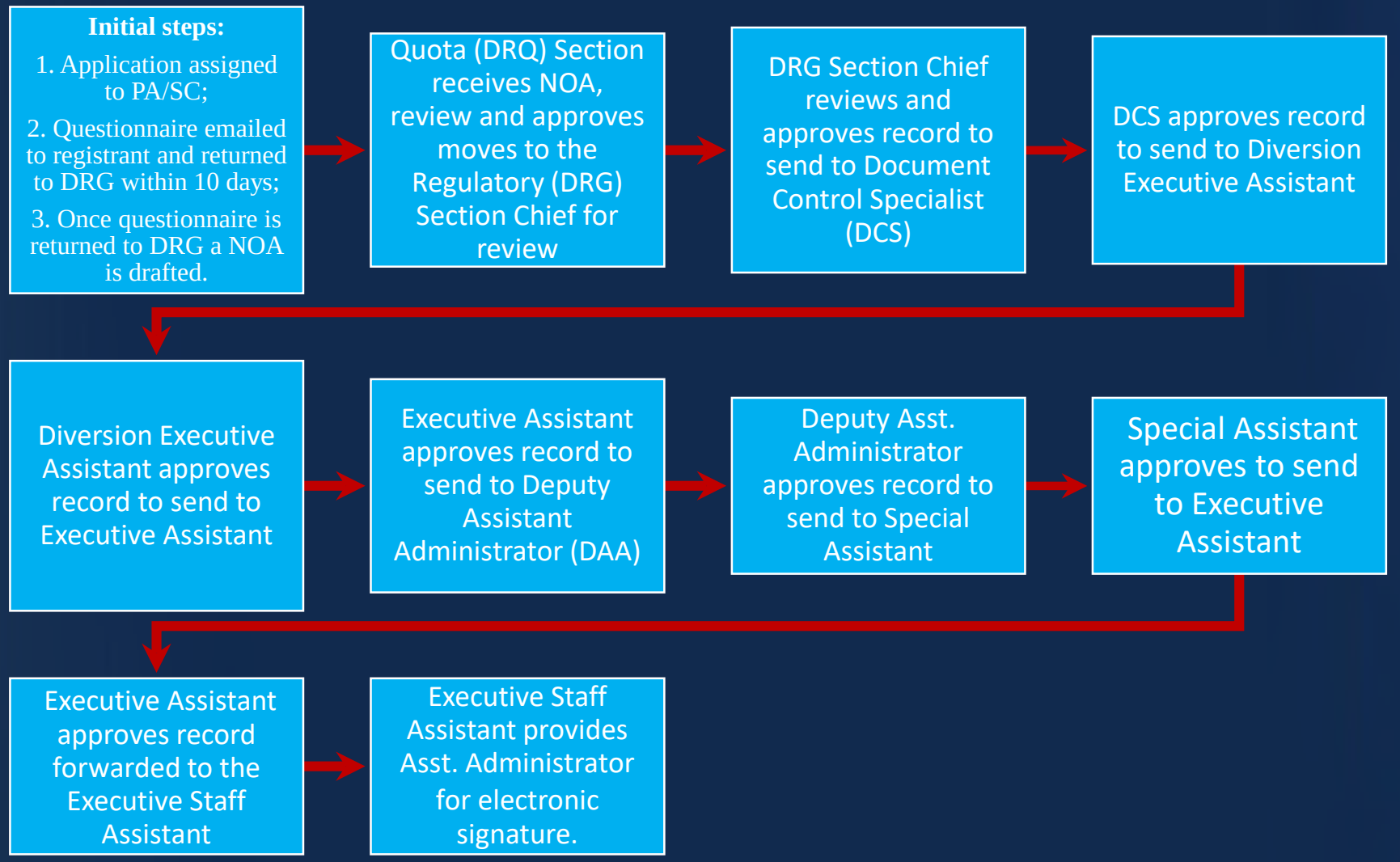
Processing 303 Applications

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 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

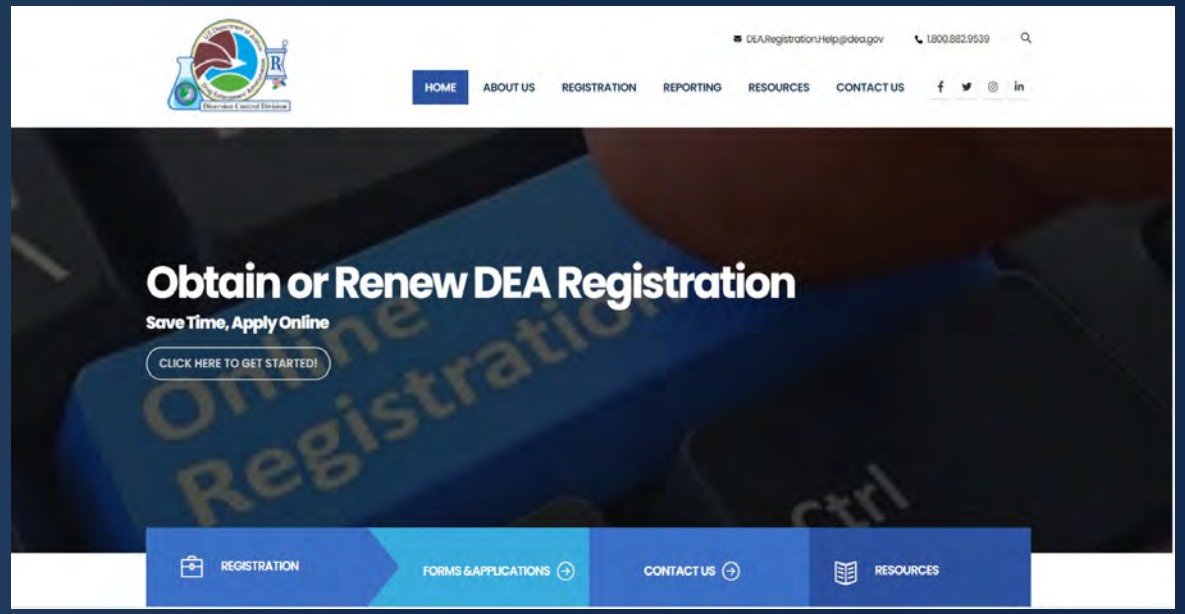
The local DEA field office conducts an on-site investigation of the applicant/registrant which includes the following six public interest factors in 21 USC § 823 (a)(1-6) addressed in their final report:

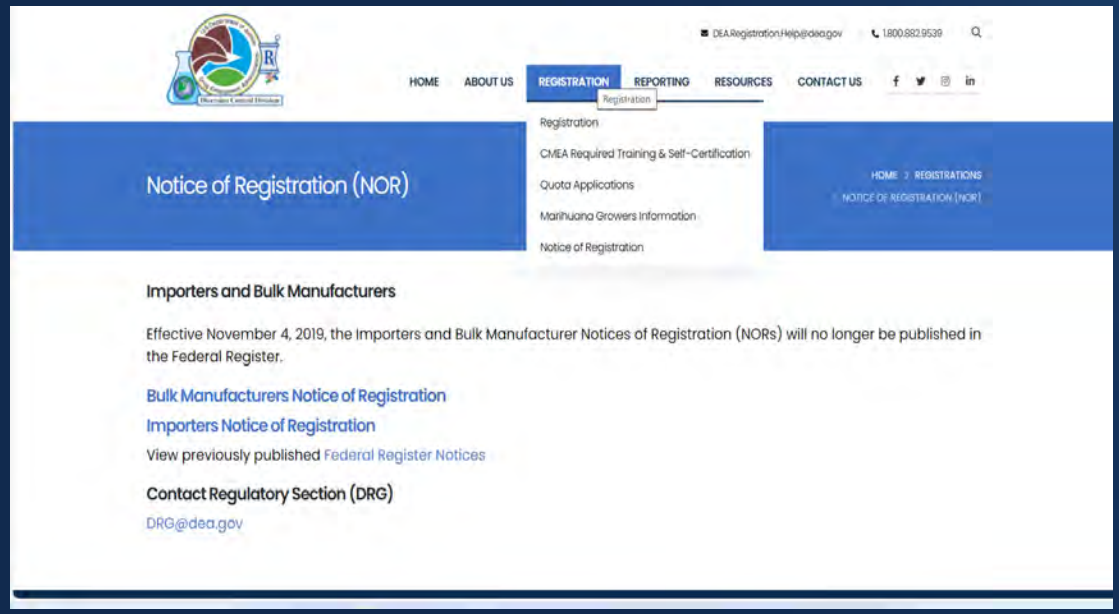
Six Public Interests Factors

- 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.





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)

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