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

Attention Applicant or Registrant:

In order to process your company's request to import Schedule I and/or II controlled substances, the DEA's Diversion Regulatory Group (DRG) must obtain the information requested in this questionnaire.

THIS QUESTIONNAIRE IS BEING SUBMITTED BY THE FOLLOWING:

SIGNATURE OF PERSON:_____
(PLEASE SIGN)

NAME OF PERSON SUBMITTING:_____
(PLEASE PRINT)

TITLE OF PERSON:_____

NAME OF COMPANY:_____

DEA REGISTRATION#_____

APPLICATION CONTROL NUMBER

TELEPHONE#_____

E-MAIL ADDRESS:_____

WEBSITE: _____

FAX NUMBER:_____

DATE OF SUBMISSION:_____

DRUG CODES:_____

THE INFORMATION IN THIS DOCUMENT IS CERTIFIED AS ACCURATE AND CURRENT AS OF:
(SIGNATURE):_____ (DATE):_____

OMB Control No. 1117-0012
Expires 09/30/2021

The following questions pertain to your request to import Schedule I and/or II controlled substances. Please provide a detailed response to the following questions for <u>each</u> Schedule I and/or II drug code your company wishes to import.

1. **What type of controlled substance does your company intend to import: bulk or dosage form?**

    a. **Is this a derivative of a basic drug class? List Drug Code(s).**

2. **What is the purpose for the importation of the controlled substance? (For example: narcotic raw material for bulk manufacture, clinical trials, research, analytical purposes, or distribution)**

3. **Why is a foreign source of supply being used instead of a domestic source? (please elaborate)**

4. **What is the name, address, method of shipment, and method of delivery for each supplier of the controlled substance your company proposes to import?**

5. **Does your company have a firm commitment from the supplier(s) of each substance proposed for importation?**

    a. **What is the time period of the commitment?**

    b. **What quantity is involved?**

    (Please attach copies of all commitment letters)

6. **What quantity of each controlled substance does your company anticipate importing on an annual basis?**

7. **Who are your current and prospective customers? Please provide a list of names, addresses, and DEA numbers for each controlled substance. (Please attach copies of letters of interest from these customers)**

8. **Will the controlled substance(s) you propose to import be used to manufacture controlled substances? If so, how, and in what quantity, are they to be manufactured? (List current and additional drug codes)**

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9. **Does your company have previous experience handling controlled substances? Please explain.**

10. **Does your company have previous experience in the importation of controlled substances? Please explain.**

11. **When does your company anticipate selling a commercial product? Will the final product be manufactured domestically or finished dosage import?**

12. **Please provide a written description of what resources your company has committed to the establishment of your importation business pertaining to these drug codes. (For example, does your company intend to make, or has it made, any changes to its physical plant, security system, production equipment, or recordkeeping system?) (Please provide a proposed time-frame for the completion of these activities)**

13. **Does your company currently possess any other registrations from the Drug Enforcement Administration pertaining to controlled substances?**
If, so, please include the registration number(s), business activity, drug schedules, and expiration date for each registration.

SUPPLEMENTAL INFORMATION FOR NEW APPLICANTS OR FOR THE ADDITION OF A SPECIFIC CONTROLLED SUBSTANCE TO AN EXISTING DEA REGISTRATION – IMPORTERS

Importer Questions:

(Note: To assist you in answering questions 14 through 16, you may wish to consult the following DEA final order published in the Federal Register: Lyle E. Craker; Denial of Application, 74 FR 2101 (January 14, 2009).
If you are requesting to import a Schedule I or II controlled substance for the first time either as an entirely new applicant for DEA registration or adding a specific controlled substance to an existing DEA registration, you must answer the following questions for each controlled substance:

14. **Please describe your company's past experience with controlled substances. Please be specific with regard to dates, types of business activity, and schedules of controlled substances handled.**

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15. **If your company is applying to obtain a registration as an importer because it cannot purchase the needed controlled substance from existing bulk manufacturers for its business activity, please provide the names of the existing registered bulk manufacturers you contacted. Please include dates of contact, persons contacted, and method of contact.**

16. **Please describe in detail whether your company's proposal to import controlled substances will promote technical advances in the art of manufacturing these substances and in the development of new substances.**

<u>Note:</u> In answering question #17, your company bears the burden of demonstrating that either the existing supply or competition is inadequate within the meaning of 21 USC § 952 (a)(2). Particular consideration should be given to whether the existing registered bulk manufacturers and importers of the controlled substance for which you seek registration can produce an adequate and uninterrupted supply of this substance under adequately competitive conditions and, if such competition among existing registrants is inadequate, whether such competition will not be rendered adequate by the registration of additional domestic bulk manufacturers. DEA has traditionally focused on the historical and present prices charged to those who lawfully acquire the controlled substance from the existing registered bulk manufacturers.

17. **Please explain how you determined the domestic supply or manufacturing is inadequate.**

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