

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:

NAME OF PERSON SUBMITTING: _____
(PLEASE PRINT)

SIGNATURE OF PERSON SUBMITTING: _____
(PLEASE SIGN)

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: _____

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Signature:

Date:

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 substance.**

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

- 4. Please provide the name, address, method of shipment and method of delivery for each supplier from which your firm intends to procure materials for the manufacture of the controlled substance(s).**

- 5. Does your company have a firm commitment from each supplier of raw material? What is the time period of this agreement and what quantity of raw material will each supplier be able to supply? Please attach copies of commitment letters from each supplier.**

- 6. What quantity of each controlled substance does your company anticipate producing in bulk? (grams/kg base)**

- 7. Who are your current and prospective customers (name, address and DEA number) for each controlled substance?**
 - a. What product(s) (e.g., active pharmaceutical ingredient or API, dosage units, materials for clinical research) does your company intend to sell to each customer listed? List drug code(s).**

 - b. What quantity of each substance have your customers indicated they would purchase?**

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- c. For what purpose are your customer(s) purchasing the controlled substances? (e.g., dosage form development, clinical trials, FDA approval). Please be specific as it relates to each customer and each controlled substance identified above.**

(Please attach copies of letters of interest from prospective customers)

- 8. What are your company's future plans with regard to the manufacture of controlled substance(s)? Please provide detailed information, as possible, including timelines, and plans to expand your production facility, addition of equipment, product development activities, research and development, batch names and batch sizes and any FDA approvals.**
- 9. When does your company anticipate commencing sales or other distribution of each controlled substance?**
- 10. Do you currently have any other controlled substance registrations from the DEA? If so, please include the name, DEA number(s), business activity, drug schedules and expiration dates(s).**
- 11. Please describe your company's past experience in manufacturing controlled substances. Please be specific with regards to dates, types of manufacturing activity, and names and schedules of controlled substances manufactured.**
- 12. Have you or anyone else who will be involved in the ownership or operation of your company previously manufactured or distributed any controlled substance without a DEA registration authorizing such activity? For each such person, please separately indicate dates, types of manufacturing or distribution activity, names of controlled substances, and quantities manufactured or distributed. Do not include persons who own less than 5 percent of the company.**
- 13. Has primary ownership of your company changed over the past 12 months? If so, please provide details.**

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(SIGNATURE): _____ (DATE): _____

14. If your company is applying to obtain a registration as a bulk manufacturer because your company is unable to purchase the needed controlled substance(s) from existing bulk manufacturers, please provide the names of the existing registered bulk manufacturers you contacted. Please include dates of contact, person contacted, and method of contact.

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

Note: In answering question 16 and 17, please note that, your company bears the burden of demonstrating that either the existing supply or competition is inadequate within the meaning of 21 USC § 823 (a)(1). Particular consideration should be given to whether the existing registered bulk manufacturers of the controlled substance for which you seek registration can produce an adequate and uninterrupted supply of this substance under adequately competitive conditions. In assessing adequacy of supply, DEA generally focuses on the ability of existing registered bulk manufacturers to provide the *quantity* of material needed to supply the lawful needs of the United States. In assessing the competition, 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, and whether such prices are reasonable.

16. Adequacy of supply – Are you seeking to become registered based on the contention that the existing registered bulk manufacturers of the controlled substance are incapable of producing an adequate and uninterrupted supply of that substance to meet lawful needs of the United States? If so please explain in detail.

17. Adequacy of competition – Are you seeking to become registered based on the contention that the existing registered bulk manufacturers of the controlled substance are incapable of supplying the lawful need of the United States under adequately competitive conditions? Is so please answer the following questions:

- a. Regarding your competitors, products, and prices, please explain why those suppliers are inadequate?**
- b. Why are current prices charged by your competitors unreasonable?**

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- c. Please provide evidence showing that current market prices are clearly and persistently excessive.**

- d. Please state your prices and explain why they are more competitive than the current prices in the existing market.**

- e. Provide evidence that you can produce the controlled substance(s) in question at a lower cost than your competitors.**

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