

**APPLICATION FOR INDIVIDUAL MANUFACTURING QUOTA  
FOR A BASIC CLASS OF CONTROLLED SUBSTANCE**

<i>SEE INSTRUCTIONS ON REVERSE SIDE</i>	No individual manufacturing quota may be issued unless a completed application form has been received, 21 CFR 1303.22.		<i>OMB APPROVAL No. 1117 - 0006</i>
1. NAME OF BASIC CLASS DESIRED ( <i>Only one basic class per DEA-189</i> )		2. SCHEDULE NUMBER	3. DEA DRUG CODE NUMBER
4. NAME AND ADDRESS OF REGISTRANT ( <i>Include No., Street, City, State and ZIP Code</i> )		5. YEAR FOR WHICH QUOTA IS REQUESTED	
		6. DEA REGISTRATION NUMBER	
7. NAME OF CONTACT PERSON		8. TELEPHONE NO. ( <i>Include ext., if applicable</i> )	9. FAX NUMBER

**NOTE: All quantities are to be expressed in grams of anhydrous acid, base or alkaloid (not as salts).**

10. QUOTA HISTORY	QUOTAS PREVIOUSLY ISSUED BY DEA			QUOTA REQUESTED  _____ Grams
	2nd PRECEDING YEAR  _____ Grams	1st PRECEDING YEAR  _____ Grams	CURRENT YEAR  _____ Grams	
11. PRODUCTION DATA	2nd PRECEDING YEAR	1st PRECEDING YEAR	ESTIMATE FOR CURRENT YEAR	ESTIMATE FOR YEAR FOR WHICH QUOTA IS REQUESTED
I. INVENTORY AS OF DEC. 31				
a. Bulk controlled substance .....				
b. In-process material .....				
c. Contained in FINISHED Dosage Forms .....				
TOTAL (a + b + c) .....				
II. DISPOSITION / UTILIZATION				
a. Domestic .....				
b. Exports .....				
TOTAL (a + b) .....				
III. ACQUISITION / PRODUCTION				
a. Domestic Sources .....				
b. Importation .....				
TOTAL (a + b) .....				

12. IF THE PURPOSE IS TO MANUFACTURE ANOTHER SUBSTANCE (S), FURNISH THE FOLLOWING INFORMATION:					
NAME OF NEW SUBSTANCE	DEA DRUG CODE NUMBER	AMOUNT USED FOR THIS PURPOSE			% YIELD (Historical)
		2nd PRECEDING YEAR	1st PRECEDING YEAR	CURRENT YEAR	

13. REMARKS		
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SIGNATURE OF APPLICANT	PRINT or TYPE NAME and TITLE of SIGNER	DATE
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**INSTRUCTIONS FOR COMPLETING THE DEA FORM 189:  
Application For Individual Manufacturing Quota**

The DEA-189 must be filed on or before May 1 of the year preceding the calendar year for which the manufacturing quota is being applied. Regulations governing quotas are included in Title 21, Code of Federal Regulations, Part 1300 to end. Copies of these regulations may be ordered from: The Government Printing Office, Superintendent of Documents, Attn: New Orders, P.O. Box 371954, Pittsburgh, PA 15250-7954. Submit the completed form to:

Drug Enforcement Administration  
Office of Diversion Control  
Drug & Chemical Evaluation Section (ODE)  
Washington, D.C. 20537

The following instructions are for those items which are not completely self-explanatory.

- Item 11(I).** This is to include all factory and branch stocks which have reached that point in manufacturing as to be identifiable, whether in bulk form, in the process of manufacture, in finished form, or otherwise (e.g., damaged, defective, or impure substances awaiting disposal, substances held in quarantine, or substances maintained for extemporaneous compounding), as a basic class of controlled substance manufactured or otherwise acquired by a registrant, whether in bulk, commercial containers, or contained in pharmaceutical preparations in the possession of the registrant (including stocks held by the registrant under separate registration as a manufacturer, importer, exporter or distributor).
- Item 13.** Enter any additional factors which may be relevant to the establishment of a manufacturing quota including the trend of and recent changes in the individual companies and the national rates of net disposal, production cycles and current inventory position, the economic and physical availability of raw materials for use in manufacturing and for inventory purposes, yield and stability problems, potential disruptions to production (including possible labor strikes) and recent unforeseen emergencies such as floods or fires.

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