INSTRUCTIONS FOR COMPLETING THE DEA FORM-189:
Application for Individual Manufacturing Quota

To be completed by Bulk Manufacturers only.

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 (ODE)
8701 Morrissette Drive
Springfield, VA 22152

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

Item 12(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 substances 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. Please provide the authority by which you may legally market the product under the Food, Drug and Cosmetic Act.

Item 14. 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.