



U. S. Department of Justice
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, Virginia 22152

www.dea.gov

DEA Registrants

Dear Bulk Manufacturer:

In light of the nationwide public health emergency declared by the Secretary of Health and Human Services (HHS) on January 31, 2020, as a result of the Coronavirus Disease 2019 (COVID-19), the Drug Enforcement Administration (DEA) has received inquiries from DEA registered bulk manufacturers with regard to a waiver of the 65 percent inventory limit.

DEA regulations provide that if at any time the inventory of a basic class held by a manufacturer exceeds 65 percent of his estimated net disposal as determined at the time his quota for that year was determined, his quota for that class is automatically suspended and shall remain suspended until his inventory is less than 60 percent of his estimated net disposal. 21 CFR 1303.24(b).

The DEA Administrator is permitted by 21 CFR 1307.03 to grant an exception to the application of any provision in 21 CFR, Chapter II. This authority has been re-delegated to the Assistant Administrator of the Diversion Control Division. In light of the public health emergency, DEA recognizes the potential for production shortages in certain classes of controlled substances. In order to ensure an uninterrupted supply of schedule II controlled substances for the duration of this public health emergency, DEA will **grant** an exception to those provisions of 21 CFR 1303.24(b) that normally require the inventory for individual manufacturers to remain at 65 percent or less. Under this exception being granted today, all DEA registered bulk manufacturers are allowed to exceed the 65 percent ceiling in order to supply dosage form manufacturers with the active pharmaceutical ingredient(s); this may be necessary to manufacture specific products to avoid existing or potential shortages. This exception does not authorize any manufacturer to exceed his previously established annual manufacturing quota.

This exception is granted from March 23, 2020, through the duration of this public health emergency as declared by the Secretary of HHS.

We hope this information is helpful. For information regarding DEA's Diversion Control Division please visit www.DEAdiversion.usdoj.gov. Please contact the Diversion Control Division, Policy Section at (571) 362-3260 if you seek additional assistance regarding this or any other matter.

Sincerely,

William T. McDermott
Assistant Administrator
Diversion Control Division

DEA0074 – March 25, 2020