



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

www.dea.gov

NOV 13 2019

Dear DEA-Registered Manufacturer:

The Drug Enforcement Administration (DEA) is required under the Controlled Substances Act (CSA) to establish aggregate production quotas (APQs) for each basic class of controlled substance in schedules I and II, and the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. These quotas represent the maximum quantity that may be manufactured to provide for the estimated medical, scientific, research, and industrial needs of the United States for lawful export requirements, and for the establishment and maintenance of reserve stocks. Whereas the CSA grants the Attorney General (delegated to the DEA Administrator) with the authority to revise the APQs at any time during the quota year, the DEA has traditionally revised them once per year after a fulsome analysis of the data required under its regulations.

DEA receives and analyzes data from multiple sources when establishing and revising the APQs. This includes information on actual manufacturing, inventory and use of controlled substances provided by DEA-registered manufacturers as well as information received from the Food and Drug Administration about new products, discontinued products and drug development efforts. For the 2019 quota year (established in 2018 through notice and comment rulemaking procedures and in accordance with DEA regulations revised earlier that year). DEA also began to obtain and consider information from state Attorneys General and other federal partners, including: the Centers for Disease Control and Prevention and the Centers for Medicare and Medicaid Services.

Further, in October 2018 Congress made several additional changes to the CSA relating to the manner in which DEA establishes the APQs when it passed the SUPPORT Act. Amongst other things, this important piece of legislation required the DEA to consider various sources of information relating to the diversion of schedule I and II controlled substances when establishing the APQ, especially for several of the most frequently misused controlled prescription opioids in the United States.

While DEA continues to observe declines in the prescribing rates of schedule II opioids by prescribers nationwide ~ a staggering 29.9% in monthly prescriptions dispensed from January 2017 to August 2019¹ ~ DEA has determined that the data received from interested parties and analyzed, do not support the need for a revision to its 2019 established APQs. Specifically, the DEA Acting Administrator has determined the 2019 established APQ's for all schedule I and II controlled substances included in 21 CFR § 1308.11 and 1308.12 and the Annual Assessment of Needs for three list I chemicals ephedrine, pseudoephedrine and phenylpropanolamine are sufficient to meet the needs of the United States.

¹ IQVIA Monthly prescriptions dispensed for the following opioids: oxycodone, hydrocodone, hydromorphone, morphine, codeine, and fentanyl

When DEA established the 2019 APQs in the Federal Register notice, it stated in response to a comment from an interested party, that it would publish data on diversion at a time in which it proposed revisions to the APQs. Now that DEA has determined that it will not revise the APQs for 2019, the DEA will be unable to publish that information. However, DEA has published information on diversion of certain controlled prescription opioids when it proposed its 2020 APQs very recently.

Please feel free to direct any questions or concerns to Stacy Harper-Avilla, Section Chief, U.N. Reporting & Quota Section, Office of Diversion Control Regulatory, Diversion Control Division, at (571) 362-3248.

Sincerely,

A handwritten signature in black ink, appearing to read "Donetta M. Spears". The signature is stylized and somewhat cursive.

Donetta M. Spears
Deputy Assistant Administrator
Diversion Control Division