



U. S. Department of Justice
Drug Enforcement Administration
Diversion Control Division

www.dea.gov

Springfield, Virginia 22152

Dear DEA-Registered Manufacturer:

The Drug Enforcement Administration (DEA) remains committed to ensuring that Americans who need medications have access to them.

In December, DEA announced that drug manufacturers would be required to apply for quota allotments on a quarterly basis. In years past, DEA found that manufacturers have not used the full amount of yearly quota allocated, resulting in shortages of critical medications.

Since then, DEA has met with several manufacturers to discuss the impact of these changes. Numerous drug manufacturers asked DEA to consider allocating quota semi-annually to assist with production planning and execution. DEA understands and appreciates the complexities of the drug supply chain. Effective immediately, applications for procurement quota for commercial manufacturing of a schedule II controlled substance will be calculated on a semi-annual basis, except for injectable drug products containing schedule II controlled substances, which will be calculated on an annual basis.

The requirement to submit regular, reporting will not change. DEA will continue to require, at a minimum, quarterly reporting. More frequent reporting by manufacturers is essential to protecting the health and safety of Americans, and ensuring an adequate supply of prescription medications. This information will allow DEA to better anticipate supply chain issues, understand the time-to-market, and inform procurement quotas for commercial manufacturing.

Manufacturers who receive a procurement quota are expected to use that quota to produce FDA-approved products, and will be expected to relinquish any unused quota allocations. DEA will monitor quota usage and take action as needed to adjust allocations. DEA will also provide future quota allocations to manufacturers that have demonstrated that they are using their quota to make and sell medications for current use.

DEA is committed to ensuring that patients who need medications have access to them and we will continue working with you and other partners inside and outside of the government to do so. DEA appreciates your cooperation in this effort.

Sincerely,

Marsha L. Ikner
Acting Deputy Assistant Administrator
Diversion Control Division