

December 23, 2019

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Drug Enforcement Administration  
Attention: DEA Federal Register Representative/DPW  
8701 Morrissette Drive  
Springfield, VA 22152

**Re: Management of Quotas for Controlled Substances and List I Chemicals**

Docket No. DEA-455; 84 Fed. Reg. 56712 (October 23, 2019)

Dear Sir or Madam:

In the October 23, 2019, *Federal Register*, the Drug Enforcement Administration invited comments on the above-referenced proposed rule to revise existing regulations that manage quotas for controlled substances and List I chemicals (ephedrine, pseudoephedrine, and phenylpropanolamine) held by DEA-registered manufacturers.

The Consumer Healthcare Products Association (CHPA), founded in 1881, is the national trade association representing manufacturers and distributors of over-the-counter (OTC) medicines, dietary supplements, and consumer medical devices in the United States. Our mission is to empower self-care by preserving and expanding choice and availability of consumer healthcare products. A number of our member manufacturers manufacture and market OTC medicines containing pseudoephedrine or ephedrine under DEA registrations. As such, we have an interest in the proposed rule. We have comments on three areas within the proposed rule:

- 1. The proposed revision to a 30% of quota inventory allowance is overly restrictive.** The proposed rule would reduce available inventory allowance for a List I chemical from one year to the next to 30% of a manufacturer's quota from the current 50% level. We do not believe this is workable. First, some of our manufacturer members report they typically hold a roughly 40% inventory level at the end of a quota year with a lead time of 6 months to purchase List I materials. Thus, a 30% quota inventory allowance would lead to manufacturing stresses and inefficiencies at best and shortages at worst. Materials on quality hold would exacerbate this stress, as manufacturers would need to drive an expedited process to scrap or salvage batches in question to address market demand. This would potentially lead to more waste. We would suggest either retaining the existing 50% quota inventory allowance for List I chemicals or, alternatively, reducing it to a 40% quota inventory level.
- 2. Longer leads time to establish and issue individual manufacturing quotas may cause supply disruptions.** The proposed rule would extend the deadlines to establish and issue individual manufacturing quotas. While we applaud DEA for seeking to set more realistic and predictable deadlines, we are concerned this will raise challenges and potential supply disruptions when a manufacturer is seeking to procure materials that require a 6-month lead time.

3. **The subcategories for types of quotas seem workable, but will reduce flexibility.** The proposed rule would add use-specific subcategories for individual manufacturing and procurement quotas. While this seems workable, there is a concern that it could create inefficiencies or shortages in the supply chain if, for instance, a manufacturing batch required rework and thus required a change in which use-specific subcategory was used. Similarly, introduction of new line extension of a medicine with a List I chemical can result in in-year shifts in the amount of material expected with little notice as development, validation or revalidation, or scale-up occur, with different sub-category quota impacts.

Thank you for the opportunity to provide these views. Please contact us at any time if we can provide additional information.

Sincerely,

/signed/

David C. Spangler  
Senior Vice President, Legal,  
Government Affairs & Policy  
e: [dspangler@chpa.org](mailto:dspangler@chpa.org)

DEA-quota-proposal-December2019