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January 17, 2006

Deputy Administrator
Drug Enforcement Administration
Washington, DC 20537

Attention: DEA Federal Register Representative/ODL

Dear Deputy Administrator:

Re: Controlled Substances and List I Chemical Registration and Reregistration Application Fees; 21 CFR Parts 1301 and 1309 [Docket No. DEA-266P] [70 Fed. Reg. 69474 (November 16, 2005)]

The Consumer Healthcare Products Association, Food Marketing Institute, Healthcare Distribution Management Association, and National Association of Chain Drug Stores are pleased to provide joint comments regarding DEA's proposed rule, "Controlled Substances and List I Chemical Registration and Reregistration Application Fees".*

While our individual associations have provided additional, more detailed comments on association-specific concerns, we are collectively concerned with the removal of the List I registration waiver, with operational and efficiency challenges from dual registrations, and a lack of performance measures related to the proposed increased fees.

* The Consumer Healthcare Products Association is the 125-year-old trade association representing manufacturers of nonprescription, or over-the-counter (OTC) medicines and nutritional supplements, as we work to promote the increasingly vital role of these products in America's healthcare system through science, education, and advocacy. The Food Marketing Institute conducts programs in research, education, industry relations and public affairs on behalf of its 1,500 member companies - food retailers and wholesalers - in the United States and around the world. The Healthcare Distribution Management Association is the national trade association representing full-service distribution companies responsible for ensuring that billions of units of medication are safely distributed to tens of thousands of retail pharmacies, hospitals, nursing homes, clinics, and other provider sites across the United States. The National Association of Chain Drug Stores represents the nation's leading retail chain pharmacies and suppliers, helping them better meet the changing needs of their patients and customers.

1. The List I registration waiver removal disproportionately raises fees.

DEA proposes to remove the registration waiver for persons who distribute, import, or export a product containing a List I chemical if that person is registered with DEA to manufacture, distribute or dispense, import or export a controlled substance. In other words, those who distribute both controlled substances and List I chemicals will be required to maintain two registrations with DEA and to pay two separate registration fees. As one example, a single controlled substances distributor that is also a List I chemical handler would see a fee increase from \$813 to \$2,386 – nearly a three-fold increase – under this redundant fee scenario.

Our associations urge the DEA to recognize that a tripling in fees for any individual facility is inequitable. Instead, rather than eliminating the waiver, DEA should reconsider its proposal and maintain it for persons who distribute, import or export a product containing a List I chemical if that person is registered to distribute controlled substances. Although we recognize that the controlled substances fees would increase for these facilities, the increase would be comparable to those experienced by other facilities.

In the alternative, DEA could move ahead with the proposed elimination of the waiver, but provide for a reduction in the second registration fee.

2. The List I registration waiver removal will likely create operational issues.

DEA's proposal does not discuss the operational implications of the dual registration requirements. Our associations are particularly concerned that the rule does not address whether handlers of both controlled substances and List I chemicals will result in a dual numbering system for these registrants if they are required to obtain two different DEA registration numbers.

Two DEA registration numbers could create significant paperwork and operational burdens that have not been assessed. Would firms be required to track these two numbers if their customers likewise have two registrations? Two numbering systems would also involve information technology costs for process revisions, records maintenance, tracking capabilities, and staff training on same.

DEA's own paperwork and tracking responsibilities will also be expanded by requiring dual registration. This would have the perverse impact of adding administrative burdens (and requiring still more fee income) on DEA at the same time the agency is seeking to improve and streamline operational efficiencies.

We urge DEA to maintain the waiver for persons who distribute, import or export a product containing a List I chemical if that person is registered to distribute controlled substances.

3. Performance measures should be established for DEA programs with increased fees.

The preamble to the proposal contains a thorough explanation of the functions for which DEA plans to use the additional registration fees. While we welcome this functional explanation on the use of the fees and their application to DEA's programs, we note the description lacks information regarding the anticipated outcomes or results of the additional fees. For example, are additional diversion prosecutions anticipated with the increased resources? Are there projected targets for the identification of illicit methamphetamine labs that should flow from having more agents? The larger point is that since reductions in the illegal diversion and use of these drug products are the ultimate end for these resources, and we encourage DEA to develop a system of reporting or performance measures to track these kinds of results – results which demonstrate a correlation to or gain from the fees being paid.

Respectfully submitted,

A handwritten signature in blue ink that reads "David C. Spangler for". The signature is fluid and cursive.

Consumer Healthcare Products Association

Food Marketing Institute

Healthcare Distribution Management Association

National Association of Chain Drug Stores