FOOD MARKETING INSTITUTE

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DEA Headquarters
Attn: DEA Federal Register Representative/ODL
2401 Jefferson-Davis Highway
Alexandria, Virginia 22301

Re: Proposed Increase in Controlled Substances and List 1 Chemical Registration and Re-registration Application Fees (Docket No. DEA-266P)

Dear Sir or Madam:

The Food Marketing Institute (FMI)[1] respectfully submits the following comments in response to the Drug Enforcement Administration's (DEA's) proposal to increase the fees by registrant category that manufacturers, distributors, importers, exporters and dispensers of controlled substances and List 1 chemicals must pay, regardless of the type or quantity of product that they handle. 70 Fed. Reg. 69474 (Nov. 16, 2005). As discussed more fully below, we believe the proposal will disproportionately impact wholesalers and self-distributing supermarket companies and we recommend that DEA hold this rulemaking in abeyance. Rather than promulgate a final rule at this time, we urge DEA to work with Congressional appropriators to obtain the necessary funding through the appropriations process.

A. Comments

1. DEA's Proposal Would Disproportionately Impact Wholesalers and Self-Distributing Supermarket Warehouses that Handle Only a Small Number of OTC Cough and Cold Products

Under the current regulations, many wholesalers and supermarket companies that operate self-distributing warehouses are required to register with DEA and pay registration and annual re-registration fees of $595 per facility because a very small percentage of the

[1] Food Marketing Institute (FMI) 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. FMI's U.S. members operate approximately 26,000 retail food stores with a combined annual sales volume of $340 billion — three-quarters of all retail food store sales in the United States. FMI's retail membership is composed of large multi-store chains, regional firms and independent supermarkets. Its international membership includes 200 companies from 50 countries.

total products that they handle are over-the-counter (OTC) cough and cold medicines and a small percentage of these products contain either pseudoephedrine (PSE) or ephedrine. The presence of PSE or ephedrine renders the OTC products "List 1 chemicals" and, therefore, these handlers must register with DEA. Under the current DEA proposal, these same non-retail distributors would be required to pay $1,193 per facility, which is more than double the current amount.

As a basis for proposing higher fees, DEA cites the Department of Commerce, Justice Appropriations Act of 1993, which changed the source of funding for the agency's Diversion Control Program (DCP) from Congressional appropriations to full funding by registration and re-registration fees through the establishment of the Diversion Control Fee Account (DCFA). DEA further references the Consolidated Appropriations Act of 2005, which includes provisions clarifying that DCP encompasses both "the controlled substance and chemical control activities of the Drug Enforcement Administration," which are defined as "activities related to the registration and control of the manufacture, distribution and dispensing, importation and exportation of controlled substances and listed chemicals." Additionally, DEA notes that this Act stipulates that reimbursements from the DCFA shall be made without distinguishing between expenses related to controlled substances activities and expenses related to chemicals activities.

DEA has interpreted the net effect of these provisions to allow the agency to deposit all registration and re-registration fees (for both controlled substances and list chemicals) into the DCFA and to fund all controlled substance and chemical diversion activities from that one account, without distinguishing as to the type of activity that is being funded. While FMI does not disagree with DEA's interpretation of the various statutes that allow the agency to use registration fees to fund both controlled substance and chemical diversion activities, we have significant concerns as to how these funds might be spent by the DEA under its recent internal reorganization.

Specifically, if fees collected from non-retail distributors of list chemicals will be spent on activities unrelated to non-retail distributor registrants, the registration fees that will be required of non-retail distributors will rise even higher to cover costs relating to other registrant categories, which in our view would be inherently unfair. Additionally, we caution that the DCFA funds should only be used to cover legitimate costs relating to controlled substance and chemical diversion activities; day-to-day general administrative and clerical functions of the agency should not be reimbursable from the DCFA. This would allow for a more prudent use of the limited funds that are generated from registration fees.

2. Given Imminent and Significant Legal and Commercial Changes, DEA Should Hold the Rule in Abeyance and Instead Seek Funding Through the Appropriations Process

More importantly, however, we encourage DEA to hold the rulemaking in abeyance and, instead, seek appropriations funding from Congress for the following reasons. As DEA is undoubtedly aware, the category of OTC products that subjects wholesalers and self-distributing supermarket companies to the registration fees is currently undergoing dramatic changes in light of pending federal legislation and recent statutes passed in several states that impose or are likely to impose significantly greater restrictions on PSE- and ephedrine-

containing OTC products. Specifically, many OTC manufacturing companies are in the process of reformulating their products so that they cannot be used in the illicit production of methamphetamine.

As a result of these reformulations taking place across the product category, far fewer cough and cold products containing a precursor chemical will be available in the marketplace. Supermarket distribution centers and warehouses may very well opt to discontinue carrying the few remaining PSE- or ephedrine-based products. We believe that this is a distinct possibility as there would be less economic incentive to warehouse a limited number of pseudoephedrine or ephedrine products simply because supermarket distribution centers will eventually be subjected to the higher DEA registration fees as called for in the proposed rulemaking. If these facilities discontinued stocking these items, they would not be subject to any registration or re-registration fees, let alone the proposed increase in these fees.

If a significant number of supermarket distribution centers and warehouses abandon stocking pseudoephedrine products, DEA's revenue estimates from the proposed fee schedule would no longer be adequate to fully fund the agency's controlled substance and chemical diversion activities. Indeed, given the likely shifts in the marketplace, DEA's revenue estimates are likely to be inaccurate in a short period of time, in which case the Agency will simply be required to undertake this exercise again. Accordingly, while we recognize that DEA is attempting to adhere to the various laws passed by Congress, we believe that it is not possible to fully fund DCP through reasonable registration fees, which are also a requirement of the law.

B. Conclusion

Therefore, we urge DEA to hold this rulemaking in abeyance until the legal and commercial landscape has had the opportunity to reach equilibrium. Instead of promulgating a final rule, FMI believes that DEA and affected industries should initiate a dialogue with the Congress to ensure that the funds necessary to allow the agency to carry out its regulatory responsibilities relating to controlled substances and listed chemicals are secured through the Appropriations process.

Sincerely,

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Regulatory Affairs