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November 2, 2001

Via Facsimile

Deputy Assistant Administrator  
Office of Diversion Control  
Drug Enforcement Administration  
Washington, DC 20537

**Re: DEA Proposal To Allow Central Fill Pharmacies To Fill Prescriptions  
for Controlled Substances on Behalf of Retail Pharmacies**

Dear Sir or Madam:

The Food Marketing Institute (FMI) respectfully submits the following comments in response to the Drug Enforcement Administration's (DEA's) notice of proposed rulemaking regarding central fill pharmacies. 66 Fed. Reg. 46567 (Sept. 6, 2001). Specifically, under the proposal, DEA would allow central fill facilities to prepare prescriptions for scheduled drugs at the request of and for delivery to retail pharmacies in those states where central fill activities are permitted, provided that certain controls applicable to other pharmacy operations, such as registration and recordkeeping, are established.

FMI conducts programs in research, education, industry relations and public affairs on behalf of its 2,300 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 food retail 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 60 countries.

FMI's retail members also operate over 8,800 in-store pharmacy departments. We estimate that supermarket pharmacies account for nearly 14 percent of all outpatient prescription drugs that are dispensed each year in the United States. Based on current industry trends toward larger store formats and the convenience of one-stop shopping, we anticipate that the number of pharmacies located in supermarkets will continue to increase in the coming years as will the number of prescriptions that are dispensed on an outpatient basis from these community settings.

A significant number of FMI member companies either already operate central fill pharmacies (for non-controlled substances) or are considering establishing such facilities in the near future. Thus, DEA's proposal is of great importance to the supermarket industry. As DEA notes in the preamble, central fill pharmacies are becoming

increasingly necessary for many companies based on the dramatic growth in the number of prescriptions that are dispensed and the need to maximize efficiencies in the pharmacy department to handle these increases. 66 Fed. Reg. at 46567. Thus, FMI commends DEA for issuing its proposal and offers the following comments.

First, we recommend that DEA clarify in the preamble or the final regulations that retail central fill pharmacies may receive prescriptions from and dispense pharmaceuticals directly to patients, in addition to delivering filled prescriptions to retail pharmacies for ultimate delivery to patients. The Controlled Substances Act defines “dispensing” as delivering a controlled substance to an ultimate user. 21 USC § 802(10). FMI agrees with DEA that central fill pharmacies “dispense” pharmaceuticals, rather than “distribute” them (see 66 Fed. Reg. at 46568); in this regard, central fill pharmacies operate in the same manner as mail order and internet pharmacies, which also dispense drugs.

Accordingly, central fill retail pharmacies should be allowed to receive prescriptions from and dispense pharmaceuticals directly to patients, in the same manner that internet and mail order pharmacies currently perform these services. See, e.g., 66 Fed. Reg. 21181, 21182 (Apr. 27, 2001) (registered central pharmacy warehouses for Internet pharmacies verify prescriptions and ship substances). Allowing retail central fill pharmacies to provide substances directly to patients, in the same way that internet and mail order pharmacies do, would enhance patient convenience in situations where, for example, an individual drops off a prescription at a retail pharmacy, but requests that the medication be delivered to the individual’s home. We understand that the purpose of the proposed regulations is to allow retail central fill pharmacies to fill prescriptions and deliver pharmaceuticals via a traditional retail pharmacy in addition to dispensing pharmaceuticals directly to patients.

Similarly, patients or practitioners on behalf of patients should be allowed to contact a company by telephone to request a refill for a controlled substance. The corporation would transmit the prescription to a central fill pharmacy which would then prepare the prescription and either transfer the substance to the patient’s pharmacy or send it to the patient’s home, if requested.

Second, central fill and retail pharmacies that are located in the same physical location and held under common ownership should not be required to maintain separate inventories of and separate records for controlled substances, as proposed by DEA. See, e.g., Proposed 21 CFR, Part 1304. We expect that the intention underlying the proposal is to maintain a high level of accountability for controlled substances; however, we believe that such accountability can be achieved in certain circumstances – such as central fill and retail pharmacies that are under common control and located in the same physical plant – without imposing excessively burdensome recordkeeping and inventory requirements. For example, a retail pharmacy with a low prescription volume may be utilized at times as a central fill facility to process prescriptions for other store locations that are owned by the same company and that have very high prescription volumes. Under these arrangements, in which a retail pharmacy periodically prepares prescriptions

for other corporate store locations, the retail pharmacy should not be required to maintain separate inventories or to keep separate licensure records.

The DEA regulations would further require that every retail pharmacy that utilizes the services of a central fill pharmacy must keep a record of each facility, including its name, address and DEA number, as well as a current copy of the facility's DEA registration certificate. Similarly, a central fill pharmacy would be required to maintain a record of all retail pharmacies that it services, including the name, address and DEA number and current copies of each pharmacy's DEA registration certificate. This recordkeeping requirement is overly burdensome for retail pharmacies and central fill facilities that are held under common ownership. As an alternative, we recommend that DEA allow the records specified to be maintained at a company's corporate headquarters and that only certification of registration be required rather than having to maintain copies of current registration certificates at each retail pharmacy and central fill center. If a retail pharmacy and a central fill facility are not under common ownership, they should be required to keep appropriate records and maintain certification of registration at their respective locations.

Finally, DEA has proposed to amend Section 1306.05, "Manner of issuance of prescriptions," which provides that, in situations in which oral orders for controlled substances from practitioners are not permitted, the prescription must be written with ink or indelible pencil or by typewriter and shall be manually signed by the practitioner. See 66 Fed. Reg. at 46570. FMI urges DEA to clarify that it is permissible for a practitioner to generate a prescription using a printer from a computer provided that the practitioner signs the prescription and that it is in compliance with all essential aspects of applicable laws and regulations.

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FMI supports and appreciates the opportunity to comment on DEA's proposal to allow central fill pharmacies to prepare and dispense prescriptions for controlled substances. If we may provide you with further information regarding the ramifications of the central fill pharmacy proposal for supermarket pharmacies, please do not hesitate to contact us.

Sincerely,

Tim Hammonds  
President and CEO