FOOD MARKETING INSTITUTE

September 24, 2008

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

Re: 21 CFR Parts 1300, 1304, 1306, 1311 Docket No. DEA-218 RIN 1117-AA61 Electronic Prescriptions for Controlled Substances

Dear Sir/Madam:

The Food Marketing Institute (FMI) appreciates the opportunity to comment on the Drug Enforcement Agency's (DEA) proposed rules on Electronic Prescriptions for Controlled Substances.

Food Marketing Institute (FMI) conducts programs in public affairs, food safety, research, education and industry relations 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 and 14,000 pharmacies. Their combined annual sales volume of $680 billion represents 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 more than 50 countries. FMI's associate members include the supplier partners of its retail and wholesale members.

We estimate that supermarket pharmacies account for nearly 14 percent of all outpatient prescription drugs dispensed 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.

FMI is pleased with the recent advances in e-prescribing and we support efforts to spur its adoption and utilization. Prescribers, pharmacies and patients all benefit from the efficiencies associated with true computer-to-computer e-prescribing. Studies have shown that e-prescribing is associated with a reduction in medication errors, higher utilization of cost-saving generic medications, improved patient compliance and enhanced overall quality of care.

HEADQUARTERS:
2345 Crystal Drive, Suite 800
Arlington, VA 22202-4801
T 202.452.8444
F 202.429.4519

WASHINGTON OFFICE:
50 F Street, NW, 6th Floor
Washington, DC 20001-1530
T 202.452.8444
F 202.220.0873

www.fmi.org
fmi@fmi.org

We appreciate the Agency's effort to support and drive adoption of e-prescribing by issuing the new proposed rule to allow health care practitioners to write, and pharmacies to receive, dispense, and archive, electronic prescriptions for controlled substances. We also recognize that the DEA's focus in this proposed rule is to provide safeguards against the diversion of controlled substances. However, FMI believes the proposed rule imposes significant burdens and costs on prescribers and pharmacies without adding apparent benefit to DEA's efforts to decrease diversion of controlled drugs.

As such, we offer the following comments.

- **1311.130(b) – Do not transmit if printed; do not print if transmitted.** DEA believes this may be a new function for most systems.
    - Situations exist in today's environment that require the need to reprint or resend a prescription to the pharmacy as in the case of a copy needed for insurance audits, caregiver records or insurance companies to name a few. FMI would like the DEA to allow a prescription to be sent and/or printed with an identifier that the copy is for "informational purposes, not for dispensing" or similar type statement. In the case of transmission failure, we recommend the DEA consider allowing for a void or recall process.

- **1311.160 – First pharmacy (or last transmitter) digitally signs the prescription as received.** DEA believes that intermediaries and at least some pharmacy system providers have digital certificates and the capability to sign records.
    - FMI does not believe that all pharmacy systems have the capability to produce true digital signatures and adding this functionality will result in additional expense for pharmacy. We would like the DEA to include the projected expense of adding this technology to existing pharmacy systems in their proposal.
    - Additionally, there is no discussion of a standard for physician software which may impact the ability to attach a digital signature. Said another way, there would be potential penalty for a pharmacy's failure to attach a digital signature, but no consideration for a physician's software creating an e-prescription incompatible with a digital signature.

- **1311.165 – Check the validity of the prescriber's DEA registration.** DEA believes that many pharmacies already check the DEA database for registration information.
    - This rule is more stringent than is currently applied to paper prescriptions where the pharmacist bears the responsibility of ensuring the prescriber's DEA registration is current. The DEA rule assumes that real-time checking of DEA registration number will be employed by e-prescribing users. This

is unprecedented in the pharmacy industry as we are unaware of a real-time DEA registration number check. Further, the NTIS data feed of invalid DEA numbers available from the Department of Commerce lags behind DEA enforcement actions, sometimes by as much as three months. Even if the process could be designed to screen DEA numbers in real-time, which is not assured, the data used to screen said prescriptions in real-time could be three months out of date. Our retail pharmacy members need assurances that prescriptions received and dispensed in good faith would not be subject to DEA action against a dispensing pharmacist or pharmacy.

- **1311.165 – Store all the DEA data in the pharmacy system**. DEA believes that pharmacy systems already do this. Some may have problems with extensions to DEA numbers.
    - DEA does not have a standard for the use of suffix extensions applied to DEA numbers, nor are these suffixes tracked in the aforementioned NTIS data feed. Therefore, it is our opinion that the Agency is placing the pharmacy in an untenable situation. The pharmacy would be expected to check and store a number on DEA's behalf for which there is no standard and under which DEA exerts no jurisdiction. The health-system or hospital choosing to employ a suffix system is tasked with the implementation and tracking of that process. Therefore, it is our suggestion that DEA require the validity of the health-system DEA be verified and that a health-system's use of a suffix system by guided by DEA directly at that user's facility.

- **1311.170 – Have an internal audit trail and analyze for auditable events.** DEA believes that most systems have this capability.
    - The proposal calls for an outside third-party to conduct system and process audits on a pharmacy's e-prescribing system. Given that all pharmacy computer systems are already subject to inspection by State Boards of Pharmacy and that pharmacy practitioners and pharmacies meet industry standards such as NCPDP and Federal HIPAA data security requirements, we resist the attempt by DEA to add another costly, questionable audit process to an already well-functioning system.

- **1311.170 – Have a backup system for records at another location.** DEA believes that many pharmacy system providers, particularly ASPs, have such backup systems.
    - DEA has proposed that pharmacies using an e-prescribing system not only have a records backup system but that it be "geographically separate and distinct" from the areas of primary pharmacy operations. Given the fact that hard copy controlled substance prescriptions are expected to be kept on-site

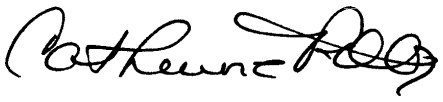
at the pharmacy where services are rendered, we resist that attempt to require pharmacies to invest in unnecessary backup servers located hundreds of miles from where the pharmacy business is conducted. If records regulated under the Federal Controlled Substance Act may be kept at a registrant's primary location, subject to weather and act-of-God risks this same standard must apply to ALL records whether hard-copy or electronic.

- DEA is also attempting to create two standards of length of retention. Currently, DEA proposes that electronic records be kept for five years, while hard copy records are to be kept for two years. This lack of consistency can only lead to enforcement and compliance problems. FMI advocates that the two year standard already present in the current Controlled Substance Act be used for all records.

The Food Marketing Institute and our members would like to commend DEA for your proactive stance on E-prescribing of controlled substances. Thank you for your consideration of our comments which represent input from membership.

If you have additional questions please contact me directly at 202-220-0631.

Sincerely,



Catherine M. Polley, RPh
Vice President, Pharmacy Services

HEADQUARTERS:
2345 Crystal Drive, Suite 800
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