



June 5, 2009

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

Dear Acting Administrator Leonhart:

Re: Docket No. DEA-322; Implementation of the Ryan Haight Online Pharmacy Consumer Protection Act of 2008

The Food Marketing Institute appreciates the opportunity to comment on DEA's interim final rules to implement the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 ("Act"). 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.

Clarification of "Online Pharmacy"

We are pleased with the DEA's exclusion from the term "online pharmacy" the filling of prescriptions that were electronically prescribed in an otherwise authorized manner, and the dispensing of controlled substances by means of the Internet consisting solely of the transmission of information between a pharmacy and an automated dispensing system located in a long-term care facility.

We would like to call your attention to occasions where a pharmacy conducts central fill and processing or conducts telepharmacy for a controlled substance prescription via the Internet. In these situations, a legitimate prescription exists, but it could be construed that these activities constitute delivering, distributing or dispensing a controlled substance, or the attempt to do so, by means of the Internet.

Since DEA has provided exclusions for some legitimate activities that make use of the Internet for delivering, distributing, or dispensing a controlled substance, we believe that it would be appropriate for DEA to amend the interim final rule with language that would provide exclusions for all legitimate activities that make use of the Internet for these purposes, such as central fill/processing and telepharmacy activities. We would like to express our support for the following recommended language submitted by the National Association of Chain Drug Stores for DEA's consideration:

§1300.04(h)(11)(i) Any registered pharmacy whose delivery, distribution, or dispensing of controlled substances by means of the Internet consists solely of the transmission of prescription information between pharmacies or pharmacy personnel and the pharmacies and pharmacy personnel are otherwise complying with this chapter.

(ii) A registered pharmacy will be deemed to meet this exception if, in view of all of its activities other than those referred to in paragraph (h)(11)(i) of this section, it would fall outside the definition of an online pharmacy.

Wholesale Distributor Concerns

We would like to reiterate the comments of the Healthcare Distribution Management Association (HDMA) and the National Association of Chain Drug Stores (NACDS) concerning wholesale distributors' responsibilities under the Act and DEA's rules to implement the Act. We urge DEA to adopt recommendations that:

- (1) should a pharmacy's ordering pattern indicate a possibility that the pharmacy is supplying customers of a Web site, the distributor's responsibility would be to confirm that the pharmacy had obtained a modified registration from DEA, but would not extend to any other elements of the Act or the final rule, and
- (2) clarify that if a pharmacy has such an ordering pattern but does not have a modified registration, an alternative explanation that justifies the order would be acceptable.

Moreover, we concur with HDMA that it is not feasible for distributors to know more about a customer's business activities than that which is available by conducting routine due diligence or by examining Registration Verification information found on the DEA Web site. We would ask DEA to review HDMA's comments for a more detailed discussion of these concerns.

Conclusion

We thank the Drug Enforcement Agency for the opportunity to comment on interim final rules to implement the Act. We concur with the comments of the National Association of Chain Drug Stores and the Healthcare Distribution Management Association and reiterate their recommendations. Please do not hesitate to contact me if I can provide any additional assistance, at cpolley@fmi.org or 202-220-0631.

Sincerely,



Catherine M. Polley, RPh

Vice President, Pharmacy