FOOD MARKETING INSTITUTE

December 14, 2007

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Behind the Counter Availability of Certain Drugs; Docket No. 2007N-0356

Dear Sir or Madam,

The Food Marketing Institute (FMI) appreciates the opportunity to comment on the Food and Drug Administration's request for input on the availability of behind-the-counter (BTC) drugs. We applaud the FDA's desire to study the public health implications of certain drugs being available without a prescription after intervention by a pharmacist. There are several issues surrounding the possible creation of a BTC class of drugs that are of particular concern to FMI, specifically how products will be evaluated for inclusion in the BTC class, what protections pharmacists will receive from claims of liability, how pharmacists will be reimbursed for their time, services and expertise, and the logistical issues that will arise with the new class. Given the complexity of this issue and the wide array of stakeholders affected, we thank the FDA for extending the comment period to ensure all stakeholders had an opportunity to be heard.

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.

In 2007, FMI committed significant resources to develop a Pharmacy Services Department to provide our members with a clinical perspective in identifying and developing federal policy impacting retail pharmacy. FMI's retail members operate over 19,000 in-store pharmacy departments. 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.

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A. Patient Access to Pharmaceuticals

As noted by the FDA in the October 4 Federal Register Notice, some groups have asserted that a BTC category could increase patient access to medications, particularly those patients without health insurance. FMI believes strongly in affordable access to medications, and actively works to ensure that its members' customers have convenient access to needed health care products and medications. However, FMI cautions that if product selection criteria are not narrowly defined and strictly applied, a BTC category may actually decrease patient access to needed medications, especially in rural and underserved markets. Many individuals living in rural areas do not have convenient access to a pharmacy, and instead rely on FMI member stores (not all of which have pharmacies) as their only convenient source of pharmaceutical and health care products. Classifying certain over-the-counter (OTC) medications as BTC would limit the products available in these stores, which would necessarily limit the access these individuals have to the products they depend on for their health and well-being. We support maintaining consumer access to those medications that can be taken safely and effectively without a prescription. Such products should remain over-the-counter medications, available to consumers through various retail outlets.

As the FDA explores the possibility of behind-the-counter availability of drugs, we remind the Agency that criteria used to identify products for inclusion in this potential category should address the concerns associated with the substantial self-diagnosis and/or self-medication role for patients. The approval process should be carefully developed and narrowly defined and should allow for input from drug manufacturers, pharmacists, other health professionals, citizens and the FDA. Likewise, the criteria used to determine acceptability in the BTC class must be based upon sound scientific evidence with a strong emphasis on safety concerns. FMI believes strongly in increasing consumers' access to the products and medications, but not at the expense of patient safety.

We also caution the FDA to only use the BTC category as a means to increase patient access to drugs that require intervention from a pharmacist, but that do not have the safety concerns that warrant physician supervision. The BTC category must not be used as a means to enforce age limits, quantity of product purchased, or other drug enforcement concerns. Pharmacists are trained health care professionals, with the expertise, education and experience to assist patients with their health care and pharmaceutical needs. As has been shown with pseudoephedrine, pharmacists are not needed to enforce quantity limits and ensure that patients purchasing particular products meet minimum age requirements. FMI urges the FDA to limit the scope of any BTC class to those situations where the intervention of a pharmacist can expand access to pharmaceuticals that would otherwise only be available by prescription.

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B. Pharmacist Liability Concerns

Every day, pharmacists help patients self-manage their medication therapy and improve their medication use through appropriate drug selection, monitoring and education. While our pharmacists are eager to help patients access the pharmaceutical care they need, the medications must be safe and effective for their intended use and they must be properly labeled for their intended audience. Drugs should not be placed behind the counter simply to transfer liability from manufacturers to pharmacists or pharmacies because the products themselves are not properly labeled for consumers to purchase in an OTC setting or because manufacturers have not adequately established the safety or efficacy of the drug. If FDA decides to proceed in the development of a BTC class of drugs, it might be appropriate to seek legislation to ensure that liability is fairly apportioned.

C. Pharmacist Reimbursement for Services

The creation of a BTC class of drugs will mean that pharmacists will have to spend greater amounts of time on patient assessment, counseling, dispensing and documentation services for these new drugs. FMI strongly believes that pharmacists must be compensated for these cognitive services. In designing a BTC class, it will be important to consider how payers will respond. For instance, will BTC drugs be treated as analogous to prescription drugs (which are typically covered by insurance) or as OTCs (which generally are "cash and carry" products)? Given the products currently being discussed for BTC status, FMI would argue that treatment closer to prescription status would be more appropriate. This status could provide a mechanism for pharmacists to be compensated for their services—but legislation might be required to accomplish this goal, particularly in the case of Medicare.

D. Logistical Challenges

Depending on the number and type of drugs placed in the BTC category, pharmacies may face considerable logistical challenges in transitioning to this new class of drugs. Behind the counter shelf-space, already at a premium in most stores, will become even more cramped and sought after. As pharmacists take a more active role in patient diagnosis and care, they will need to communicate and coordinate care with labs, physicians and other health care providers. This increased level of communication will also present new challenges. And if pharmacists are required to interview and examine patients, pharmacies will need to rethink and redesign their space in order to provide a private space for the pharmacist to consult with the patient, draw blood, etc. A standardized documentation system will be required beyond the simple registry of the sale to include the BTC medication dispensed and the related services. Communication back to the patient's primary care provider (if known), with patient consent, must also be addressed. Given the considerable logistical changes that will be required, FDA should continue to include the pharmacy community in discussions about the possible creation of the BTC class.

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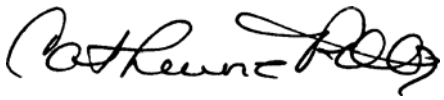
E. Conclusion

Again, FMI credits FDA for accepting public comment on the possible creation of a BTC class. We look forward to working with the FDA as you continue to explore behind-the-counter availability of certain drugs. Please feel free to contact me at 202-220-0631 with any questions you might have.

Sincerely,



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