FOOD MARKETING INSTITUTE

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25 Years of Leadership

December 23, 2002

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Food and Drug Administration
Dockets Management Branch (HFA-305)
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

Re: Docket No. 02N-0417: Proposed Rule – Patent Listing Requirements and Application of 30-month Stays on Approval of Abbreviated New Drug Applications

Dear Sir or Madam:

The Food Marketing Institute (FMI) respectfully submits the following comments in response to the Food and Drug Administration's (FDA's) proposed rule to amend its patent listing requirements for new drug applications and the 30-month stay provisions under the Drug Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments) to the Federal Food, Drug and Cosmetic Act. 67 Fed. Reg. 65448 (Oct. 4, 2002).

For your information, FMI is a non-profit association that conducts programs in research, education, industry relations and public affairs on behalf of its 2,300 members and their subsidiaries. Our membership includes food retailers and wholesalers, as well as their customers, in the United States and around the world. FMI's domestic member companies operate approximately 26,000 retail food stores with a combined annual sales volume of $340 billion, which represents three-quarters of all grocery store sales in the United States. Some 3.5 million individuals are employed by FMI supermarket member companies.

FMI's retail members also operate close to 12,000 in-store pharmacy departments. 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.

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Because of the growing importance of pharmacy in the supermarket industry, and recognizing that rising drug costs adversely affects all consumers who have prescription drug needs, including patients that are covered under federal health care programs, seniors with limited incomes, the underinsured and the uninsured, as well as employees in our industry who receive their drug coverage from FMI member companies, we have an overriding interest in this very important FDA regulatory proposal.

From the outset, FMI wishes to convey our industry's strong support for FDA's proposed rule because it seeks to address certain shortcomings or unintended consequences in current law that deny consumers access to more affordable prescription drugs. As a matter of record throughout the course of this year, FMI has been extremely supportive of both legislative and regulatory reforms that are designed at promoting fair and equitable competition for pharmaceutical products. Specifically, we endorsed legislation in the 107th Congress that would close loopholes in the Hatch-Waxman law that allow brand-name companies to unfairly delay less expensive generic drugs from entering the marketplace, and we also praised the White House when it announced plans on October 21, 2002, to issue a rule that would provide patients with greater and more predictable access to safe, effective, low-cost generic alternatives to brand-name drugs.

The potential benefits of reforming the Hatch-Waxman law are substantial. The Congressional Budget Office (CBO) estimates that modest but long overdue changes to the 1984 law will save consumers and employers some $60 billion over the next 10 years. The White House believes its initiative that would make it easier for Americans to buy generics and could shave $3 billion a year off the nation's rapidly escalating expenditures on prescription medications. These projected savings are clearly realistic and achievable based on price comparisons between generic medications and brand-name drugs. According to industry statistics, the average price of a generic drug is about $17, whereas the average price for a brand-name product is more than $70. Without question, the key to maximizing our limited health care dollars is to encourage vigorous competition between generic drugs and brand-name products and to increase generic utilization rates that have remained relatively stagnant since 1995.

As for the need for reform, FMI holds the same view as the White House that a number of brand-name manufacturers have learned how to "game" the system, by exploiting loopholes in Hatch-Waxman, that result in long delays in the introduction of quality generic drugs. This was not the intent of Congress when it enacted the landmark Hatch-Waxman amendments, which provides for expedited approval procedures for generics while extending patent protection to new brand-name medications for up to an additional five years to compensate innovator companies for the time that was lost in obtaining market approval from FDA. The law performed extremely well up until about five years ago when certain brand-name companies began to file questionable last-minute patents that effectively blocked a generic from being introduced. As a result, prescription drug purchasers in both the private and public sectors have no way to predict with any

degree of certainty when less expensive generic alternatives will be available. This practice is simply unfair and needs to be corrected.

In brief, the FDA proposed rule would define the types of patents that would be permitted to be listed in the agency's "Orange Book". Additionally, the rule calls for an enhanced declaration that patent holders would have to provide in order to list their patents with FDA. And finally, the regulations would limit NDA holders to one 30-month stay during pending patent litigation. FMI believes that these proposed revisions would begin the process of bringing much needed reforms toward curtailing abuses that are occurring in the system. It is our view that the FDA rulemaking is very timely because without reforming Hatch-Waxman, it will become increasingly more difficult for consumers to obtain prescription drugs at affordable prices.

FMI, therefore, urges FDA to finalize this important rulemaking expeditiously, and we respectfully request that the Administration work closely with the Congress in the furtherance of additional legislative reforms that cannot be achieved through rulemaking.

Sincerely,

Tim Hammonds

Tim Hammonds
President and CEO