NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

December 20, 2002

Dockets Management Branch (HFA-305)
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: Docket No. 02N-0417; Applications for FDA Approval to Market a New Drug: Patent Listing Requirements and Application of 30-Month Stays on Approval of ANDAs Certifying That a Patent Claiming a Drug is Invalid or Will Not Be Infringed

To Whom it May Concern:

The National Association of Chain Drug Stores (NACDS) is pleased to provide comments on the Food and Drug Administration's (FDA) proposed rule regarding changes to the current generic drug application approval process. These changes are made pursuant to the 1984 Drug Price Competition and Patent Term Restoration Act, also known as "Hatch-Waxman". We support efforts to increase the availability of low cost generic drugs by closing a number of loopholes in existing law that delay the introduction of these products to the market. We believe that the proposed rule takes a first positive step in moving toward this goal.

413 North Lee Street
P.O. Box 1417-D49
Alexandria, Virginia
22313-1480

NACDS membership consists of about 217 retail chain community pharmacy companies, operating over 35,000 retail community pharmacies. Chain operated community retail pharmacies fill over 70 percent of 3 billion prescriptions dispensed annually in the United States. Community-based retail pharmacies have always promoted the use of lower-cost generic drugs when available and appropriate. The use of generic pharmaceuticals helps save billions in health care costs.

Our comments will review the impact on generic competition of the current interpretation of the regulations, and compare it to changes that would have been made under S. 812 – the Greater Access to Affordable Pharmaceuticals Act (GAPP) – passed by the Senate last July, as well as the proposed regulations.

Issues Relating to Single 30-Month Stay

Central to increasing access to generic drugs is minimizing the extent to which brand name manufacturers can inappropriately delay the launch of generic drugs by seeking additional 30-month stays of approval of generic drugs. Under current regulations, brand manufacturers have been able to use successive 30-month stays to delay marketing of generic products each time the NDA holder listed a new patent. This has, in effect, provided protection for "late listed patents", as well as patents declaring minor product changes.

S. 812 would have only allowed for one 30-month stay per generic application, and only if the brand name manufacturer (a) listed the patent within 30 days after the patent was granted, and (b) commenced legal action within 45 days after the generic application was filed. For patents listed beyond the 30 days, the brand name manufacturer would be able to file for preliminary injunction within 45 days of the generic drug application.

(703) 549-3001
Fax (703) 836-4869
www.nacds.org

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Similarly, the proposed rule would only allow a single 30-month stay for each generic application. However, the proposed rule has no limitation on when a patent must be listed in order to qualify for a 30-month stay, and it does not require the brand name manufacturer to sue in a timely fashion. This means that brand name manufacturers will still be able to delay generic approval on late listed patents, and may in fact, wait until the product is almost approved before taking legal action to delay the launch of the product. The proposed rule should adopt patent filing provisions similar to those in S.812 to avoid unnecessary delays caused by late listed patents.

Issues Relating to 180-Day Exclusivity for Generic Manufacturers

The proposed rule does not address important issues relating to the 180-day exclusivity period granted to some generic manufacturers. There has been considerable debate over whether changes should be made to the 180 day "first to file" exclusivity granted to some generic manufacturers. This exclusivity period provides an incentive for generic manufacturers to challenge the patents on branded drugs in order to bring generic versions to market sooner. However, it is likely that sufficient incentives already exist in the market for generic manufacturers to challenge brand name patents, thus reducing the need for a specific exclusivity incentive to achieve this goal. In fact, because some competing generic versions of popular drugs have been blocked from the market because of this exclusivity provision, private and public payors sometimes pay more for generics than they otherwise would.

Under Hatch-Waxman, the 180-day exclusivity period belongs to the first generic manufacturer to file paragraph IV certification. If that manufacturer fails to market the product, the exclusivity period is relinquished, and later generic manufacturers may not benefit from the 180-day exclusivity. The July 2002 FTC report "Generic Drug Entry Prior to Patent Expiration" expressed concern with the Hatch-Waxman provision that allows forfeiture of the 180-day exclusivity period. In particular, the FTC recommended adopting regulations that discourage settlement agreements between generic companies and brand manufacturers. Settlement agreements between manufacturers are generally drafted with the goal of delaying generic marketing.

S.812 proposed a rollover of the 180-day exclusivity period to the next generic manufacturer in line under certain conditions. That is, if the first manufacturer fails to market a generic product, the 180-day exclusivity period would be forfeited, and awarded to the next in line to file an ANDA. If the second applicant does not market the product, then all applicants with approved ANDAs can market the product. We support this approach to assure that this 180-day exclusivity is not used as a way to deter generic competition.

Until Congress addresses this issue in light of market changes over the past 18 years, provisions should be added to the proposed rule to allow for a rollover of the 180-day exclusivity period, and provide incentive and opportunity for subsequent generic manufacturers to market their products.

Issues Relating to Required Patent Information for New Drug Application (NDA)

To date, the FDA has not actively participated in regulating patent information submitted by NDA applicants for inclusion in the Orange Book. Instead, the FDA has relied on the applicant's own assurance that the listed information was proper and in accordance with statutory and regulatory requirements. Hatch-Waxman required listing of patents for drug product, drug [substance] and method of use only. Nevertheless, brand manufacturers are still able to list patents for process, packaging and other unrelated drug characteristics. Because the FDA has not actively regulated patent listings, brand name manufacturers have been able to use unrelated patent listings as the basis for infringement actions to delay generic marketing.

Provisions in S.812 were not as specific in defining which patents may be listed. However, S.812 would require a declaration by the patent holder that all listed information is complete and accurate. Like the proposed rule, S. 812 does not require active participation by the FDA in determining whether a listing is proper.

The proposed rule defines which patent information is required for listing. The rule limits required patent listing information to drug substance, drug product, method of use, and product by process patents only. Additional information may not be listed. Manufacturers could no longer list patents claiming "packaging", "metabolites", and "intermediaries", which have been used as the basis of 30-month stays in the past. Because brand manufacturers have successfully delayed generic marketing by listed various other patents, the rule should clarify the FDA's role in reviewing information listed.

The proposed rule requires listing of "method of use" patents only for patents that claim indications or conditions of use. This requirement has the potential to stifle development of therapeutic alternatives. New drugs that work by the same mechanism of action could potentially violate a method of use patent. Therapeutic benefits for specific indications or conditions of use are not limited to the mechanism of action. Many patients also benefit from decreased side effects, for example. Alternative therapies that offer additional benefits should not be denied approval because they rely on the same mechanism of action. For method of use patents and all other patents, the FDA should clarify that the intent of the listing is not to stifle therapeutic alternatives.

Issues Relating to Lawsuits for Improper Orange Book Listings

The proposed rule does not address the opportunity for ANDA applicants to challenge improper Orange Book listings. Since infringement actions rely heavily on Orange Book listings, ANDA applicants should be allowed to challenge improper listings that would serve to delay marketing of a generic product.

Currently, no remedies are available to ANDA applicants whose approval is delayed by an improper listing in the Orange Book. S.812 would permit generic companies to sue in Federal court to correct patent listing information or de-list patents that are improperly listed.

While the proposed rule attempts to clarify the Orange Book listing process by specifying proper listing information, there is no instruction regarding the FDA's role in assuring proper listing. Allowing generic manufacturers to challenge an improper listing would alert the FDA to violations of the rule in the absence of active FDA review of Orange Book listing.

NACDS appreciates your consideration of these views when considering final regulations. Please contact us if we can provide further elaboration on these comments. Thank you.

Sincerely,

S. Lawrence Kocot
Senior Vice President and General Counsel