December 23, 2002

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

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

The Coalition for a Competitive Pharmaceutical Market ("CCPM") is pleased to submit the following comments on the Food and Drug Administration's ("FDA's") proposed rule addressing the patent listing and 30-month stay provisions of the Drug Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman) to the Federal Food, Drug, and Cosmetic Act. CCPM is an organization of large national employers, insurers, generic drug manufacturers, and others committed to improving consumer access to high quality generic drugs and restoring a vigorous, competitive prescription drug market. In furtherance of this goal, CCPM supports legislative and regulatory reforms aimed at promoting fair competition and access to affordable, equally effective generic drugs. Accordingly, CCPM has a keen interest in the issues addressed in FDA's proposed rule.

CCPM members include more than 20 national organizations that collectively represent over 100 million Americans. While we acknowledge the value of pharmaceuticals in preventing and treating disease, CCPM members who are purchasers cannot continue to sustain cost

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increases of up to 20 percent annually. These extraordinary pharmaceutical costs are leading to increased premiums, higher co-payments, and reductions in benefits, and are limiting the ability of American businesses to compete in the world marketplace.

Generic drugs are a critical component of CCPM members' strategies to manage pharmaceutical costs when providing meaningful health care coverage to enrollees, employees, retirees and their families. Generic drugs, which are approved for marketing only after the same rigorous FDA review as their brand counterparts, offer consumers, employers and insurers quality care options at affordable prices. For example, the average price of a prescription dispensed with a generic drug in 2001 was $17 compared to $72 for the brand counterpart. (IMS Health.)

As the President stated when introducing the FDA proposed rule, generic drugs are not only "just as safe and effective" as their brand counterparts; "generic drugs make American health care far more affordable."

I. General Comments

CCPM applauds the Administration for issuing a proposed rule to address some of the abuses of the current statute. As the FDA notes, when Congress enacted Hatch-Waxman, it intended to facilitate competition in the pharmaceutical market that would contain costs and to encourage new drug application (NDA) holders to develop new, innovative products.[1] Our

[1] *See* H.R. Rep. No. 98-857, pt. II (1984) *reprinted in* 1984 U.S.C.C.A.N. 2716-17 (declaring that one of the principal policy objectives of Hatch-Waxman was to "get[] safe and effective generic substitutes on the market as quickly as possible after the expiration of a patent.")

business members understand the value of intellectual property protections and know that robust competition is the engine that drives innovation. In the pharmaceutical market, the absence of competition stalls innovation and the cost savings that can be achieved through the free market process are never realized. By fostering competition in the pharmaceutical market, Hatch-Waxman has increased the availability of quality, effective and affordable generic drugs.

However, as a recent report by the Federal Trade Commission (FTC) notes, Hatch-Waxman has become "susceptible to strategies that ... may have prevented the availability of more generic drugs." In announcing the FDA proposed rule, President Bush acknowledged that "some brand name drug manufacturers may have manipulated the law to delay the approval of competing generic drugs."

CCPM agrees with the Administration that some brand drug companies have exploited loopholes in Hatch-Waxman in an effort to block legitimate competition from generic drugs. For example, by submitting numerous patents to the FDA that do not claim the brand company's approved drug or a method of using the approved drug, some brand companies have undermined the system for listing patents in FDA's "Orange Book." The presence of these "listed" patents often triggers multiple 30-month stays even when the brand company has no reasonable likelihood of success in the underlying infringement suit.

As a result, prescription drug purchasers in both the private and public sectors can no longer predict, with any degree of certainty, when affordable generic drug products will enter the marketplace. The cumulative effect of the exploitation of these loopholes has been continued delays in the public's access to affordable medicine and significant reductions in the cost-

savings that were originally intended to flow from the passage of Hatch-Waxman. It is ultimately the American consumer who is denied access to affordable medicine and who, as a taxpayer, must shoulder the burden of the nation's health care bill.

FDA's proposed rule attempts to close the loopholes in Hatch-Waxman by:

1) Defining the types of patents that may be listed in the "Orange Book;"
2) Strengthening the declaration that patent holders must provide to "list" their patents; and
3) Limiting NDA holders to a single 30-month stay.

These are the issues that are at the heart of the abuses of the current system.

CCPM applauds the agency's efforts to undertake reform to stop the abuses of the current system. However, due to the limitations of the statute and constraints on administrative authority the proposed rule does not completely close the loopholes that are being exploited to delay legitimate competition. Many of the abuses of the current system stem from the language of Hatch-Waxman, rather than FDA's implementation of the statute. As such, certain provisions of the proposed rule can at best mitigate the abuses that are costing consumers billions in lost savings. CCPM believes that to restore predictability, legislative measures must be taken concurrently with the proposed rule to close current loopholes without any collateral damage to other pivotal elements of Hatch-Waxman.

II. Specific Comments

A. Defining the Types of Patents that are Eligible for "Listing" in FDA's "Orange Book"

The proposed rule provides guidance to the pharmaceutical industry on the types of patents that are eligible for listing in FDA's "Orange Book." The patent listing criteria is vitally important because only "listed" patents can result in an automatic 30-month stay of generic drug approval. CCPM agrees that further clarification of the patent listing requirements could help to prevent the patent listing abuses that currently cause unwarranted delays in consumer access to generic drugs. However, any such regulation must adhere to the plain language of the statutory patent listing requirements. Namely, FDA should refuse to list a patent in the "Orange Book" unless:

1) The patent claims the patent holder's approved drug or a method of using the approved drug; and

2) A claim of patent infringement could reasonably be asserted if a person not licensed by the patent owner manufactures, sells or uses the approved drug. See 21 U.S.C. § 355(b)(1).

In many respects, the proposed rule is consistent with the statutory requirements. For example, CCPM agrees that patents claiming packaging, metabolites, and intermediates, as well as "process patents," do not meet the statutory listing requirements and should not be accepted for listing. However, the proposed rule is overly broad in its attempts to list specific types of

patents that *may* be listed. For example, the proposed rule would allow the listing of patents that claim unapproved forms of the brand drug's active ingredient and "product-by-process" patents. As the FTC noted in its July 2002 report on generic drugs, there are numerous examples where the proposed rule would permit the listing of patents that do not "claim" the approved drug and therefore cannot be said to meet the statutory requirements for listing. See FTC Report at App. G and H.

CCPM urges FDA to adopt the FTC's recommendation by simply giving the word "claim" its standard meaning under patent law. See FTC Report at 54. To ensure a competitive market, FDA should only list a patent if the "claims" section of the patent specifically describes either the approved drug or its use. Adopting this approach would allow FDA to achieve the President's objective of providing meaningful guidance on patent listings while avoiding the appearance of or any actual conflict with the statutory language.

Nevertheless, FDA oversight is needed to ensure the listing requirements are satisfied. Oversight is especially important because the courts have held that generic manufacturers have no legal recourse to challenge the appropriateness of a patent listing in court. See Andrx Pharm., Inc. v. Biovail Corp., 276 F.3d 1368 (Fed. Cir. 2002); Mylan Pharm., Inc. v. Thompson, 268 F.3d 1323 (Fed. Cir. 2001).

If FDA does not enforce the patent listing requirements of section 505(b)(1) of the FFDCA — and in the absence of the legislative reform that would ensure timely resolution of

patent disputes — measures to address the inappropriate listing of patents are critical to ensuring predictability of generic drug market entry.

B. Strengthening the Patent Listing Declaration

CCPM agrees that the patent listing declaration should be strengthened. Aggressive implementation and enforcement of the patent listing requirements should be included in reform measures. There must be accountability and enforcement to address anticompetitive tactics with respect to patent listings.

C. The 30-Month Stay

As the FTC noted in its report, the 30-month stay has been increasingly abused by some companies to delay legitimate competition and deny consumers access to affordable drugs. Of considerable concern is that inappropriately listed patents have delayed competition unfairly, to the detriment of consumers. We commend the President's measures to address abuses of the current statute. The Administration's position with respect a single 30-month stay is a significant improvement over the current system. However, we are concerned that the 30-month stay provision may alter the fundamental balance of Hatch-Waxman.

One of primary goals of the Hatch-Waxman patent challenge process is to provide faster public access to generic drugs by ensuring that the underlying patent litigation and the FDA

review of the generic drug occur simultaneously. Under current law, a brand company must sue a generic company for patent infringement within 45 days of receipt of notice of the generic company's Paragraph IV certification. If the brand company files suit within this 45-day window, the FDA's approval of the generic application is stayed automatically for 30 months or until a court has resolved the patent dispute, whichever comes first.

Under the proposed rule, there is no potential for more than a single 30-month stay per generic application. Therefore, brand companies will no longer have an incentive to bring timely suits on any subsequent patents listed after the first 30-month stay has begun. On the contrary, there will be an incentive for brand companies to wait as long as possible before suing on any reasonable patents that are listed after the first 30-month stay has begun.[2] In other words, the proposed rule most likely will have the unintended consequence of shifting the timing of patent litigation downstream. This result actually would cause more of a delay in generic access than may occur today. Rather than initiating patent dispute resolution early in the process, brand companies may elect not to list patents and thereby push the litigation outside of the Hatch-Waxman process.

Thus, any attempt to limit brand-drug companies to a single 30-month stay must include safeguards to avoid such collateral damage and ensure that the patent litigation and FDA review occur simultaneously so that affordable generic drugs reach consumers as soon as possible.[3] For

[2] By doing so, a brand company will be able to use the threat of potential treble damages to keep generic competition from entering the market before the patent dispute is resolved.

[3] The Greater Access to Affordable Pharmaceuticals Act (S.812), recently passed by the Senate, would have provided these safeguards by: (1) requiring NDA holders to list their patents within 30 days of

this reason, CCPM believes that the single 30-month stay provision in the proposed rule must be augmented with measures to ensure timely resolution of patent disputes. To the extent that such augmentation is beyond the scope of administrative authority, CCPM encourages the FDA to support legislation to effectuate timely market entry of generic drugs.[4]

III. Conclusion

CCPM is very appreciative of the President's strong stance on the equivalence of generic drugs to their brand counterparts and the necessity of allowing affordable competition to enter the market in accordance with Congress' envisioned timeline. The Administration's support for reform could not come at more important time for our country. At the current rate of escalation, public and private purchasers of prescription pharmaceuticals simply will not be able to continue to provide the public with the drug products that it needs at an acceptable price. Affordable generic drugs must be made available as soon as all valid patents and exclusivity periods expire. The proposed rule is an unprecedented and critical first step towards controlling drug costs and increasing the public's access to affordable generic drugs. We look forward to working with the FDA throughout the implementation process and to develop legislative proposals to address other important prescription drug issues.

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issuance or lose their right to sue generic applicants; and (2) requiring NDA holders to sue generic applicants within 45 days of receiving notice of a generic challenge or forfeit the right to sue that particular generic applicant.

[4] CCPM supports additional measures to ensure timely market entry of generic drugs, including reform of the 180-day market exclusivity provisions of Hatch-Waxman, which the FTC report concluded have lead to anticompetitive agreements between brand and generic companies.