Testimony of

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June 17, 2003

INTRODUCTION

Mr. Chairman and Members of the Subcommittee, I am Daniel E. Troy, Chief Counsel for the United States Food and Drug Administration (FDA or the Agency). I am pleased to be with you today to discuss the Federal Trade Commission's July 2002 report entitled Generic Drug Entry Prior to Patent Expiration: An FTC Study (FTC Report) and FDA's implementation of the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Amendments.

This testimony will discuss a number of issues that affect the timely introduction of generic drugs into the U.S. marketplace. It will focus in particular on whether certain "later-listed" patents or inappropriate patent submissions by the sponsors of innovator drug products have resulted in the delay of generic drug approvals. These matters were the subject of the FTC Report, which FDA has found to be invaluable in informing the Agency's response to the delays to generic drug approvals. As you may know, on
June 12, 2003, FDA announced its final rule intended to speed access to and increase the availability of generic drugs by limiting the use of 30-month stays by brand-name drug sponsors and by clarifying the types of patents that must be submitted to FDA for listing in the Orange Book.

The Hatch-Waxman Amendments were intended to balance two important public policy goals. First, Congress wanted to ensure that brand-name (also known as innovator) drug manufacturers would have meaningful patent protection and a period of marketing exclusivity to enable them to recoup their investments in the development of valuable new drugs. Second, Congress sought to ensure that, once the statutory patent protection and marketing exclusivity for these new drugs has expired, consumers would benefit from the rapid availability of lower priced generic versions of innovator drugs.

Since its enactment in 1984, Hatch-Waxman has governed the generic drug approval process. In general, the law has been working well. Since 1984, over 10,000 generic drugs have entered the market, and generics now account for close to 50 percent of prescriptions. Attention has recently focused on two key provisions of the law that allow for 180 days of marketing exclusivity to certain generic drug applicants, and for the 30-month stay on generic approvals. Both of these provisions are discussed in detail below.

FDA's objective is to enhance the ability of innovators, generic firms and the Agency to achieve the goals embodied in Hatch-Waxman. While the new rule will improve FDA's implementation of the law, this is only one part of a set of FDA initiatives that will reduce drug costs by encouraging innovation and speeding up the drug development and approval process, while maintaining FDA's high standards for safety and effectiveness. Our reforms in the generic approval process will generally shave months off the time to availability of generic drugs across the board. Similarly, new pathways for approving inhaled and topical drugs will potentially affect many products. This broad improvement in drug availability, both new drugs and generic drugs, will have a positive impact on all patients, not just those affected by imperfections in the operation of Hatch-Waxman.

STATUTORY PROVISIONS

The Hatch-Waxman Amendments amended the Federal Food, Drug, and Cosmetic (FD&C) Act and created a statutory generic drug approval process with section 505(j). Section 505(j) established the abbreviated new drug application (ANDA) approval process, which permits generic versions of previously approved innovator drugs to be approved without submitting a full new drug application (NDA). An ANDA refers to the clinical research and data in a previously approved NDA (the "listed drug") and relies on the Agency's finding of safety and effectiveness for the listed drug product.

The timing of an ANDA approval depends in part on patent protections for the innovator drug. Innovator drug applicants must include, in an NDA, information about patents relating to the drug product that is the subject of the NDA. FDA is required to publish the patent information submitted. The statute establishes a process that requires that ANDA applicants certify to the patents listed, provide notice to the NDA holder and patent owner, and, if patent infringement litigation is filed, imposes a 30-month stay on the approval of an ANDA. The Hatch-Waxman Amendments also created a period of market exclusivity for certain generic applicants.

"ORANGE BOOK" LISTINGS

Only certain types of patent information can be submitted to FDA. FDA publishes patent information on approved drug products in the Agency's publication Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the "Orange Book." The Orange Book is available on FDA's website and is updated every few weeks. The book is printed in hardcover yearly by the Government Printing Office, updated monthly and available to the public. It lists all approved drug products with their therapeutic equivalence codes in addition to the products' patent and exclusivity information (if such information exists).

Concerns have been expressed over FDA's role in the listing of patents in the "Orange Book," which can have an impact on generic drug approvals by delaying their approval and the initiation of 180-day exclusivity. Under the FD&C Act, pharmaceutical companies seeking to market innovator drugs must submit, as part of an NDA or supplement, information on any patent that: 1) claims the pending or approved drug or a method of using the approved drug, and 2) for which a claim of patent infringement could reasonably be asserted against an unauthorized party. Patents that may be submitted are drug substance (active ingredient) patents, drug product (formulation and composition) patents, and method of use patents. Process (or manufacturing) patents may not be submitted to FDA.

When an NDA applicant submits a patent covering the formulation, composition, or method of using an approved drug, the applicant must also submit a signed declaration stating that the patent covers the formulation, composition, or use of the approved product. The required text of the declaration is described in FDA's regulations.
The process of patent certification, notice to the NDA holder and patent owner, a 45-day waiting period, possible patent infringement litigation and the statutory 30-month stay may result in a considerable delay in the approval of ANDAs when an innovator company submits a new patent listing to FDA. Therefore, ANDA applicants often closely scrutinize these listings. FDA's regulations provide that, in the event of a dispute as to the accuracy or relevance of patent information submitted to and subsequently listed by FDA, an ANDA applicant must provide written notification of the grounds for dispute to the Agency. FDA will then ask the NDA holder to confirm the correctness of the patent information and listing. Unless the patent information is withdrawn or amended by the NDA holder, FDA does not change the patent information in the "Orange Book."

If a patent is listed in the "Orange Book," an applicant seeking approval for an ANDA must submit a certification to the patent. Even an applicant whose ANDA is pending when additional patents are submitted for listing by the sponsor must certify to the new patents, unless the additional patents are submitted by the patent holder more than 30-days after issuance by the U.S. Patent and Trademark Office. Until the final rule effective date, pending generic drug applications are subject to multiple overlapping 30-month stays if new patents are listed for the innovator drug.

FDA does not undertake an independent review of the patents submitted by the NDA sponsor. The statute requires FDA to publish patent information upon approval of the NDA. This strongly suggests - and FDA has long held - that the Agency's role in the patent-listing process is intended to be ministerial. Issues of patent claim and infringement are matters of patent law, and FDA lacks the authority, the resources, and the capability to assess whether a submitted patent claims an approved drug and whether a claim of patent infringement could reasonably be made against an unauthorized use of the patented drug. As such, FDA has implemented the statutory patent listing provisions by informing interested parties of what patent information is to be submitted, who must submit the information, and when and where to submit the information. Generic and innovator firms may resolve any disputes concerning patents in private litigation.

Over the past few years, new patents have occasionally been submitted to FDA for listing in the "Orange Book" shortly before patents already listed in the "Orange Book" were scheduled to expire. These new patents have been submitted to FDA within the required 30-days of issuance by the Patent and Trademark Office. If the NDA sponsor

complies with the requirements of the statute and regulations in submitting a patent for listing in the "Orange Book," the Agency may not reject a patent merely on the basis that, but for the filing of the patent, ANDAs would be eligible for final approval.

It has been suggested that FDA should review drug patents to determine if they should be listed in the "Orange Book" as protection for innovator drug products -- that is, FDA should assess whether a submitted patent properly claims the approved drug product and could support a claim of patent infringement. The Agency believes that, even if it had the authority and expertise (which it does not), such a review would not speed the availability of generic drugs. Rather, it would instead add a layer of complexity and delay, leading to litigation between FDA and the generic or innovator, in addition to any litigation between the generic and innovator.

Moreover, FDA review of patents would be unlikely to speed approval and marketing of generic drugs in a meaningful way even if FDA were to decide not to list a patent, the innovator company could obtain an injunction against approval or marketing of the generic drug until the patent listing question is resolved. In such a case, FDA's review of the patents would have done nothing to speed approval of generic drugs. Patent reviews would lead to substantial litigation that will impose a new and substantial burden on FDA's Office of the Chief Counsel and Department of Justice litigation resources. Finally, the Agency does not have the resources or expertise to review patents and, even with additional funding, is unlikely to be able to obtain the expert resources to do so.

DELAYS IN GENERIC DRUG APPROVALS - 30-MONTH STAYS

The FD&C Act requires that generic drug applicants include, in their ANDAs, a certification for each patent listed in the "Orange Book" for the innovator drug. Similar information is required for applicants filing 505(b)(2) applications under section 505(b)(2) of the FD&C Act. This certification must state one of the following:
(I) that the required patent information relating to such patent has not been filed;
(II) that such patent has expired;
(III) that the patent will expire on a particular date; or
(IV) that such patent is invalid or will not be infringed by the drug, for which approval is being sought.
A certification under paragraph I or II permits the ANDA to be approved immediately, if it is otherwise eligible. A certification under paragraph III indicates that the ANDA may be approved when the patent expires.

A paragraph IV certification, however, begins a process in which the question of whether the listed patent is valid or will be infringed by the proposed generic product may be answered by the courts before the expiration of the patent. The ANDA applicant who files a paragraph IV certification to a listed patent must notify the patent owner and the NDA holder for the listed drug that it has filed an ANDA containing a patent challenge. Until the effective date of FDA's final rule, all patents submitted and listed in the Orange Book, which are the subject of a paragraph IV certification, require notice to the NDA holder and patent owner. The notice must include a detailed statement of the factual and legal basis for the ANDA applicant's opinion that the patent is not valid or will not be infringed.

The submission of an ANDA for a drug product claimed in a patent is an infringing act if the generic product is intended to be marketed before expiration of the patent. Accordingly, the ANDA applicant who submits an application containing a paragraph IV certification may be sued for patent infringement. If the NDA holder or patent owner files a patent infringement suit against the ANDA applicant within 45 days of the receipt of notice, FDA may not give final approval to the ANDA for at least 30 months from the date of that notice.

This 30-month stay will delay approval of the generic drug product unless the court reaches a decision earlier in the patent infringement case or otherwise orders a longer or shorter period for the stay. A court may modify the length of a stay, under the FD&C Act, "if either party in the action failed to reasonably cooperate in expediting the action." (21 U.S.C. 335(j)(5)(iii))

Under FDA's traditional interpretation of the Hatch-Waxman Amendments, multiple 30-month stays have been possible. Submission of newly issued patents after an ANDA application has been filed with FDA has required the appropriate certification and notice to the NDA holder and patent owner with the possibility of a 30-month stay if patent infringement litigation resulted. As a result, there have been a number of instances in which delays in ANDA approval have exceeded 30-months.

A recent review of FDA's records indicates that of the 442 active ANDAs that contained paragraph IV certifications, only 17 have had multiple 30-month stays, representing 3.8 percent of all applications with patent challenges. However, we note that a significant number of these products have high dollar value annual sales, and we are aware of some instances where multiple stays have resulted in the delay of a generic drug approval for a number of years.

180-DAY EXCLUSIVITY

The Hatch-Waxman Amendments provide an incentive of 180 days of market exclusivity to the "first" generic applicant who challenges a listed patent by filing a paragraph IV certification and thereby runs the risk of having to defend a patent infringement suit. The statute provides that the first applicant to file a substantially complete ANDA containing a paragraph IV certification to a listed patent will be eligible for a 180-day period of exclusivity beginning either from the date it begins commercial marketing of the generic drug product, or from the date of a court decision finding the patent invalid, unenforceable or not infringed, whichever is first. These two events -- first commercial marketing and a court decision favorable to the generic -- are often called "triggering" events, because under the statute they can trigger the beginning of the 180-day exclusivity period.

In some circumstances, an applicant who obtains 180-day exclusivity may be the sole marketer of a generic competitor to the innovator product for 180 days. But 180-day exclusivity can begin to run -- with a court decision -- even before an applicant has received approval for its ANDA. In that case, some, or all of the 180-day period, could expire without the ANDA applicant marketing its generic drug. Conversely, if there is no court decision and the first applicant does not begin commercial marketing of the generic drug, there may be prolonged or indefinite delays in the beginning of the first applicant's 180-day exclusivity period. Approval of an ANDA has no affect on exclusivity, except if the sponsor begins to market the approved generic drug. Until an eligible ANDA applicant's 180-day exclusivity period has expired, FDA cannot approve subsequently submitted ANDAs for the same drug. This is true even if the later ANDAs are otherwise ready for approval and the sponsors are willing to begin marketing immediately. Therefore, an ANDA applicant who is eligible for exclusivity can often delay all generic competition for the innovator product.

Only an ANDA containing a paragraph IV certification may be eligible for exclusivity. If an applicant changes from a paragraph IV certification to a paragraph III certification, for example, upon losing its patent infringement litigation, the ANDA will no longer be eligible for exclusivity.

The 180-day exclusivity provision has been the subject of considerable litigation and administrative review in recent years, as the courts, industry, and FDA have sought to interpret it in a way that is consistent both with the statutory text and with the legislative goals underlying the Hatch-Waxman Amendments. A series of Federal court decisions beginning with the 1998 Mova case describe acceptable interpretations of the 180-day exclusivity provision, identify potential problems in implementing the statute, and establish certain principles to be used by the Agency in interpreting the statute. As described in a June 1998 guidance for industry, FDA currently is addressing on a case-by-case basis those 180-day exclusivity issues not addressed by existing regulations.

One of the most fundamental changes to the 180-day exclusivity program, resulting from the legal challenges to FDA's regulations, is the determination by the courts of the meaning of the phrase "court decision." The courts have determined that the "court decision" that can begin the running of the 180-day exclusivity period may be the decision of the district court, if it finds that the patent at issue is invalid, unenforceable, or will not be infringed by the generic drug product. FDA had previously interpreted the "court decision" that could begin the running of 180-day exclusivity (and the approval of the ANDA) as the final decision of a court from which no appeal can be or has been taken - generally a decision of the Federal Circuit. FDA's interpretation had meant that an ANDA applicant could wait until the appeals court had finally resolved the patent infringement or validity question before beginning the marketing of the generic drug.

FDA had taken this position so that the generic manufacturer would not have to run the risk of being subject to potential treble damages for marketing the drug, if the appeals court ruled in favor of the patent holder. The current interpretation means that if the 180-day exclusivity is triggered by a decision favorable to the ANDA applicant in the district court, the ANDA sponsor who begins to market during that exclusivity period now may run the risk of treble damages if the district court decision is reversed on appeal to the Federal Circuit. As a practical matter, it means that

many generic applicants may choose not to market the generic and thus the 180-day exclusivity period could run during the pendency of an appeal.

FEDERAL TRADE COMMISSION STUDY

In response to reports of brand-name and generic drug companies engaging in anti-competitive behavior, the FTC conducted a study to determine if the 180-day exclusivity and the 30-month stay provisions of the Hatch-Waxman Amendments have been used strategically to delay consumer access to generic drugs. In July 2002, FTC published the findings of their study and provided two primary recommendations.

FTC recommended that only one automatic 30-month stay per drug product per ANDA be permitted to resolve infringement disputes over patents listed in the "Orange Book" prior to the filing date of the generic applicant's ANDA. FDA agrees with FTC's conclusion that recently, more ANDAs have been subject to 30-month stays, and more multiple 30-month stays, than in years past, and more patents on average are now being litigated per generic drug application than in the past.

FTC's second recommendation was to pass legislation to require brand-name companies and first generic applicants to provide copies of certain agreements to FTC. This is a response to FTC's finding that brand-name companies and first generic applicants have on occasion entered into agreements to delay generic competition. FDA has no objection to this recommendation.

FDA agrees with many of the conclusions of the FTC study and has found the factual information provided in the report to be extremely valuable in our own deliberations regarding the generic drug approval process. One example of this is the compilation of information on the disposition of litigation surrounding patents filed after NDA approval. Finally, we note that FTC's report recognized that FDA does not have the capacity to review the appropriateness of patent listings.

FDA RULEMAKING

On June 12, 2003, President Bush, HHS Secretary Thompson and FDA Commissioner McClellan announced a new regulation to be effective in 60 days that will streamline the process for making safe, effective generic drugs available to consumers. This rule was first proposed on October 24, 2002, in response, in part, to the FTC recommendations and other changes the Agency identified as being useful in improving generic competition. The new rule will limit an innovator drug company to only one 30-month stay of a generic drug applicant's entry into the market for resolution of a patent challenge. The changes in the regulations will save consumers an estimated $35 billion over ten years by making generic alternatives to certain more costly brand-name drugs available more quickly, by avoiding time-consuming legal delays. The new regulations will be published as a final rule in the Federal Register on June 18, 2003. The rule will be effective on August 18, 2003.

The rule provides a full opportunity for only one 30-month stay per ANDA or 505(b)(2) application; prohibits the submission of patents claiming packaging, intermediates, or metabolites; requires the submission of certain patents claiming a different polymorphic form of the active ingredient described in the NDA; adds a requirement that, for submission of polymorph patents, the NDA holder must have test data demonstrating that a drug product containing the polymorph will perform the same as the drug product described in the NDA; makes changes to the patent information required to be submitted and provides declaration forms for submitting that information to FDA, both with the NDA and after NDA approval; and does not require claim-by-claim listing on the declaration form except for method-of-use patents claiming approved methods of use.

30-Month Stay Provisions

The final rule limits brand-name companies to only one 30-month stay. The rule accomplishes this by establishing when generic companies must provide notice of a paragraph IV patent challenge to a brand-name sponsor and the patent owner (which initiates the 30-month stay process). Notice of a paragraph IV certification must be provided with an initial paragraph IV certification and when a previous certification and notice did not result in a full opportunity for a single 30-month stay.

If an ANDA or 505(b)(2) application is amended to include a paragraph IV certification, notice must be provided to the NDA holder and patent owner only if the application did not already contain a paragraph IV certification or there was not a full opportunity for a 30-month stay. If an ANDA or 505(b)(2) applicant changes its paragraph IV certification before the 45-day period after notice to the NDA holder and patent owner has expired, and the NDA holder or patent owner has not initiated patent litigation, such paragraph IV certification and related notice are not considered to have satisfied the requirement of providing one notice of a paragraph IV certification and a full opportunity for a 30-month stay.

Generic drug applicants will still have to file paragraph IV certifications to FDA, and the ability of brand-name firms to obtain patents and to challenge alleged infringement in court is undiminished. They will not, however, be able to forestall approval of a generic version of a drug by engaging in submitting later-issued patents or repeated patent filings. These later submissions will no longer result in multiple 30-month stays.

Requirements for Drug Patent Submissions
Under the final rule, drug manufacturers will not be allowed to submit patent information for listing in the Orange Book for drug packaging, drug metabolites, and intermediate forms of a drug. Permitted submissions include patent information on drug product (active ingredients), drug substance (formulation/composition), and approved uses of a drug.

In addition, patent submission declarations will be more detailed. There are mandatory forms that must be used to submit patent information to FDA. The forms include a series of questions with check-off boxes to be completed that provide details on the type of patent information submitted. The questions request information on whether the patent is one of the type permitted or not under the regulations, whether the patent is a product-by-process patent and the product claimed is novel, whether the method of use is an approved method of use and the relevant indication included in the approved labeling, and other relevant information.

The declarations must be filed with the NDA, amendment, or supplement, and for patent information submitted after NDA approval. The check-off questions are designed so that FDA does not have to do anything more than quickly review the form to determine whether the patent information is eligible for listing. A signed attestation is required on the declaration form that requires that the submitter attest to the familiarity with the regulations and the information submitted. A warning is included that a willfully and knowingly false statement in the attestation can lead to criminal charges. These changes will significantly reduce opportunities to submit inappropriate patents for listing in order to delay approval of generic drugs and prevent fair competition

INITIATIVE ON IMPROVING ACCESS TO GENERIC DRUGS

Concurrent with FDA's June 12, 2003, announcement on publication of its final rule, President Bush announced an initiative on Improving Access to Generic Drugs, which includes the following components:

? A proposed increase of $13 million in Fiscal Year 2004 in FDA resources devoted to improving access to generic drugs.
The proposed addition in the President's fiscal year 2004 budget of an additional $13 million in spending for FDA's generic drug programs would be the largest annual infusion of resources into the generic drug program ever, increasing the program's size by about one-third. FDA will be able to hire about 40 additional staff in generic drugs and expand the new chemistry review division in the Office of Generic Drugs. This expansion should help reduce the average review time by at least two months, increase the percentage of reviews that are completed within 180 days, approach the goal of reviewing 100 percent within 180 days and further reduce the time it takes FDA to review.

? New processes to reduce the time and cost of generic drug approvals.
Beginning in the next fiscal year, FDA will make significant changes in its processes for approving generic drugs. In particular, the FDA will implement early communications with generic drug manufacturers to discuss their applications. FDA will increase the number of guidances available for generic manufacturers regarding what is required to prepare and submit quality, complete applications. FDA will also institute regular meetings with generic trade associations to discuss the process for improving the quality of applications and to impart information on changes in policies and procedures. Studies of FDA processes for new drugs indicate that early communications and

more explicit guidances can often improve drug applications and allow deficiencies to be corrected while an application is under review, rather than having to wait for additional review cycles to fix problems. This can significantly reduce the time it takes to approve a drug.

? Enhanced public education and scientific study of generic drugs.
FDA will expand its educational programs and partnerships involving generic drugs to help health care practitioners and consumers get accurate information about the availability of generic drugs for health care needs. FDA will also undertake additional scientific studies of certain types of generic drugs where adequate bioavailability methods have not been adequately developed, to make it easier to approve these generic drugs. FDA will also enhance the monitoring of the safety of generic drugs currently on the market.

These steps to improve access to generic drugs are expected to reduce the average time for most generic drug approvals by three months or more. Because this approach to increase availability will apply to all generic drugs, it can have a substantial impact on health care costs. In particular, faster access and a lower-cost approval process for the hundreds of generic drugs expected to come on the market would be expected to save consumers many billions. Improved consumer education and generic drug science is also intended to lead to additional savings from greater confidence and use of generic drugs.

OTHER SIGNIFICANT BARRIERS TO GENERIC DRUG AVAILABILITY

Although patent-related challenges have delayed approval of generic drugs in a number of high-profile cases, there are a number of other important barriers to generic competition. These barriers, which usually result from insufficient scientific knowledge and standards, are likely to become even more significant as scientific advances in drug development lead to new forms of therapy.

Currently, some classes of drug products entirely lack generic versions because scientific methods for evaluating their bioequivalence are not available. Examples include the nasal and inhaled corticosteroids used for allergy and asthma treatment. Prospective manufacturers of inhaled or topical generic drugs face uncertainty and high development costs, and thus few such products have been developed. Other widely used drugs, such as conjugated estrogens (available since the 1940s), lack generic competition due to scientific uncertainty about the composition of the active ingredient (s). Disputes over composition and bioequivalence standards also have caused delays in approval of many generic drugs while innovator challenges to the standards are evaluated. Scientific research to support the development of additional standards in these areas would enable FDA to approve drugs in additional classes, and also to deal with scientific challenges to pending generic drug approvals more expeditiously.

Innovations in drug therapy are leading to new methods of drug delivery, including via liposomes, implantable systems, transcutaneous or transmucosal products, and inhalation methods. At the same time, due to innovations in chemistry, drugs with very complex molecular structures are possible. If generic copies of such innovative therapies are eventually to be made available, standards must be developed to accommodate these products within the Hatch-Waxman framework. This includes work on issues of composition, formulation and bioequivalence. Scientific research in each of these areas is needed to support new standards.

Some of the FY 2004 budget increase for the generic drug program noted above will allow for additional bioequivalence research on inhalers, topical generics, and other dosage forms, so that in the future, new classes of generics can be made possible. This is a long-term research need that will take time and a lot of effort, but FDA is dedicated to opening up these new product areas.

RECENT SENATE ACTION ON GENERICS LEGISLATION

We are pleased to note that in addition to our actions designed to speed access to generic drugs, last week the Senate Committee on Health, Education, Labor and Pensions by unanimous consent ordered reported legislation on generic drug access. This agreement is an important step forward. We recognize and appreciate Chairman Gregg's leadership in achieving a bipartisan agreement with the other original sponsors of the bill. We are pleased that the proposed legislation includes key ideas embodied in FDA's regulation to improve access to generic drugs, and does

not include certain other problematic provisions contained in legislation (S. 812) that passed the Senate last year. In this highly complex and technical area of law, we do have some concerns with the workability of the bill that we believe must be resolved for the legislation to achieve its intended effect, and we are working with the original sponsors and other Members to address the various technical and policy issues.

CONCLUSION

Greater access to generic drugs will reduce health care costs because the price of generic drugs is typically much lower than the brand-name drug. Reducing expensive lawsuits over drug patents and making the approval process more efficient will also help to lower national health care costs by reducing the cost of bringing safe and effective generic drugs to market. Thanks to the President's leadership, we are making real progress to build on his initiatives on speeding access to generic drugs by finalizing a generic drug rule that will save consumers $35 billion over 10 years by increasing access and availability to generic drugs.

FDA continues to implement the Hatch-Waxman Amendments exclusivity provisions in the best manner possible given the text and history of the legislation, and the numerous court challenges. In doing so, FDA has tried to maintain a balance between innovation in new drug development and expediting the approval of lower-cost generic drugs, as Congress sought to do in enacting this statute. We are confident that the President's initiative and the Agency's regulatory changes will go far towards achieving these goals, and improving health care outcomes as a result.

Thank you for the opportunity to discuss these important issues with you, and I will be happy to answer any questions you may have.