## News & Events

### FDA NEWS RELEASE

FOR IMMEDIATE RELEASE
P04-25
March 2, 2004

Media Inquiries: 301-827-6242
Consumer Inquiries: 888-INFO-FDA

### FDA Announces Measures to Improve Generic Drug Access

The Food and Drug Administration (FDA) today announced that it will provide more information to the public to help generic drug applicants determine if they are eligible for 180-day marketing exclusivity for their products. This period of marketing exclusivity is generally provided to the first generic drug that challenges a patent for the innovator product. This marketing exclusivity is an effective incentive for generic drug development provided under the Hatch-Waxman Amendments to the Federal Food Drug and Cosmetic Act. With better, more transparent information, generic manufacturers will be able to plan their development of additional generic products more effectively. FDA also announced a process to effectively implement the major reforms in the Hatch-Waxman law contained in the Medicare Modernization Act of December 2003.

"The steps we are announcing today will further spur the development and availability of generic drugs, which are an increasingly important way to provide the American people with safe, effective and affordable medical treatment," said FDA Commissioner Mark B. McClellan, M.D., Ph.D. at the Generic Pharmaceutical Association's 2004 Annual Conference. "We have the most competitive generic drug industry in the world with some of the lowest generic drug prices in the world, and we intend to enhance it to help consumers."

In response to two citizen petitions, FDA will now disclose on its website the date on which the first substantially complete generic drug application containing a challenge to a patent listed for the innovator drug was submitted to the agency. FDA had previously posted on the website certain other information regarding generic drug applications. The agency also had provided additional information in response to individual inquiries - a burdensome and ineffective approach. By displaying the submission date along with the trade and generic name of the drug, its dosage form, and the strengths of the drug products, the agency will provide a fairer, more transparent way for all interested parties to gain access to this information.

It is important to note, however, that FDA will continue its policy of not disclosing the identity of the firm making the submission.

In addition, the agency will publish a Federal Register notice seeking public comment on how best to implement reforms to the Hatch-Waxman Amendments that were outlined in the recently enacted Medicare Law. These reforms are designed to clarify the conditions under which 180-day marketing exclusivity can be given. The Medicare Law also established a limit on how long approval of generic drugs can be delayed while patent rights are being litigated in court. FDA is requesting public comment within 60 days, so the agency can continue to effectively implement these important legislative reforms that speed the approval of generics. The agency will also issue a Federal Register notice revoking a regulation the agency had issued last year that limited how long approval of a generic drug can be delayed while patent rights are litigated in court. The intent of FDA's regulation is fully reflected in the reforms to the Hatch-Waxman amendments that were subsequently enacted into law, with technical assistance from the FDA. Thus, as a result of the subsequent Congressional action, last year's regulation is no longer necessary to improve access to generics.

FDA plans to begin its posting of generic drug application dates soon at http://www.fda.gov/cder/ogd/ppiv.htm

#

RSS Feed for FDA News Releases[1] [what is RSS?][2]

---

**Links on this page:**

1. http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/PressReleases/rss.xml
2. http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/ucm144575.htm