

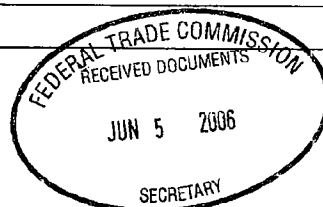
Lilly

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June 5, 2006

Federal Trade Commission
Office of the Secretary, Room H-135 (Annex J)
600 Pennsylvania Avenue, NW
Washington, DC 20580

Re: Authorized Generic Drug Study: FTC Project No. P062105; Request for Comments;

Dear Sir or Madam:

Eli Lilly and Company (Lilly) appreciates the opportunity to submit comments on the Federal Trade Commission's proposed collection of information to analyze the economic effects of authorized generic drugs. The Commission invited comments on, among other points,

[w]hether the proposed collections of information are necessary for the proper performance of the functions of the FTC, including whether the information will have practical utility.

71 Fed. Reg. 16779 (April 4, 2006).

Lilly's comments focus on the necessity and utility of the information to be collected in light of the stated goals of this study. In summary, Lilly believes that a narrow or isolated look at the issue of authorized generics would be a meaningless exercise unless coupled with a broader analysis of the context in which the 180-day exclusivity provisions of Hatch-Waxman operate. Indeed, any information related to the 180-day exclusivity provisions should be utilized only to assess the impact of authorized generics as part of the mosaic of the impact of the 180-day generic exclusivity provisions on competition and consumers.

The Commission also invited comments on the scope and extent of information being requested. On these points Lilly supports the comments filed by the Pharmaceutical Research and Manufacturers of America as to the need for the Commission to more closely tailor its information requests to the objectives of the study.

Background on 180-Day Generic Exclusivity

The first generic company to file an ANDA containing a paragraph IV certification may be eligible for 180-day exclusivity. This "exclusivity" has been described as the incentive and the reward to a generic company that exposes itself to the risk of patent litigation. FDA's Response to Citizen Petition Docket Nos. 2005P-0008/CP1 and 2005P-0046/CP1 at 6. The Hatch-Waxman Act, as amended by the Medicare Modernization Act of 2003 (MMA), provides:

Subject to subparagraph (D), if the application contains a certification described in paragraph (2)(A)(vii)(IV) and is for a drug for which a first applicant has submitted an application containing such a certification, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant.

21 U.S.C. § 355(j)(5)(B)(iv)(I). This provision only prevents the FDA from approving a subsequent ANDA containing a paragraph IV certification during the 180-day period.

Answers That Matter.

