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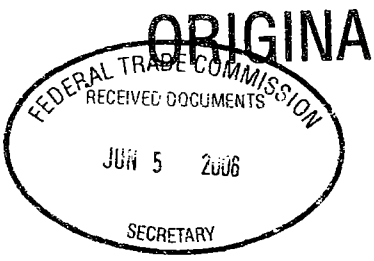

PRASCO

Via E-mail to: paperworkcomment@ftc.gov
And via overnight delivery

June 2, 2006

Federal Trade Commission
Office of the Secretary
Room H-135 (Annex J)
600 Pennsylvania Ave., N.W.
Washington, D.C. 20580

Re: Authorized Generic Drug Study: FTC Project No. P062105

Dear Sir/Madam:

Prasco, LLC ("Prasco") appreciates the opportunity to respond to the Federal Trade Commission (FTC) comment request of March 29, 2006 on its proposed study of the competitive impact of authorized generics.

Background on Prasco

Prasco is a privately held pharmaceutical company headquartered in Cincinnati, Ohio. Prasco has marketed a number of authorized generic drug products during the period covered by the proposed study. Prasco is not owned, wholly or in part, by any brand-name drug company and appears to fall within the definition of "authorized generic company" in the notice for the study issued by the FTC.

Comments

The numbered questions that follow correspond to the questions raised in the FTC's notice of its proposed study. Prasco addresses each of these questions based upon its experience as a company in the business of selling generic drugs and based upon our belief that the generic drug industry's continued growth and strength is in the interest of the American consumer and the public health, both in the short- as well as long-term.

(1) whether 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

- Prasco believes the request for information in IMS Integrated Promotional Services Total Promotion Reports (concerning detailing, consumer advertising and other

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marketing efforts) has limited relevance to the consideration, analysis and judgment of the short- and long-run competitive effects of authorized generics.

This data may be relevant in the context of an FTC review of other specific aspects of the pharmaceutical industry, but these areas have little if anything to do with the consumer impact of authorized generics. The production of such information will only burden responding companies, sidetrack the central purpose of the FTC study, take up FTC staff resources, and undermine the stated focus of the inquiry.

(2) the accuracy of the FTC's estimate of the burden of the proposed collections of information

- Prasco does not have any comment on the accuracy of the FTC's estimates but notes that the burden of providing the requested information can only be assessed in relation to the size of the company responding.

- Complying with this study will be both costly and time consuming, and it is therefore important that the scope of the information request be properly defined to the relevant parameters of the FTC's stated areas of inquiry.

(3) ways to limit the number of companies included in the study without undermining the validity and reliability of the study results (*e.g.*, reduce the number of drug products studied by only including those products in an oral solid form, eliminate those generic companies that have filed only one ANDA during the study period, reduce the study time period, etc.)

- Prasco believes limiting the number of companies included in the study could undermine the validity and reliability of the study results. There are a number of situations where authorized generics enter the market, and Prasco believes the study needs to take into account all of those situations in order to properly analyze the competitive effect of authorized generics. Many of these situations do not involve a 180-day exclusivity period. For example, one or more ANDA generics can be launched after the expiration of the brand patent, and an authorized generic can enter the market simultaneously with those ANDA generics or after they have been on the market. Prasco believes that limiting the number of companies in the study could prevent the collection of information relevant to these and other situations.

(4) ways to enhance the quality, utility, and clarity of the information to be collected

- Prasco believes the FTC should consider whether the information requested enables the FTC to address the following as part of the study:

- The short- and long-run competitive effects of multiple paragraph IV ANDA filings and how that compares to the effect of authorized generic drugs. Specifically, is there a difference in the short and long-run competitive effects between the following two outcomes: (a) multiple paragraph IV filers during the 180-day exclusivity period, and (b) a single paragraph IV filer and an authorized generic during the period of exclusivity? Given that a generic company has no control over whether there will be multiple filers or authorized generic competition, is there any difference in the generic company's decision to proceed with a paragraph IV challenge in these two scenarios?
- The apparent diminishing number of brand products available for paragraph IV ANDA challenges and how that, in addition to potential authorized generics, may affect the number of paragraph IV ANDA filers.
- The return-on-investment generated by generic products with and without competition from authorized generics and the methodology used by financial analysts in calculating that return-on-investment; and whether the return-on-investment generated during the 180-day exclusivity period with competition from an authorized generic exceeds the minimum necessary to incentivize paragraph IV ANDA filings.

(5) ways to minimize the burden of collecting the information on those who are to respond, including through the use of collection techniques or other form of information technology, *e.g.*, permitting electronic submissions of responses.

- Prasco supports the use of any efficient method to transmit its response to the FTC, provided that the security of such transmission can be fully assured.

Prasco is also concerned about the confidential treatment of proprietary information it submits. It would be helpful if any special orders pursuant to Section 6(b) of the FTC Act could provide direction on how the FTC intends to maximize the confidential treatment of proprietary information (including how to designate all or part of a submission as confidential), particularly as this relates to Congressional oversight and the confidentiality of any information shared with the Congress.

If you have any questions about the above comments, please contact Jack Painter at 513-618-3333, ext. 3507.

Submitted on behalf of Prasco, LLC by:

Jack Painter, Esq.

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