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June 5, 2006

VIA E-MAIL

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

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

Dear Sir or Madam:

As counsel for Actavis Group ("Actavis" or "Company"), I write in response to the Federal Trade Commission's ("FTC" or "Commission") request for comments regarding the proposed Authorized Generic Drug Study. Founded in 1956, Actavis is one of the five leading generic pharmaceutical companies in the world, with employees in over 30 countries. With approximately 600 products on the market and over 200 in the development pipeline, Actavis has a strong interest in the regulation of brand and generic pharmaceuticals and in the FTC's efforts to assess the degree to which authorized generics affect the incentives of the Hatch-Waxman Act aimed at encouraging generic entry.

Although Actavis appreciates the FTC's interest in this issue, the Company believes that the scope of the proposed Information Request is broader than what is needed to fully realize the Commission's goal of understanding the "short- and long-run competitive effects of authorized generic drugs in the prescription drug marketplace." Actavis believes the Commission can curtail the proposed requests, in the manner described below, without hindering its ability to obtain the information necessary for the proposed Authorized Generic Drug Study.

I. Date Range

The Commission's proposed survey seeks information going back to January 1, 1998, an approximate nine year period. As the Commission itself recognizes, however, it has only been in

"recent years and with increasing frequency" that brand-name drug companies have begun marketing authorized generic drugs during the same time as the generic firm's 180-day exclusivity period. Because the problem is a more recent phenomena, the FTC will be able to obtain the information it needs by reviewing the more recent documents of generic companies.

By requesting documents over a nine-year period and not limiting the request to instances where an authorized generic was a consideration to the generic company, the Commission will receive a large volume of documents that are unrelated to the purpose of the Study. Moreover, the breadth of the request will create a significant burden for responding companies. Documents going back even a few years are often only available in off-site storage facilities or on back-up tapes, which are time-consuming and burdensome to search. In particular, older electronic data is often on systems that the company no longer supports and, therefore, require significant time and effort from IT personnel to retrieve. Furthermore, Actavis, along with other pharmaceutical companies, has grown through acquisitions over the past several years. The burden, therefore, of searching for and retrieving archived documents will be compounded for companies that must search the archived records of predecessor firms.

Accordingly, Actavis recommends that the Commission modify the date range of the document requests to January 1, 2003. This should provide the Commission ample information to understand the short-term and long-term impact of authorized generic entry, while minimizing the burden on responding firms.

II. Independent Generic Company Question #1a

This request calls for "any documents, including studies, surveys, analyses, and reports (both internal and external), that are dated after January 1, 1998 and were prepared or received by or for any senior vice president (or equivalent position) with product line responsibility for the specified drug product or and officer(s) or director(s) of the company . . . that evaluated, considered, analyzed, or discussed whether or how to proceed with generic entry . . ."

As the Commission correctly recognizes, this request will create the most significant burden for responding companies. Moreover, this request is unnecessarily broad and burdensome in two respects. First, because the purpose of the study is to understand the "competitive effects of authorized generic drugs," Actavis recommends that the Commission limit this request so as to only cover documents that discuss authorized generic entry, either on the part of the responding firm or others. By limiting the request in this manner, the Commission will gain the insight it needs into the impact of authorized generic drugs without being overwhelmed with all documents that more generally discuss how the responding firm plans to proceed with generic entry. Furthermore, Actavis suggests that the FTC limit the drug lines for which it requests information to only those drugs for which there was an authorized generic launch or an announced agreement for an authorized generic launch. It is quite unlikely that a potential

authorized generic had an impact on generic entry in instances where there was no public announcement regarding the authorized generic.

Second, the request is unduly broad and creates an unnecessary burden for responding firms by virtue of the request for "any document." As a generic firm, most of Actavis' documents will relate to whether or how to proceed with generic entry. The Commission, however, will be able to obtain the information it needs by requesting only the final strategy documents that were authored by, or provided to, the ultimate decision maker. Because such documents would constitute the operative documents upon which decisions were made, these documents will most fully articulate the affect of authorized generic entry (or potential entry) on whether and how a generic firm proceeds with generic entry. Actavis, therefore, recommends that the Information Requests be limited to such final strategy documents.

III. IMS Health Data

The Commission seeks a variety of IMS data from every company responding to the Information Requests who obtains such information in the ordinary course. First, IMS data is readily available to the Commission, just as it is available to industry members, and, therefore, can be obtained by the Commission directly from IMS. Consequently, there is no need to require each pharmaceutical company to search its records and review and submit that data. Second, IMS data is not company-specific. Each company that subscribes to IMS data for particular drug products, therefore, will be producing the same data and the Commission will receive an unnecessary amount of duplicative information. Therefore, Actavis recommends that the request for IMS data be deleted from the proposed Information Requests.

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We trust these comments have been helpful. Please contact me if you have any questions or require additional information.

Sincerely,

/s/ William M. Rubenstein

William M. Rubenstein