HFA-305

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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Joseph J. Simons
Director, Bureau of Competition
Federal Trade Commission
600 Pennsylvania Ave., NW
Room 374
Washington, DC 20580

Todd J. Zywicki
Director, Office of Policy Planning
Federal Trade Commission
600 Pennsylvania Ave., NW
Room 494
Washington, DC 20580

Re: Docket No. 01P-0248

Dear Mr. Simons and Mr. Zywicki:

On May 16, 2001, the Federal Trade Commission (FTC) submitted a citizen petition that asked for guidance on the listing of patents in *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the "Orange Book." The FTC's citizen petition asked us to address four issues:

(1) what criteria a patent must meet before it can be listed in the Orange Book;
(2) whether an NDA holder may list a patent claiming an unapproved aspect of an approved drug;
(3) whether a drug product is defined as only that product which is the subject of the NDA as approved by FDA; and
(4) whether a patent may be listed that claims only a chemical compound that FDA has not approved for use as the drug substance in an approved drug product.

FDA's answers to the questions posed by the FTC are fully provided and explained in our recently published final rule, *Applications for FDA Approval to Market a New Drug: Patent Submission and Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug Is Invalid or Will Not Be Infringed*, a copy of which is enclosed with this letter.

We wish to commend the FTC's initiative in asking FDA to address its questions. In answering those questions, we decided to address a number of broader issues affecting the approval of generic drugs and the operation of the Orange Book. In formulating the final rule, we made extensive use of the information and analysis contained in your agency's report entitled "Generic Drug Entry Prior to Patent Expiration: An FTC Study."

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We appreciate the contribution the FTC has made relating to important issues that have arisen in the operation of the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act.

Sincerely yours,

William K. Hubbard
Associate Commissioner for
Policy and Planning

Enclosure