DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the General Counsel

Office of the Chief Counsel
Food and Drug Administration
5600 Fishers Lane, GCF-1
Rockville, MD 20857

June 12, 2003

Michael S. Labson
Covington & Burling
1201 Pennsylvania Avenue NW
Washington, DC 20004-2401

RE: Request for Extension of Comment Period
Docket No. 02N-0417

Dear Mr. Labson:

On February 14, 2003, you submitted a Request for Extension of Comment Period for the Food and Drug Administration's proposed rule on "Applications for FDA Approval to Market a New Drug: Patent 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," Docket No. 02N-0417, on behalf of the Pharmaceutical Research and Manufacturers of America (PhRMA). The request for the extension and re-opening of the comment period was to allow PhRMA to submit supplemental comments. The comment period for Docket No. 02N-0417 closed on December 23, 2002.

A request to extend and reopen a comment period can be submitted under 21 C.F.R. 10.35. The request must comply with 21 C.F.R. 10.40(3). The request must "discuss the reasons comments could not feasibly be submitted within the time permitted, or that important new information will shortly be available, or that sound public policy otherwise supports and extension of the time for comment." 21 C.F.R. 10.20(3)(i).

A decision has been made by the Commissioner that the comment period will not be reopened or extended for Docket No. 02N-0417. The request fails to establish that the comments could not feasibly have been submitted within the comment period nor is there important "new" information. In fact, the request states that the supplemental comments "do not raise any new issues," "clarify and elaborate on an issue raised in PhRMA's prior submission," and provide "additional legal support for PhRMA's previously stated position." One contention is made that the "additional legal theory" "constitutes important new information for FDA's rulemaking proceeding" but the request does not establish that the legal theory itself is new or that it could not have been submitted previously by PhRMA. Also, there is no sound public policy reason to extend the comment period to accept the supplemental comments.

02N-0417 LET 1

For the reasons stated above, I regret that your request to extend and reopen the comment period for Docket No. 02N-0417 is denied.

Sincerely,

Daniel E. Troy
Chief Counsel
Food and Drug Administration