PUBLIC VERSION

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

In the Matter of	)	
Schering-Plough Corporation, a corporation,	)	
Upsher-Smith Laboratories, a corporation,	)	Docket No. 9297
and	)	
American Home Products Corporation, a corporation.	)	

SUPPLEMENT AND CORRECTION TO MOTION OF RESPONDENT SCHERING-PLOUGH CORPORATION FOR LEAVE TO SUBMIT ONE ADDITIONAL EXPERT REPORT

Respondent Schering-Plough Corporation ("Schering") hereby respectfully files this supplement to its recent motion for leave to submit one very important additional expert report.

In its motion for leave filed November 8, 2001, Schering stated that Complaint Counsel's rebuttal expert, Dr. Bertram Pitt, was the first expert to opine on whether Niacor SR would be approved by the FDA. Schering also stated that "none of respondents' experts rendered an opinion" on this issue. (Motion for Leave at 2). Closer review of the expert report submitted by Kenneth McVey on behalf of Schering reveals that Mr. McVey did comment,

albeit in passing in a report addressing the valuation of the Niacor SR license, that he saw "no reason" why Niacor SR would not be approved by the FDA. (McVey Report at 13).

Schering apologizes for overlooking Mr. McVey's comment when it filed its motion for leave. Schering's need to file a report by someone who can specially address the approvability of Niacor SR by the FDA is nonetheless compelling, and Schering would suffer severe prejudice if it were not permitted to do so.

Complaint Counsel's initial expert to address the Niacor SR licenses submitted an opinion on the question whether the $60 million payment Schering made to Upsher "can reasonably be considered to have been a licensing fee for Niacor-SR." He opined that the payment exceeded the value of Niacor SR and that Schering did not perform the due diligence required to detect "flaws" in the product. He did not profess special expertise in the FDA new drug approval process, nor did he render an opinion that these alleged "flaws" would have precluded FDA approval for Niacor SR.[1]

Schering submitted a report by Mr. McVey in response to this initial expert report submitted by Complaint Counsel. Mr. McVey is a former pharmaceutical industry executive, with particular expertise in the licensing of controlled release drug delivery technology and the marketing of pharmaceutical products in Europe. (McVey Report at 1-2). He professed no special expertise in the FDA approval process. In response to the opinion of Complaint Counsel's initial expert, Mr. McVey submitted an opinion on the value of the Niacor SR licensing opportunity. Mr. McVey concluded that, under the terms of the license agreement,

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[1] The most he said on this subject was that the non-contingent nature of the license fee was "odd" in light of approvability "risks." He did not purport to render an opinion on FDA approvability.

Schering would have received a reasonable rate of return on its $60 million investment in Niacor SR. In reaching that conclusion, he noted in passing that he saw no reason to believe that Niacor SR would not have been approved by the FDA. *See supra*.

Complaint Counsel then submitted the report by Dr. Pitt squarely addressed to the question "whether [Niacor SR] was likely to be approved by the Federal Food and Drug Administration." (Pitt Report at 3). Although styled a rebuttal expert report, Complaint Counsel states that it "plans to call" Dr. Pitt "in its case in chief." (*See* Complaint Counsel's Identification of Rebuttal Experts). Dr. Pitt is proffered by Complaint Counsel as an expert specially qualified to address FDA approval issues. (*Id.* at 2, 6-7). Dr. Pitt's opinion puts front and center the question whether Niacor SR could have obtained FDA approval.

If Complaint Counsel believed that Niacor SR would not be approvable by the FDA, one would have expected Complaint Counsel to submit an expert report on that question as an initial matter, rather than in rebuttal. If Complaint Counsel had done so, Schering would have submitted a report by an expert specially qualified to respond to such a claim. Schering should not be denied the right to do so now solely because Complaint Counsel waited until its rebuttal report to raise the significant allegation that Niacor SR could not have obtained FDA approval.

For the foregoing reasons and those stated in Schering's motion, Schering respectfully requests that its motion for leave to submit one additional expert report be granted.

Respectfully submitted,

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Dated: November 13, 2001

CERTIFICATION

I hereby certify that this 13th day of November, 2001, I caused an electronic copy of the Supplement And Correction To Motion of Respondent Schering-Plough Corporation for Leave to Submit One Additional Expert Report to be filed with the Secretary of the Commission. I further certify that these are true and correct copies of the paper original and that a paper copy with an original signature is being filed with the Secretary of the Commission.

Erik T. Koons

CERTIFICATE OF SERVICE

I hereby certify that this 13th day of November, 2001, I caused an original, one paper copy and an electronic copy of the foregoing Supplement And Correction To Motion of Respondent Schering-Plough Corporation for Leave to Submit One Additional Expert Report to be filed with the Secretary of the Commission, and that two paper copies were served by hand upon:

Honorable D. Michael Chappell
Administrative Law Judge
Federal Trade Commission
Room 104
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

and one paper copy was hand delivered upon:

Karen Bokat
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