December 20, 2001

VIA HAND DELIVERY

Donald S. Clark
Secretary
Federal Trade Commission - Office of the Secretary
6th and Pennsylvania Avenue, NW
Room 172
Washington, D.C. 20580

Re: Schering-Plough Corp., Upsher-Smith Laboratories, Inc., American Home Products Corporation, Docket No. 9297

Dear Secretary Clark:

Enclosed please find an original and one copy of the public version of Upsher-Smith's Opposition To Complaint Counsel's Cross-Motion To Limit Expert Testimony On FDA Approval Of Niacor SR. This motion will be filed in public version only.

If you have any questions, please do not hesitate to contact me at (202) 626-3705.

Sincerely,

Paul F. Stone

Enclosures

cc: Karen G. Bokat, Esq.
Laura S. Shores, Esq.

because it merely buttressed Complaint Counsel's case-in-chief witness Dr. Levy. Upsher-Smith's motion to exclude Dr. Pitt is clear on this point.

Complaint Counsel's attempt to limit Upsher-Smith's experts is purely strategic. This case indisputably does not involve a naked payment for delay of entry of a generic drug. Rather, this case involves the novel accusation by Complaint Counsel that an arms-length licensing transaction, in which Upsher-Smith licensed several pharmaceutical products to Schering-Plough, was actually a sham transaction at the time that it was entered into (June 1997). The only supporting "evidence" that the products were worthless is provided by Plaintiffs expert Dr. Levy, who opines that Niacor SR the most promising drug licensed to Schering, was neither safe nor efficacious. In response, Upsher-Smith proffers extensive factual evidence and expert testimony of Drs. Knopp and Keenan and former FDA – official Robert Pollock. Complaint Counsel seek to exclude testimony of these experts, timely disclosed to Complaint Counsel, that responds to the heart of the FTC's case.

The Cross-motion erroneously assumes that Your Honor's Order of November 28 "found that Upsher's two medical experts (Drs. Knopp and Keenan) did not offer an opinion on FDA approval of Niacor SR." Cross-mot. at 6. In fact, the Order allowing Dr. Davidson as a rebuttal witness on the issue of FDA approvability was based on the limited (and accurate) express holding that "when Schering submitted its expert reports to Complaint Counsel, it did not submit an 'FDA approval expert.'" Order at 2. Thus, the Court's ruling to permit Dr. Davidson as an FDA approval expert follows naturally from the Court's conclusion that the opinion rendered by Dr. Pitt was as "an FDA approval expert." *Id.* The Order simply permitted Schering to answer in kind Complaint Counsel's new "FDA approval expert."

Upsher-Smith's experts in its defense case in chief had simply answered in kind Complaint-Counsel's case-in-chief witness, Dr. Levy. As Complaint Counsel admits, Dr. Levy put the safety, efficacy and approvability of Niacor SR into issue. *See* Opp. to Schering Mot. For

Leave to Submit One Additional Expert Rep. at 4. As Complaint Counsel also admits, Upsher-Smith's experts, Drs. Knopp and Keenan and Mr. Pollock, all responded in kind. *See* Cross-mot. at 7-8; Opp. to Mot. To Add Schering's One Additional Expert at 7-8; Opp. to Mot. To Strike Bertram Pitt at 4. Accordingly, the Cross-motion should be denied.

Finally, both of the cases cited by Complaint Counsel are inapposite. In *Ferriso v. Conway Org.*, No. 93 Civ. 7962, 1995 U.S. Dist. LEXIS 14328, *4 (S.D.N.Y. Oct. 3, 1995) the district court upheld the magistrate judge's limitation of an expert's testimony because the

CONCLUSION

For all the reasons stated above, Complaint Counsel's Cross-Motion In Limine To Limit Expert Testimony On FDA Approval On Niacor SR should be denied.

Dated: December 20, 2001 Respectfully submitted,