UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

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

UPSHER-SMITH'S OBJECTIONS AND RESPONSES TO COMPLAINT COUNSEL'S REVISED THIRD REQUESTS FOR ADMISSIONS

Pursuant to Federal Trade Commission Rules of Practice for Adjudicative Proceedings § 3.32, Upsher-Smith hereby submits these responses and objections to Complaint Counsel's Revised Third Requests for Admissions. Upsher-Smith's response to any Request shall not constitute a waiving any applicable objection privilege, immunity or other right. Furthermore, Upsher-Smith notes that it is responding to the Requests on an accelerated basis and therefore reserves the right to modify its answers in any respect.

UPSHER-SMITH'S OBJECTIONS AND RESPONSES

Request No. 4: As of September 2001, the FDA is prohibited from approving another generic version of the branded product until either (1) the First Filer's 180-day Exclusivity Period has elapsed, or (2) the First Filer relinquishes or loses its eligibility to the 180-day Exclusivity Period.

Answer:

Upsher-Smith objects insofar as the Request calls for a legal conclusion. Upsher-Smith further objects to the Request as vague and ambiguous due to, among other reasons, the lack of clarity as to the terms "prohibited," "branded product," "approving," and "eligibility." Additionally, Upsher-Smith objects that the Request is circular in that it essentially asks if exclusivity exists until it is lost. Subject to and without waiving its objections, Upsher-Smith denies the Request as it calls for information that is necessarily beyond Upsher-Smith's factual knowledge.

Request No. 8: Upsher's 180-day Exclusivity Period was triggered on September 1, 2001.

Answer:

Upsher-Smith objects to the request to the extent it requires a legal conclusion as to, among other reasons, whether Upsher-Smith has exclusivity and as to what constitutes a "trigger." Upsher-Smith further objects to the Request insofar as it does not specify the product at issue, and the term "triggered" is vague and ambiguous as used in the Request. Subject to and without waiving its objections, even assuming the Request refers to Klor-Con M20, Upsher-Smith admits that it began commercial marketing Klor-Con M20 on September 1, 2001. Upsher-Smith denies the remainder of the Request, and refers Complaint Counsel to the January 28, 1999 letter from FDA to Upsher-Smith ( ), but offers no opinion as to whether

FDA's grant of eligibility for 180-day exclusivity survived until September 2001 or would have withstood a legal challenge from a competitor.

Request No. 9: As of September 2001, no ANDA for a generic version of K-Dur 20, other than ANDA 74-726, can receive final approval from the FDA until Upsher's 180-day Exclusivity Period has expired.

Answer:

Upsher-Smith objects to the Request because it calls for a legal conclusion. Upsher-Smith further objects to the Request as overbroad and ambiguous. Subject to and without waiving its objections, Upsher-Smith denies the Request and refers Complaint Counsel to the January 28, 1999, letter from FDA to Upsher-Smith ( ), but offers no opinion as to whether FDA's grant of eligibility for 180-day exclusivity survived until September 2001 or would have withstood a legal challenge from a competitor.

Request No. 10:

Answer:

Upsher-Smith objects to the Request as vague and ambiguous because, among other reasons, the meaning of "bioequivalent to a brand product" and "brand product" is not clear.

Subject to and without waiving its objections, Upsher-Smith denies the Request as vague and confusing, and it is unclear what information is being

requested. Upsher-Smith admits that it consistently offers cost-effective alternatives to high-cost brand products.

Request No. 21:

Answer:

Upsher-Smith objects to the Request because it is vague and ambiguous, because, among other reasons, the terms "meeting," "possible," "scenarios" and "discussed" are unclear.

Request No. 22:

Answer:

Upsher-Smith objects to the Request because it is vague and ambiguous, because, among other reasons, the terms "meeting," "possible," "scenarios" and "discussed" are unclear.

Request No. 23:

Answer:

Upsher-Smith objects to the Request because it is vague and ambiguous, because, among other reasons, the terms "meeting," "possible," "scenarios" and "discussed" are unclear.

Request No. 24:

Answer:

Upsher-Smith objects to the Request because it is vague and ambiguous, because, among other reasons, the terms "meeting," "possible," "scenarios" and "discussed" are unclear.

Request No. 25:

Answer:

Upsher-Smith objects to the Request because it is vague and ambiguous, because, among other reasons, the terms "meeting," "possible," "scenarios" and "discussed" are unclear.

Request No. 26:

Answer:

Upsher-Smith objects to the Request as vague and ambiguous because, among other things, the meaning of " " is unclear. Subject to and without waiving its objections, Upsher-Smith denies the Request

Request No. 27:

Answer:

Upsher-Smith objects to the Request as vague and ambiguous because, among other things, the meaning of " " is unclear. Subject to and without waiving its objections, Upsher-Smith denies the Request as

Request No. 28:

Answer:

Upsher-Smith objects to the Request as vague and ambiguous because, among other reasons, the meaning of " " is unclear as used in the Request. Subject to and without waiving its objections, Upsher-Smith admits that

Request No. 29:

Answer:

Upsher-Smith objects to the Request as vague and ambiguous because, among other reasons, the meaning of " " and " " is unclear as used in the Request. Upsher-Smith further objects that the Request calls for information beyond Upsher-Smith's knowledge. Subject to and without waiving its objections, Upsher-Smith denies the Request because

Request No. 40: In the Schering/Upsher Patent Litigation, Upsher never took the position in papers filed with the New Jersey District Court that Upsher's generic version of K-Dur 20 infringed the '743 Patent listed in the Orange Book for K-Dur 20.

Answer:

Complaint Counsel has access to all the papers and documents referred to in the Request, and these documents provide the best evidence to the positions Upsher-Smith may or may not have taken in the litigation referenced in the Request. Upsher-Smith objects to the Request

insofar as it requires Upsher-Smith to review information already provided to Complaint Counsel to answer the Request. Moreover, Upsher-Smith notes that a position taken in a court proceeding does not necessarily constitute an admission in a subsequent proceeding. Finally, Upsher-Smith notes that the New Jersey District Court never found non-infringement. Subject to and without waiving its objections, Upsher-Smith on information and belief admits the Request.

Request No. 41: In the Schering/Upsher Patent Litigation, Upsher had a reasonable basis for asserting that, with respect to the '743 Patent, prosecution history estoppel applied so as to preclude Schering from asserting that Upsher's generic version of K-Dur 20 infringed the '743 Patent.

Answer:

Upsher-Smith objects on the grounds that the Request calls for a legal conclusion as to whether an argument advanced in litigation had a "reasonable basis." Upsher-Smith further objects to the Request because the issue posed in the Request was never considered by the Court. Upsher-Smith notes that a position taken in a prior court proceeding does not constitute an admission in a subsequent proceeding. Subject to and without waiving its objections, after diligent inquiry Upsher-Smith can neither admit nor deny the Request.

Request No. 43 : In the Schering/Upsher Patent Litigation, Upsher never took the position in papers filed with the New Jersey District Court that the '743 Patent was valid.

Answer:

Complaint Counsel has access to all the papers and documents referred to in the Request, and these documents provide the best evidence to the positions Upsher-Smith may or may not have taken in the litigation referenced in the Request. Upsher-Smith objects to the Request insofar as it requires Upsher-Smith to review information already provided to Complaint Counsel to answer the Request. Moreover, Upsher-Smith notes that a position taken in a court proceeding does not necessarily constitute an admission in a subsequent proceeding. Upsher-

Smith further notes there is a strong presumption as to the validity of a patent. Subject to and without waiving its objections, Upsher-Smith upon information and belief admits it did not take the position that the '743 Patent was valid, but Schering-Plough did and the Court never resolved the issue.

Request No. 44: In the Schering/Upsher Patent Litigation, Upsher never took the position in papers filed with the New Jersey District Court that the '743 Patent was enforceable.

Answer:

Complaint Counsel has access to all the papers and documents referred to in the Request, and these documents provide the best evidence to the positions Upsher-Smith may or may not have taken in the litigation referenced in the Request. Upsher-Smith objects to the Request insofar as it requires Upsher-Smith to review information already provided to Complaint Counsel to answer the Request. Moreover, Upsher-Smith notes that a position taken in a court proceeding does not necessarily constitute an admission in a subsequent proceeding. Subject to and without waiving its objections, upon information and belief Upsher admits it did not take the position that the '743 Patent was enforceable, but Schering-Plough did and the court never resolved the issue.

Request No. 51: The New Jersey District Court made no finding that Upsher's generic version of K-Dur 20 was likely to infringe the '743 Patent.

Answer:

Upsher-Smith objects to the Request insofar as it requires Upsher-Smith to review the information already provided to Complaint Counsel to answer the Request. Moreover, Upsher-Smith notes that a position taken in a court proceeding does not necessarily constitute an admission in a subsequent proceeding. Subject to and without waiving its objections, upon

information and belief, Upsher-Smith admits that the District Court made no finding that Upsher-Smith's generic version of K-Dur 20 was likely or unlikely to infringe the '743 Patent.

Request No. 52: The New Jersey District Court made no finding that the '743 Patent is not invalid.

Answer:

Upsher-Smith objects to the Request insofar as it requires Upsher-Smith to review the information already provided to Complaint Counsel to answer the Request. Moreover, Upsher-Smith notes that a position taken in a court proceeding does not necessarily constitute an admission in a subsequent proceeding. Upsher-Smith also objects to the Request on the grounds that it is confusing, as Complaint Counsel prepared the Request in terms of a triple-negative. Further, Upsher-Smith notes that there is a strong presumption as to the validity of a patent. Subject to and without waiving its objections, upon information and belief, Upsher-Smith admits that the District Court made no finding that the '743 patent was valid or invalid.

Request No. 53: The New Jersey District Court made no finding that the '743 Patent is enforceable.

Answer:

Upsher-Smith objects to the Request insofar as it requests Upsher-Smith to review all of the information already provided to Complaint Counsel to answer the Request. Moreover, Upsher-Smith notes that a position taken in a court proceeding does not necessarily constitute an admission in a subsequent proceeding. Subject to and without waiving its objections, upon information and belief Upsher-Smith admits that the New Jersey District Court made no finding that the '743 patent is enforceable or unenforceable.

Request No. 58: At the time of the Schering/Upsher Agreement, there was a possibility that Upsher could have won the Schering/Upsher Patent Litigation if it continued the Schering/Upsher Patent Litigation.

Answer:

Upsher-Smith objects that the Request requires a legal conclusion. Upsher-Smith further objects to the Request as vague. The terms "possibility" and "won" have not been defined and are confusing and ambiguous. The Request is also argumentative. Furthermore, the Request calls for speculation and is therefore denied.

Request No. 59: At the time of the Schering/Upsher Agreement, Upsher believed that it could have won the Schering/Upsher Patent Litigation if it continued the Schering/Upsher Patent Litigation.

Answer:

Upsher-Smith objects to the Request as vague and overbroad. Upsher-Smith objects to the Request in that it seeks information protected by Attorney-Client Privilege. The terms "Upsher believed" and "won" have not been defined and are vague and ambiguous. Upsher-Smith is a corporation and unable to form a collective belief as a factual matter. Thus, the Request is denied.

Request No. 60: At the time of the Schering/Upsher Agreement, it was not certain that Schering would prevail in the Schering/Upsher Patent Litigation.

Answer:

Upsher-Smith objects to the Request as vague and ambiguous. The terms "not certain" and "would prevail" have not been defined and are vague and confusing. Upsher-Smith is a corporation unable to form a collective belief as a factual matter. Upsher-Smith objects to and denies the Request insofar as it requires speculation on the part of Upsher-Smith.

Request No. 72: On November 20, 1998, Upsher received final FDA approval for its generic version of K-Dur 20.

Answer:

Upsher-Smith objects to the Request as it seeks a legal conclusion as to final FDA approval. Upsher-Smith objects to the term "final" as vague and ambiguous. Upsher-Smith refers Complaint Counsel to which is the best evidence of the information sought in the Request. Subject to and without waiving its objections, Upsher-Smith admits the Request.

Request No. 73: As of November 20, 1998, FDA law and regulations permitted Upsher to begin the commercial sale of its generic version of K-Dur 20.

Answer:

Upsher-Smith objects to the Request insofar as it requires a legal conclusion as to "FDA law and regulations." Moreover, Upsher-Smith objects to the term "FDA law and regulations" as vague and ambiguous. Upsher-Smith denies the Request because, upon information and belief, Upsher-Smith had to meet other FDA requirements prior to beginning the commercial sale of Klor Con M20.

Request No. 74: Upsher did not begin the commercial sale of its generic version of K-Dur 20 on November 20, 1998 or at any time prior to September 1, 2001.

Answer:

Upsher-Smith objects to the Request to the extent the term "commercial sale" requires a legal conclusion. Upsher-Smith further objects to the Request as vague, because the phrase "begin the commercial sale" is vague and can have multiple meanings. Subject to and without waiving its objections, Upsher-Smith admits the Request.

Request No. 78:

Answer:

Request No. 83:

Answer:

Request No. 84:

Answer:

Request No. 85:

Answer:

Request No. 87:

Answer:

Request No. 88:

Answer:

Request No. 89:

Answer:

Request No. 90:

Answer:

Upsher-Smith objects to the Request as it calls for information necessarily beyond its knowledge as to action by

Request No. 95:

Answer:

Upsher-Smith objects to the Request because it calls for information beyond Upsher-Smith's knowledge.

Request No. 96:

Answer:

Upsher-Smith objects to the Request because it calls for information beyond Upsher-Smith's knowledge.

Request No. 97:

Answer:

Upsher-Smith objects to the Request because it calls for information beyond Upsher-Smith's knowledge.

Request No. 98:

Answer:

Upsher-Smith objects to the Request as it requests information beyond the knowledge of Upsher-Smith.

Request No. 99:

Answer:

Request No. 100:

Answer:

Request No. 103:

Answer:

Request No. 104:

Answer:

Request No. 105:

Answer:

Request No. 106:

Answer:

Request No. 120: The Schering/Upsher Agreement was not presented to the New Jersey District Court for approval.

Answer:

Upsher-Smith objects to the Request insofar as it requests Upsher-Smith to review the information already provided to Complaint Counsel to answer the Request. Subject to and without waiving its objections, Upsher-Smith, upon information and belief, admits that the Schering/Upsher Agreement was not presented to the New Jersey District Court for approval.

Further, Upsher-Smith, upon information and belief, notes that the New Jersey District Court never requested and never required that the Agreement be submitted.

Request No. 121: The New Jersey District Court did not approve the Schering/Upsher Agreement.

Answer:

Upsher-Smith objects to the Request insofar as it requests Upsher-Smith to review the information already provided to Complaint Counsel to answer the Request. Subject to and without waiving these objections, Upsher-Smith, upon information and belief, admits that the New Jersey District Court did not approve the Schering/Upsher-Smith Agreement. Upsher-Smith notes, upon information and belief, that the New Jersey District Court never required and did not request approval of the Agreement.

Request No. 122: The Schering/Upsher Agreement was not presented to any federal district court for approval.

Answer:

Upsher-Smith objects to the Request insofar as it requests Upsher-Smith to review the information already provided to Complaint Counsel to answer the Request. Subject to and without waiving its objections, Upsher-Smith, upon information and belief, admits that the Schering/Upsher-Smith Agreement was not presented to any federal district court for approval. Upon information and belief, Upsher-Smith notes that no federal district court required or requested that the Agreement be so presented.

Request No. 123: The Schering/Upsher Agreement was not approved by any federal district court.

Answer:

Upsher-Smith objects to the Request insofar as it requests Upsher-Smith to review the information already provided to Complaint Counsel to answer the Requests. Subject to and without waiving its objections, Upsher-Smith, upon information and belief, admits that the Agreement was not approved by any federal district court. Upsher-Smith notes, upon information and belief, that no federal district court required or requested that the Agreement be approved.

Request No. 124:

Answer:

Request No. 129:

Answer:

Request No. 130:

Answer:

Request No. 131:

Answer:

Request No. 132:

Answer:

Request No. 133:

Answer:

Request No. 135:

Answer:

Request No. 136:

Answer:

Request No. 138:

Answer:

Request No. 139:

Answer:

Request No. 140:

Answer:

Request No. 141:

Answer:

Request No. 142:

Answer:

Request No. 143:

Answer:

Request No. 157: Warrick, a part of Schering, began selling a bioequivalent alternative to K-Dur 20 in September 2001.

Answer:

Upsher-Smith objects to the Request because it seeks information beyond Upsher-Smith's knowledge. Subject to and without waiving its objections, Upsher-Smith, upon information and belief, admits that Warrick began selling a generic alternative to K-Dur 20 earlier this year.

Request No. 158: Substitution from a brand product to its biocquivalent or AB-rated generic product occurs at a faster rate in 2001 than it did in 1997.

Answer:

Upsher-Smith objects to the Request because it is vague and overbroad, because, among other reasons, the terms "substitution," and "biocquivalent" are vague as used in the Request. Upsher-Smith further objects because the Request calls for information beyond its knowledge, and any such answer would require speculation on the part of Upsher-Smith. Upsher-Smith further objects to the Request insofar as it requests information that is irrelevant to the allegations in this matter. Subject to and without waiving its objections, Upsher-Smith denies the Request because it calls for speculation, and calls for information irrelevant to this matter.

Request No. 161:

Answer:

Request No. 163:

Answer:

Request No. 173:

Answer:

Request No. 174:

Answer:

Request No. 176:

Answer:

Request No. 178:

Answer:

Request No. 179:

Answer:

Request No. 180:

Answer:

Request No. 241:

Answer:

Request No. 274: Elevated levels of liver enzyme SGOT in the bloodstream are an indication of either liver disease or liver damage.

Answer:

Upsher-Smith objects to the Request as vague and ambiguous. Subject to and without waiving its objections, Upsher-Smith denies the Request. Assuming SGOT refers to "serum glutamic oxaloacetic transaminase," elevated SGOT levels may be found in organs other than the

liver and may be the result of muscle damage unrelated to the liver, such that elevated SGOT levels do not necessarily indicate "liver disease or liver damage."

Request No. 275: Elevated levels of liver enzyme SGPT in the bloodstream are an indication of either liver disease or liver damage.

Answer: Upsher-Smith objects to the Request as vague and ambiguous. Subject to and without waiving its objections, Upsher-Smith denies the Request. Assuming SGPT refers to "transaminase, serum glutamic pyruvic," this enzyme is normally present in liver and heart cells and may be elevated due to an insult to the heart, such as from a heart attack, or even from certain medications, such as, for example, Advil. Interpretation of elevated SGPT depends on context.

Request No. 285:

Answer:

Request No. 286:

Answer:

Request No. 287:

Answer:

Request No. 288:

Answer:

Request No. 289:

Answer:

Request No. 290:

Answer:

Request No. 291:

Answer:

Request No. 292:

Answer:

Request No. 294:

Answer:

Request No. 299:

Answer:

Request No. 301:

Answer:

Request No. 302:

Answer:

Request No. 304:

Answer:

Request No. 306:

Answer:

Request No. 310:

Answer:

Request No. 312: Kos's Niaspan product was a once-daily formulation of niacin.

Answer:

Upsher-Smith objects to "was" as used in the Request as vague, confusing and ambiguous as to time. Upsher-Smith objects to the Request to the extent it implies the formulation of Kos's Niaspan changed at some point. Subject to and without waiving its objections, Upsher-Smith admits that in 1997 Kos's Niaspan product was a once-daily formation of niacin.

Request No. 318:

Answer:

Request No. 319:

Answer:

Request No. 320:

Answer:

Request No. 322:

Answer:

Request No. 324:

Answer:

Request No. 329:

Answer:

Request No. 330:

Answer:

Request No. 332:

Answer:

Request No. 334:

Answer:

Dated: November 13, 2001

Respectfully submitted,

WHITE & CASE LLP

By: _____

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Attorneys for Upsher-Smith Laboratories, Inc.

CERTIFICATE OF SERVICE

I, Dennis Kelly, hereby certify that on November 13, 2001, I caused a copy of Upsher-Smith's Responses And Objections To Complaint Counsel's Revised Third Request For Admissions to be served upon the following persons by facsimile, electronic mail and on November 14, 2001 by hand delivery:

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

Karen G. Bokat
Federal Trade Commission, 3115
601 Pennsylvania Avenue, N.W.
Washington, DC 20580

Laura S. Shores
Howrey Simon Arnold & White
1299 Pennsylvania Avenue, N.W.
Washington, DC 20004

Dennis M. Kelly

UNITED STATES OF AMERICA
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.	)	

PROTECTIVE ORDER GOVERNING DISCOVERY MATERIAL

For the purpose of protecting the interests of the parties and third parties in the above captioned matter against improper use and disclosure of confidential information submitted or produced in connection with this matter:

IT IS HEREBY ORDERED THAT this Protective Order Governing Confidential Material ("Protective Order") shall govern the handling of all Discovery Material, as hereafter defined.

DEFINITIONS

1. "Matter" means the matter captioned *In the Matter of Schering-Plough Corporation, Upsher-Smith Laboratories, and American Home Products Corporation*, Docket Number 9297, pending before the Federal Trade Commission, and all subsequent appellate or other review

proceedings related thereto.

2. "Commission" or "FTC" means the Federal Trade Commission, or any of its employees, agents, attorneys, and all other persons acting on its behalf, excluding persons retained as consultants or experts for the purposes of this Matter.

3. "Schering-Plough" means Schering-Plough Corporation, a corporation organized, existing, and doing business under and by virtue of the laws of the State of New Jersey, with its office and principal place of business located at Kenilworth, New Jersey.

4. "Upsher-Smith" means Upsher-Smith Laboratories, Inc., a corporation organized, existing, and doing business under and by virtue of the laws of the state of Minnesota, with its office and principal place of business located at Plymouth, Minnesota.

5. "AHP" means American Home Products, a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware, with its office and principal place of business located at Madison, New Jersey.

6. "Party" means either the FTC, Schering-Plough, Upsher-Smith, or AHP.

7. "Respondents" means Schering-Plough, Upsher-Smith, and AHP.

8. "Outside Counsel" means the law firms that are counsel of record for Respondents in this Matter and their associated attorneys; or other persons regularly employed by such law firms, including legal assistants, clerical staff, and information management personnel and temporary personnel retained by such law firm(s) to perform legal or clerical duties, or to provide logistical litigation support with regard to this Matter; provided that any attorney associated with Outside Counsel shall not be a director, officer or employee of Respondents. The term Outside Counsel does not include persons retained as consultants or experts for the purposes of this Matter.

9. "Producing Party" means a Party or Third Party that produced or intends to produce Confidential Discovery Material to any of the Parties. For purposes of Confidential Discovery Material of a Third Party that either is in the possession, custody or control of the FTC or has been produced by the FTC in this Matter, the Producing Party shall mean the Third Party that originally provided the Confidential Discovery Material to the FTC. The Producing Party shall also mean the FTC for purposes of any document or material prepared by, or on behalf of the FTC.

10. "Third Party" means any natural person, partnership, corporation, association, or other legal entity not named as a party to this Matter and their employees, directors, officers, attorneys and agents.

11. "Expert/Consultant" means experts or other persons who are retained to assist Complaint Counsel or Respondents' counsel in preparation for trial or to give testimony at trial.

12. "Document" means the complete original or a true, correct and complete copy and any non-identical copies of any written or graphic matter, no matter how produced, recorded, stored or reproduced, including, but not limited to, any writing, letter, envelope, telegraph meeting minute, memorandum statement, affidavit, declaration, book, record, survey, map, study, handwritten note, working paper, chart, index, tabulation, graph, tape, data sheet, data processing card, printout, microfilm, index, computer readable media or other electronically stored data, appointment book, diary, diary entry, calendar, desk pad, telephone message slip, note of interview or communication or any other data compilation, including all drafts of all such documents. "Document" also includes every writing, drawing, graph, chart, photograph, phono record, tape, compact disk, video tape, and other data compilations from which information can

be obtained, and includes all drafts and all copies of every such writing or record that contain any commentary, notes, or marking whatsoever not appearing on the original.

13. "Discovery Material" includes without limitation deposition testimony, deposition exhibits, interrogatory responses, admissions, affidavits, declarations, documents produced pursuant to compulsory process or voluntarily in lieu thereof, and any other documents or information produced or given to one Party by another Party or by a Third Party in connection with discovery in this Matter.

14. "Confidential Discovery Material" means all Discovery Material that is designated by a Producing Party as confidential and that is covered by Section 6(f) of the Federal Trade Commission Act, 15 U.S.C. § 46(f), and Commission Rule of Practice § 4.10(a)(2), 16 C.F.R. § 4.10(a)(2); or Section 26(c)(7) of the Federal Rules of Civil Procedure and precedents thereunder. Confidential Discovery Material shall include non-public commercial information, the disclosure of which to Respondents or Third Parties would cause substantial commercial harm or personal embarrassment to the disclosing party. The following is a nonexhaustive list of examples of information that likely will qualify for treatment as Confidential Discovery Material: strategic plans (involving pricing, marketing, research and development, product roadmaps, corporate alliances, or mergers and acquisitions) that have not been fully implemented or revealed to the public; trade secrets; customer-specific evaluations or data (e.g., prices, volumes, or revenues); personnel files and evaluations; information subject to confidentiality or non-disclosure agreements; proprietary technical or engineering information; proprietary financial data or projections; and proprietary consumer, customer or market research or analyses applicable to current or future market conditions, the disclosure of which could reveal

Confidential Discovery Material.

TERMS AND CONDITIONS OF PROTECTIVE ORDER

1. Discovery Material, or information derived therefrom, shall be used solely by the Parties for purposes of this Matter, and shall not be used for any other purpose, including without limitation any business or commercial purpose, except that with notice to the Producing Party, a Party may apply to the Administrative Law Judge for approval of the use or disclosure of any Discovery Material, or information derived therefrom, for any other proceeding. Provided, however, that in the event that the Party seeking to use Discovery Material in any other proceeding is granted leave to do so by the Administrative Law Judge, it will be required to take appropriate steps to preserve the confidentiality of such material. Additionally, in such event, the Commission may only use or disclose Discovery Material as provided by (1) its Rules of Practice, Sections 6(f) and 21 of the Federal Trade Commission Act and any cases so construing them; and (2) any other legal obligation imposed upon the Commission. The Parties, in conducting discovery from Third Parties, shall attach to such discovery requests a copy of this Protective Order and a cover letter that will apprise such Third Parties of their rights hereunder.

2. This paragraph concerns the designation of material as "Confidential" and "Restricted Confidential, Attorney Eyes Only."

(a) Designation of Documents as CONFIDENTIAL - FTC Docket No. 9297.

Discovery Material may be designated as Confidential Discovery Material by Producing Parties by placing on or affixing, in such manner as will not interfere with the legibility thereof, the notation "CONFIDENTIAL - FTC Docket No. 9297" (or other similar notation containing a

reference to this Matter) to the first page of a document containing such Confidential Discovery Material, or, by Parties by instructing the court reporter to denote each page of a transcript containing such Confidential Discovery Material as "Confidential." Such designations shall be made within fourteen days from the initial production or deposition and constitute a good-faith representation by counsel for the Party or Third Party making the designations that the document constitutes or contains "Confidential Discovery Material."

(b) Designation of Documents as "RESTRICTED CONFIDENTIAL, ATTORNEY EYES ONLY – FTC Docket No. 9297."

In order to permit Producing Parties to provide additional protection for a limited number of documents that contain highly sensitive commercial information, Producing Parties may designate documents as "Restricted Confidential, Attorney Eyes Only, FTC Docket No. 9297" by placing on or affixing such legend on each page of the document. It is anticipated that documents to be designated Restricted Confidential, Attorney Eyes Only may include certain marketing plans, sales forecasts, business plans, the financial terms of contracts, operating plans, pricing and cost data, price terms, analyses of pricing or competition information, and limited proprietary personnel information; and that this particularly restrictive designation is to be utilized for a limited number of documents. Documents designated Restricted Confidential, Attorney Eyes Only may be disclosed to Outside Counsel, Complaint Counsel, in-house counsel (designated pursuant to paragraph 5, hereof), and to Experts/Consultants (paragraph 4(c), hereof) that are not current officers, directors or employees of pharmaceutical companies (other than in-house counsel designated pursuant to paragraph 5 hereto). Such materials may not be disclosed to Experts/Consultants or to witnesses or deponents at trial or deposition (paragraph 4(d) hereof),

where the Experts/Consultants, deponents or witnesses are current officers, directors, or employees of pharmaceutical companies (other than in-house counsel designated pursuant to paragraph 5 hereto), except in accordance with subsection (c) of this paragraph 2. In all other respects, Restricted Confidential, Attorney Eyes Only material shall be treated as Confidential Discovery Material and all references in this Protective Order and in the exhibit hereto to Confidential Discovery Material shall include documents designated Restricted Confidential, Attorney Eyes Only.

(c) Disclosure of Restricted Confidential, Attorney Eyes Only Material to Experts/Consultants, Deponents or Witnesses Who Are Current Officers, Directors, or Employees of Pharmaceutical Companies (other than in-house counsel designated pursuant to paragraph 5 hereto).

If any Party desires to disclose Restricted Confidential, Attorney Eyes Only material to any Expert/Consultant, deponent or witness that is a current officer, director, or employee of a pharmaceutical company, other than in-house counsel designated pursuant to paragraph 5 hereto, the disclosing Party shall notify the Producing Party of its desire to disclose such material. Such notice shall identify the specific individual to whom the Restricted Confidential, Attorney Eyes Only material is to be disclosed. Such identification shall include, but not be limited to, the full name and professional address and/or affiliation of the identified individual. The Producing Party may object to the disclosure of the Restricted Confidential, Attorney Eyes Only material within five business days of receiving notice of an intent to disclose the Restricted Confidential, Attorney Eyes Only material to an individual by providing the disclosing Party with a written statement of the reasons for objection. If the Producing Party timely objects, the disclosing Party

shall not disclose the Restricted Confidential, Attorney Eyes Only material to the identified individual, absent a written agreement with the Producing Party, order of the Administrative Law Judge or ruling on appeal. The Producing Party lodging an objection and the disclosing Party shall meet and confer in good faith in an attempt to determine the terms of disclosure to the identified individual. If at the end of five business days of negotiating the parties have not resolved their differences or if counsel determine in good faith that negotiations have failed, the disclosing Party may make written application to the Administrative Law Judge as provided by paragraph 7(c) of this Protective Order. If the Producing Party does not object to the disclosure of Restricted Confidential, Attorney Eyes Only material to the identified individual within five business days, the disclosing Party may disclose the Restricted Confidential, Attorney Eyes Only material to the identified individual.

(d) Disputes Concerning Designation or Disclosure of Restricted Confidential, Attorney Eyes Only Material

Disputes concerning the designation or disclosure of Restricted Confidential, Attorney Eyes Only material shall be resolved in accordance with the provisions of paragraph 7.

(e) No Presumption or Inference

No presumption or other inference shall be drawn that material designated Restricted Confidential, Attorney Eyes Only is entitled to the protections of this paragraph.

(f) Due Process Savings Clause

Nothing herein shall be used to argue that a Party's right to attend the trial of, or other proceedings in, this Matter is affected in any way by the designation of material as Restricted Confidential, Attorneys Eyes Only.

3. All documents heretofore obtained by the Commission through compulsory process or voluntarily from any Party or Third Party, regardless of whether designated confidential by the Party or Third Party, and transcripts of any investigational hearings, interviews and depositions, that were obtained during the pre-complaint stage of this Matter shall be treated as "Confidential," in accordance with paragraph 2(a) on page five of this Order. Furthermore, Complaint Counsel shall, within five business days of the effective date of this Protective Order, provide a copy of this Order to all Parties or Third Parties from whom the Commission obtained documents during the pre-Complaint investigation and shall notify those Parties and Third Parties that they shall have thirty days from the effective date of this Protective Order to determine whether their materials qualify for the higher protection of Restricted Confidential, Attorney Eyes Only and to so designate such documents.

4. Confidential Discovery Material shall not, directly or indirectly, be disclosed or otherwise provided to anyone except to:

(a) Complaint Counsel and the Commission, as permitted by the Commission's Rules of Practice;

(b) Outside Counsel;

(c) Experts/Consultants (in accordance with paragraph 6 hereto);

(d) witnesses or deponents at trial or deposition;

(e) the Administrative Law Judge and personnel assisting him;

(f) court reporters and deposition transcript reporters;

(g) judges and other court personnel of any court having jurisdiction over any appeal proceedings involving this Matter; and

(h) any author or recipient of the Confidential Discovery Material (as indicated on the face of the document, record or material), and any individual who was in the direct chain of supervision of the author at the time the Confidential Discovery Material was created or received.

5. In addition to the above-described persons, certain named designated individuals and in-house counsel, not to exceed two attorneys per corporate party, who do not have day to day business responsibilities, shall be provided with access to Confidential Discovery Material, including material designated as "Confidential" and "Restricted Confidential, Attorney Eyes Only"on the condition that each such in-house counsel or designated executive signs a declaration in the form attached hereto as Exhibit "A," which is incorporated herein by reference. For Respondent Schering-Plough the designated individuals are John Hoffman, Staff Vice President and Associate General Counsel; and Jonathon Wasserman, Senior Antitrust Counsel. For Respondent Upsher-Smith, the designated individual is Mark Robbins, Director of Scientific Affairs. For Respondent AHP, the designated individuals are Louis L. Hoynes, Jr., Executive Vice President and General Counsel; and Elliot Feinberg, Assistant General Counsel, Antitrust.

6. Confidential Discovery Material, including material designated as "Confidential" and "Restricted Confidential, Attorney Eyes Only," shall not, directly or indirectly, be disclosed or otherwise provided to an Expert/Consultant, whether or not that Expert/Consultant is currently an officer, director, or employee of a pharmaceutical company, unless such Expert/Consultant agrees in writing:

(a) to maintain such Confidential Discovery Material in separate locked rooms or locked cabinet(s) when such Confidential Discovery Material is not being reviewed;

(b) to return such Confidential Discovery Material to Complaint Counsel or

Respondents' Outside Counsel, as appropriate, upon the conclusion of the Expert/Consultant's assignment or retention or the conclusion of this Matter;

(c) to not disclose such Confidential Discovery Material to anyone, except as permitted by the Protective Order; and

(d) to use such Confidential Discovery Material and the information contained therein solely for the purpose of rendering consulting services to a Party to this Matter, including providing testimony in judicial or administrative proceedings arising out of this Matter.

7. This paragraph governs the procedures for the following specified disclosures and challenges to designations of confidentiality.

(a) Disclosure of Confidential Discovery Material to Experts Who Are Current Officers, Directors or Employees of Pharmaceutical Companies (other than in-house counsel designated pursuant to paragraph 5 hereto).

If any Party desires to disclose Confidential Discovery Material to any Expert who may testify and who is a current officer, director or employee of a pharmaceutical company (other than in-house counsel designated pursuant to paragraph 5 hereto), the disclosing Party shall notify the Producing Party of its desire to disclose such material. Such notice shall identify the specific expert who may testify to whom the Confidential Discovery Material is to be disclosed. Such identification shall include, but not be limited to, the full name and professional address and/or affiliation of the proposed expert who may testify, and a current curriculum vitae of such expert identifying all other present and prior employees and/or firms in the pharmaceutical industry for which or on behalf of which the identified expert has been employed or done consulting work in the preceding four years. The Producing Party may object to the disclosure of

the Confidential Discovery Material within five business days of receiving notice of an intent to disclose the Confidential Discovery Material to the identified expert by providing the disclosing Party with a written statement of the reasons for the objection. If the Producing Party timely objects, the disclosing Party shall not disclose the Confidential Discovery Material to the identified expert, absent a written agreement with the Producing Party or order of the Administrative Law Judge. The Producing Party lodging an objection and the disclosing Party shall meet and confer in good faith in an attempt to determine the terms of disclosure to the identified expert. If at the end of five business days of negotiating the parties have not resolved their differences or if counsel determine in good faith that negotiations have failed, the disclosing Party may make written application to the Administrative Law Judge as provided by paragraph 7(c) of this Protective Order. If the Producing Party does not object to the disclosure of Confidential Discovery Material to the identified expert within five business days; the disclosing Party may disclose the Confidential Discovery Material to the identified expert.

(b) Challenges to Confidentiality Designations

If any Party seeks to challenge a Producing Party's designation of material as Confidential Discovery Material or any other restriction contained within this Protective Order, the challenging Party shall notify the Producing Party and all Parties to this action of the challenge to such designation. Such notice shall identify with specificity (i.e., by document control numbers, deposition transcript page and line reference, or other means sufficient to locate easily such materials) the designation being challenged. The Producing Party may preserve its designation within five business days of receiving notice of the confidentiality challenge by providing the challenging Party and all Parties to this action with a written statement of the reasons for the

designation. If the Producing Party timely preserves its rights, the Parties shall continue to treat the challenged material as Confidential Discovery Material, absent a written agreement with the Producing Party or order of the Administrative Law Judge. The Producing Party, preserving its rights, and the challenging Party shall meet and confer in good faith in an attempt to negotiate changes to any challenged designation. If at the end of five business days of negotiating the parties have not resolved their differences or if counsel determine in good faith that negotiations have failed, the challenging Party may make written application to the Administrative Law Judge as provided by paragraph 7(c) of this Protective Order. If the Producing Party does not preserve its rights within five business days, the challenging Party may alter the designation as contained in the notice. The challenging Party shall notify the Producing Party and the other Parties to this action of any changes in confidentiality designations.

Regardless of confidential designation, copies of published magazine or newspaper articles, and excerpts from published books and public documents filed with the Securities and Exchange Commission may be used by any Party without reference to the procedures of this subparagraph.

(c) Resolution of Disclosure or Confidentiality Disputes

If negotiations under subparagraphs 7(a)-(b) of this Protective Order have failed to resolve the issues, a Party seeking to disclose Confidential Discovery Material or challenging a confidentiality designation or any other restriction contained within this Protective Order may make written application to the Administrative Law Judge for relief. Such application shall be served on the Producing Party and the other Party, and be accompanied by a certification that the meet and confer obligations of this paragraph have been met, but that good faith negotiations

have failed to resolve outstanding issues. The Producing Party and any other Parties shall have five business days to respond to the application. While an application is pending, the Parties shall maintain the pre-application status of the Confidential Discovery Material. Nothing in this Protective Order shall create a presumption or alter the burden of persuading the Administrative Law Judge of the proprietary of a requested disclosure or change in designation.

8. Confidential Discovery Material shall not be disclosed to any person described in subparagraphs 4(c) and 4(d) and paragraph 5 of this Protective Order until such person has executed and transmitted to Respondent's counsel or Complaint Counsel, as the case may be, a declaration or declarations, as applicable, in the form attached hereto as Exhibit "A," which in incorporated herein by reference. Respondents' counsel and Complaint Counsel shall maintain a file of all such declarations for the duration of the litigation. Confidential Discovery Material shall not be copied or reproduced for use in this Matter except to the extent such copying or reproduction is reasonably necessary to the conduct of this Matter, and all such copies or reproductions shall be subject to the terms of this Protective Order. If the duplication process by which copies or reproductions of Confidential Discovery Material are made does not preserve the confidentiality designations that appear on the original documents, all such copies or reproductions shall be stamped "CONFIDENTIAL – FTC Docket No. 9297."

9. The Parties shall not be obligated to challenge the propriety of any designation or treatment of information as confidential and the failure to do so promptly shall not preclude any subsequent objection to such designation or treatment, or any motion seeking permission to disclose such material to persons not referred to in paragraphs 4 and 5 above. If Confidential Discovery Material is produced without the legend attached, such document shall be treated as

Confidential from the time the Producing Party advises Complaint Counsel and Respondents' counsel in writing that such material should be so designated and provides all the Parties with an appropriately labeled replacement. The Parties shall return promptly or destroy the unmarked documents.

10. If the FTC: (a) receives a discovery request that may require the disclosure by it of a Third Party's Confidential Discovery Material; or (b) intends to or is required to disclose, voluntarily or involuntarily, a Third Party's Confidential Discovery Material (whether or not such disclosure is in response to a discovery request), the FTC promptly shall notify the Third Party of either receipt of such request or its intention to disclose such material. Such notification shall be in writing and, if not otherwise done, sent for receipt by the Third Party at least five business days before production, and shall include a copy of this Protective Order and a cover letter that will apprise the Third Party of its rights hereunder.

11. If any person receives a discovery request in another proceeding that may require the disclosure of a Producing Party's Confidential Discovery Material, the subpoena recipient promptly shall notify the Producing Party of receipt of such request. Such notification shall be in writing and, if not otherwise done, sent for receipt by the Producing Part at least five business days before production, and shall include a copy of this Protective Order and a cover letter that will apprise the Producing Party of its rights hereunder. The Producing Party shall be solely responsible for asserting any objection to the requested production. Nothing herein shall be construed as requiring the subpoena recipient or anyone else covered by this Order to challenge or appeal any such order requiring production of Confidential Discovery Material, or to subject itself to any penalties for noncompliance with any such order, or to seek any relief from the

Administrative Law Judge or the Commission.

12. This Order governs the disclosure of information during the course of discovery and does not constitute an *in camera* order as provided in Section 3.45 of the Commission's Rules of Practice, 16 C.F.R. § 3.45.

13. Nothing in this Protective Order shall be construed to conflict with the provisions of Sections 6, 10, and 21 of the Federal Trade Commission Act, 15 U.S.C. §§ 46, 50, 57b-2, or with Rules 3.22, 3.45 or 4.11(b)-(e), 16 C.F.R. §§ 3.22, 3.45 and 4.11(b)-(e).[1]

Any Party or Producing Party may move at any time for *in camera* treatment of any Confidential Discovery Material or any portion of the proceedings in this Matter to the extent necessary for proper disposition of the Matter. An application for *in camera* treatment must met the standards set forth in 16 C.F.R. § 3.45 and explained in *In re Dura Lube Corp.*, 1999 FTC LEXIS 255 (Dec. 23, 1999).

14. At the conclusion of this Matter, Respondents' counsel shall return to the Producing Party, or destroy, all originals and copies of documents and all notes, memoranda, or other papers containing Confidential Discovery Material which have not been made part of the public record in this Matter. Complaint Counsel shall dispose of all documents in accordance with Rule 4.12, 16 C.F.R. § 4.12.

15. The provisions of this Protective Order, insofar as they restrict the communication and use of Confidential Discovery Material shall, without written permission of the Producing Party

[1] The right of the Administrative Law Judge, the Commission, and reviewing courts to disclose information afforded *in camera* treatment or Confidential Discovery Material, to the extent necessary for proper disposition of the proceeding, is specifically reserved pursuant to Rule 3.45, 16 C.F.R. § 3.45.

or further order of the Administrative Law Judge hearing this Matter, continue to be binding after the conclusion of this Matter.

16. This Protective Order shall not apply to the disclosure by a Producing Party or its Counsel of such Producing Party's Confidential Discovery Material to such Producing Party's employees, agents, former employees, board members, directors, and officers.

17. The production or disclosure of any Discovery Material made after entry of this Protective Order which a Producing Party claims was inadvertent and should not have been produced or disclosed because of a privilege will not automatically be deemed to be a waiver of any privilege to which the Producing Party would have been entitled had the privileged Discovery Material not inadvertently been produced or disclosed. In the event of such claimed inadvertent production or disclosure, the following procedures shall be followed:

(a) The Producing Party may request the return of any such Discovery Material within twenty days of discovering that it was inadvertently produced or disclosed (or inadvertently produced or disclosed without redacting the privileged content). A request for the return of any Discovery Material shall identify the specific Discovery Material and the basis for asserting that the specific Discovery Material (or portions thereof) is subject to the attorney-client privilege or the work product doctrine and the date of discovery that there had been an inadvertent production or disclosure.

(b) If a Producing Party requests the return, pursuant to this paragraph, of any such Discovery Material from another Party, the Party to whom the request is made shall return immediately to the Producing Party all copies of the Discovery Material within its possession, custody, or control—including all copies in the possession of experts, consultants, or others to

whom the Discovery Material was provided—unless the Party asked to return the Discovery Material in good faith reasonably believes that the Discovery Material is not privileged. Such good faith belief shall be based on either (i) a facial review of the Discovery Material, or (ii) the inadequacy of any explanations provided by the Producing Party, and shall not be based on an argument that production or disclosure of the Discovery Material waived any privilege. In the event that only portions of the Discovery Material contain privileged subject matter, the Producing Party shall substitute a redacted version of the Discovery Material at the time of making the request for the return of the requested Discovery Material.

(c) Should the Party contesting the request to return the Discovery Material pursuant to this paragraph decline to return the Discovery Material, the Producing Party seeking return of the Discovery Material may thereafter move for an order compelling the return of the Discovery Material. In any such motion, the Producing Party shall have the burden of showing that the Discovery Material is privileged and that the production was inadvertent.

18. Entry of the foregoing Protective Order is without prejudice to the right of the Parties or Third Parties to apply for further protective orders or for modification of any provisions of this Protective Order.

ORDERED:

D. Michael Chappell
Administrative Law Judge

Date: May 10, 2001

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

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

DECLARATION CONCERNING PROTECTIVE ORDER GOVERNING DISCOVERY MATERIAL

I, [NAME], hereby declare and certify the following to be true:

1. [Statement of employment]

2. I have read the "Protective Order Governing Discovery Material" (Protective Order") issued by Administrative Law Judge D. Michael Chappell on May 10, 2001, in connection with the above captioned matter. I understand the restrictions on my use of any Confidential Discovery Material (as this term is used in the Protective Order) in this action and I agree to abide by the Protective Order.

3. I understand that the restrictions on my use of such Confidential Discovery Material include:

   a. that I will use such Confidential Discovery Material only for the purposes of preparing for this proceedings, and hearing(s) and any appeal of this proceeding and for no other purpose;

   b. that I will not disclose such Confidential Discovery Material to anyone, except as permitted by the Protective Order; and

   c. that upon the termination of my participation in this proceeding I will

promptly return all Confidential Discovery Material, and all notes, memoranda, or other papers containing Confidential Discovery Material, to Complaint Counsel or Respondent's counsel, as appropriate.

4. I understand that if I am receiving Confidential Discovery Material as an Expert/Consultant, as that term is defined in this Protective Order, the restrictions on my use of Confidential Discovery Material also include the duty and obligation:

a. to maintain such Confidential Discovery Material in separate locked room(s) or locked cabinet(s) when such Confidential Discovery Material is not being reviewed;

b. to return such Confidential Discovery Material to Complaint Counsel or Respondent's Outside Counsel, as appropriate, upon the conclusion of my assignment or retention; and

c. to use such Confidential Discovery Material and the information contained therein solely for the purpose of rendering consulting services to a Party to this matter, including providing testimony in judicial or administrative proceedings arising out of this matter.

5. I am fully aware that, pursuant to Section 3.42(h) of the Commission's Rules of Practice, 16 C.F.R. § 3.42(h), my failure to comply with the terms of the Protective Order may constitute contempt of the Commission and may subject me to sanctions imposed by the Commission.

_____ Date: _____

Full Name [Typed or Printed]

_____

Signature