[redacted]

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

FDA's grant of eligibility for 180-day exclusivity survived until September 2001 or would have

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:

[redacted]

[redacted]

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

[redacted]

Request No. 26:

Answer:

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

Request No. 27:

Request No. 28:

Answer:

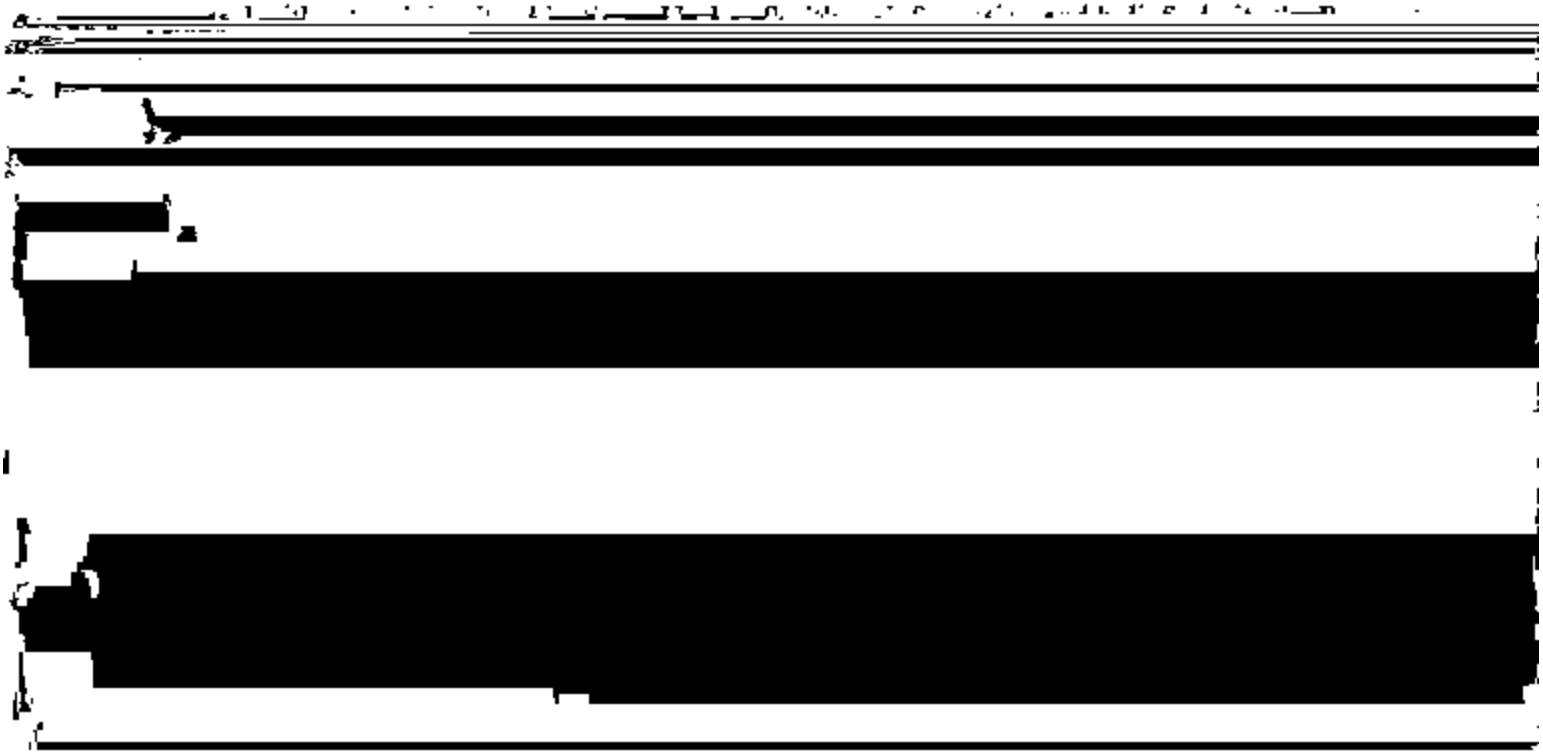
Upsher-Smith objects to the Request as vague and ambiguous because, among other reasons, the meaning of " " is unclear as used in the Request. Subject to and without waiving its objections, Upsher-Smith admits that

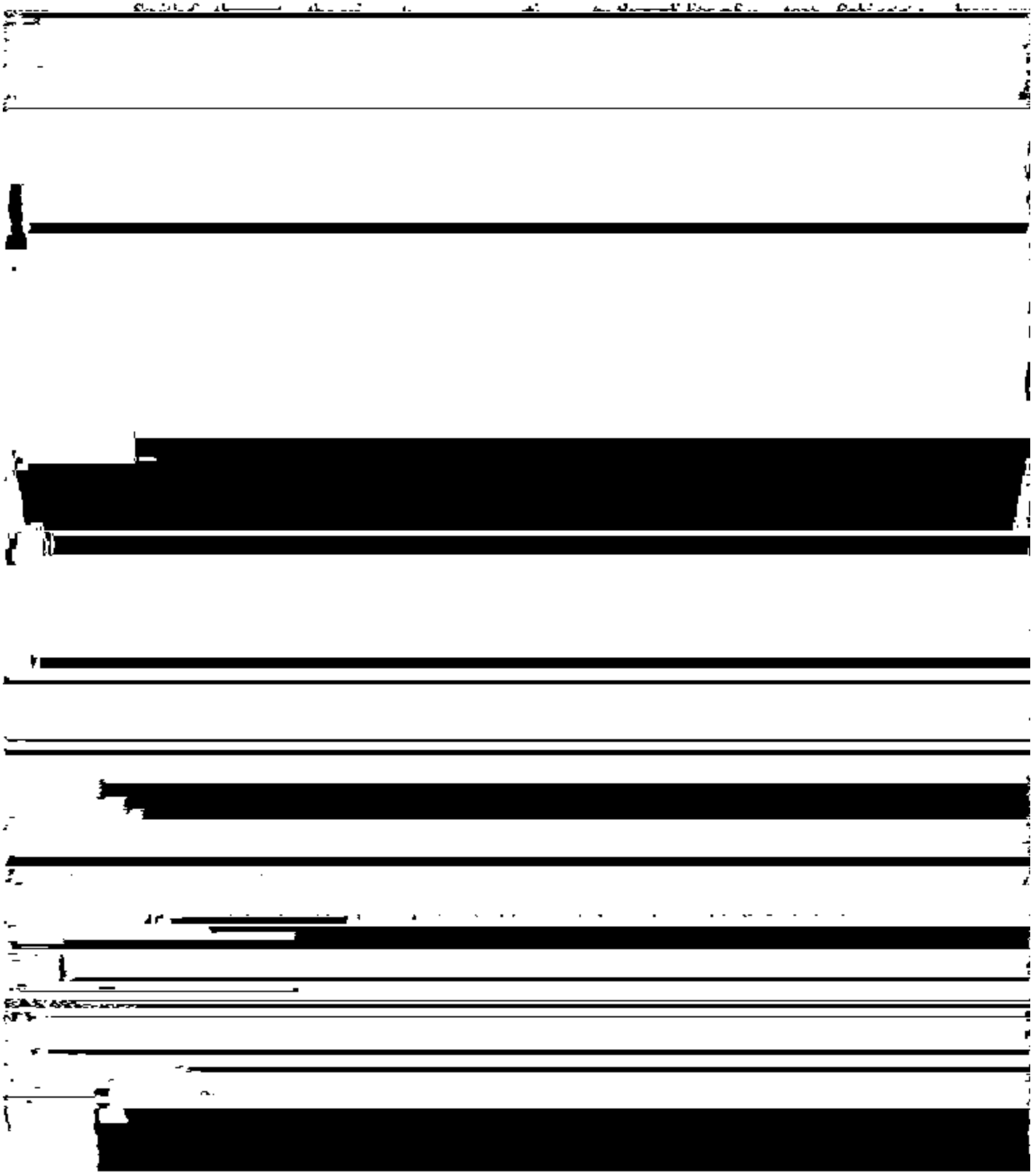
Request No. 29:

Answer:

Upsher-Smith objects to the Request as vague and ambiguous because, among other

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





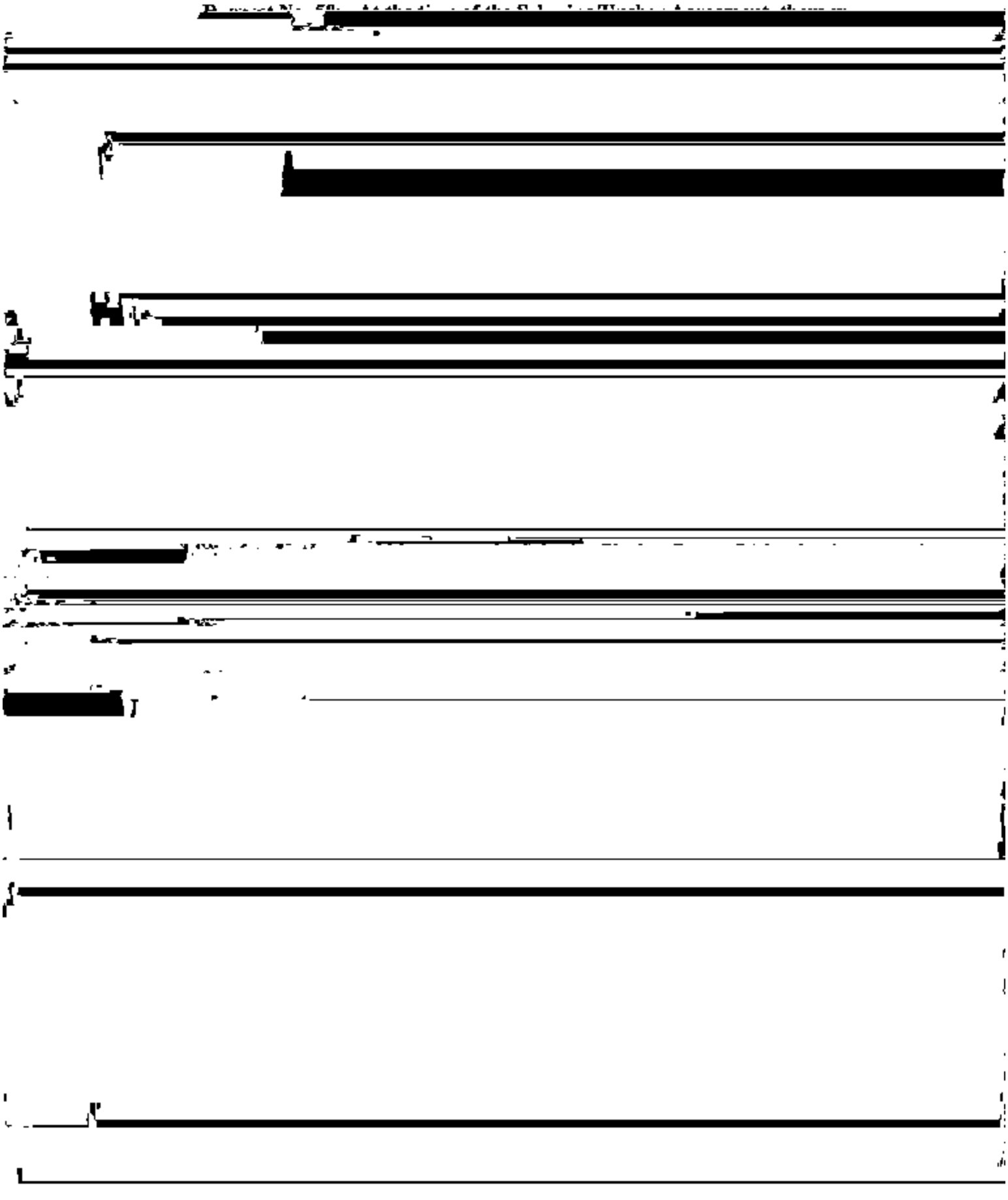
information and belief, Upsher-Smith admits that the District Court made no finding that Upsher-Smith's generic version of K-Dur 20 was likely or unlikely to infringe the '743 Patent.

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.

[redacted]



Request No. 72: On November 20, 1998, Upsher received final FDA approval for

[redacted]

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 [redacted] which is the best evidence of the information sought in the Request. Subject to and without waiving its objections, Upsher-Smith admits the Request.

[redacted]

[redacted]

Answer:

Request No. 83:

[redacted]

Request No. 84:

Answer:

Request No. 85:

Answer:

Request No. 87:

Answer:

Request No. 88:

Answer:

Request No. 89:

Answer:

Request No. 90:

Answer:

[redacted]

knowledge as to action by

Request No. 95:

Request No. 98:

Answer:

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

[redacted]

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.

[redacted]

Schering/Upsher Agreement.

Answer:

[redacted]

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 states upon

[redacted]

information and belief, that no federal district court required or requested that the Agreement be approved.

Request No. 124:

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:

[redacted]

Request No. 142:

Answer:

Request No. 143:

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.

[redacted]

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 [redacted]

[redacted]

Request No. 173:

[redacted]

Request No. 174:

Answer:

Request No. 176:

Answer:

Request No. 178:

Answer:

Request No. 179:

Answer:

Request No. 180:

Answer:

Request No. 241:

Answer:

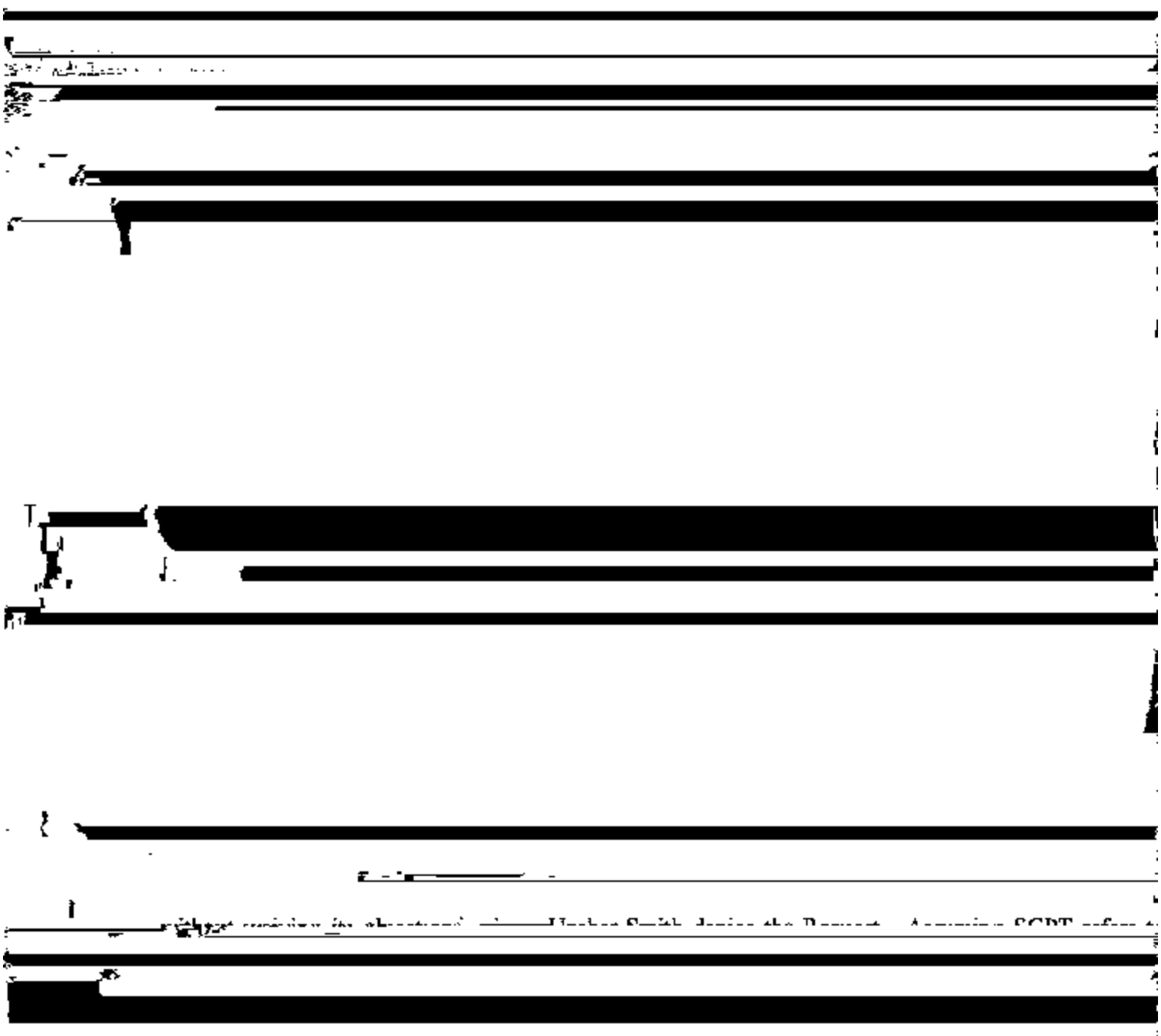
Request No. 274: Elevated levels of liver enzyme SGOT in the bloodstream are an indication of either liver disease or liver damage.

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.



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:

[redacted]

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

[redacted]

November 14, 2001 by hand delivery:

Hon. D. Michael Chappell

[redacted]

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

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

PROTECTIVE ORDER GOVERNING DISCOVERY MATERIAL

[redacted]

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. [redacted]

9. "Producing Party" means a Party or Third Party that produced or intends to produce

[redacted]

Material of a Third Party that either is in the possession, custody or control of the FTC or has

[redacted]

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.

[redacted]

exhibits, interrogatory responses, admissions, affidavits, declarations, documents produced [redacted]

Confidential Discovery Material

TERMS AND CONDITIONS OF PROTECTIVE ORDER

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

where the Experts/Consultants, deponents or witnesses are current officers, directors, or employees of pharmaceutical companies (other than in-house counsel designated pursuant to

[redacted]

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

shall not disclose the Restricted Confidential, Attorney Eyes Only material to the identified

[redacted]

3. All documents heretofore obtained by the Commission through compulsory process [illegible]

Party or Third Party, and transcripts of any investigational hearings, interviews and depositions

(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

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.

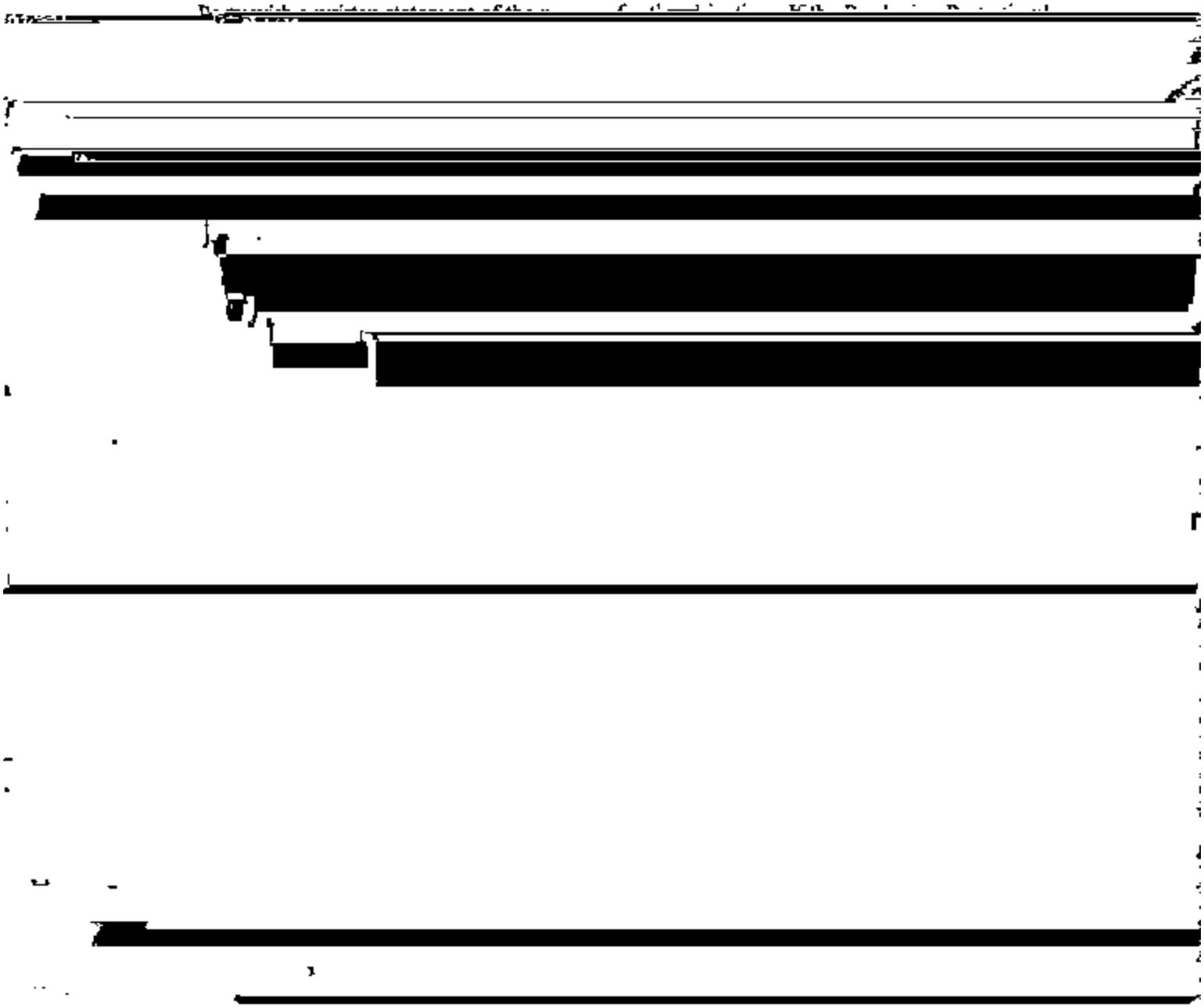
(a) Disclosure of Confidential Discovery Material to Experts Who Are Current

[redacted]

Officers, Directors or Employees of Pharmaceutical Companies (other than in-house counsel

[redacted]

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



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

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

[redacted]

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 proof in the Administrative

Law Judge of the propriety of a requested disclosure or change in designation.

[redacted]

counsel in writing that such material should be so designated and provides all the Parties with an

[redacted]

Administrative Law Judge or the Commission.

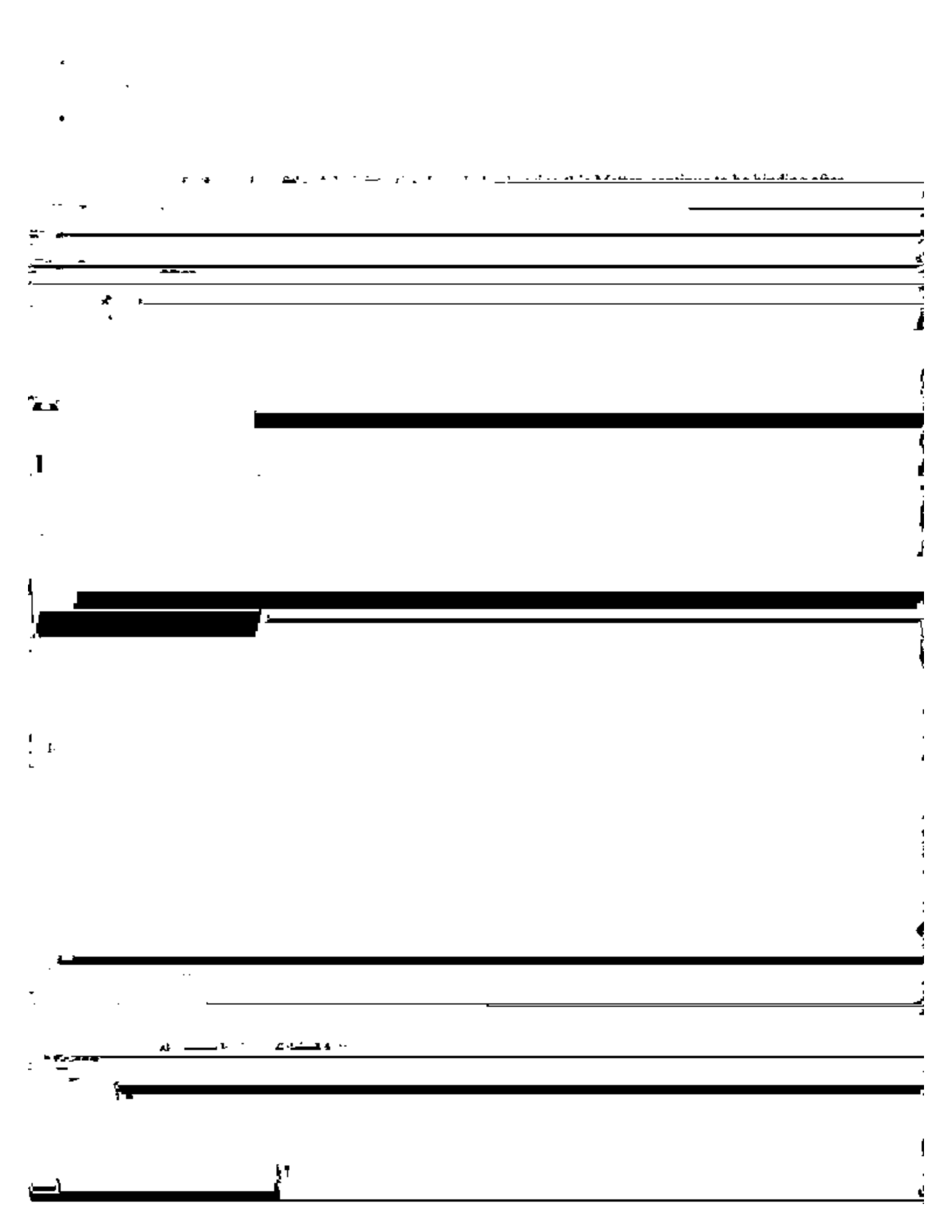
12. This Order governs the disclosure of information during the course of discovery and does not constitute an *in camera* order as provided in Section 3.45 of the Commission's Rules of Practice, 16 C.F.R. § 3.45.

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

[redacted]

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

[redacted]



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 [redacted]. In the [redacted] 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

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

promptly return all Confidential Discovery Material, and all notes,

[redacted]

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

[redacted]