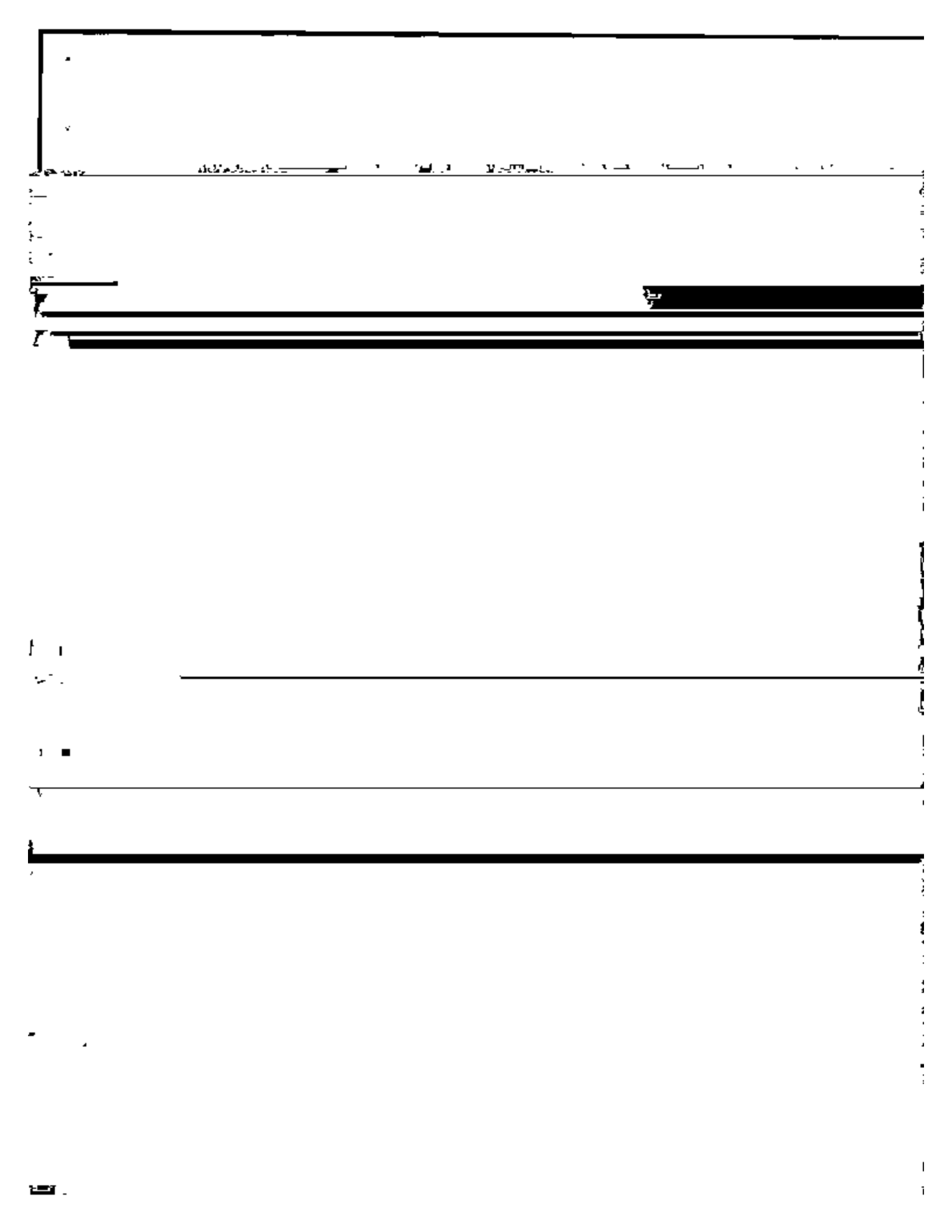
UNITED STATES OF AMERICA

Andrx's proposed generic potassium chloride supplement, and communications with regulatory bodies concerning Andrx's ANDA. The first category includes documents that contain sales forecasts, projections, assumptions, and projected requirements for a product

of an ANDA before a letter is sent to the applicant stating that the application is "approvable". 21 C.F.R. § 314.430(b). Thereafter, except for providing a "summary" of



denied FOIA request for abandoned drug applications where disclosure would result in competitive harm to originator of application) (citing *Webb v. HHS*, 696 F.2d 101, 103 (D.C. Cir. 1982) (recognizing competitive harm that may result from public disclosure of New Drug Applications)). That FDA treats such information as non-public under 21 C.F.R. § 314.430 further underscores the inherently confidential nature of any information concerning a pending ANDA.

As explained in the Searle Declaration, ANDAs generally contain detailed scientific

show a confidential document to a non-party witness or expert). Nor is this a case in which

CONCLUSION

For the foregoing reasons, Andrx respectfully requests that this Court determine that the documents identified in Appendix A properly contain nonpublic information under 16 C.F.R. § 4.10(a)(2) and are entitled to *in camera* protection pursuant to 16 C.F.R. § 3.45. In addition, in the event that the Commission intends to disclose *in camera* Andrx information in a final decision, Andrx respectfully requests that the Commission notify both Andrx outside counsel, Colin A. Underwood of Solomon, Zauderer, Ellenhorn, Frischer & Sharp, 45 Rockefeller Plaza, New York, New York, 10111, telephone: 212-956-3700, facsimile 212-

APPENDIX B

CODE OF FEDERAL REGULATIONS
TITLE 21—FOOD AND DRUGS

or acknowledged before the agency sends an approval letter to the applicant. no data or

(a) Names and any information that would identify

(f) All safety and effectiveness data and information which have been submitted in an application and

20.117 are available for public disclosure.

[50 FR 21238, May 23, 1985; 50 FR 23798, June 6, 1985; 55 FR 11580, March 29, 1990; 57 FR 17996, April 28, 1992; 61 FR 51530, Oct. 2, 1996; 63 FR 26698, May 13, 1998; 63 FR 48576, Sept. 11, 1998; [illegible]

[illegible] 999; 66 FR 1832, Jan. 10, 2001]

<General Materials (GM) - References, Annotations, or Tables>

21 C. F. R. § 314.430

21 CFR § 314.430

END OF DOCUMENT

UNITED STATES OF AMERICA

BEFORE THE FEDERAL TRADE COMMISSION

In the Matter of

SCHERING-PLOUGH CORPORATION,

UPSHER-SMITH LABORATORIES,

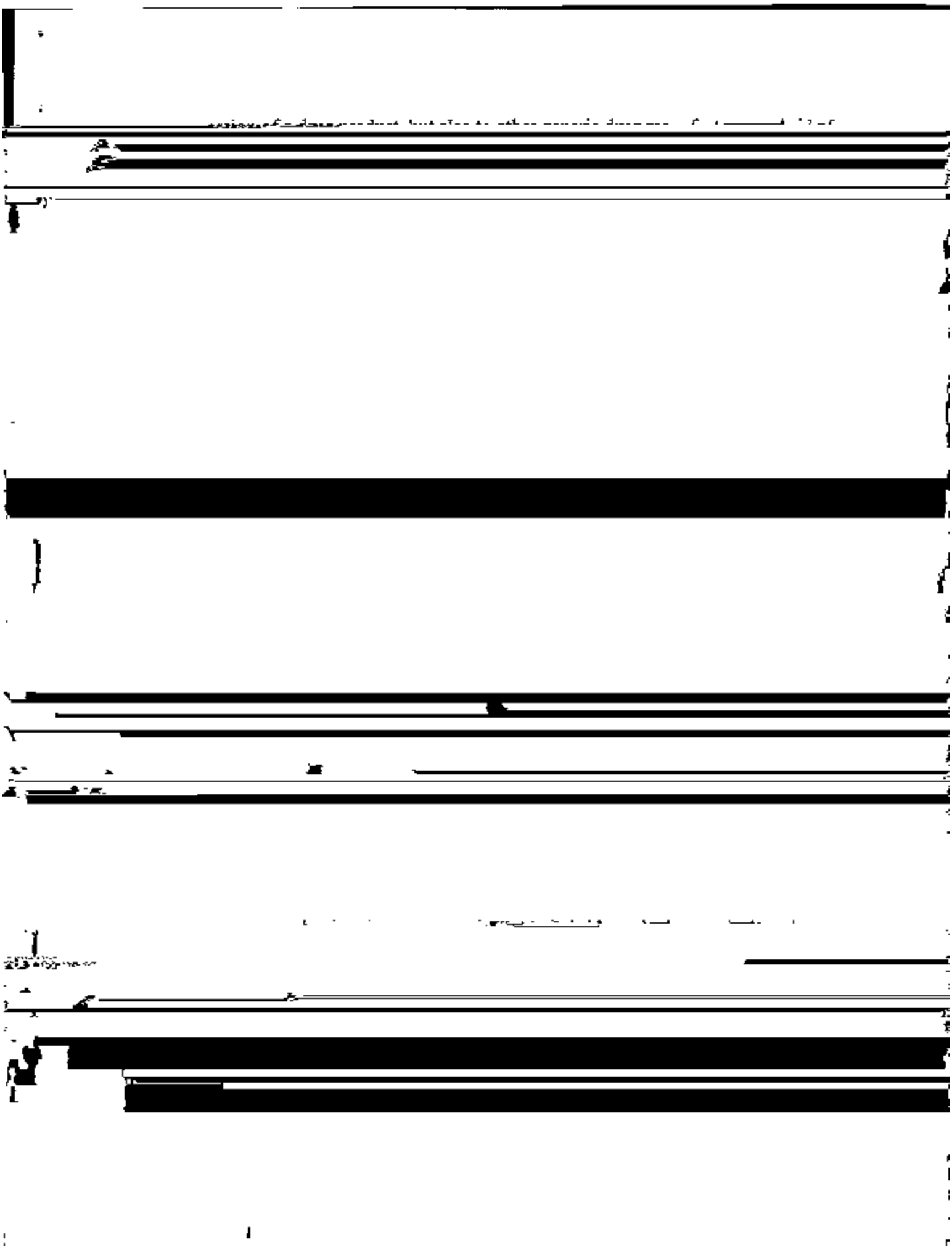
and

AMERICAN HOME PRODUCTS CORPORATION.

Docket No. 9297

DECLARATION OF HERSCHEL E. SPARKS, JR. IN SUPPORT

unless the information has otherwise been made public, FDA will not even produce



publicly available. In fact, even when the USP publishes a submission from a manufacturer in the *U.S. Pharmacopeia*, it does not disclose the identity of that manufacturer. In my experience, correspondence with the USP is treated as carefully and privately as correspondence with the FDA, for without such confidentiality

[redacted]

CERTIFICATE OF SERVICE

I, Peter M. Todaro, hereby certify that on January 4, 2002 I caused a true and correct