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

NON-PARTY ANDRX CORPORATION'S SUPPLEMENTAL APPLICATION FOR *IN CAMERA* PROTECTION OF CERTAIN OF ITS CONFIDENTIAL MATERIALS

Non-Party Andrx Corporation (Andrx) submits this supplemental memorandum pursuant to Section 3.45 of the Commission's Rules of Practice, 16 C.F.R. § 3.45, in further support of its prior application for *in camera* treatment of certain of its confidential materials.

ARGUMENT

On December 27, 2001, Andrx filed its Application for *in camera* treatment of an Andrx document that Complaint Counsel had identified as a potential exhibit during the hearing on this matter. As set forth in that application, because Andrx did not receive notice from respondents Schering and Upsher-Smith concerning the Andrx documents they intend to use at the hearing until December 26, Andrx was unable to address those documents in the December 27 application. Andrx has reviewed the documents identified by respondents and now requests *in camera* treatment for most of them. A complete list of the documents for which Andrx is seeking *in camera* protection is attached hereto as Appendix A.

The documents for which Andrx requests *in camera* treatment fall into two basic categories: documents containing proprietary sales and marketing information concerning

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 that has not yet been approved by the FDA or brought to market. As set forth in more detail in Andrx's December 27, 2001 application, if such information were to become public, Andrx would suffer significant competitive injury, yet no public interest would be served. In addition to the document specifically addressed in Andrx's original application (ANDX-SP 001158), Andrx now seeks *in camera* treatment for two more documents in this category, designated as ANDX-SP 001159-001160 and ANDX-SP 001161. For all of the reasons set forth in Andrx's December 27 application, these documents should also be granted *in camera* treatment without a definite expiration date.

The second category of documents for which Andrx now seeks *in camera* treatment consists of nonpublic correspondence, primarily between Andrx and FDA, concerning Andrx's generic potassium chloride product. FDA has not yet finally approved Andrx's ANDA. As explained below (and in the accompanying declaration of Andrx's Litigation Counsel, Herschel E. Sparks, Jr., dated January 3, 2002 (the "Sparks Declaration" or "Sparks Decl.")), information about a pending, unapproved ANDA is among the most competitively sensitive in the generic pharmaceutical industry.

Recognizing the confidentiality of such information (including the communications at issue now), FDA itself has promulgated regulations prohibiting public disclosure of nearly all information concerning a pending ANDA. 21 C.F.R. § 314.430 (prohibiting public disclosure concerning pending ANDAs). A copy of the relevant provisions is attached hereto as Appendix B. Under those regulations, FDA may not even publicly disclose the *existence*

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 "selected portions of the safety and effectiveness data . . . appropriate for public consideration of a specific issue", FDA will disclose **"no data or information"** in an ANDA until the applicant receives final approval. 21 C.F.R. § 314.430(c) & (d) (emphasis added). Communications between FDA and the applicant (such as those that FDA seeks to file here), are available for public disclosure only "[a]fter FDA sends an approval letter to the applicant". 21 C.F.R. § 314.430(e)(7).

In accordance with its regulations, FDA routinely denies FOIA requests for information about unapproved ANDAs and other drug product applications, and, when they have addressed the matter, the courts have directed FDA to produce that information pursuant to a protective order or under seal.[1] Indeed, until an ANDA is finally approved, the only publicly available information about an ANDA is the date on which it receives so-called "tentative approval". FDA posts tentative approval information for pending ANDAs on its website, http://www.fda.gov/cder/approval/ index.htm. FDA regulations themselves, 21 C.F.R. § 20.61, define "privileged or confidential" "commercial or financial information" as "valuable data or information which is used in one's business and is of a type customarily held in strict confidence or regarded as privileged and not disclosed to any member of the

[1] *E.g., Genentech, Inc. v. Bowen*, 1987 WL 10500 *1-2 (D.D.C. April 21, 1987) (in action concerning New Drug Applications, FDA filed administrative record under seal and supported motion for protective order designating as confidential all non-public information under 21 C.F.R. §§ 20.61 or 314.430); *Del Laboratories, Inc. v. United States*, 86 F.R.D. 676, 677 n.1 (D.D.C. 1980) (administrative record filed under seal to protect trade secret); *see also Serono Labs. v. Shalala*, 35 F. Supp.2d 1 (D.D.C. 1999) (FDA did not deny obligation to protect trade secrets in documents; agency ordered to purge all trade secrets before submitting administrative record).

public by the person to whom it belongs". That precisely describes the documents at issue here.

As the accompanying Sparks Declaration makes clear, the public disclosure of the documents at issue here would cause Andrx serious competitive and business harm. As the regulatory prohibitions on disclosure confirm, every aspect of a pending ANDA (save its "tentative approval" status) is extraordinarily sensitive information for a manufacturer such as Andrx.

In submitting this application, Andrx is mindful of the importance of public access to judicial proceedings. *Nixon v. Warner Communications*, 435 U.S. 589 (1978). Access to judicial records is not an all or nothing proposition, however. Because court records may "become a vehicle for improper purposes", "the right to inspect and copy judicial records is not absolute." *Id.* at 598 (denying application to unseal recordings). Thus, as the Supreme Court noted in *Nixon*, every court retains the power to control access to its files. *Id.* Here, Andrx's need to maintain the confidentiality of its pending ANDA substantially outweighs any legitimate public interest in the specific information at issue.

First, in light of FDA's regulations, the general presumption of public access to judicial records does not apply to information about a pending ANDA.

Second, the concern here is not simply disclosure of information to the general public (although FDA regulations clearly prohibit that too) but disclosure of critical business information about Andrx and its product that could be used by competitors to attempt to undermine Andrx's competitive position. Sparks Decl. ¶¶ 5-7. The threat of harm by competitors to a legitimate business interest is a compelling reason to limit public access. *See Public Citizen Health Research Group*, 185 F.3d at 905-06 (holding that FDA properly

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 Sparks Declaration, ANDAs generally contain detailed scientific, manufacturing, and marketing information about the proposed drug product. Sparks Decl. ¶ 5. Such information is clearly protected as trade secrets. More importantly, however, the mere *fact* of communications, including their dates, between FDA and Andrx is itself competitively sensitive information. Sparks Decl. ¶ 7. To other ANDA holders and drug manufacturers, such communications may reveal not only the approval status of an ANDA but the likelihood of approval and how close the ANDA is to obtaining that approval. *Id.* Armed with such information, other manufacturers have used and will use "citizen's petitions" and other regulatory and judicial devices to attempt to delay approval of Andrx's ANDA and position their own ANDAs for faster approval — even though the dealings between such manufacturers and FDA will remain non-public and beyond Andrx's reach, placing Andrx at a severe competitive disadvantage. *Id.*

The need for public access varies greatly depending on the specific documents at issue and their role in the case. *U.S. v. Amodeo*, 71 F.3d 1044, 1048-49 (2d Cir. 1995). Although respondents intend to rely on non-public documents concerning Andrx's ANDA in their filings, they have not indicated that *public* disclosure of the documents is somehow necessary to the arguments they intend to present (as, for example, where a party desires to

show a confidential document to a non-party witness or expert). Nor is this a case in which the public has an independent interest in the contents of the documents. (By definition, because Andrx's ANDA is not yet approved, the documents cannot and do not speak to any public safety concerns about a currently marketed product.) And since information about a pending ANDA is non-public under FDA regulations, guarded from disclosure under FOIA, and generally subject to protective orders limiting public access in other cases, the documents are not among those "traditionally" made public in any event. *Amodeo*, 71 F.3d at 1050. Thus, on balance, the need to protect the confidential nature of Andrx's pending ANDA substantially outweighs the public interest in such documents in the context of this case. *Id.* at 1044-47.

The documents identified by respondents also include one letter from Andrx to the United States Pharmacopeial Convention, Inc. ("USP"), which has been designated ANDX-SP 005348. That letter is entitled to the same protection as the correspondence with FDA discussed above. As set forth in the Sparks Declaration, correspondence with the USP is not made public. Sparks Decl. ¶ 8. In fact, even when the USP publishes material in the *U.S. Pharmacopeia* based on submissions from manufacturers such as Andrx, it does not identify *who* made the submission. *Id.*

Andrx simply seeks to keep confidential the very records and information that already are deemed non-public under the regulations and practice of the FDA and USP. Therefore, Andrx respectfully requests *in camera* protection for the correspondence identified in Appendix A. The confidential nature of this information will not decrease at least until Andrx obtains final FDA approval. Because Andrx cannot now predict when that will occur, it respectfully requests that indefinite *in camera* protection be granted to these documents.

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 212-956-4068, and Andrx in-house counsel Herschel E. Sparks, Jr., 4955 Orange Drive, Davie, Florida 33314, telephone 954-585-1709, facsimile 954-581-8750.

Dated: New York, New York
January 3, 2002

Respectfully Submitted,

SOLOMON, ZAUDERER, ELLENHORN,
FRISCHER & SHARP

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Counsel for Non-Party Andrx Corporation

APPENDIX B

CODE OF FEDERAL REGULATIONS
TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER D--DRUGS FOR HUMAN USE
PART 314--APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG
SUBPART G--MISCELLANEOUS PROVISIONS

Current through December 4, 2001; 66 FR 63093

§ 314.430 Availability for public disclosure of data and information in an application or abbreviated application.

(a) The Food and Drug Administration will determine the public availability of any part of an application or abbreviated application under this section and part 20 of this chapter. For purposes of this section, the application or abbreviated application includes all data and information submitted with or incorporated by reference in the application or abbreviated application, including investigational new drug applications, drug master files under § 314.420, supplements submitted under § 314.70 or § 314.97, reports under § 314.80 or § 314.98, and other submissions. For purposes of this section, safety and effectiveness data include all studies and tests of a drug on animals and humans and all studies and tests of the drug for identity, stability, purity, potency, and bioavailability.

(b) FDA will not publicly disclose the existence of an application or abbreviated application before an approvable letter is sent to the applicant under § 314.110, unless the existence of the application or abbreviated application has been previously publicly disclosed or acknowledged. The Center for Drug Evaluation and Research will maintain and make available for public disclosure a list of applications or abbreviated applications for which the agency has sent an approvable letter to the applicant.

(c) If the existence of an unapproved application or abbreviated application has not been publicly disclosed or acknowledged, no data or information in the application or abbreviated application is available for public disclosure.

(d)(1) If the existence of an application or abbreviated application has been publicly disclosed or acknowledged before the agency sends an approval letter to the applicant, no data or information contained in the application or abbreviated application is available for public disclosure before the agency sends an approval letter, but the Commissioner may, in his or her discretion, disclose a summary of selected portions of the safety and effectiveness data that are appropriate for public consideration of a specific pending issue; for example, for consideration of an open session of an FDA advisory committee.

(2) Notwithstanding paragraph (d)(1) of this section, FDA will make available to the public upon request the information in the investigational new drug application that was required to be filed in Docket Number 95S-0158 in the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857, for investigations involving an exception from informed consent under § 50.24 of this chapter. Persons wishing to request this information shall submit a request under the Freedom of Information Act.

(e) After FDA sends an approval letter to the applicant, the following data and information in the application or abbreviated application are immediately available for public disclosure, unless the applicant shows that extraordinary circumstances exist. A list of approved applications and abbreviated applications, entitled "Approved Drug Products with Therapeutic Equivalence Evaluations," is available from the Government Printing Office, Washington, DC 20402. This list is updated monthly.

(1) [Reserved]

(2) If the application applies to a new drug, all safety and effectiveness data previously disclosed to the public as set forth in § 20.81 and a summary or summaries of the safety and effectiveness data and information submitted with or incorporated by reference in the application. The summaries do not constitute the full reports of investigations under section 505(b)(1) of the act (21 U.S.C. 355(b)(1)) on which the safety or effectiveness of the drug may be approved. The summaries consist of the following:

(i) For an application approved before July 1, 1975, internal agency records that describe safety and effectiveness data and information, for example, a summary of the basis for approval or internal reviews of the data and information, after deletion of the following:

(a) Names and any information that would identify patients or test subjects or investigators.

(b) Any inappropriate gratuitous comments unnecessary to an objective analysis of the data and information.

(ii) For an application approved on or after July 1, 1975, a Summary Basis of Approval (SBA) document that contains a summary of the safety and effectiveness data and information evaluated by FDA during the drug approval process. The SBA is prepared in one of the following ways:

(a) Before approval of the application, the applicant may prepare a draft SBA which the Center for Drug Evaluation and Research will review and may revise. The draft may be submitted with the application or as an amendment.

(b) The Center for Drug Evaluation and Research may prepare the SBA.

(3) A protocol for a test or study, unless it is shown to fall within the exemption established for trade secrets and confidential commercial information in § 20.61.

(4) Adverse reaction reports, product experience reports, consumer complaints, and other similar data and information after deletion of the following:

(i) Names and any information that would identify the person using the product.

(ii) Names and any information that would identify any third party involved with the report, such as a physician or hospital or other institution.

(5) A list of all active ingredients and any inactive ingredients previously disclosed to the public as set forth in § 20.81.

(6) An assay method or other analytical method, unless it serves no regulatory or compliance purpose and is shown to fall within the exemption established for trade secrets and confidential commercial information in § 20.61.

(7) All correspondence and written summaries of oral discussions between FDA and the applicant relating to the application, under the provisions of Part 20.

(f) All safety and effectiveness data and information which have been submitted in an application and which have not previously been disclosed to the public are available to the public, upon request, at the time any one of the following events occurs unless extraordinary circumstances are shown:

(1) No work is being or will be undertaken to have the application approved.

(2) A final determination is made that the application is not approvable and all legal appeals have been exhausted.

(3) Approval of the application is withdrawn and all legal appeals have been exhausted.

(4) A final determination has been made that the drug is not a new drug.

(5) For applications submitted under section 505(b) of the act, the effective date of the approval of the first abbreviated application submitted under section 505(j) of the act which refers to such drug, or the date on which the approval of an abbreviated application under section 505(j) of the act which refers to such drug could be made effective if such an abbreviated application had been submitted.

(6) For abbreviated applications submitted under section 505(j) of the act, when FDA sends an approval letter to the applicant.

(g) The following data and information in an application or abbreviated application are not available for public disclosure unless they have been previously disclosed to the public as set forth in § 20.81 of this chapter or they relate to a product or ingredient that has been abandoned and they do not represent a trade secret or confidential commercial or financial information under § 20.61 of this chapter:

(1) Manufacturing methods or processes, including quality control procedures.

(2) Production, sales distribution, and similar data and information, except that any compilation of that data and information aggregated and prepared in a way that does not reveal data or information which is not available for public disclosure under this provision is available for public disclosure.

(3) Quantitative or semiquantitative formulas.

(h) The compilations of information specified in §

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; 64 FR 402, Jan. 5, 1999; 64 FR 26657, May 17, 1999; 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 OF NON-PARTY ANDRX CORPORATION'S APPLICATION FOR *IN CAMERA* PROTECTION OF CERTAIN OF ITS CONFIDENTIAL MATERIALS

HERSCHEL E. SPARKS, JR., pursuant to 28 U.S.C. § 1746, declares as follows:

1. I am Litigation Counsel to Non-Party Andrx Corporation.

2. I submit this declaration in support of Andrx's application for *in camera* protection of its confidential documents reflecting communications with regulatory bodies concerning Andrx's proposed generic potassium chloride product that have been identified by respondents as material that they expect to use as exhibits at the hearing of this matter.

3. FDA treats all information about a pending ANDA as confidential and is prohibited by its regulations (including 21 C.F.R. § 314.430) from publicly disclosing information about an ANDA before it is finally approved. The prohibition includes both the ANDA itself (except for a summary of certain safety and efficacy information), any submissions by the applicant in connection with the ANDA, and any communications from FDA concerning the ANDA. Andrx has been advised repeatedly by FDA that,

unless the information has otherwise been made public, FDA will not even produce copies of documents concerning an ANDA in response to a request under the Freedom of Information Act. Andrx relies on FDA's confidentiality regulations and procedures in communicating with FDA concerning its ANDAs.

4. To my knowledge, until an ANDA is given final approval, the only information about an ANDA that FDA makes public is whether the application has been "tentatively approved". Even then, FDA only reveals the name of the applicant whose ANDA is tentatively approved, the product for which the ANDA seek approval, and the date of the tentative approval. FDA posts this information on its web-site (http://www.fda.gov/cder/approval/index.htm). However, until the ANDA receives final approval, all communications between the applicant and the agency are deemed confidential.

5. Andrx also maintains all of its communications with FDA about its pending ANDAs in strict confidence due to their competitively sensitive nature. Such communications reveal detailed information about the safety, efficacy, chemical formulation, and/or manufacturing process for the proposed generic product. Moreover, the mere fact that an applicant and FDA are communicating about a pending ANDA is itself competitively sensitive because those communications reveal the approval status of an ANDA and, to those within the industry, may also reveal whether the ANDA is or is not likely to gain approval and how close the ANDA is to obtaining approval. Even the dates of communications with FDA are typically kept confidential.

6. The information conveyed in and by communications between an applicant and FDA is valuable not only to manufacturers of the existing brand-name

version of a drug product, but also to other generic drug manufacturers. Aside from FDA's determination that a prospective generic is bioequivalent to the brand, the singularly most significant avenue of competition both between a generic and the brand and among generics is one of timing. With respect to the brand, the question is whether the generic can get its product on the market before the brand, for example, erects road blocks within FDA (such as by filing so-called "citizen petitions" or changing some non-therapeutic aspect of the branded product), or shifts the market by switching patients to a "new" version of the brand product that, the brands will claim, is not bioequivalent to the approved generic product. Between one generic and another, the question is simply which product will get to market first and with which strengths.

7. Normally, one generic drug applicant has no idea where it stands vis-á-vis other applicants. If one ANDA applicant learns of the status of another ANDA, it may take steps to try to position its ANDA to gain approval before the other in order to be the first to market a generic version of a product. Andrx also is legitimately concerned about the practice whereby companies make use of "citizen petitions" to raise all manner of issues with FDA concerning the approvability of a pending ANDA and/or the manner in which FDA is reviewing a particular ANDA with the effect of delaying FDA approval of the ANDA. Information about the progress of an ANDA application is thus a key piece of information to assess a competitor's timing and speed, and any information that one can learn about the status and progress of an ANDA application is highly significant.

8. The documents identified by respondents also included one letter from Andrx to the United States Pharmacopeial Convention, Inc. (USP). The USP, like the FDA, does not make correspondence between pharmaceutical manufacturers and itself

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 pharmaceutical manufacturers could gain unfair advantages over their competitors.

9. Any information, including the competitively sensitive information in the correspondence at issue -- if known about a potential competitor's ANDA -- would be highly beneficial to Andrx and prejudicial to the potential competitor. It would allow Andrx to know where to put its resources, what to do first, what to focus on, and what not to focus on. One might have designed a system that had all of this information public for all potential competitors, but Congress and FDA did not do so.

10. Because the status of an ANDA is so confidential, only the most senior officers of Andrx (and Andrx's scientific personnel, on a need-to-know basis) are aware of the status of a pending ANDA before its final approval. Circulation of documents reflecting communications to and from FDA concerning a pending ANDA is likewise strictly limited.

11. Andrx is involved in numerous other ANDA litigation matters. Although disclosure of this type of information may be necessary in such litigation, it is recognized that the public disclosure of this same information would put the ANDA applicant at a severe competitive disadvantage vis-á-vis the brand as well as other potential generics. It is for that reason that, in my experience, one of the first matters Andrx and other parties pursue in such litigation is the entry of a confidentiality order that protects against the public disclosure of such information. I am not aware of any litigation where

competitively sensitive information such as that in the documents at issue has been publicly disclosed in connection with the ongoing litigations. I am not aware of any difficulties that courts have had in rendering public decisions because of this.

I declare under penalty of perjury that the foregoing is true and correct. Executed on January 3, 2002 in New York, New York.

HERSCHEL E. SPARKS, JR.

CERTIFICATE OF SERVICE

I, Peter M. Todaro, hereby certify that on January 4, 2002 I caused a true and correct copy of the foregoing Non-Party Andrx Corporation's Supplemental Application For *In Camera* Protection Of Certain Of Its Confidential Materials (including accompanying Appendices and Declaration of Herschel E. Sparks) to be served by hand delivery upon the following:

Secretary
Federal Trade Commission
Room 172
600 Pennsylvania Ave., N.W.
Washington, D.C. 20580
(One with original signature and two copies)

Hon. D. Michael Chappell
Administrative Law Judge
Federal Trade Commission
Room 104
600 Pennsylvania Ave., N.W
Washington, D.C. 20580
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Assistant Director
Bureau of Competition
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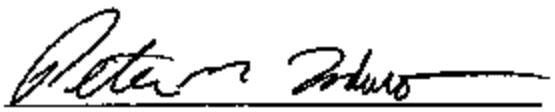
Counsel for Schering-Plough Corp.

I further certify that on January 4, 2002, I sent a true and correct electronic copy (in Microsoft Word 97 format) of the paper original of the foregoing Non-Party Andrx Corporation's Supplemental Application For *In Camera* Protection Of Certain Of Its Confidential Materials (including accompanying Appendices and Declaration of Herschel E. Sparks) by e-mail to secretary@ftc.gov. A paper copy of the foregoing with an original signature has been filed by hand delivery on the same day with the Secretary of the Federal Trade Commission.

Dated: January 4, 2002



PETER M. TODARO