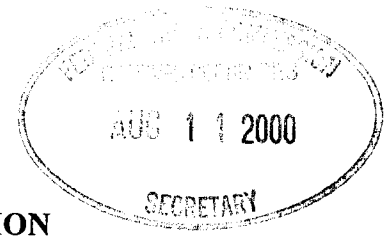

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

In the Matter of	)	
	)	Docket No. 9293
HOECHST MARION ROUSSEL, INC.,	)	
a corporation,	)	The Honorable
	)	D. Michael Chappell
CARDERM CAPITAL L.P.,	)	Administrative Law Judge
a limited partnership,	)	
	)	
and	)	
	)	
ANDRX CORPORATION,	)	
a corporation.	)	
	)	

MOTION OF THE UNITED STATES FOOD AND DRUG ADMINISTRATION TO QUASH SUBPOENA SERVED BY ANDRX CORPORATION

Pursuant to § 3.34(c) of the Federal Trade Commission's Rules of Practice, 16 C.F.R. § 3.34(c), nonparty United States Food and Drug Administration respectfully moves to quash the subpoena duces tecum served on it by Andrx Corporation in this proceeding. The grounds for this motion are set forth in the accompanying Memorandum.

Dated: August 10, 2000

Respectfully Submitted,

MARGARET JANE PORTER
CHIEF COUNSEL

By: _____

Claudia J. Zuckerman
Assistant Chief Counsel
U.S. Food and Drug Administration
5600 Fishers Lane, GCF-1
Rockville, Maryland 20857
(301) 827-1147
Attorney for the United States
Food and Drug Administration

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

In the Matter of	)	
	)	Docket No. 9293
HOECHST MARION ROUSSEL, INC.,	)	
a corporation,	)	The Honorable
	)	D. Michael Chappell
CARDERM CAPITAL L.P.,	)	Administrative Law Judge
a limited partnership,	)	
	)	
and	)	
	)	
ANDRX CORPORATION,	)	
a corporation.	)	
	)	

MEMORANDUM OF THE UNITED STATES FOOD AND DRUG ADMINISTRATION IN SUPPORT OF ITS MOTION TO QUASH SUBPOENA SERVED BY ANDRX CORPORATION

Pursuant to § 3.34(c) of the Federal Trade Commission's ("FTC") Rules of Practice, 16 C.F.R. § 3.34(c), nonparty United States Food and Drug Administration ("FDA") respectfully moves to quash the subpoena duces tecum served on it by Andrx Corporation ("Andrx"), dated June 26, 2000, and served on July 7, 2000. As demonstrated below, the subpoena seeks documents without making the requisite showing pursuant to § 3.36 of FTC's Rules of Practice. Accordingly, the subpoena should be quashed.

FACTS

The documents Andrx seeks from FDA fall into three categories: (1) communications between FDA and two drug companies, Biovail and Faulding, regarding each company's respective drug applications ("Category 1"); (2) FDA's internal documents regarding Biovail's and Faulding's applications ("Category 2"); and (3) communications

between FDA and any "third party" regarding Biovail's, Faulding's, or Andrx's applications, explicitly including communications between FDA and FTC regarding Andrx's drug application ("Category 3").[1]

On July 14, 2000, Claudia J. Zuckerman, the undersigned counsel for FDA, and Jonathan D. Lupkin, counsel for Andrx, agreed to a narrowing of the subpoena as well as an extension of time until August 15, 2000, to produce documents responsive to the narrowed request. Declaration of Claudia J. Zuckerman ("Zuckerman Decl."), ¶ 2. During that telephone conversation, Ms. Zuckerman stated that the documents requested were subject to certain statutes and privileges that may prevent release of information such as trade secret, confidential commercial, and deliberative process information. *Id.* at ¶ 3. Moreover, the narrowed request did not include an agreement by FDA to produce communications between FDA and FTC. *See id.* at ¶ 4.

At the time that Ms. Zuckerman agreed that FDA would produce responsive documents subject to certain statutes and privileges, Ms. Zuckerman was unaware that documents in Category 1 had already been, or were in the process of being, obtained by Andrx through other means. *See* Zuckerman Decl., ¶¶ 5, 6. Since the July 14, 2000, conversation between Ms. Zuckerman and Mr. Lupkin, Ms. Zuckerman learned from Francis D. Landrey, Biovail's counsel, that Biovail, in another proceeding, already

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[1] *See* Subpoena Duces Tecum (attached as Exhibit 1). Category 1 covers Request Nos. 1(a) and 2(a); Category 2 covers Request Nos. 1(c) and 2(c); and Category 3 covers Request Nos. 1(b), 2(b), and 3.

produced documents relating to its drug application and that Andrx had copies of those documents.[2] *Id.* at ¶ 5. Moreover, since July 14, 2000, Ms. Zuckerman learned from Hal S. Shaftel, counsel for Andrx, that Andrx had served a subpoena in the instant proceeding on Faulding for substantially the same documents about Faulding's application that Andrx was seeking from FDA. *Id.* at ¶ 6.

On August 1, 2000, Mr. Shaftel stated to Ms. Zuckerman that, by August 4, 2000, he would be in a better position to discuss whether Andrx would continue to seek from FDA "Category 1" documents. Zuckerman Decl., ¶ 7. As of August 9, 2000, Ms. Zuckerman has not received any additional information from any counsel for Andrx. *Id.* at ¶ 8. Also as of that date, there is neither an agreement in place for responsive documents containing information covered by the deliberative process privilege ("Category 2" documents) nor is there an agreement regarding FDA communications between FDA and FTC (part of "Category 3" documents).

ARGUMENT

Section 3.36 of the FTC's Rules of Practice require that an application for a subpoena for records of governmental agencies other than the FTC contain a specific showing that:

(1) the material sought is reasonable in scope;

---

[2] Apparently, these documents are covered by a protective order which may prohibit the use of the documents in the instant proceeding, and Andrx is attempting to have that protective order modified to allow use of the documents in this case.

(2) if for purposes of discovery, the material falls within the limits of discovery under § 3.31(b)(1) . . .; and

(3) the information or material sought cannot reasonably be obtained by other means.

Section 3.31(b)(1) references § 3.31(c)(1), which limits discovery "to the extent that it may be reasonably expected to yield information relevant . . . to the defenses of any respondent." *See In re Exxon Corp.*, 95 F.T.C. 919, 1980 FTC Lexis 64 at *8 (June 30, 1980) (Interlocutory Order) ("If a party requests information of another government agency, the administrative law judge shall carefully consider the relevance of the requested information and its availability through other means."); *see also In re Automotive Breakthrough Sciences, Inc.*, Dkt. No. 9275, 1996 FTC Lexis 286 at *1-2 (June 19, 1996) (Order Denying Motion for Issuance of Subpoena Duces Tecum).

Andrx has not made a specific showing pursuant to § 3.36 of FTC's Rules of Practice that "the information or material sought cannot reasonably be obtained by other means," with respect to communications between: (1) FDA and Biovail regarding Biovail's applications; (2) FDA and Faulding regarding Faulding's application; and (3) FDA and FTC regarding Andrx's application.

Andrx is in the process of attempting to resolve whether it can use the documents it already possesses regarding Biovail's applications. In addition, Andrx has already served a subpoena on Faulding for documents regarding Faulding's applications. Because Andrx has other means to reasonably obtain the information it seeks on other companies' drug applications, there is no need for Andrx to burden a nonparty government agency with such

a request. Moreover, given the extreme commercial sensitivity of information contained in the drug applications and in correspondence with FDA relating to the applications, drug companies themselves are in the best position to make agreements regarding the release of their own documents.

With respect to communications between FDA and FTC regarding Andrx's application, Andrx, if it has not already done so, can request such documents from FTC. There is no need for Andrx to burden a nonparty with such a request when it can reasonably obtain the documents from a party to the proceeding.

With respect to FDA's internal documents, Andrx has not made a specific showing pursuant to § 3.36 of FTC's Rules of Practice that "the material falls within the limits of discovery under § 3.31(b)(1)." FDA's internal documents concerning Biovail's and Faulding's drug applications are not relevant nor are they likely to lead to information relevant to Andrx's defenses. Andrx's defenses appear to rest on its contention that no application's approval was delayed as a result of the agreement between Andrx and Hoechst because no generic drug application was otherwise ready for approval during the pendency of the agreement. Even it the Court were to accept the merit of such a defense, FDA has no internal documents that are relevant to that defense. Where an application has a significant deficiency that delays or precludes approval, such deficiency is communicated in writing to the applicant. Andrx can obtain those communications, if relevant, from the application sponsors who received them and need not seek them from a nonparty government entity. Those correspondences and the issues surrounding them have been

discussed above. Additional predecisional documents that reflect the agency's deliberative process and individual reviewers' opinions regarding the nature of an application's deficiencies will neither bolster nor undercut the argument that competitor applications were otherwise not ready for approval during the pendency of the agreement.

Moreover, even if Andrx could establish the relevance of predecisional agency documents, such documents are covered by the deliberative process privilege. The deliberative process privilege protects documents from disclosure unless there are compelling circumstances that necessitate their release. *See In re Champion Spark Plug Co.*, Dkt. No. 9141,1980 FTC Lexis 200 *10-11 (December 16, 1980) (Order Granting, In Part, Motion To Quash Access Order). Given that Andrx can obtain the documents containing the decisions that were ultimately made during the review process (including letters detailing application deficiencies, if any) through other means, and that the internal agency decisionmaking process that led to the identification of the deficiencies is, at best, only marginally relevant to Andrx's defense, there are no compelling circumstances here to justify release of internal predecisional documents.

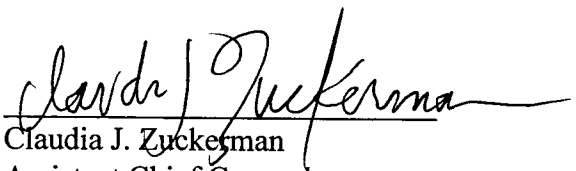
CONCLUSION

For the foregoing reasons, FDA respectfully requests that its motion be granted.

Dated: August 10, 2000

Respectfully Submitted,

MARGARET JANE PORTER
CHIEF COUNSEL

By: 

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(301) 827-1147
Attorney for the United States
Food and Drug Administration

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

In the Matter of	)	
	)	Docket No. 9293
HOECHST MARION ROUSSEL, INC.,	)	
a corporation,	)	The Honorable
	)	D. Michael Chappell
CARDERM CAPITAL L.P.,	)	Administrative Law Judge
a limited partnership,	)	
	)	
and	)	
	)	
ANDRX CORPORATION,	)	
a corporation.	)	
	)	

STATEMENT OF CLAUDIA J. ZUCKERMAN PURSUANT TO RULE 3.22(F) OF THE FEDERAL TRADE COMMISSION'S RULES OF PRACTICE

I am an attorney with the Office of Chief Counsel for the United States Food and Drug Administration and submit this statement pursuant to Rule 3.22(f) of the Federal Trade Commission's Rules of Practice, 16 C.F.R. § 3.22(f), in connection with the Motion of the United States Food and Drug Administration to Quash Subpoena Served by Andrx Corporation dated June 26, 2000. I have discussed with Jonathan D. Lupkin (on July 31, 2000, and August 1, 2000) and Hal S. Shaftel (on August 1, 2000) of Solomon, Zauderer, Ellenhorn, Frischer & Sharp, counsel for Andrx, in good faith to resolve by agreement the issues raised by FDA's Motion to Quash. During those conversations, we were unable to reach agreement resolving the objections to the subpoena.

Dated: August 10, 2000

Respectfully Submitted,

MARGARET JANE PORTER
CHIEF COUNSEL

By: Claudia Zuckerman

Claudia J. Zuckerman
Assistant Chief Counsel
U.S. Food and Drug Administration
5600 Fishers Lane, GCF-1
Rockville, Maryland 20857
(301) 827-1147
Attorney for the United States
Food and Drug Administration

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

In the Matter of	)	
	)	Docket No. 9293
HOECHST MARION ROUSSEL, INC.,	)	
a corporation,	)	The Honorable
	)	D. Michael Chappell
CARDERM CAPITAL L.P.,	)	Administrative Law Judge
a limited partnership,	)	
	)	
and	)	
	)	
ANDRX CORPORATION,	)	
a corporation.	)	
	)	

DECLARATION IN SUPPORT OF MOTION OF THE UNITED STATES FOOD AND DRUG ADMINISTRATION TO QUASH SUBPOENA SERVED BY ANDRX CORPORATION

CLAUDIA J. ZUCKERMAN, a member in good standing of the Bar of the State of Maryland, declares:

1. I am an assistant chief counsel in the Office of Chief Counsel, United States Food and Drug Administration ("FDA"), a nonparty to the above-captioned proceeding. I make this declaration in support of FDA's motion to quash the subpoena (the "Subpoena"), dated June 26, 2000, issued in this proceeding by Andrx Corporation ("Andrx").

2. On July 14, 2000, I had a telephone conversation with Jonathan D. Lupkin, of Solomon, Zauderer, Ellenhorn, Frischer & Sharp ("Solomon Zauderer"), counsel for Andrx, with respect to the Subpoena. We agreed to a narrowing of the subpoena as well as an extension of time for production of documents. August 15, 2000, is the agreed-upon deadline for production of certain documents responsive to the subpoena, as narrowed.

3. During the July 14, 2000, conversation with Mr. Lupkin, I stated that the documents requested were subject to certain statutes and privileges that may prevent release of information such as trade secrets, confidential commercial information, and internal agency deliberations.

4. During the July 14, 2000 conversation with Mr. Lupkin, I did not agree to produce communications between FDA and FTC.

5. On July 25, 2000, I had a telephone conversation with Francis D. Landrey of Proskauer Rose LLP, counsel for Biovail Corporation. It was during that conversation that I learned that Biovail had produced documents relating to its drug application in another proceeding and that Andrx had copies of those documents.

6. On August 1, 2000, I had a telephone conversation with Hal S. Shaftel of Solomon Zauderer, counsel for Andrx. It was during that conversation that I learned that Andrx had served a subpoena in this proceeding on Faulding, requesting substantially the same documents about Faulding's application that Andrx was seeking from FDA.

7. During the August 1, 2000, conversation with Mr. Shaftel, he stated that he would have more information by August 4, 2000, as to whether Andrx would continue to seek documents from FDA regarding communications between FDA and Biovail and between FDA and Faulding about each company's respective applications.

8. As of the close of business on August 9, 2000, I have not had any communications with Mr. Shaftel, Mr. Lupkin, or any other counsel for Andrx, subsequent to the August 1, 2000, telephone conversation.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on August 10, 2000.

CLAUDIA J. ZUCKERMAN

EXHIBIT 1

SUBPOENA DUCES TECUM

Issued Pursuant to Rule 3.34(b), 16 C.F.R. § 3.34(b)(1997)

1. TO

United States Food & Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

2. FROM

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

This subpoena requires you to produce and permit inspection and copying of designated books, documents (as defined in Rule 3.34(b)), or tangible things - or to permit inspection of premises - at the date and time specified in Item 5, at the request of Counsel listed in Item 9, in the proceeding described in Item 6.

3. PLACE OF PRODUCTION OR INSPECTION

Shook, Hardy & Bacon, L.L.P.
600 14th Street, N.W.
Suite 800
Washington, D.C. 20005

4. MATERIAL WILL BE PRODUCED TO

Solomon, Zauderer, Ellenhorn, Frischer & Sha
Counsel for Respondent Andrx Corporation

5. DATE AND TIME OF PRODUCTION OR INSPECTION

July 31, 2000
10:00 a.m.

6. SUBJECT OF PROCEEDING

In the matter of Hoechst Marion Roussel, Inc., et al.

7. MATERIAL TO BE PRODUCED

See Exhibit A

8. ADMINISTRATIVE LAW JUDGE

The Honorable D. Michael Chappell

Federal Trade Commission
Washington, D.C. 20580

9. COUNSEL REQUESTING SUBPOENA

Solomon, Zauderer, Ellenhorn, Frischer & Sharp
45 Rockefeller Plaza, 7th Floor
New York, New York 10111

Attorneys for Respondent Andrx

DATE ISSUED

[illegible] 2000

SECRETARY'S SIGNATURE

Donald S. Clark

GENERAL INSTRUCTIONS

APPEARANCE

The delivery of this subpoena to you by any method prescribed by the Commission's Rules of Practice is legal service and may subject you to a penalty imposed by law for failure to comply.

MOTION TO LIMIT OR QUASH

The Commission's Rules of Practice require that any motion to limit or quash this subpoena be filed within the earlier of 10 days after service or the time for compliance. The original and ten copies of the petition must be filed with the Secretary of the Federal Trade Commission, accompanied by an affidavit of service of the document upon counsel listed in Item 9, and upon all other parties prescribed by the Rules of Practice.

TRAVEL EXPENSES

The Commission's Rules of Practice require that fees and mileage be paid by the party that requested your appearance. You should present your claim to counsel listed in Item 9 for payment. If you are permanently or temporarily living somewhere other than the address on this subpoena and it would require excessive travel for you to appear, you must get prior approval from counsel listed in Item 9.

This subpoena does not require approval by OMB under the Paperwork Reduction Act of 1980.

EXHIBIT "A"

Documents Requested

1. All documents concerning any ANDA and NDA submitted by Biovail for the manufacture and production of a pharmaceutical product that is the bioequivalent of Cardizem® CD, excluding the ANDA and NDA themselves. This request includes, by way of example, but is not limited to:

    a) All communications between the FDA and Biovail; and

    b) All communications between the FDA and any third party; and

    c) All responsive internal FDA documents.

2. All documents concerning the ANDA submitted by Faulding for the manufacture and production of a pharmaceutical product that is the bioequivalent of Cardizem® CD, excluding the ANDA itself. This request includes, by way of example, but is not limited to:

    a) All communications between the FDA and Faulding.

    b) All communications between the FDA and any third party; and

    c) All responsive internal FDA documents.

3) All communications between the FDA and any other party (excluding Andrx) concerning Andrx's ANDA for the manufacture and production of a pharmaceutical product that is the bioequivalent of Cardizem® CD. This request includes, by way of example, but is not limited to:

    a) All communications between the FDA and the FTC concerning Andrx's ANDA; and

b) All documents concerning the FDA's decision to grant approval for Andrx's ANDA, including Andrx's reformulated product approved by the FDA on June 9, 1999 .

Definitions and Instructions

a. "Andrx" means Andrx Corporation, and any of its parents, subsidiaries, affiliates, divisions, employees, officers, directors, agents, representatives, predecessors or successors.

b. "Biovail" means Biovail Corporation International and any of its parents, subsidiaries, affiliates, divisions, employees, officers, directors, agents, lawyers, representatives, predecessors or successors. The term "Biovail" specifically includes Biovail's outside counsel, Cleary Gottlieb Steen & Hamilton.

c. "Faulding" means Faulding, Inc. and any of its parents, subsidiaries, affiliates, divisions, employees, officers, directors, agents, lawyers, representatives, predecessors or successors.

d. "FDA" means the Federal Food and Drug Administration and its divisions, agents, representatives, predecessors or successors.

e. "FTC" means the Federal Trade Commission, and its divisions (including its enforcement divisions), bureaus (including its Bureau of Competition), agents, representatives, predecessors or successors

f. "NDA" means a New Drug Application submitted to the FDA for approval for the manufacture and marketing of a pharmaceutical product.

g. "ANDA" means an Abbreviated New Drug Application submitted to the FDA for approval for the manufacture and marketing of a

pharmaceutical product that is the "bioequivalent" of an FDA approved, brand name pharmaceutical product.

h. The terms "document" and "documents" are used in their broadest sense, to the full extent permitted by the Federal Rules of Civil Procedure to mean , without limitation, any original written, recorded, filmed, or graphic matter of every type and description, whether produced or reproduced on paper, cards, tapes, film, electronic facsimile, computer storage disks, tapes, or devices, or any other media, and each copy of such writing, record, film, or graphic matter that is different in any way from the original or where such copy contains any commentary or notation whatsoever that does not appear on the original whether by interlineation, receipt stamp notation, inclusion of comments or notations, or otherwise and drafts. Documents specifically include, by way of illustration, but not by way of limitation, all letters, notes, diaries, E-mails, reports, studies, charts, graphs, memoranda, instruments, minutes, ledgers, records, recordings, tapes, microfilm, photographs, correspondence, telegrams, diaries, bookkeeping entries, financial statements, tax returns, checks, check stubs, notebook statements, affidavits, agreements, applications, books, pamphlets, periodicals, appointment calendars and work papers.

i. "Concern" and "concerning" mean relating to, referring to, describing, evidencing, or constituting.

j. The terms "and" and "or" include both the conjunctive and disjunctive, as necessary, to bring within the scope of this request all responses that might otherwise be construed to be outside of its scope.

k. The terms "any" "all" and "each" each shall be construed to mean "any, all and each".

l. The use of a singular form of any word includes the plural, and vice-versa.

m. The terms "include" and "including" are used for illustration and not by way of limitation.

n. If any documents that are responsive to the document requests herein are withheld from production, furnish a list of all such documents withheld. Said list shall contain a complete description of each document, including: (i) the type, date, and number of pages of the document; (ii) its title (if any); (iii) a general description of its subject matter; (iv) the identity of any attachments or appendices to the document; (v) the name and identification of each person to whom it is addressed; (vi) the name and identification of each person who received a copy thereof; (vii) the name and identification of the persons or person by whom it was written or generated; (viii) its present custodian; (ix) the ground or grounds upon which it is being withheld.

o. In the event that any document called for by this document request has been destroyed or discarded, please identify each such document by stating: (i) any addresser and addressee; (ii) the addressees of any indicated or blind copies; (iii) the type, date, subject matter and number of pages of the document; (iv) a description of any attachment or appendices to the document; (v) the names and identification of all persons to whom the document was distributed, shown or explained; (vi) the date when it was destroyed or discarded, and the manner in which it was

destroyed or discarded; and (vii) the names and identification of the persons authorizing and carrying out such destruction or discarding.

p. Unless otherwise indicated, this subpoena calls for the production of documents that were created or utilized during, or otherwise concern, the period from January, 1993 through and including the date of production.

q. This subpoena should be construed as not calling for the production of any documents prepared, authored, created, submitted or filed by Andrx.

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

In the Matter of HOECHST MARION ROUSSEL, INC., a corporation, CARDERM CAPITAL L.P., a limited partnership, and ANDRX CORPORATION, a corporation.	)	Docket No. 9293

ORDER GRANTING RESPONDENT ANDRX'S MOTION FOR THE ISSUANCE OF A SUBPOENA DUCES TECUM TO THE FOOD AND DRUG ADMINISTRATION

On June 12, 2000, pursuant to Commission Rule 3.36, Respondent Andrx Corporation filed a motion for an order authorizing the issuance of a subpoena duces tecum to the United States Food and Drug Administration. The other respondents consented to the motion and Complaint Counsel did not oppose the motion. Respondent's motion is GRANTED.

Pursuant to Rule 3.34, in the event that the Food and Drug Administration (FDA) seeks to limit or quash the subpoena, the FDA shall have ten days after service of the subpoena or the time for compliance therewith to file any such motion.

Andrx shall serve a copy of this order on the Food and Drug Administration at the time it serves the subpoena.

ORDERED:

D. Michael Chappell
Administrative Law Judge

Date: July 5, 2000

CERTIFICATE OF SERVICE

I, Sandra K. Pixley, hereby certify that on August 10, 2000, I caused a copy of the Memorandum of the United States Food and Drug Administration in Support of its Motion to Quash Subpoena Served by Andrx Corporation to be served upon the following persons by overnight mail:

Hon. D. Michael Chappell
Administrative Law Judge
Federal Trade Commission
Room 104
600 Pennsylvania Avenue, NW
Washington, DC 20580

James M. Spears, Esq.
Shook, Hardy & Bacon, L.L.P
600 14th Street, NW
Suite 800
Washington, DC 20005

Donald S. Clark, Secretary
Federal Trade Commission
Room 172
600 Pennsylvania Avenue, NW
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Peter O. Safir, Esq.
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Markus H. Meier, Esq.
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601 Pennsylvania Avenue, NW
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Louis M. Solomon, Esq.
Solomon, Zauderer, Ellenhorn,
Frischer & Sharp
45 Rockefeller Plaza
New York, NY 10111

Sandra K. Pixley