UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

In the Matter of	)	
SCHERING-PLOUGH CORP., a corporation,	)	DOCKET NO. 9297
UPSHER-SMITH LABORATORIES, a corporation,	)	
and	)	
AMERICAN HOME PRODUCTS CORP., a corporation.	)	

BRISTOL-MYERS SQUIBB COMPANY'S UNOPPOSED MOTION TO OBTAIN *IN CAMERA* TREATMENT OF CERTAIN HIGHLY CONFIDENTIAL INFORMATION

Pursuant to 16 C.F.R. § 3.45, Bristol-Myers Squibb Co. ("BMS"), a third party in this proceeding, respectfully submits the following motion to obtain *in camera* treatment of certain highly confidential information (primarily portions of business planning documents and responses to interrogatories that requested pricing data) pertaining to its prices, profits and strategies for one of its generic products. As set forth in more detail below, the information at issue relates to BMS's internal pricing strategies, competitive analyses, and sales strategies, including sales, pricing, and profit data for BMS's potassium supplement products. This information is confidential proprietary data that is not in the public domain

and is competitively sensitive in nature. Neither the proponent of these documents, Upsher-Smith Laboratories, nor the attorneys for the FTC opposes this Motion.

As the Commission has stated, "It is difficult to imagine items of business information more sensitive than . . . profit data . . . . That data constitutes the most significant competitive information possessed by [the parties requesting nondisclosure] -- literally the 'corporate jewels' of those firms." *In re General Motors Corp.*, 103 F.T.C. 58 (1984) (footnote omitted). Public disclosure of third-party BMS's secret and material information would likely result in a clearly defined, serious injury to BMS. Accordingly, BMS respectfully requests that the information specified below be given *in camera* treatment, kept confidential, and not placed on the public record of this proceeding for at least the next five years.

I. DOCUMENTS FOR *IN CAMERA* TREATMENT

Bristol-Myers Squibb requests *in camera* treatment for the highly confidential information in the following documents:

- The portions of APOT/CRET/02644 – 02650, Exh. USX 68, a Potassium Supplement presentation entitled "A Global Perspective" (undated):
    - APOT/CRET/02648: bullet point entitled "Primary Focus" and all the information listed below that bullet point;
    - APOT/CRET/02649
- The portions of APOT/RENJ/00168, Exh. USX 69, a spreadsheet entitled "Potassium Chloride Capsules and Tablets" (undated):
    - Columns 4 – 6 (3 columns to the right of column entitled "NDC"), including column headings
- The portions of APOT/RENJ/00361 – 00365, Exh. USX 70, assorted documents related to Potassium Chloride (undated):

- APOT/RENJ/00363 through APOT/RENJ/00365

- The portions of APOTHECON (BMS)/8 – 22, Exh. USX 74, a letter from A. Cummings to K. Bokat regarding Civil Investigative Demand with attachments (dated Nov. 16, 2000):

  - APOTHECON (BMS)/0000013: Response to subpart (e) of Specification 3
  - APOTHECON (BMS)/0000014 (Exhibit 3-1)

- The portion of APOTHECON (BMS)/23 – 36, Exh. USX 75, a letter from A. Cummings to K. Bokat regarding Civil Investigative Demand with attachments (dated Nov. 17, 2000):

  - APOTHECON (BMS)/0000029 through APOTHECON (BMS)/0000036 (Exhibit 4-2)

II. BRISTOL-MYERS SQUIBB CLEARLY MEETS THE STANDARD FOR *IN CAMERA* TREATMENT FOR THE SPECIFIED INFORMATION

"There can be no question that the confidential records of businesses involved in Commission proceedings should be protected insofar as possible." *H. P. Hood & Sons, Inc.*, 58 F.T.C. 1184 (1961). This is particularly true where the business records at issue are documents submitted by a non-party to the proceeding. Moreover, Administrative Law Judges have broad discretion in determining what information should be placed *in camera*. *See In re General Foods Corp.*, 95 F.T.C. 352 (1980). As the Commission has stated, a request for *in camera* treatment by a corporation such as BMS, which is not a party to the FTC proceedings, should be given "special solicitude." *In re Crown Cork & Seal Co.*, 71 F.T.C. 1714 (1967) ("[P]etitioner's plea warrants special solicitude coming as it does from a third party bystander in no way involved in the proceedings whose records, if *in camera* treatment is denied, will be open to the scrutiny of its competitors

including respondent herein"); *accord Kaiser Aluminum & Chemical Corp.*, 103 F.T.C. 500 (1984) (requests for *in camera* treatment by third parties should be given special solicitude because, as a policy matter, such treatment encourages the third party to cooperate with future adjudicative discovery requests); *In re R. R. Donnelley & Sons Co.*, 1993 FTC LEXIS 32 (Feb. 18, 1993) (same).

For information to be afforded *in camera* treatment, a corporation must show that public disclosure of the information for which it seeks *in camera* treatment would result in a clearly defined, serious injury to the corporation. *Id.* In making this showing, the requesting corporation may rely on the information itself or extrinsic evidence, and it need not specifically demonstrate how a competitor would use the information to undermine the requesting corporation's competitive position. *Id.*; *E. I. Dupont de Nemours & Co.*, 97 F.T.C. 116 (1981).

To demonstrate serious injury, the requesting corporation must show that the information at issue is secret and material to its business. *In re General Foods Corp.*, 95 F.T.C. 352 (1980); *In re Bristol-Myers Co.*, 90 F.T.C. 455 (1977). The following factors should be considered in determining secrecy and materiality:

> (1) the extent to which the information is known outside of [the] business;
>
> (2) the extent to which it is known by employees and others involved in [the] business;
>
> (3) the extent of measures taken by [the business] to guard the secrecy of the information;
>
> (4) the value of the information to [the business] and to [its] competitors;

(5) the amount of effort or money expended by [the business] in developing the information;

(6) the ease or difficulty with which the information could be properly acquired or duplicated by others.

In re Bristol-Myers Co., 90 F.T.C. 455.

The information at issue for BMS clearly meets these standards. Significantly, all the confidential information referred to in this motion is competitively sensitive information that BMS guards and maintains as confidential in order to preserve its internal decision-making processes and data from disclosure to competitors in the pharmaceutical industry. It is not publicly available, and its creation represents a significant cost to BMS. In addition, the information BMS seeks to protect from public disclosure could be used by its competitors in an effort to extrapolate BMS's profits, margins and costs for specific products as well as internal processes with respect to determining pricing and sales strategies for its products.

Despite the fact "there is a presumption that *in camera* treatment will not be provided to information that is three or more years old," *In re Dura Lube Corp.*, 1999 FTC LEXIS 255 (1999) (citing *In re General Foods Corp.*, 95 F.T.C. at 353 (1980); *In re Crown Cork & Seal*, 71 F.T.C. at 1715 (1967)), the FTC has recognized that this presumption is rebuttable and, on numerous occasions, granted *in camera* protection to older documents containing this type of sensitive financial and pricing information. *See In re The Coca-Cola Company*, 1990 FTC LEXIS 364 (Oct. 17, 1990) (noting that a three-year standard is sometimes used, but holding that the age of a particular document offers "little guidance" as to whether in

camera treatment is warranted; instead it is the actual justification for the treatment that matters); *Kaiser Aluminum & Chemical Corp.*, 103 F.T.C. 500 (1984) (extending protection to information over five years of age related to "sales of specific lines of refractories and related products"); *In re E.I. Dupont de Nemours & Co.*, 97 F.T.C. 116 (1981) (protecting 6-year-old "investment, earnings, profit, operative return and cost information" related to the sales).

Furthermore, BMS respectfully requests *in camera* treatment for the information in question for at least the next five years. 16 C.F.R. § 3.45(b)(3); *In re General Foods Corp.*, 95 F.T.C. 352 n.4 (1980) (noting that *in camera* treatment may be granted indefinitely or for a period of years); *see also In re The Coca-Cola Company*, 1990 FTC LEXIS 364 (Oct. 17, 1990) (noting that, while the sensitivity of various documents may decrease over time at different rates, it is "sensible to treat all documents consistently" for purposes of *in camera* treatment). Non-disclosure of this information over the next five years will prevent BMS's competitors from learning about and taking advantage of BMS's secret and vital thinking about its business plans and strategies, as well as some of its most sensitive and important financial data. Certainly, the general public can have little, if any, legitimate interest over the next five years in this information. Moreover, even if there were any public interest here, it would be heavily outweighed by the serious injury BMS would suffer from disclosure.

Because the FTC has established specific criteria for granting *in camera* treatment, BMS has limited those portions of documents for which it is requesting such treatment. They are set forth below.

A. Portions of USX 68 [APOT/CRET/02644 – 02650]

There are two portions of the presentation entitled "A Global Perspective" that should be subject to *in camera* treatment. The first, the bullet point entitled "Primary Focus" and the contents beneath it, deals directly with BMS's marketing strategies. The second portion deals with BMS's pricing trends, and offers insight into BMS's general strategy for marketing and pricing products once they lose patent exclusivity or similar protections. This information also deals with acquisition pricing for customers. 1/ This is precisely the type of competitively sensitive information that should not be shared with competitors. The information at issue is not in the public domain or otherwise known outside of BMS, and is not generally accessible or duplicable by others in the pharmaceutical business and would be valuable to competitors in a way that could harm competition. As noted above, confidential pricing information that would aid a corporation's competitors has been afforded *in camera* treatment on many occasions. *See, e.g., Kaiser Aluminum & Chemical Corp.*, 103 F.T.C. 500 (1984); *In re E.I. Dupont de Nemours & Co.*, 97 F.T.C. 116 (1981).

B. Portions of USX 69 [APOT/RENJ/00168]

Columns 4 – 6 (the three columns to the right of column entitled "NDC", including the column headings), found on the Potassium Chloride Capsules

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1/ Although Klotrix has never been a patented product, its pricing structure is similar to other innovator products that have lost patent exclusivity. Branded products that have lost patent protection often face rapidly increasing price competition from generic versions. Strategic information about pricing at launch and in response to competitors' pricing points is therefore competitively sensitive information.

and Tablets spreadsheet detail product launch strategies, including pricing points, relating to the introduction of generic products. Accordingly, for the reasons discussed above, this information should be subject to *in camera* treatment.

C. Portions of USX 70, [APOT/RENJ/00361 – 00365]

Information in the above-specified portions of the assorted Potassium Chloride documents provides insight into the process behind BMS's internal process for amending a pricing point, and thus is still considered by BMS to be especially sensitive. As such, for the reasons discussed above, this information should be subject to *in camera* treatment.

D. Portions of USX 74 [APOTHECON (BMS)/8 – 22]

There are two excerpts from the letter from A. Cummings to K. Bokat regarding Civil Investigative Demand (with attachments) that require *in camera* treatment. BMS's response to sub-part (e) of Specification 3, as well as Exhibit 3 – 1, can easily be used to yield profit data and overall pricing trends and strategies.

E. Portions of USX 75 [APOTHECON (BMS)/23 – 36]

Exhibit 4-2, contained in USX 75, should be afforded *in camera* treatment, as it contains information deemed confidential by statute. *See* 42 U.S.C. § 1396r-8(b)(3)(D).

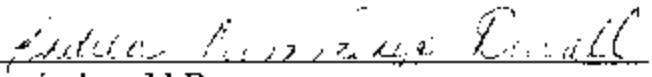
IV. CONCLUSION

For the foregoing reasons, BMS respectfully requests that the information in the documents listed in Part I of this Motion be given *in camera* treatment, kept confidential, and not placed on the public record of this proceeding

for at least the next five years. This information meets the criteria set forth in FTC precedent as qualifying for *in camera* treatment, and therefore, should be accorded such protection. In the event that the Commission intends to disclose *in camera* BMS information in a final decision, BMS respectfully requests that the Commission notify both Sharis A. Pozen of Hogan and Hartson, LLP, 555 13th Street, N.W., Washington, D.C., 20004, telephone: 202-637-6948, facsimile: 202-637-5910, and BMS in-house counsel, Scott Applebaum, 777 Scudders Mill Road, Mail Code P12-06, Plainsboro, NJ 08536, telephone: 609-897-3688, and facsimile: 609-897-5704.

Respectfully submitted,

HOGAN & HARTSON L.L.P.



Sharis Arnold Pozen
Andrea Cummings Duvall

555 13th Street, N.W.
Washington, D.C. 20004
(202) 637-5600

Attorneys for Bristol-Myers Squibb Co.

DATED: January 22, 2002

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

In the Matter of	)	
SCHERING-PLOUGH CORP., a corporation,	)	DOCKET NO. 9297
UPSHER-SMITH LABORATORIES a corporation,	)	
and	)	
AMERICAN HOME PRODUCTS CORP., a corporation.	)	

ORDER

Upon consideration of the Motion of Third Party Bristol-Myers Squibb Co. ("BMS") to obtain *in camera* treatment of certain highly confidential information pursuant to 16 C.F.R. § 3.45, and any opposition thereto,

IT IS HEREBY ORDERED that BMS's Motion is GRANTED. The information set forth in the following documents (or portions of documents) will be subject to *in camera* treatment under 16 C.F.R. § 3.45 and will be kept confidential and not placed on the public record of this proceeding:

- The following portions of APOT/CRET/02644 – 02650, Exh. USX 68, a Potassium Supplement presentation entitled "A Global Perspective" (undated):
- APOT/CRET/02648: bullet point entitled "Primary Focus" and all the information listed below that bullet point;

- APOT/CRET/02649

- The following portions of APOT/RENJ/00168, Exh. USX 69, a spreadsheet entitled "Potassium Chloride Capsules and Tablets" (undated):

    - Columns 4 – 6 (3 columns to the right of column entitled "NDC"), including column headings

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    - APOTHECON (BMS)/0000029 through APOTHECON (BMS)/0000036 (Exhibit 4-2)

IT IS FURTHER ORDERED that only the respondent, their counsel, authorized Federal Trade Commission ("Commission") personnel, and court personnel concerned with judicial review may have access to the above-referenced information, provided that I, the Commission, and reviewing courts may disclose such *in camera* information to the extent necessary for the proper disposition of the proceeding.

_____

D. Michael Chappell
Administrative Law Judge

Date: _____

CERTIFICATE OF SERVICE

I hereby certify that on January 22, 2002, I caused an original, one paper copy and a true and accurate electronic copy of the foregoing motion to be filed with the Secretary of the Commission, and that two paper copies were served by hand upon:

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

and one paper copy was hand delivered upon:

David Pender
Assistant Director
Bureau of Competition
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

Karen Bokat, Esquire
Bureau of Competition
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

Laura S. Shores, Esq.
Howrey Simon Arnold & White
1299 Pennsylvania Avenue, N.W.
Washington, D.C. 20004-2402

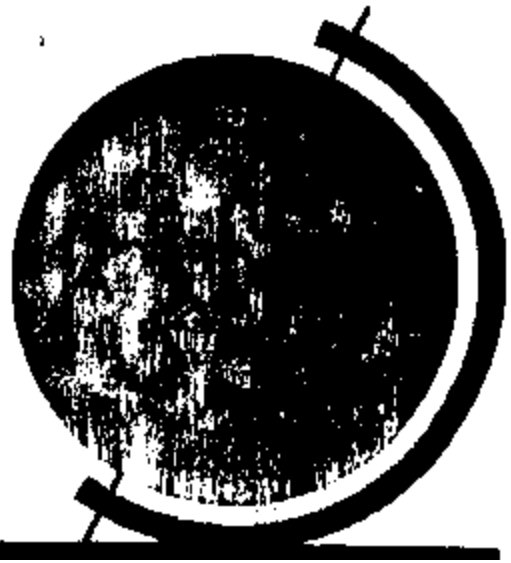
and

Christopher Curran, Esquire
White & Case L.L.P.
601 13th Street, N.W.
Washington, D.C. 20005

Andrea Cummings Duvall

A Global Perspective

- New Products
  - Generic Klotrix
  - Generic Desyrel 150 mg
  - Captopril Update
- Jan/Feb S.O.
- Marketing Update
- Bidding Procedures

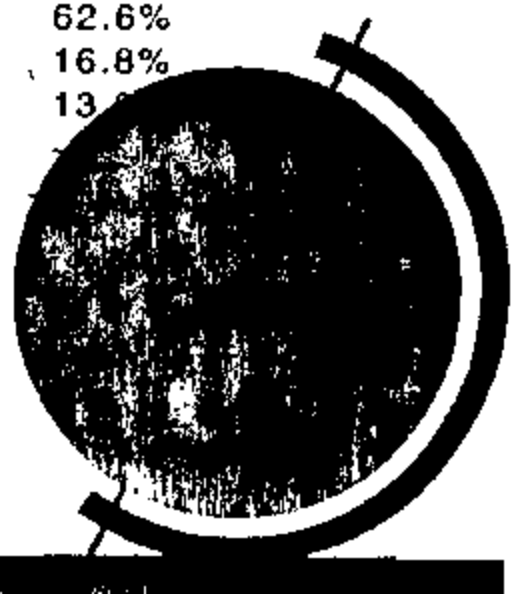


Generic Klotrix

- 10 mEq Potassium Supplement
- $ 82.8 Million Market

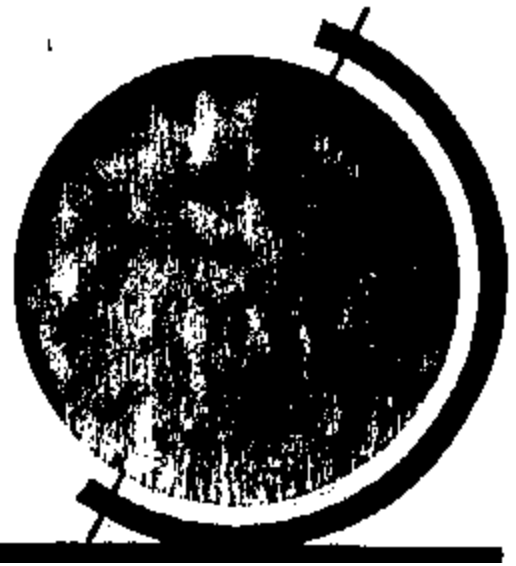
Product	Manufacturer	1994 Share	94/93 Change
KCL*	Ethex	17.3%	62.6%
Klor-Con 10	Upsher-Smith	15.1%	16.8%
K-Dur	Key	8.6%	13.[illegible]
KCL	Rugby	2.3%	[illegible]
K-Tab	Abbott	21.0%	[illegible]
Micro K*	Wyeth	25.0%	[illegible]
Ten K	Summit	2.6%	[illegible]
Klotrix	Apothecon	5.6%	[illegible]

* Capsules



A Global Perspective

- New Products
  - Generic Klotrix
  - Generic Desyrel 150 mg
  - Captopril Update
- Jan/Feb S.O.
- Marketing Update
- Bidding Procedures



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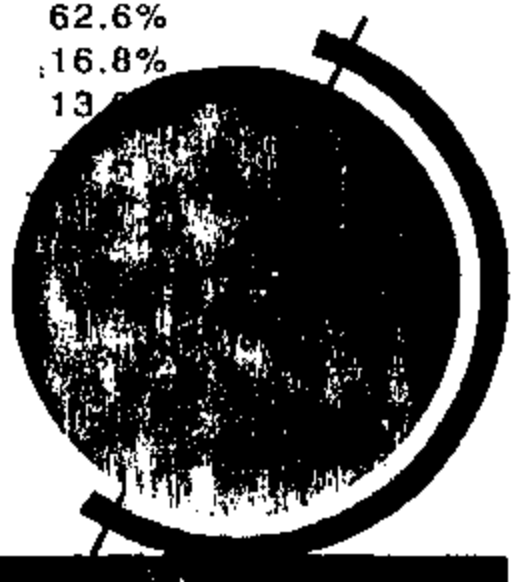
KCL	Rugby	2.3%	
K-Tab	Abbott	21.0%	
Micro K*	Wyeth	25.0%	
Ten K	Summit	2.6%	
Klotrix	Apothecon	5.6%	

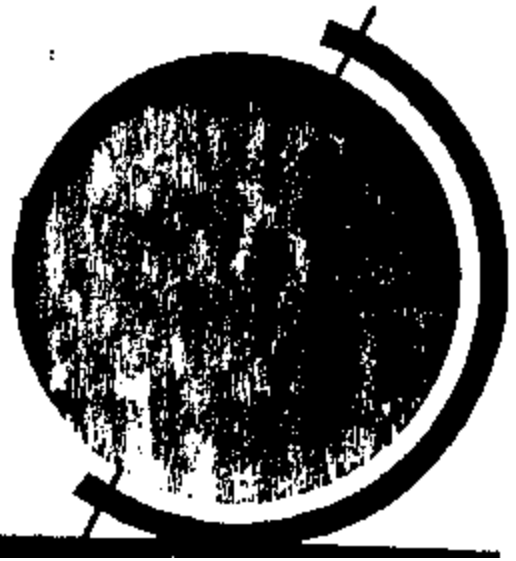
* Capsules



Promotion

- **Available in 100's and 1000's**
- **Include with Jan/Feb Prebooks**
- **All 10 mEq Supplements BC Rated**

REDACTED



REDACTED

PRICE INCREASE

[redacted]/APOT/CRET/02650

Restricted Confidential, Attorney Eyes Only, FTC Docket No. 9297

POTASSIUM CHLORIDE 10 mEq - CAPSULES

BRAND	SIZE	NDC
Ethex	100's	58177-0001-04
Ethex	500's	58177-0001-08

REDACTED

POTASSIUM CHLORIDE 10 mEq - TABLETS

BRAND	SIZE	NDC
Upsher-Smith makes Klor-Con 10		
Klor-Con 10	100's	00245-0041-11
Klor-Con 10	500's	00245-0041-15
H.L. Moore	100's	00839-7737-06
H.L. Moore	500's	00839-7194-12
Qualitest	100's	00603-5241-21
Goldline	100's	00182-1840-01
Goldline	500's	00182-1840-05
Rugby	100's	00536-4311-01
Rugby	1000's	00536-4311-10
Ten-K	100's	57267-0146-30
K-Dur	100's	00085-0263-01
K.TAB	100's	00074-7804-13
Apothecon	100's	59772-691-01
Apothecon	1000's	59772-691-02

REDACTED

POTASSIUM CHLORIDE

Note: Please complete form with 12 pitch type   **Pharmaceutical Products** ☒ New Item ☐ Promotion/Deal ☐ Open Stock

NWDA Standard Product Information

[illegible] #
Manufacturer Name: Apothecon
Address: P.O. Box 4500
City, State, Zip: Princeton, NJ 08543
Key Contact: Customer Service
Phone: 1-800-[illegible]
[illegible]: 5 CPU
[illegible] ☐ Yes ☒ No
Certificate of Product Liability Insurance Coverage
☐ Attached ☐ On file ☒ Available on Request
Is this Product a Controlled Drug?
☐ Yes ☒ No

Special Handling and Storage Requirements
a. Temperature – Indicate the [illegible] temperature range for this product
i. Controlled room temperature (59-77° F) ☐
ii. Room temperature (59-86° F) ☒
iii. [illegible] ☐
iv. Refrigerated ☐
v. Frozen ☐
vi. No requirements ☐
b. If frozen or refrigerated, how long can it be kept out of [illegible] temperature range?
___ hrs 30 days
c. If [illegible] temperatures [illegible], does [illegible] affect the product?
☐ Yes ☐ No
d. Are temperature indicators needed for this product? ☐ Yes ☒ No
If Yes, are they supplied at no charge? ☐ Yes ☐ No
e. Are special shipping containers required? ☐ Yes ☐ No
If Yes, are they supplied at no charge? ☐ Yes ☐ No
PLEASE ATTACH A COPY OF STABILITY DATA

Date ______ Page ___ of ___
Minimum Prepaid Shipment ______
Terms 2% net 31 ______
Number of [illegible] ______ Buy Period ______
Shipping Period ______
Type of Promotion: ☐ National ☐ Regional ☐ [illegible]
New Item: ☒ National ☐ Regional ☐ [illegible]
Regular Item: ☐ National ☐ Regional ☐ [illegible]
[illegible] on Any Price Decrease? ☐ Yes ☐ No
If Yes, Please [illegible]

ITEM AND PACKING INFORMATION

PRODUCT DESCRIPTION AND MANUFACTURER CODE #	Size/Strength	Unit of Sale	UPC Code	[illegible]	Inner Case Pk	Case Wt. LBS	Case Cube	Case Dimensions	Item Dimensions	Pallet Dimensions	# of Cases per Pallet
Potassium Chloride Slow Release tablet 10 Meq (750mg) List No. [illegible]	10 Meq	Box of 100	Case [illegible] / Item [illegible]	12	None	3.10	.15	D 7.52 / H 5.09 / W 6.94	D 7.07 / H 4.25 / W 7.35	D / H / W	170

For Generic Drug Products: I. FDA Orange Book Rating BC II. Product Color Light Orange
III. Brand Name Equivalent 10 meq (750 mg) Tab IV. Generic Name For Brand ______

[illegible] 3377[illegible]
[illegible] #____ [illegible] ______

COST INFORMATION

	$ Regular Cost	Purchase Allowance ☐ Off ☐ Bill: $	%	[illegible]	[illegible]	[illegible]	$ Average Actual Price	$ [illegible]	$ [illegible] ☐ $ ☐ %	[illegible]
[illegible]	156.73					195.84				
[illegible]	11.06					16.32				
[illegible]	156.73					195.84				

[illegible] Information
a. Department of Transportation (DOT) I.D. # ______
b. [illegible] ______
c. Attach copy of Material Safety Data Sheet (MSDS)

[illegible] – Check appropriate class(es) for the particular product
I ORGANIC
II INORGANIC
III CORROSIVE/OXIDIZER
IV AEROSOL
V AEROSOL CLASS
VI ANTINEOPLASTIC
VII [illegible]
VIII ESSENTIAL CHEMICAL
IX PRECURSOR CHEMICAL
X MAXIMUM QUANTITY LEVEL

This offer is made on a proportionally equal basis to all sellers' [illegible] customer
Signature [signature]

APOT/RENJ/0036

Memorandum

APOTHECON

REDACTED

REDACTED

REDACTED

HOGAN & HARTSON
L.L.P

COLUMBIA SQUARE
555 THIRTEENTH STREET, NW
WASHINGTON, DC 20004-1109
TEL (202) 637-5600
FAX (202) 637-5910
WWW.HHLAW.COM

November 16, 2000

Karen G. Bokat, Esq.
Federal Trade Commission
Room 3112
601 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

Re: File No. 9910256; Civil Investigative Demand and *Subpoena Duces Tecum* Issued to Bristol-Myers Squibb on August 18, 2000

Dear Karen:

Enclosed is Bristol-Myers Squibb's ("BMS") response to the Civil Investigative Demand ("CID") issued August 18, 2000. BMS has previously submitted, on October 17, 2000 and November 3, 2000, all responsive documents in the possession, custody or control of the individuals included in the scope of search as per Sharis Arnold Pozen's September 22, 2000 and September 27, 2000 letters. This concludes BMS' response to both the CID and *subpoena duces tecum*.

BMS has not provided documents responsive to Specification 3 of the *subpoena duces tecum* issued to BMS, which requests that BMS provide "IMS data and reports in Machine Readable Form relating to all potassium supplement products." While it is possible to purchase from IMS data in machine-readable form, BMS has not purchased any such data relating to potassium supplements during the relevant time period.

The information and documents included with this letter are being submitted to the Federal Trade Commission, in accordance with Sections 20 and 21 of the Federal Trade Commission Act, 15 U.S.C. §§ 57b-1 and -b-2, and should receive all the confidentiality to which it is entitled under Section 21 and all other applicable statutes and regulations.

Please call if you have any questions or comments with regard to the above.

Sincerely,

Andrea T. Cummings

Andrea T. Cummings

CummiAT/cummiat

Enclosures

cc: Zenola Harper, Esq.
Scott Applebaum, Esq.
Timothy Crew

BRISTOL-MYERS SQUIBB

Response to the Civil Investigative Demand
Issued by the Federal Trade Commission
File No. 9910256

BRISTOL-MYERS SQUIBB CLAIMS THE FULL MEASURE OF CONFIDENTIALITY AND PROTECTION AGAINST DISCLOSURE AVAILABLE UNDER THE FEDERAL TRADE COMMISSION'S STATUTES AND REGULATIONS.

US OFFICE PRODUCTS

Bristol-Myers Squibb
Response to Specification 1
Of the CID
Issued by the Federal Trade Commission

1. *State the name, chemical entity, manufacturer, formulation(s), and dosage strength(s) for each BMS Potassium Supplement Product ("PSP").*

Response

The chart below identifies the name, chemical entity, manufacturer, formulation and dosage strength of each BMS Potassium Supplement Product. BMS sold all of the products listed below during each of the relevant years. Some of these products are sold in varying package sizes (i.e., box of 30 tablets versus box of 100 tablets). In addition, K-Lyte is sold in a number of flavors.

BMS Potassium Supplement Products

Name	Chemical Entity	Manufacturer	Formulation	Dosage Strength
Klotrix	Potassium Chloride	Bristol-Myers Squibb	Slow Release Tablet	10mEq
K-Lyte	Potassium bicarbonate	Bristol-Myers Squibb	Effervescent Tablet	25mEq
K-Lyte DS	Potassium bicarbonate	Bristol-Myers Squibb	Effervescent Tablet	50mEq
K-Lyte/CL	Potassium bicarbonate and Chloride	Bristol-Myers Squibb	Effervescent Tablet	25mEq
K-Lyte/CL 50	Potassium bicarbonate and Chloride	Bristol-Myers Squibb	Effervescent Tablet	50mEq
Potassium Chloride Generic	Potassium Chloride	Bristol-Myers Squibb	Slow Release Tablet	10mEq

Bristol-Myers Squibb
Response to Specification 2
Of the CID
Issued by the Federal Trade Commission

2. *State whether the company has any plans to develop additional dosage strengths and formulations for any BMS Potassium Supplement Product. If so, briefly describe such plans and state the expected FDA approval and launch dates.*

Response

BMS does not currently have any plans to develop additional dosage strengths or formulations for any BMS Potassium Supplement Product.

Bristol-Myers Squibb
Response to Specification 3
Of the CID
Issued by the Federal Trade Commission

3. *State the following for each dosage strength of each BMS Potassium Supplement Tablet or Capsule:*

   (a) *date of FDA approval of the product's New Drug Application or Abbreviated New Drug Application;*

   (b) *date of commercial product introduction to the United States market;*

   (c) *annual sales in dollars;*

   (d) *annual sales in units;*

   (e) *annual net and gross profits; and*

   (f) *annual market share in dollars and in units.*

Response

(a) The FDA approved the New Drug Application for Klotrix (17-850) on January 25, 1979. All forms of the K-Lyte product were grandfathered in the Federal Food, Drug, and Cosmetic Act and therefore did not require FDA approval. BMS' generic potassium chloride supplement contains the same components as Klotrix. As a "private label" version of Klotrix, the generic potassium chloride supplement does not require FDA approval. The labeling for the generic supplement was submitted in the 1996 annual report for NDA 17-850.

(b) Klotrix was initially launched or introduced in June of 1989. K-Lyte CL and K-Lyte CL 50 were initially launched or introduced in January of 1988 and April of 1989 respectively. K-Lyte and K-Lyte DS, in their various flavors and package sizes, were initially launched or introduced in the spring of 1989. BMS introduced its generic potassium chloride supplement in January of 1996.

(c) Exhibit 3-1 provides annual sales in dollars, as reported internally at BMS, for Klotrix, K-Lyte and Potassium Chloride for each of the relevant years. Data for the current year is provided as of September 30, 2000. There were no sales of a generic potassium supplement in 1995, as BMS did not launch its generic potassium supplement until 1996.

(d) Exhibit 3-1 provides annual sales in units, as reported internally at BMS, for Klotrix, K-Lyte and Potassium Chloride for each of the relevant years. A "unit" sale represents the sale of a package of the product. Data for the current year is provided as of September 30, 2000. There were no sales of a generic potassium supplement in 1995, as BMS did not launch its generic potassium supplement until 1996.

REDACTED

(f) To the extent BMS has tracked such data during the relevant time period, information responsive to this Specification is contained in the documents produced in response to the *subpoena duces tecum* issued to BMS in connection with this CID. In addition, third parties, such as IMS, track such market data.

Exhibit 3-1

REDACTED

Bristol-Myers Squibb
Response to Specification 4
Of the CID
Issued by the Federal Trade Commission

4. *For each stock keeping unit (SKU) of each BMS Potassium Supplement Tablet or Capsule, state the following, by month, since the date of commercial product introduction identified in response to Specification 3(b):*

   (a) *wholesale acquisition cost;*

   (b) *average wholesale price (AWP);*

   (c) *net sales in dollars;*

   (d) *net sales in units; and*

   (e) *average transactional price (net dollars/net units)*

Response

Pursuant to the September 22, 2000 letter from Sharis Arnold Pozen to Karen Bokat (the September 22 letter), BMS is providing data responsive to this Specification by quarter rather than on a monthly basis. In addition, BMS is providing wholesale list price in response to subpart (a) in lieu of the wholesale acquisition cost. The wholesale list price for Apothecon's Potassium Supplement Products does not generally reflect a price at which the product is invoiced or sold, and it does not include discounts, rebates, chargebacks, and other price reductions. In addition, pursuant to the September 22 letter, BMS is providing the average manufacturing price ("AMP") in lieu of providing the information requested by subparts (c) through (e) of this Specification.

(a) Exhibit 4-1, attached, identifies the wholesale list price for each SKU of each BMS Potassium Supplement Tablet or Capsule during the relevant time period. Exhibit 4-1 identifies each date, during the relevant time period, on which the wholesale list price changed. The wholesale list price listed on Exhibit 4-1 is provided on a per package basis for each SKU of each product.

(b) Exhibit 4-1, attached, identifies the FirstDataBank average wholesale price for each SKU of each BMS Potassium Supplement Tablet or Capsule during the relevant time period. Exhibit 4-1 identifies each date, during the relevant time period, on which the FirstDataBank AWP changed. The

FirstDataBank AWP listed on Exhibit 4-1 is provided on a per package basis for each SKU of each product.

(c -e) Exhibit 4-2, attached, identifies the average manufacturing price, by quarter, for each SKU of each BMS Potassium Supplement Tablet or Capsule during the relevant time period. The AMP listed on Exhibit 4-1 is calculated on a per unit (rather than on a per package) basis for each SKU of each product.

US OFFICE PRODUCTS

Bristol-Myers Squibb
Response to Specification 5
Of the CID
Issued by the Federal Trade Commission

5. *For each product which the company believes competes with any BMS Potassium Supplement Tablet or Capsule ("competitor product"):*

   (a) *identify the brand name, chemical entity, dosage strength, formulation, and manufacturer of the competitor product;*

   (b) *indicate the BMS Potassium Supplement Tablet(s) or Capsule(s), and dosage strength(s) with which the competitor product competes;*

   (c) *state the basis for the company's belief that the competitor product competes, if at all, with each dosage strength of each BMS Potassium Supplement Tablet or Capsule;*

   (d) *state whether the competitor product is an AB rated generic equivalent of each dosage strength of each any BMS Potassium Supplement Tablet or Capsule; and*

   (e) *state whether each dosage strength of each BMS Potassium Supplement Tablet or Capsule is an AB rated generic equivalent of the competitor product.*

Response

Information responsive to this Specification is contained in the documents BMS produced in response to the *subpoena duces tecum* issued to BMS in conjunction with this Civil Investigative Demand. BMS also notes that equivalence is heavily regulated by the FDA. As such, BMS respectfully refers you to the FDA. FDA ratings for all FDA-approved drugs may be found in the Orange Book, which is available online at http://www.fda.gov. BMS notes that other Potassium Supplement products might be considered therapeutic equivalents under a broader definition of that term. The *Red Book* also publishes information with respect to equivalence for generic drugs. Other third party sources, such as IMS, also track and analyze competition in the pharmaceutical industry.

Bristol-Myers Squibb
Response to Specification 6
Of the CID
Issued by the Federal Trade Commission

6. *For each product which the company believes will compete in the future with any BMS Potassium Supplement Tablet or Capsule ("future competitor product"):*

   (a) *identify the brand name, chemical entity, dosage strength, formulation, and manufacturer of the future competitor product;*

   (b) *indicate the BMS Potassium Supplement Tablet(s) or Capsule(s), and dosage strength(s) with which the future competitor product will compete; and*

   (c) *state the basis for the company's belief that the future competitor product will compete, if at all, with each dosage strength of each BMS Potassium Supplement Tablet or Capsule;*

Response

BMS does not, in the ordinary course of business or otherwise, track or maintain information sufficient to identify each product that will compete with any BMS Potassium Supplement Tablet or Capsule in the future. BMS is neither aware of any plans by any company to introduce a new potassium supplement tablet or capsule, nor has BMS been actively tracking potential developments in this area during the relevant time period.

Bristol-Myers Squibb
Response to Specification 7
Of the CID
Issued by the Federal Trade Commission

7. *Identify the name, dosage strength, formulation, developer and manufacturer of any potassium supplement product that has not yet received final marketing approval from the Food and Drug Administration, other than those products identified in response to Specification 6.*

Response

BMS does not, in the ordinary course of business, track or maintain information sufficient to identify potassium supplement products that have not yet received final marketing approval from the FDA. BMS is not aware of any potassium supplement products that have not yet received final marketing approval from the FDA.

Bristol-Myers Squibb
Response to Specification 8
Of the CID
Issued by the Federal Trade Commission

8. *As of June 1, 1997, state the date on which the company expected the introduction of the first bioequivalent or generic version of K-Dur 20 and give the basis for that expectation, including the name(s) of any company expected to introduce such a product.*

Response

BMS did not, as of June 1, 1997, possess any information, belief or expectation with respect to when the first bioequivalent or generic version of K-Dur 20 would be introduced or by whom.

Bristol-Myers Squibb
Response to Specification 9
Of the CID
Issued by the Federal Trade Commission

9. *State the date on which the company currently expects the introduction of the first bioequivalent or generic version of K-Dur 20 and give the basis for that expectation, including the name(s) of any company expected to introduce such a product.*

Response

BMS does not currently have any information, belief or expectation with respect to when the first bioequivalent or generic version of K-Dur 20 will be introduced or by whom.

Bristol-Myers Squibb
Response to Specification 10
Of the CID
Issued by the Federal Trade Commission

10. For each dosage strength of each BMS Potassium Supplement Tablet or Capsule, estimate the potential increase or decrease in price (in dollars), market share (in percentage points), sales (in both dollars and units) and profit (in dollars) resulting from the introduction of a generic version of K-Dur 20, after:

(a) 1 month

(b) 12 months; and

(c) 2 years

Response

BMS has not conducted any analyses, studies or models of the potential impact of the introduction of a generic version of K-Dur 20 on the sales, price, or profits derived from, its potassium supplement tablets or capsules. Moreover, the fact that BMS does not manufacture or sell a 20mEq potassium supplement further complicates the determination of whether a generic equivalent of K-Dur 20 would compete with any BMS potassium supplement.

HOGAN & HARTSON
L.L.P.

COLUMBIA SQUARE
555 THIRTEENTH STREET, NW
WASHINGTON, DC 20004-1109
TEL (202) 637-5600
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WWW.HHLAW.COM

November 17, 2000

Karen G. Bokat, Esq.
Federal Trade Commission
Room 3112
601 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

Re: File No. 9910256; Civil Investigative Demand Issued to Bristol-Myers Squibb on August 18, 2000

Dear Karen:

Enclosed are two exhibits which were inadvertently ommitted from the response to the Civil Investitagtive Demand that BMS submitted on November 16, 2000. Please place these in the binder with the response to Specification 4.

The information and documents included with this letter are being submitted to the Federal Trade Commission, in accordance with Sections 20 and 21 of the Federal Trade Commission Act, 15 U.S.C. §§ 57b-1 and -b-2, and should receive all the confidentiality to which it is entitled under Section 21 and all other applicable statutes and regulations.

Please call if you have any questions or comments with regard to the above.

Sincerely,

Andrea T. Cummings

Andrea T. Cummings

Apotheon (BMS) 0000023
Schering et al., 991-0256

Exhibit 4-1

POTASSIUM SUPPLEMENTS

NDC NUMBER	DESCRIPTION	ADDITIONAL DESCRIPTION	FirstData Bank AWP Date	FirstData Bank AWP	WHOLESALE LIST PRICE DATE	WHOLESALE LIST PRICE
00087-0770-43	KLOTRIX 10MEQ TABLET SA	U-D	03/13/2000	$40.64	03/13/2000	$33.73
		0700-03	06/02/1999	$38.01	06/02/1999	$31.55
			12/01/1998	$35.36	12/01/1998	$29.35
			06/12/1998	$33.36	06/12/1998	$27.69
			09/12/1997	$31.77	09/12/1997	$26.37
			03/04/1997	$30.84	03/04/1997	$25.60
			03/01/1996	$29.37	03/01/1996	$24.38
			03/01/1995	$28.24	03/01/1995	$23.44
00087-0770-42	KLOTRIX 10MEQ TABLET SA	0770-02	03/13/2000	$326.22	03/13/2000	$270.75
			06/02/1999	$305.16	06/02/1999	$253.27
			12/01/1998	$283.87	12/01/1998	$235.60
			06/12/1998	$267.80	06/12/1998	$222.26
			09/12/1997	$255.05	09/12/1997	$211.68
			03/04/1997	$247.61	03/04/1997	$205.51
			03/01/1996	$235.82	03/01/1996	$195.72
			03/01/1995	$226.75	03/01/1995	$188.19
00087-0770-41	KLOTRIX 10MEQ TABLET SA	0770-01	03/13/2000	$33.65	03/13/2000	$27.93
			06/02/1999	$31.48	06/02/1999	$26.13
			12/01/1998	$29.29	12/01/1998	$24.31
			06/12/1998	$27.63	06/12/1998	$22.93
			09/12/1997	$26.31	09/12/1997	$21.84
			03/04/1997	$25.54	03/04/1997	$21.20
			03/01/1996	$24.33	03/01/1996	$20.19
			03/01/1995	$23.39	03/01/1995	$19.41

Exhibit 4-1

POTASSIUM SUPPLEMENTS

00087-0771-42	K-LYTE DS TABLET EFF	0771-02	03/13/2000	$217.51	03/13/2000	$180.52
		50 mEq Tablets	06/02/1999	$203.47	06/02/1999	$168.87
		100 Tabs /Orange	12/01/1998	$189.28	12/01/1998	$157.09
			06/12/1998	$178.57	06/12/1998	$148.20
			09/12/1997	$170.06	09/12/1997	$141.14
			03/04/1997	$165.11	03/04/1997	$137.03
			03/01/1996	$157.24	03/01/1996	$130.50
			03/01/1995	$151.19	03/01/1995	$125.48
00087-0771-41	K-LYTE DS TABLET EFF	0771-01	03/13/2000	$72.51	03/13/2000	$60.18
		50 mEq Tablets	06/02/1999	$67.84	06/02/1999	$56.30
		30 Tabs / Orange	12/01/1998	$63.10	12/01/1998	$52.37
			06/12/1998	$59.53	06/12/1998	$49.41
			09/12/1997	$56.70	09/12/1997	$47.06
			03/04/1997	$55.05	03/04/1997	$45.69
			03/01/1996	$52.42	03/01/1996	$43.51
			03/01/1995	$50.41	03/01/1995	$41.84
00087-0761-43	K-LYTE TABLET EFF	0761-08	03/13/2000	$127.47	03/13/2000	$105.79
		25 mEq Tablets	06/02/1999	$119.24	06/02/1999	$98.96
		100 Tabs / Orange	12/01/1998	$110.92	12/01/1998	$92.06
			06/12/1998	$104.64	06/12/1998	$86.85
			09/12/1997	$99.66	09/12/1997	$82.71
			03/04/1997	$96.75	03/04/1997	$80.30
			03/01/1996	$92.15	03/01/1996	$76.48
			03/01/1995	$86.61	03/01/1995	$73.54
00087-0761-02	K-LYTE TABLET EFF	0761-06	03/13/2000	$301.78	03/13/2000	$250.46
		25 mEq Tablets	06/02/1999	$282.29	06/02/1999	$234.29
		250 Tabs / Orange	12/01/1998	$262.59	12/01/1998	$217.94
			06/12/1998	$247.72	06/12/1998	$217.94
			09/12/1997	$235.93	09/12/1997	$205.60
			03/04/1997	$229.06	03/04/1997	$195.81
			03/01/1996	$218.16	03/01/1996	$190.11
			03/01/1995	$209.77	03/01/1995	$181.06

Exhibit 4-1

POTASSIUM SUPPLEMENTS

00087-0761-01	K-LYTE TABLET EFF	0761-01	03/13/2000	$40.29	03/13/2000	$33.44
		25 mEq Tablets	06/02/1999	$37.69	06/02/1999	$31.28
		30 Tabs / Orange	12/01/1998	$35.06	12/01/1998	$29.10
			06/12/1998	$33.07	06/12/1998	$27.45
			09/12/1997	$31.50	09/12/1997	$26.14
			03/04/1997	$30.58	03/04/1997	$25.38
			03/01/1996	$29.12	03/01/1996	$24.17
			03/01/1995	$28.00	03/01/1995	$23.24
00087-0760-43	K-LYTE TABLET EFF	0760-08	03/13/2000	$127.47	03/13/2000	$105.79
		25 mEq Tablets	06/02/1999	$119.24	06/02/1999	$98.96
		100 Tabs / Lime	12/01/1998	$110.92	12/01/1998	$92.06
			06/12/1998	$104.64	06/12/1998	$86.85
			09/12/1997	$99.66	09/12/1997	$82.71
			03/04/1997	$96.75	03/04/1997	$80.30
			03/01/1996	$92.15	03/01/1996	$76.48
			03/01/1995	$88.61	03/01/1995	$73.54
00087-0760-01	K-LYTE TABLET EFF	0760-01	03/13/2000	$40.29	03/13/2000	$33.44
		25 mEq Tablets	06/02/1999	$37.69	06/02/1999	$31.28
		30 Tablets / Lime	12/01/1998	$35.06	12/01/1998	$29.10
			06/12/1998	$33.07	06/12/1998	$27.45
			09/12/1997	$31.50	09/12/1997	$26.14
			03/04/1997	$30.58	03/04/1997	$25.38
			03/01/1996	$29.12	03/01/1996	$24.17
			03/01/1995	$28.00	03/01/1995	$23.24

Exhibit 4-1

POTASSIUM SUPPLEMENTS

00087-0767-43	K-LYTE/CL 25MEQ TABLET EFF	0767-03	03/13/2000	$127.47	03/13/2000	$105.79
		25 mEq Tablets	06/02/1999	$119.24	06/02/1999	$98.96
		100 Tablets	12/01/1998	$110.92	12/01/1998	$92.06
		Fruit Punch	06/12/1998	$104.64	06/12/1998	$86.85
			09/12/1997	$99.66	09/12/1997	$82.71
			03/04/1997	$96.75	03/04/1997	$80.30
			03/01/1996	$92.15	03/01/1996	$76.48
			03/01/1995	$88.61	03/01/1995	$73.54
00087-0767-41	K-LYTE/CL 25MEQ TABLET EFF	0767-01	03/13/2000	$40.29	03/13/2000	$33.44
		25 mEq Tablets	06/02/1999	$37.69	06/02/1999	$31.28
		30 Tabs	12/01/1998	$35.06	12/01/1998	$29.10
		Fruit Punch	06/12/1998	$33.07	06/12/1998	$27.45
			09/12/1997	$31.50	09/12/1997	$26.14
			03/04/1997	$30.58	03/04/1997	$25.38
			03/01/1996	$29.12	03/01/1996	$24.17
			03/01/1995	$28.00	03/01/1995	$23.24
00087-0766-43	K-LYTE/CL 25MEQ TABLET EFF	0766-03	03/13/2000	$127.47	03/13/2000	$105.79
		25 mEq Tablets	06/02/1999	$119.24	06/02/1999	$98.96
		100 Tabs / Citrus	12/01/1998	$110.92	12/01/1998	$92.06
			06/12/1998	$104.64	06/12/1998	$86.85
			09/12/1997	$99.66	09/12/1997	$82.71
			03/04/1997	$96.75	03/04/1997	$80.30
			03/01/1996	$92.15	03/01/1996	$76.48
			03/01/1995	$88.61	03/01/1995	$73.54
00087-0766-41	K-LYTE/CL 25MEQ TABLET EFF	0766-01	03/13/2000	$40.29	03/13/2000	$33.44
		25 mEq Tablets	06/02/1999	$37.69	06/02/1999	$31.28
		30 Tabs / Citrus	12/01/1998	$35.06	12/01/1998	$29.10
			06/12/1998	$33.07	06/12/1998	$27.45
			09/12/1997	$31.50	09/12/1997	$26.14
			03/04/1997	$30.58	03/04/1997	$25.38
			03/01/1996	$29.12	03/01/1996	$24.17
			03/01/1995	$28.00	03/01/1995	$23.24

Exhibit 4-1

POTASSIUM SUPPLEMENTS

00087-0758-41	K-LYTE/CL 50MEQ CITRUS TAB	0758-01	03/13/2000	$72.51	03/13/2000	$60.16
		50 mEq Tablets	06/02/1999	$67.84	06/02/1999	$56.30
		30 Tabs / Citrus	12/01/1998	$63.10	12/01/1998	$52.37
			06/12/1998	$59.53	06/12/1998	$49.41
			09/12/1997	$56.70	09/12/1997	$47.06
			03/04/1997	$55.05	03/04/1997	$45.69
			03/01/1996	$52.42	03/01/1996	$43.51
			03/01/1995	$50.41	03/01/1995	$41.84
59772-6910-02	POTASSIUM CL 10MEQ TAB SA	6910-20	12/01/1998	$224.91	12/01/1998	$179.93
			01/15/1996	$159.75	12/14/1995	$127.80
59772-6910-01	POTASSIUM CL 10MEQ TAB SA	6910-10	12/01/1998	$23.20	12/01/1998	$18.56
			01/15/1996	$16.32	12/14/1995	$13.06

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Exhibit 4-2

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