B.F. ASCHER & COMPANY, INC. • *Pharmaceuticals* • *Consumer Products*

February 10, 2003

Dockets Management Branch (HFA-305)
Food & Drug Administration
5630 Fishers Lane
Rm. 1061
Rockville, MD 20852

re: Docket No. 98N-1109

Salutations;

Pursuant to a request for information, Federal Register, Vol. 68, No.22, pp5299, "Mercury Compounds in Drugs and Food; List", acknowledgment is hereby given that the 3 products distributed by B. F. Ascher & Co. shown in the list "Mercury in Drug and Biologic Products" have been reformulated and no longer contain thimerosal or any other mercury compound.

The three, as they appear in the listing:

Baby AYR Saline Nose Spray/Drops

AYR Saline Nasal Drops

AYR Saline Nasal Mist

It was requested in the same Docket that the labeling for subject products be updated to reflect the reformulation pursuant to § 207. Enclosed are copies of our June, 2001 Drug Product Listing to show that this requirement has been met.

Respectfully,

Marc Elton
Manager, QA/QC

98N-1109

SUP 1

ME
Cc: DW, JAJ, CBA, JJA

15501 West 109th Street, Lenexa, Kansas 66219-1308
P.O. Box 717, Shawnee Mission, Kansas 66201-0717
Phone (913) 888-1880 Fax (913) 888-2250 Email bfascher@msn.com

B.F. ASCHER & COMPANY, INC. • *Pharmaceuticals • Consumer Products*

July 17, 2001

Gary Anderson
Team Leader, IMT
Food & Drug Administration
CDER/OIT/DDMS/IMT HFD-095
7520 Standish PL, Rm 161
Rockville, MD 20855

Dear Mr. Anderson:

In accordance with CFR 207, B. F. Ascher & Co., Inc. is submitting Forms FDA 2657 (10/98) to fulfill the semiannual reporting requirements.

The brands covered in this submission are:

1.) AYR SALINE NASAL DROPS (removed thimerosal, added disodium EDTA, new manufacturer).

2.) AYR SALINE NASAL MIST (removed thimerosal, added disodium EDTA, new manufacturer).

3.) BABY AYR SALINE NOSE DROPS/SPRAY (removed thimerosal, added disodium EDTA, new manufacturer).

4.) MOBIGESIC (added povidone, new manufacturer).

Copies of the artwork for the AYR DROPS, AYR MIST and BABY AYR cartons and bottles have been enclosed. The actual cartons will be sent as shipments arrive.

Cartons and labels are enclosed for the three sizes of MOBIGESIC.

Please contact me if more information is needed.

Sincerely,

Richard O. Welch

Richard O. Welch
Director - Scientific
& Legal Affairs

ROW:djc
cc: JJA, JAJ, ME
Certified/Return Receipt Requested

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P.O. Box 717, Shawnee Mission, Kansas 66201-0717
Phone: (913) 888-1880 Fax: (913) 888-2250 Email: bfascher@msn.com

Form Approved: OMB No. 0910-0045. Expiration Date: April 30, 2001. See OMB Statement on Reverse

DEPARTMENT OF HEALTH AND HUMANS SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

DRUG PRODUCT LISTING

(In accordance with Public Law 92-387)

NAME AND ADDRESS OF FIRM

B. F. ASCHER & CO., INC.
15501 WEST 109th ST
LENEXA, KS 66219

LABELING REVISON

CHANGE OF:

☐ RTE OF ADMIN ☐ INDICATION
☒ NAME / DOSE / STR / INGR
☒ OTHER (Specify) NEW MFR

FOR FDA USE — CONTROL NO. — RECORD ID

LABELING: REMOVED THIMEROSAL
ADDED DISODIUM EDTA

SEC	S	U	PRODUCT TRADE NAME OR CATALOG NAME	NATIONAL DRUG CODE: LABELER	PRODUCT
01			CAYR SALINE NASAL DROPS	00022	5038 2

FDA APPLICATION NO.	REPORT DATE: MO	DA	YR	TYPE MKT	TYPES OF BUSINESS: OTHER (Specify)	PRODUCT TYPE	PRODUCT TYPE: OTHER (Specify)	BMOD	LEGAL STATUS	NCHRD	PROP VET	PRODUCT DISCONTINUED: OTHER (Specify)	BASIS OF CONCENTRATION: WHOLE NUMBERS	DECIMAL	UNIT
	06	29	01	L		H		0							

DOSAGE FORM	ROUTES OF ADMINISTRATION: 1	2	3	OTH	PT	SEC	S	U	§	PKG CODE	PACKAGE SIZE	PACKAGE TYPE
299014						03				8250	mL	BOT
						03						
						03						
						03						
						03						

INITIAL MARKETING DATE: MO	YEAR	MOST RECENT MARKETING DATE: MO	YEAR	DISCONTINUED DATE: MO	YEAR

NOTICE. This report is required by law (21 C.F.R. 207.20). Failure to report can result in imprisonment for not more than one year or a fine of not more than $1 000, or both (FD&C Act, Section 303).

SEC	S	U	TYPE	PT	ESTABLISHED NAME OF PRODUCT AND / OR INGREDIENT(S) OR BIOLOGIC PROPER NAME, TEST OBJECTIVE / EQUIPMENT / REAGENT NAME, ETC.	FDA USE ONLY: INGREDIENT NO.	AMOUNT: WHOLE NUMBER	DECIMAL	UNIT
05		DI			THIMEROSAL		0	0002	% WV
05		CI			DISODIUM EDTA		0	0100	% WV
05									
05									
05									
05									
05									
05									
05									
05									

SEC	S	U	SITE OR FIRM ESTABLISHMENT REGISTRATION NUMBER	ACTUAL MANUFACTURING SITE OF THE ABOVE DRUG PRODUCT	STATE	FOREIGN COUNTRY	NDC LABELER CODE	SHORT NAME
07			1831301	APPLIED LABORATORIES INC	IN		052645	
07								
07								

FORM FDA 2657 (10/98) PEVIOUS EDITION IS OBSOLETE.

Form Approved: OMB No. 0910-0045, Expiration Date: April 30, 2001. See OMB Statement on Reverse

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☒ OTHER (Specify) NEW MFR

FOR FDA USE — CONTROL NO. — RECORD ID

SEC	S	U	PRODUCT TRADE NAME OR CATALOG NAME	NATIONAL DRUG CODE: LABELER	PRODUCT
01			CAYR SALINE NASAL MIST	00022	5038 0

LABELING: REMOVED THIMEROSAL ADDED DISODIUM EDTA

FDA APPLICATION NO.	REPORT DATE MO	DA	YR	TYPE CHG	TYPES OF BUSINESS: OTHER (Specify)	PRODUCT TYPE	OTHER (Specify)	BKGD	LEGAL STATUS	BCHED	PROP NAME	PRODUCT DISCONTINUED: OTHER (Specify)	BASIS OF CONCENTRATION: WHOLE NUMBERS	DECIMAL	UNIT
	06	29	01	L		H		0							

DOSAGE FORM	ROUTES OF ADMINISTRATION 1	2	3	OTH	PT	SEC	S	U	FIL	PKG CODE	PACKAGE SIZE	PACKAGE TYPE
29901 4						03				8050	mL	BOT
						03						
						03						
						03						
						03						

INITIAL MARKETING DATE MO	YEAR	MOST RECENT MARKETING DATE MO	YEAR	DISCONTINUED DATE MO	YEAR

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05		DI			THIMEROSAL		00	002	% WV
05		CI			DISODIUM EDTA		00	010	% WV
05									
05									
05									
05									
05									
05									
05									
05									

SEC	S	U	SITE OR FIRM ESTABLISHMENT REGISTRATION NUMBER	ACTUAL MANUFACTURING SITE OF THE ABOVE DRUG PRODUCT	STATE	FOREIGN COUNTRY	NDC LABELER CODE	SHORT NAME
07			1831301	APPLIED LABORATORIES INC	IN		052645	
07								
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☐ RTE OF ADMIN ☐ INDICATION
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FOR FDA USE — CONTROL NO. — RECORD ID

SEC	S	U	PRODUCT TRADE NAME OR CATALOG NAME	NATIONAL DRUG CODE: LABELER	PRODUCT
01			CBABY AYR SALINE NOSE SPRAY DROPS	00022	0550

LABELING: REMOVED THIMEROSAL ADDED DISODIUM EDTA

FDA APPLICATION NO.	REPORT DATE: MO	DA	YR	TYPE ACT	TYPES OF BUSINESS: OTHER (Specify)	PRODUCT TYPE	OTHER (Specify)	BARCD	LEGAL STATUS	SCHED	PACK SIZE	PRODUCT DISCONTINUED: OTHER (Specify)	BASIS OF CONCENTRATION: WHOLE NUMBERS	DECIMAL	UNIT
	06	29	01	L		H			0						

DOSAGE FORM	ROUTES OF ADMINISTRATION: 1	2	3	OTH	PT
29901	4				

SEC	S	U	LOT	PKG CODE	PACKAGE SIZE	PACKAGE TYPE
03				5030	mL	BOT
03						
03						
03						
03						

INITIAL MARKETING DATE: MO	YEAR	MOST RECENT MARKETING DATE: MO	YEAR	DISCONTINUED DATE: MO	YEAR

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SEC	S	U	TYPE	PT	ESTABLISHED NAME OF PRODUCT AND / OR INGREDIENT(S) OR BIOLOGIC PROPER NAME, TEST OBJECTIVE / EQUIPMENT / REAGENT NAME, ETC.	FDA USE ONLY: INGREDIENT NO.	AMOUNT: WHOLE NUMBER	DECIMAL	UNIT
05		DI			THIMEROSAL		0	0002	%WV
05		CI			DISODIUM EDTA		0	0100	%WV
05									
05									
05									
05									
05									
05									
05									

SEC	S	U	SITE OR FIRM ESTABLISHMENT REGISTRATION NUMBER	ACTUAL MANUFACTURING SITE OF THE ABOVE DRUG PRODUCT	STATE	FOREIGN COUNTRY	NDC LABELER CODE	SHORT NAME
07			1831301	APPLIED LABORATORIES INC	IN		052645	
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