MERCURY COMPOUNDS IN DRUGS AND FOOD

Under section 4 13(a) of the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105-115), entitled "Food and Drug Administration Study of Mercury Compounds in Drugs and Food," the Food and Drug Administration (FDA) is required to: (1) Compile a list of drugs and foods that contain intentionally introduced mercury compounds, and (2) provide a quantitative and qualitative analysis of the mercury compounds in this list. The statute did not differentiate between mercury as an active or an inactive ingredient.

In the FEDERAL REGISTERs of December 14, 1998 (63 FR 68775) and April 29, 1999 (64 FR 23083), FDA published requests for data and information on mercury compounds in drugs and food. The agency asked all manufacturers of any food, including dietary supplements, and human and veterinary drug products (prescription or over-the-counter (OTC)) containing any intentionally introduced mercury compounds, whether used as an active or inactive ingredient, to provide information about the products to the agency. The agency requested the following information for each product: (1) its commercial name, (2) the chemical name of the mercury compound present in the product, the Chemical Abstract Service (CAS) registry (Reg.) Number (No.) and the CAS preferred chemical name of the mercury compound(s), (3) the quantitative amount present in the product, (4) the purpose of the mercury compound in the product, (5) a copy of the product's labeling, and (6) an estimate of the amount of the mercury compound used annually in manufacturing the product. -General comments on the subject could also be submitted.

The agency received 41 responses to the request-for-data notices; 38 from manufacturers of products, 1 from an association of homeopathic pharmacists, and 2 from consumers. Of the

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38 responses from manufacturers, 15 were from manufacturers of homeopathic drug products, and 23 were from manufacturers of drug and/or biologic products (13 drug manufacturers, 8 biologic manufacturers, and 2 manufacturers of both types of products). Five of the drug manufacturers informed the agency that they had no products containing any mercury compounds. One drug manufacturer was an animal health corporation providing information on a veterinary drug product, and two manufacturers of homeopathic products included information on five veterinary drug products as well as human drug products. The product information submitted with the comments is summarized below in separate sections based on the types of products: Human drug products (nonhomeopathic and homeopathic), veterinary drug products (nonhomeopathic and homeopathic), biological products, food and dietary supplement products, and other products (where the type of product could not be determined from the information that was submitted).

I. Information from the Responses

A. Human Drug Products (nonhomeopathic).

The nine manufacturers of human drug products submitted information on a total of 32 products, half of which are prescription products and half of which are OTC products. The prescription products included 7 ophthalmic, 4 otic, 3 injectable (1 bacteriostatic water for injection and 2 hyaluronidase for injection), and 2 topical (for treating candidiasis) products. The OTC products included 14 nasal spray/drop and 2 ophthalmic products. None of the products contained any mercury compounds as active ingredients.

The 32 products contained the following mercury compounds as inactive ingredients used as a preservative: 27 contained thimerosal (TM), 4 contained phenylmercuric acetate (PMA),

and 1 contained phenylmercuric nitrate (PMN). TM was used in the 13 ophthalmic and otic products at the following concentrations: 0.001% (5 products), 0.002% (1 product), 0.004% (2 products), 0.005% (2 products), and 0.01% (3 products). TM was used in 10 nasal spray/drop products at 0.00025% (3 products), 0.001% (6 products), and 0.002% (1 product). The 2 topical products contained 0.01% TM, and the 2 hyaluronidase injection products contained 0.075 or 0.1 milligram (mg) TM per 150 United States Pharmacopeia (USP) units of drug (0.01%).

PMA was used in 4 nasal spray/drop products at 0.002%. One manufacturer reported subsequently that its product had been reformulated to delete the PMA. (This reduced the total number of products to 3 1.) PMN was used in the bacteriostatic water for injection at 0.0 1%.

The manufacturers reported estimated annual amounts of TM used as 1,086 grams (g) for 10 nasal spray/drop products, 1 ,123 g for 9 ophthalmic products, 6,015 g for 4 otic products, 40 g for 2 topical products, and 192 g for the 2 hyaluronidase injection products. The manufacturers estimated annual amounts used were 482 g for PMA for the 4 nasal spray/drop products and 1.6 g for PMN for the 1 bacteriostatic water for injection product.

B. Human Drug Products (homeopathic).

The agency considers homeopathic products as drugs. These drugs may be either prescription or OTC products. Mercury compounds are used in very dilute concentrations in homeopathic products for a variety of purposes. Homeopathic dosages are based on principles of serial dilution, and homeopathic products are marketed in strengths that indicate the number of dilutions that the substance has undergone in the manufacturing process. Homeopathic products are marketed with either "X" or "C" potencies. "X" potencies are prepared by 1 to 10 dilutions, and "C" potencies are prepared by 1 to 100 dilutions.

For example, a mercury compound is completely dissolved in solvent/diluent in a ratio of 1 part mercury compound to 10 parts or 100 parts solution. The resulting solution is known as the 1X or 1 C dilution. To manufacture the 2X or 2C dilution, one part of the 1X solution is mixed with 9 parts of the solvent/diluent and one part of the 1C solution is mixed with 99 parts of the solvent/diluent. The 3X or 3C dilution is made from one part of the 2X or 2C dilution plus 9 or 99 parts, respectively, of the solvent/diluent. This dilution is repeated as many times as desired.

For substances that are insoluble in alcohol and water, the insoluble substance is mixed with 9 times its weight of lactose. This process is repeated until the substance has been diluted to at least a 6X potency, at which point it is sufficiently diluted to allow solubility in a fluid, and the process can be continued to the desired dilution.

A homeopathic product marketed at a 6X potency would contain 0.000001 g of mercury compound per 1 g of tablet or pellet. This represents 1 part per million (ppm) by weight. The American Association of Homeopathic Pharmacists stated that a typical dose of a 6X dilution of a mercury compound contains from 0.000066 to 0.000495 mg of elemental mercury. Mercury concentrations in submitted products generally ranged from 6X to 200X.

The 15 manufacturers of homeopathic products submitted information on 494 human products containing 22 different mercury compounds, as follows:

Homeopathic name	CAS preferred or chemical name	Number of products
Aethiops antimonialis	antimony sulfide/mercury mixture	2
Aethiops mercurialis-mineralis	black mercuric sulfide	8
Mercurius aceticus	mercurous acetate	4

Mercurius auratus	mercury and gold amalgam	3
Mercurius biniodatus	mercuric iodide	3
Mercurius bromatus	mercurous bromide	3
Mercurius corrosivus	mercuric chloride	80
Mercurius cum kali iodatus	potassium tetraiodomercurate	3
Mercurius cyanatus	mercuric cyanide	20
Mercurius dulcis	mercurous chloride	21
Mercurius iodatus flavus	mercurous iodide	23
Mercurius iodatus ruber	mercuric iodide	28
Mercurius methylenus	dimethylmercury	3
Mercurius nitricus	mercuric nitrate	4
Mercurius praecipitatus albus	ammoniated mercury (chloride)	11
Mercurius praecipitatus ruber	red mercuric oxide	31
Mercurius protoiodatus	mercurous iodide	2
Mercurius solubilis	[Hahnemann's] soluble mercury	126
Mercurius sulphocyanatus	mercuric thiocyanate	3
Mercurius sulphuratus ruber	red mercuric sulfide	10
Mercurius sulphuricus	mercuric sulfate	13
Mercurius vivus [Quicksilver]	mercury	72
Combination products		18

Due to the large number of dilutions in the manufacture of homeopathic products, the amount of mercury compounds used annually in manufacturing these products is minimal. One

manufacturer stated that 1 g of a mercury compound provides enough active ingredient for 1,000 kilograms (kg) of 6X tablets or pellets. Thus, most manufacturers annual requirements for any mercury compound used in manufacturing a homeopathic drug product should not exceed 1 g.

C. Veterinary Drug Products (nonhomeonathic and homeonathic).

Three manufacturers submitted information on six products. One manufacturer of nonhomeopathic veterinary drug products stated that it marketed one ophthalmic ointment for dogs containing a mercury compound (0.002% PMN) as a preservative. Two of the veterinary homeopathic drug products contained mercurius corrosivus or mercurius dulcis, both at a 15X potency. The other three veterinary homeopathic drug products contained mercurius corrosivus, mercurius cyanatus, or mercurius vivus and are marketed in 1 OX, 30X, and 100X potencies.

D. Biological Products.

The ten manufacturers of biological products submitted information on a total of 3 8 products: 30 vaccines, 7 other biological products, and 1 diluent for a vaccine. Eight of the 30 vaccines were variations of diphtheria (D or d) and tetanus (T) toxoids; 6 were tetanus toxoids (TT); 2 were DTaP (diphtheria and tetanus toxoids and acellular pertussis); 1 was DTP (diphtheria and tetanus toxoids and whole cell pertussis); and 2 were DTP or DTaP combined with Haemophilus influenzae type b (DTP-HIB or DTaP-HIB). The other vaccines were 5 influenza, 2 hepatitis B, 2 HIB, 1 pneumococcal, and 1 Japanese encephalitis. The 7 other biological products were 3 antivenins, 2 human immune globulins, 1 mumps skin test antigen, and 1 normal horse serum. The final product was a diluent for a meningococcal vaccine. None of the products contained any mercury compounds as active ingredients.

The 38 products all contained TM as the mercury compound used as a preservative. TM

was present at a 0.01% concentration in 29 of the products; 0.003% in 3 products (1 Td and 2 immune globulins); 0.005% in 5 products (2 hepatitis B, 2 antivenins, and 1 normal horse serum), and 0.007% in 1 Japanese encephalitis virus vaccine. For products containing 0.01% TM, the amount of TM per 0.5 milliliters (mL) of product is 50 micrograms, and the amount of elemental mercury per 0.5 mL dose is approximately 25 micrograms.

The manufacturers reported estimated annual amounts of TM used as 3,125 g for the 19 products containing any form of D and T, 24,408 g for the other 11 vaccine products (one manufacturer estimated 20,000 g for a hepatitis B vaccine), 60 g for 2 human immune globulins, 7 g for the 3 antivenins, 4 g for 1 mumps skin test antigen, 1 g for the 1 normal horse serum product, and 50 g for the diluent for 1 meningococcal vaccine. The total estimated amount for the 38 products is 27,655 g of TM.

E. Food and Dietary Supplement Products.

No manufacturer of any food or dietary supplement products submitted any information in response to the agency's requests.

F. Other Products.

One consumer provided some information about the mercury content of some herbal pills from China that had been sold to her by an acupuncturist as part of acupuncture treatment for a sinus condition. The consumer had the pills analyzed and they were found to contain 62 ppm (0.0062%) mercury. The information provided did not enable the agency to determine the ingredients these pills contain, whether the product would be considered a drug or dietary supplement, or what the exposure to mercury would be from its use.

II. Information from Other Sources

A. Human Drug Products (nonhomeopathic).

The agency has reviewed information from its Drug Registration and Listing System (DRLS) and other sources to identify additional drug products that contain intentionally introduced mercury compounds. All but one of the 32 submitted drug products (see section I.A. above) were included in the DRLS files. These 3 1 products are not discussed in this section.

The agency identified 13 8 additional nonhomeopathic products containing mercury compounds. Of these, 13 contained mercury compounds as an active or bulk chemical ingredient and 125 contained mercury compounds as a preservative (124) or inactive ingredient (1).

Eleven of the 13 products contained mercury compounds (TM (8), merbromin(2), and mercuric oxide yellow (1)) as a bulk chemical ingredient, and only 2 products (merbromin (mercurochrome) solution) had active drug uses. The agency does not believe either of these products that had active drug uses is currently marketed because of a final rule that the agency issued on April 22, 1998 (63 FR 19799). In that final rule, the agency declared merbromin (and other mercury active ingredients) as not generally recognized as safe and effective as an active ingredient for OTC first aid antiseptic and antimicrobial diaper rash uses. Products containing these ingredients for these uses could no longer be initially introduced or initially delivered for introduction into interstate commerce after October 19, 1998.

Of the 124 products containing mercury compounds as a preservative, 52 were nasal solutions/sprays, 41 were ophthalmic solutions/ointments, 18 were otic solutions, 8 were topical products, and 5 were injectable products. The 124 products contained TM (62), PMA (54), mercuric acetate (believed to be PMA) 1, PMN (5), and mercuric nitrate (believed to be PMN) (2). The agency believes that the 7 ointment or suppository products containing PMN as a

preservative are no longer marketed because the PMN was present in a product that contained live yeast cell derivative (LYCD). The agency declared LYCD as not generally recognized as safe and effective for OTC anorectal use in a final rule issued on September 2, 1993 (58 FR 46746). Products containing LYCD for anorectal use could no longer be initially introduced or initially delivered for introduction into interstate commerce after September 2, 1994. Based on current product information and information about similar products that were previously marketed, the agency believes that when these products were reformulated to remove the LYCD, the PMN preservative was also removed from the products. One topical ointment listed mercury as an inactive ingredient at less than 0.02 ppm.

When preservative concentration information was provided in the DRLS files, TM was present at 0.0005 to 0.01% (about 75% of the products) in the ophthalmic solutions and at 0.002 to 0.01% (over 75% of the products) in the otic solutions. PMA was present in most of the nasal solutions/sprays at 0.002% and at 0.0008% in 1 ophthalmic ointment. Mercuric acetate was listed at 0.002% in one nasal solution/spray product.

The agency is able to estimate only the amounts of mercury compounds used annually as a preservative in these products. Based on manufacturers' information provided for submitted products (see section I.A. above), 1,086 g of TM is used annually to manufacture 10 nasal spray/drop products. For 2 additional nasal spray/drop products, the estimated amount would be approximately an additional 217 g (0.2 times 1,086), making a total of 1,303 g. The agency is unable to determine the accuracy of this proration because it cannot correlate the 10 and 2 product quantities in terms of total number of products sold. But the calculation provides an estimate that approximately 1,300 g of TM would be used annually as a preservative in the

manufacture of approximately 12 nasal spray/drop drug products. The agency believes that this number will be less for these products in the future because many manufacturers of these products have reformulated or are currently reformulating the products to replace TM as the preservative with another (nonmercury compound) preservative, e.g., benzalkonium chloride.

Manufacturers estimated 1,123 g of TM used annually as a preservative for 9 ophthalmic products. Using the same type of calculation as above, 4,492 g (4 times 1,123) would be used for 36 additional products, making a total estimate of 5,615 g for 45 products. Similarly, 6,015 g of TM was estimated for 4 otic products. This would estimate as 27,068 g (4.5 times 6,015) for 18 additional products, making a total estimate of 33,083 g for 22 products. The agency believes this estimate is high because of the large quantity used for 1 of the 4 submitted products. The agency does not believe that many of the other 18 products have the same volume of sales; thus, the actual amount used would be much lower.

Manufacturers estimated 192 g of TM are used for 2 injectable products and 40 g are used for 2 topical products. The 5 injectable products and the 1 topical ointment product containing TM that were identified in the DRLS are significantly different types of products than the submitted products for which estimates of annual use were made. Therefore, the agency is not able to make an estimate for these 6 products in the DRLS.

Manufacturers estimated 482 g of PMA are used annually in 4 nasal spray/drop products. This would estimate as 6,025 g (12.5 times 482) for 50 additional products, making a total of 6,507 g for 54 products. No ophthalmic products containing PMA were included in the submissions. Therefore, the agency has no estimate for the 5 ophthalmic products containing PMA that were identified in the DRLS. Manufacturers provided an estimate of 1.6 g for only 1

product (a bacteriostatic water for injection) containing PMN as a preservative. The agency believes that none of the topical products in the DRLS that contained PMN as a preservative are currently marketed. Therefore, the amount of PMN used as a preservative annually is minimal.

B. Human Drug Products (homeopathic).

The agency identified 607 additional single ingredient and 39 combination (more than one ingredient) homeopathic products containing 19 mercury compounds as active ingredients. Most of these ingredients were previously identified above (see section I.B.), but a few additional ingredients were included in the DRLS files. The ingredients and the number of products in which they appear are as follows:

Ingredient	Number of products
Mercuric acetate	3
Mercurous acetate	2
Mercury and gold amalgam	3
Mercurous bromide	4
Mercuric chloride	130
Mercuric chloride ammoniated	6
Mercurous chloride	21
Mercuric cyanide	17
Mercury cyanide oxide	1
Mercurous iodide	28
Mercuric iodide red	52
Mercuric nitrate	6

Mercuric oxide red	34
Mercurialis perennis (dog's mercury)	17
Soluble mercury	133
Mercuric sulfate	30
Mercurous sulfate	1
Mercuric sulfide red	25
Mercury (mercurius vivus)	94
Combination products	39

As noted above (see section I.B.), these products are marketed in various potencies, and mercury concentrations generally ranged from 6X to 200X. Based on information provided in the submissions, 1 g of a mercury compound provides enough active ingredient for 1,000 kg of 6X tablets or pellets. Thus, annual requirements for these 646 additional homeopathic products containing mercury should be minimal.

C. Veterinary Drug Products (nonhomeopathic and homeopathic).

Information from the Center for Veterinary Medicine's drug listing files and other sources indicates that there are some limited uses of mercury compounds as active or inactive ingredients in animal drug products. The only FDA approved product containing PMN as a preservative was included in the product information manufacturers provided (see section I.C. above). Other products that contain mercury are typically unapproved products for use in nonfood animals. Examples include mercuric chloride (bichloride of mercury) and red iodide of mercury as a counterirritant for use on horses, TM (in tincture of merthiolate) as a mild antiseptic or for the treatment of equine fungal infections of the hoof, and merbromin (mercurochrome) used in

treating ornamental fish. The agency typically considers regulatory action when it becomes aware of counterirritant or similar products that contain mercury. Occasional use of mercury compounds as a preservative in unapproved products also occurs. Based on the information available, the agency is unable to determine the total amount of mercury used annually in these products.

D. Biological Products.

The agency has reviewed information from its DRLS and other sources to identify additional biological products that contain intentionally introduced mercury compounds. The agency identified 11 additional products, all containing TM as a preservative. The products included 6 vaccines (1 DT, 1 TT, 1 DTP, 1 DTaP, 1 P, and 1 rabies), 3 immune globulins, 1 allergen patch test, and 1 coccidioidin skin test antigen. TM was present in 10 of the products at 0.01% and in 1 product at 0.0065 mg per patch. The agency believes many of these products have limited distribution and, thus, is not estimating an annual amount of TM used in these products.

E. Food and Dietary Supplement Products.

Foods, including dietary supplements, do not have to be registered with the FDA. Therefore, the agency has no compilation of product formulations that provide information on the intentional use of mercury compounds in foods or dietary supplements. The agency is not aware of other reports or information on the use of mercury in foods or dietary supplements. Further, the agency is not aware of any manufacturer who is intentionally adding any mercury compounds in foods or dietary supplements.

F. Other Products.

The agency is aware of a warning issued by the Therapeutic Products Programme of Health Canada concerning two Chinese herbal products that were analyzed and found to contain unacceptable levels of mercury. It is not clear whether the mercury found in the products was a contaminant or an intentionally introduced mercury compound(s). The information in the Health Canada warning did not enable the agency to determine whether these products would be a drug or a dietary supplement or whether they are presently marketed in the United States.

III. Summary and Conclusions

The information provided by manufacturers, in the agency's DRLS files, and from other sources shows that mercury compounds were marketed in the past as an active ingredient in a small number of nonhomeopathic human and veterinary drug products and are marketed as an active ingredient in miniscule amounts in approximately 1,000 to 1,100 homeopathic drug products. There may be some additional products in the marketplace that were not found in the sources that the agency reviewed.

The primary use of mercury compounds in the marketplace is as a preservative in drug and biological products. The attached list identifies 2 19 products as of October 26, 1999. These products are primarily nasal solutions/sprays, ophthalmic solutions/ointments, otic solutions, vaccines, and injectable products. The agency estimates that 15 to 20 of the products included on the list are currently not marketed for two reasons. First, the agency was unable to locate 10 of the manufacturers/distributors on the list to determine whether their products are or are not currently marketed. Second, as discussed in section II.A., the 7 ointment or suppository products containing PMN on the list are probably no longer marketed.

The two primary mercury compounds used as a preservative are TM and PMA. The most

widely used concentrations are 0.01% TM and 0.002% PMA. Some concentrations are as dilute as 0.0005%. PMN is used in a few products. The agency is aware that some manufacturers have voluntarily reformulated their products in recent years to delete the mercury preservatives and to replace them with a nonmercury preservative, e.g., benzalkonium chloride. The agency anticipates that additional products will be reformulated in the future.

FDA has no information on the intentional use of mercury compounds in food or dietary supplements.

Based on the information provided by manufacturers and the agency's estimates, the amount of mercury compounds used annually as an active and inactive ingredient in all products appears to be 75,000 to 80,000 g (75 to 80 kg). The amount used in all drug products appears to be 45,000 to 50,000 g (45 to 50 kg), and the amount used in all biological products appears to be 25,000 to 30,000 g (25 to 30 kg). As noted above, this amount should be reduced in the future as more products are reformulated to delete the mercury preservative.

Mercury in Drug and Biologic Products

The information in this list is derived from submissions made by manufacturers in response to the agency's call-for-data notices of December 14, 1998 (63 FR 68775) and April 29, 1999 (64 FR 23083), the agency's Drug Registration and Listing System, and other agency sources. Products submitted in response to the call-for-data are preceded by an asterisk (*). The mercury ingredients are abbreviated as TM for thimerosal, PMA for phenylmercuric acetate, PMN for phenylmercuric nitrate, MA for mercuric acetate, MN for mercuric nitrate, MB for merbromin, and MOY for mercuric oxide yellow. The list includes nonhomeopathic human and veterinary drug products and human biological products. Homeopathic drug products are not included because of the low amounts of mercury present in the product. The abbreviation NS under the % column means that the information was "not stated" in the agency's Drug Registration and Listing System.

	Manufacturer	Name of Product	Mercury Ingredient	%
	Akorn Inc.	AK Spore Ophthalmic Solution	TM	.001
	Akorn Inc.	AK Spore HC Ophthalmic Combo Drops	TM	NS
	Akorn Inc.	Fluoracaine Ophthalmic Solution	TM	NS
	Akom Inc.	AK Spore HC Otic Suspension	TM	NS
*	Alcon Laboratories	Profenal 1% Ophthalmic Solution	TM	.005
*	Alcon Laboratories	Adsorbonac 2% Ophthalmic Solution	TM	.004
*	Alcon Laboratories	Adsorbonac 5% Ophthalmic Solution	TM	.004
	ALK Laboratories Pharmacia	Coccidioidin Vaccine	TM	.01
	Allergan Inc.	Blephamide SOP Ophthalmic Ointment	PMA	.0008
	Allergan Inc.	Bleph-10 Ophthalmic Ointment 10%	PMA	.0008
	Allergan Inc.	FML SOP Ophthalmic Ointment 0.1%	PMA	.0008
	Allergan America	Ocufen Ophthalmic Solution	TM	.005
	Allergan Inc.	Poly Pred Ophthalmic Suspension	TM	.001
	Allergan America	Poly Pred Ophthalmic Suspension	TM	.001
	Altaire Pharmaceuticals	Nasal Relief 12 Hour Spray	PMA	NS
	American Assn. Retired Persons	Oxymetazoline Nasal Spray	PMA	.002
	American International Chemical	Thimerosal (bulk chemical)	TM	100
	American International Chemical	Thimerosal (bulk chemical)	TM	100
	American International Chemical	Thimerosal USP 97% (bulk chemical)	TM	97
	American Pharmaceutical	12 Hour Nasal Solution	PMA	NS

	Appletree Markets	Long Lasting Nasal Spray	PMA	NS
*	B. F. Ascher & Co.	Baby AYR Saline Nose Spray/Drops	TM	.00025
*	B. F. Ascher & Co.	AYR Saline Nasal Drops	TM	.00025
*	B. F. Ascher & Co.	AYR Saline Nasal Mist	TM	.00025
*	Bausch & Lomb	Flurbiprofen Sodium Ophthalmic Solution	TM	.005
*	Bausch & Lomb	Neomycin & Polymyxin B Sulfates & Gramicidin Ophthalmic Solution	TM	.001
*	Bausch & Lomb	Neomycin & Polymyxin B Sulfates & Hydrocortisone Otic Suspension	TM	.01
*	Bausch & Lomb	Sulfacetamide Sodium & Prednisolone Sodium Phosphate Ophthalmic Solution 10%/.23%	TM	.01
	Baxter Healthcare Corporation	Immune Globulin Vaccine	TM	.01
*	Bayer Corporation	Nasal Saline Moisturizer Spray	TM	.001
*	Bayer Corporation	Neo-Synephrine 12-Hour Nasal Decongestant Spray	PMA	.002
*	Bayer Corporation	Neo-Synephrine Extra Strength Drops	TM	.001
*	Bayer Corporation	Neo-Synephrine Mild Formula Spray	TM	.001
*	Bayer Corporation	Neo-Synephrine Regular Strength Spray	TM	.001
*	Bayer Corporation	Neo-Synephrine Extra Strength Spray	TM	.001
*	Bayer Corporation	Neo-Synephrine Regular Strength Drops	TM	.001
*	Bayer Corporation	Neo-Synephrine 12-Hour Extra Moisturizing Spray	PMA	.002
*	Berna Products	Tetanus Vaccine Adsorbed	TM	.01
	Bioport Corporation	Tetanus Toxoid Adsorbed	TM	.01
	Bioport Corporation	Rabies Vaccine Adsorbed	TM	.01
	Bioport Corporation	Immune Globulin (Human)	TM	.01
	Bioport Corporation	Pertussis Vaccine Adsorbed	TM	.01
	Bioport Corporation	Diphtheria & Tetanus Toxoids Adsorbed	TM	.01

	Bioport Corporation	Diphtheria & Tetanus Toxoids & Pertussis Vaccine Adsorbed	TM	.01
*	Bristol-Myers Squibb	Fungizone Lotion	TM	.01
*	Bristol-Myers Squibb	Fungizone Cream	TM	.01
	C.O. Truxton Inc.	Bio-Cot Otic Suspension	TM	.01
	C.O. Truxton Inc.	Decongest Nasal Spray	PMA	NS
	Carlisle Laboratories	Oxymetazoline Nasal Relief Spray	PMA	NS
	Carlisle Laboratories	Neomycin Polymyxin B Sulfates Gramicidin Ophthalmic Solution	TM	.01
	Carlisle Laboratories	Neomycin Polymyxin B Sulfates Hydrocortisone Otic Suspension	TM	.01
	Cheshire Pharmaceutical	Otocort Otic Suspension	TM	.01
	Cheshire Pharmaceutical	Ocutricin Ophthalmic Solution	TM	.01
	Cheshire Pharmaceutical	Sulfapred Ophthalmic Solution	TM	NS
	Clay Park Labs,	PREP Hemorrhoidal Ointment	MN	NS
	Clay Park Labs.	Little Noses Saline Spray/Drops	MA	.002
	Clay Park Labs	Cheracol Nasal Spray 12 Hour	PMA	.005
	Clay Park Labs	PREP-HEM Hemorrhoidal Suppositories	PMN	NS
	Clay Park Labs	Long Acting Nasal Spray	PMA	NS
	Conair Corp.	Decongestant Nasal Spray	PMA	NS
*	Connaught Laboratories	Diphtheria & Tetanus Toxoids Adsorbed	TM	.01
*	Connaught Laboratories	Diphtheria & Tetanus Toxoids & Pertussis Vaccine Adsorbed	TM	.01
*	Connaught Laboratories	Mumps Skin Test Antigen	TM	.01
*	Connaught Laboratories	Influenza Virus Vaccine, Trivalent, Types A & B	TM	.01
*	Connaught Laboratories	Tetanus Toxoid for Booster Use Only	TM	.01
*	Connaught Laboratories	Influenza Virus Vaccine, Trivalent, Types A & B	TM	.01

*	Connaught Laboratories	Haemophilus b Conjugate Vaccine Reconstituted with Diphtheria & Tetanus Toxoids & Acellular Pertussis Vaccine Adsorbed	TM	.01
*	Connaught Laboratories	Tetanus Toxoid Adsorbed	TM	.01
*	Connaught Laboratories	Diphtheria & Tetanus Toxoids & Acellular Pertussis Vaccine Adsorbed	TM	.01
*	Connaught Laboratories	Haemophilus b Conjugate Vaccine	TM	.01
*	Connaught Laboratories	Tetanus and Diphtheria Toxoids Adsorbed	TM	.01
*	Connaught Laboratories	Japanese Encephalitis Virus Vaccine	TM	.007
*	Connaught Laboratories	Diluent for Meningococcal Vaccine Groups	TM	0.1
	CVS Revco DS Inc.	12 Hour Decongestant Pump Nasal Spray	PMA	NS
	CVS	Nasal Spray Pump	PMA	NS
	Darby Group Companies	Neomycin Polymyxin B Sulfates Hydrocortisone Otic Suspension	TM	.01
	Dolder Ltd.	Thimerosal (bulk chemical)	TM	100
	Dorex International Corp.	Long Acting Nasal Spray	PMA	.002
	Drug Guild Distributors	Long Acting Decongestant Nasal Spray	PMA	NS
	Drug Guild Distributors	Nasal Spray 12 Hour Pump	PMA	NS
	Drug Guild Distributors	Long Acting Nasal Spray Kolex LA	PMA	.002
	DRX Pharmaceutical	Blephamide Ophthalmic Ointment	PMA	NS
	DRX Pharmaceutical	Cortisporin Ophthalmic Suspension	TM	.001
	DRX Pharmaceutical	Neomycin Polymyxin B Sulfates Hydrocortisone Ophthalmic Suspension	TM	NS
	DRX Pharmaceutical	Neomycin Polymyxin B Hydrocortisone Otic Suspension	TM	.01
	DRX Pharmaceutical	Neomycin Polymyxin B Gramicidin Ophthalmic Solution	TM	.01
	DRX Pharmaceutical	Vasocidin Ophthalmic Solution	TM	NS
	DRX Pharmaceutical	Colymycin S Otic Suspension	TM	.002
	DRX Pharmaceutical	Pediotic Otic Suspension	TM	NS

	Dysers Sal	Thimerosal (bulk chemical)	TM	NS
	Family Independent Pharmacy	12 Hour Nasal Decongestant Spray	PMA	NS
	Family Independent Pharmacy	Long Acting Nasal Spray	PMA	NS
	Farm Fresh Inc.	Hemorrhoid Relief Ointment	PMN	.01
	Fays Drug Services	12 Hour Nasal Spray Pump	PMA	NS
	Federated Foods	Long Acting Nasal Spray	PMA	.002
	Fleming Companies	12 Hour Nasal Spray	PMA	.002
	Foxmeyer Drug Co.	Nasal Spray Pump	PMA	NS
	Global Source	Nasin Long Acting Nasal Spray	PMA	NS
	Harco Drug	Mercurochrome Aqueous Solution	MB	2
	Harris-Teeter	Oxymetazoline Nasal Spray	PMA	.002
	Hi Tech Pharmacal Co.	Long Acting Nasal Spray	PMA	.002
	Hudson Corp.	Nasal Spray Extended Relief	PMA	NS
	Hurst Pharmaceutical	Duomycin-HC Otic Suspension	TM	.01
	K and B Distributors	Mercurochrome Aqueous Solution	MB	2
*	King Pharmaceuticals	Cortisporin Ophthalmic Suspension	TM	.001
*	King Pharmaceuticals	Neosporin Ophthalmic Suspension	TM	.001
*	King Pharmaceuticals	Viroptic Ophthalmic Solution	TM	.001
	King Pharmaceuticals	Neomycin Polymyxin B Sulfates Hydrocortisone Otic Suspension	TM	NS
*	King Pharmaceuticals	Pediotic Suspension	TM	.001
*	King Pharmaceuticals	Cortisporin Otic Suspension	TM	.01
	Kinray	Oxymetazoline Nasal Spray	PMA	.002
	Laboratori Derivati	Adrenal Cortex Injection	TM	.01
	Leader	12 Hour Nasal Spray	PMA	NS
	Leader	Nasal Pump Spray	PMA	NS
	Longs Drug Stores	Nasal Spray Pump	PMA	NS
	LS Raw Materials Ltd.	Mercurochrome NF 12 100% (bulk chemical)	MB	100

	Major Pharmaceuticals	Cortomycin Ophthalmic Suspension	TM	NS
	Major Pharmaceuticals	Sulfacetamide Sodium & Prednisolone Sodium Phosphate Ophthalmic Solution	TM	.01
	Major Pharmaceuticals	Cortomycin Otic Suspension	TM	.01
	Major Pharmaceuticals	Neocidin Ophthalmic Solution	TM	.01
	Martin Surgical Supply	Testosterone Injection Suspension 50 mg	TM	.008
	Martin Surgical Supply	Testosterone Injection Suspension 100 mg	TM	NS
*	Massachusetts Public Health Biologic Labs	Tetanus and Diphtheria Toxoids Adsorbed For Adult Use	TM	.003
*	Massachusetts Public Health Biologic Labs	Diphtheria and Tetanus Toxoids Adsorbed	TM	.01
	Mays Drug Stores	Hemorrhoid Relief Ointment	PMN	.01
	Medalist Laboratories	Long Lasting Nasal Spray Pump	PMA	NS
*	Medeva Pharmaceuticals	Influenza Virus Vaccine	TM	.01
*	Merck & Co.	Hepatitis B Vaccine, recombinant	TM	.005
*	Merck & Co.	Antivenin (Lactrodectus Mactans)	TM	.01
	Meyers Supply Inc.	Long Acting Nasal Spray	PMA	.002
	Naska Pharmacal Co.	Hemorrhoid Relief Ointment	PMN	.01
	Navresso	Long Acting Nasal Spray	PMA	NS
	North American Vaccine	Diphtheria & Tetanus Toxoids & Pertussis Adsorbed	TM	.01
	Omicron Quimica SA	Thimerosal USP 97% (bulk chemical)	TM	97
*	Ortho-Clinical Diagnostics	Rho (D) Immune Globulin (Human)	TM	.003
*	Ortho-Clinical Diagnostics	Rho (D) Immune Globulin (Human)	TM	.003
	Parade (Grocer's Supply)	Oxymetazoline Nasal Spray	PMA	.002
	Parke Davis	Elase-Chloromycetin Topical Ointment	TM	NS
*	Parkedale Pharmaceuticals	Coly-Mycin S Otic Suspension	TM	.002
*	Parkedale Pharmaceuticals	Influenza Virus Vaccine, Trivalent, Types A & B	TM	.01
	Pay N Save Corp.	Decongestant Nasal Spray	PMA	NS

	Pharmacia & Upjohn	Anti-Thymocyte Immune Globulin, Human	TM	.01
	Pharmacia & Upjohn	Allergen Patch Test	TM	[1]
	Pharmedix	Bleph 10 Ophthalmic Solution 10%	TM	.005
	Pharmedix	Viroptic Ophthalmic Solution 1%	TM	.001
	Pharmedix	Blephamide Ophthalmic Ointment	PMA	NS
	Pharmedix	Triple Antibiotic Ophthalmic Solution	TM	.01
	Pharmedix	Colymycin S Otic Solution	TM	.002
	Pharmedix	Neo Poly with HC Otic Suspension	TM	.01
	Physicians Total Care	NeoSynephrine Nasal Spray 0.25%	TM	NS
	Physicians Total Care Inc.	Neomycin Polymyxin B Sulfates Hydrocortisone Ophthalmic Suspension	TM	NS
	Physicians Total Care Inc.	Viroptic Ophthalmic Solution	TM	.001
	Physicians Total Care Inc.	Cortisporin Ophthalmic Suspension	TM	.001
	Physicians Total Care Inc.	Ocufen Ophthalmic Solution	TM	.0005
	Physicians Total Care Inc.	Vasocidin Ophthalmic Solution	TM	NS
	Ping On Ointment Co. Ltd.	Ping On Topical Ointment	Mercury	NS
	Prime Natural Health	12 Hour Nasal Spray	PMA	NS
	Primedics Laboratories	Testerone Injection Suspension 50 mg	TM	.008
	Publix Supermarkets	Long Acting Decongestant Nasal Spray	PMA	NS
	Publix Inc.	Long Acting Nasal Spray	PMA	NS
	Qualitest Pharmaceuticals	Nasal Spray Solution	PMA	NS
	Qualitest Pharmaceuticals	Antibiotic HC Otic Suspension	TM	NS
	RDS Acquisition Corp.	12 Hour Nasal Spray	PMA	NS
	Republic Drug Co.	12 Hour Nasal Spray	PMA	.002
	Rugby Laboratories	Nasal Relief Spray Long Acting	PMA	.002
	Schein Pharmaceutical	Neomycin Polymyxin B Sulfates Hydrocortisone Ophthalmic Suspension	TM	NS
	Schein Pharmaceutical	Sulfacetamide Sodium & Prednisolone Sodium Phosphate Ophthalmic Solution	TM	NS

	Schein Pharmaceutical	Testosterone Injection Suspension 100 mg	TM	NS
	Schein Pharmaceutical	Neomycin Polymyxin B Sulfates Hydrocortisone Otic Suspension	TM	.01
	Schein Pharmaceutical	Trifluridine Ophthalmic Solution	TM	NS
	Schein Pharmaceutical	Oxymetazoline HC1 Nasal Spray	PMA	NS
	Schein Pharmaceutical	Phenylephrine HC1 Nasal Solution 1%	TM	NS
*	Schering-Plough Animal Health	Gentocin Durafilm Ophthalmic Solution (for dogs only)	PMN	.002
	Scrivner, Inc.	Hemorrhoid Relief Ointment	PMN	.01
	Sight Pharmaceuticals	Neomycin Polymyxin B Sulfates Hydrocortisone Otic Suspension	TM	NS
	Sight Pharmaceuticals	Sulfacetamide Sodium & Prednisolone Sodium Phosphate Ophthalmic Solution	TM	.01
*	SmithKline Beecham	Hepatitis B Vaccine, recombinant	TM	.005
	Spectrum Quality Products	Merbromin (bulk chemical)	MB	100
	Spectrum Quality Products	Mercuric Oxide Yellow (bulk chemical)	MOY	100
	Spectrum Quality Products	Thimerosal (bulk chemical)	TM	100
	Spectrum Quality Products	Thimerosal (bulk chemical)	TM	100
	Super Laboratories	Long Acting Nasal Spray	PMA	NS
	Super D Drugs	Long Acting Nasal Spray	PMA	NS
*	Taro Pharmaceuticals	Taro Nasal Decongestant Spray	PMA	.002
	Teral Laboratories	Oticin HC Otic Suspension	TM	.01
	Thames Pharmacal Co.	12 Hour Nasal Spray	PMA	NS
	Thrift Drugs	Long Acting Nasal Spray	PMA	NS
	Thrifty Payless Inc.	Nasal Spray Pump Formula	PMA	NS
	Thrifty Payless Inc.	Decongestant Nasal Spray Pump	PMA	NS
	United Research Labs	Antibiotic Ear Suspension	TM	.01
	United Research Labs	Neomycin Polymyxin B Sulfates Gramicidin Ophthalmic Solution	TM	.01
	US Ophthalmics	Fluorescein Sodium Ophthalmic Solution	TM	NS

	US Ophthalmics	Sulf-10 Ophthalmic Solution	TM	NS
	US Ophthalmics	Vasocidin Ophthalmic Solution	TM	NS
	US Ophthalmics	Phenylephrine HC1 Ophthalmic Solution 10%	TM	NS
	USCO Logistics	Procofen Ophthalmic Solution	TM	.005
	USCO Logistics	Profenal Ophthalmic Solution	TM	.005
	VEDCO Inc.	Tribiotic Ophthalmic Solution	TM	NS
	Waldbaum Inc.	Hemorrhoidal Ointment	MN	NS
	Weeks and Leo Co. Inc.	Long Acting Nasal Spray Solution	PMA	.002
*	Whilehall-Robins	Dristan 12-Hour Nasal Spray	TM	.002
*	Wyeth Laboratories	Antivenin (Micrurus Fulvius)	TM	.005
*	Wyeth Laboratories	Normal Horse Serum (1:10 dilution)	TM	.005
*	Wyeth Laboratories	Influenza Virus Vaccine, Trivalent, Types A & B	TM	.01
*	Wyeth Laboratories	Diphtheria and Tetanus Toxoids Adsorbed	TM	.01
*	Wyeth Laboratories	Antivenin (crotalidae) Polyvalent	TM	.005
*	Wyeth Laboratories	Tetanus and Diphtheria Toxoids Adsorbed	TM	.01
*	Wyeth Laboratories	Tetanus Toxoid, fluid	TM	.01
*	Wyeth Laboratories	Tetanus Toxoid Adsorbed	TM	.01
*	Wyeth Laboratories	Wydase Lyophilized Solution	TM	.01
*	Wyeth Laboratories	Wydase Solution Stabilized	TM	.01
*	Wyeth Laboratories	Bacteriostatic Water for Injection	PMN	.001
*	Wyeth-Lederle Vaccines	Diphtheria and Tetanus Toxoids & Acellular Pertussis Vaccine Adsorbed	TM	.01
*	Wyeth-Lederle Vaccines	Pneumococcal Vaccine, Polyvalent	TM	.01
*	Wyeth-Lederle Vaccines	Diphtheria and Tetanus Toxoids & Pertussis Vaccine Adsorbed & Haemophilus b Conjugate Vaccine	TM	.01
*	Wyeth-Lederle Vaccines	Tetanus Toxoid Adsorbed	TM	.01
*	Wyeth-Lederle Vaccines	Tetanus and Diphtheria Toxoids Adsorbed	TM	.01

*	Wyeth-Lederle Vaccines	Diphtheria and Tetanus Toxoids Adsorbed	TM	.01
*	Wyeth-Lederle Vaccines	Haemophilus b Conjugate Vaccine	TM	.01

1. .0065 mg/patch.