

**Wyeth**

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March 19, 2003

Dockets Management Branch  
HFA-305  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

RE: Comments on Docket No. 98N-1109 Mercury Compounds in Drugs and Foods; List, published in the Federal Register / Vol. 68, No. 22 / Monday, February 3, 2003 / Notices

Dear Sir or Madam:

Wyeth Pharmaceuticals, a Division of Wyeth, hereby submits comments to the Notice; request for information, published in the Federal Register pertaining to the Mercury Compounds in Drugs and Foods List, Federal Register / Vol. 68, No. 22 / Monday, February 3, 2003, Docket No. 98N-1109.

Wyeth Pharmaceuticals is a major research-oriented pharmaceutical company with leading products in the areas of women's health, cardiovascular disease therapies, central nervous system drugs, anti-inflammatory agents, anti-infective agents, vaccines, and biopharmaceuticals. Wyeth is one of the world's largest research-based pharmaceutical and healthcare products companies, and is a leading developer, manufacturer, and marketer of prescription drugs and over-the-counter medications.

The attached table (Attachment I) represents the 19 mercury-containing products which were published in the August 9, 2001 version of the "Mercury in Drug and Biologic Products" list and which were manufactured, marketed, and/or distributed by Whitehall-Robins, Wyeth Laboratories, or Wyeth-Lederle Vaccines (all of which are businesses of Wyeth). Of the 19 products listed at the time, only four remain on the market. Of the remaining 15 products (shaded in Attachment I, items 1, 5, 7-19), 14 have been discontinued and are no longer manufactured or marketed by Wyeth. The other product (item 19), the multi-dose vial presentation of Haemophilus b Conjugate Vaccine, is no longer manufactured or marketed, and only the preservative-free, single-dose vial presentation remains on the market. Therefore, Wyeth requests that items 1, 5, and 7-19 be removed from the "Mercury in Drug and Biologic Products" list.

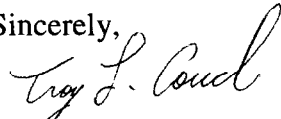
98N-1109

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# Wyeth

This letter, along with Attachment I, is submitted in duplicate. Wyeth appreciates the opportunity to provide this constructive input in ensuring up-to-date information is available to the FDA and the public. Please contact the undersigned at 845-602-4482 if there are any questions regarding the submitted comments.

Sincerely,

A handwritten signature in black ink that reads "Troy L. Couch". The signature is written in a cursive style with a large, looping initial "T".

Troy L. Couch, Ph.D.

### ATTACHMENT I

Item	Notation	Manufacturer	Name of Product	Ingredient	%
1	I, II	Whitehall-Robins	Dristan 12-Hour Nasal Spray	TM	.002
2	III	Wyeth Laboratories	Antivenin (Micrurus Fulvius)	TM	.005
3	III	Wyeth Laboratories	Normal Horse Serum (1:10 dilution)	TM	.005
4	II, IV	Wyeth Laboratories	Influenza Virus Vaccine, Trivalent, Types A&B	TM	.01
5	II	Wyeth Laboratories	Diphtheria and Tetanus Toxoids Adsorbed	TM	.01
6	III	Wyeth Laboratories	Antivenin (crotalidae Polyvalent)	TM	.005
7	II	Wyeth Laboratories	Tetanus and Diphtheria Toxoids Adsorbed	TM	.01
8	II	Wyeth Laboratories	Tetanus Toxoid, fluid	TM	.01
9	II	Wyeth Laboratories	Tetanus Toxoid Adsorbed	TM	.01
10	II	Wyeth Laboratories	Wydase Lyophilized Solution	TM	.01
11	II	Wyeth Laboratories	Wydase Solution Stabilized	TM	.01
12	II	Wyeth Laboratories	Bacteriostatic Water for Injection	PMN	.001

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13	II	Wyeth-Lederle Vaccines	Diphtheria and Tetanus Toxoids & Acellular Pertussis Vaccine Adsorbed	TM	.01
14	II	Wyeth-Lederle Vaccines	Pneumococcal Vaccine, Polyvalent	TM	.01
15	II	Wyeth-Lederle Vaccines	Diphtheria and Tetanus Toxoids & Pertussis Vaccine Adsorbed & Haemophilus b Conjugate Vaccine	TM	.01
16	II	Wyeth-Lederle Vaccines	Tetanus Toxoid Adsorbed	TM	.01
17	II	Wyeth-Lederle Vaccines	Tetanus and Diphtheria Toxoids Adsorbed	TM	.01
18	II	Wyeth-Lederle Vaccines	Diphtheria and Tetanus Toxoids Adsorbed	TM	.01
19	II	Wyeth-Lederle Vaccines	Haemophilus b Conjugate Vaccine	TM	.01

NOTATIONS:

- I. The NDA for this product (Dristan 12-Hour Nasal Spray) was sold to Baxter. Expiration of last lot of product distributed by Wyeth was Dec. 2002.
- II. Product which is no longer manufactured or marketed by Wyeth.
- III. Product which is currently manufactured and marketed by Wyeth.
- IV. Product (Influenza Virus Vaccine, Trivalent, Types A&B) for which Wyeth no longer manufactures or markets. There will be no in-date product on the market after June 2003.

TM = Thimerosal

PMN = Phenylmercuric nitrate