

Aventis Pasteur



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

Re: Docket No. 98N-1109

Mercury Compounds in Drugs and Food [68 FR 5299, February 3, 2003]

04 April 2003

Dear Sir/Madam:

Aventis Pasteur is providing the following update in response to the request for information published in the Federal Register Notice of 03 February 2003 to update the list entitled "Mercury in Drug and Biologic Products" as part of the requirements related to Section 413 of FDAMA (21 November 1997).

The listing below provides a summary of Aventis Pasteur vaccines that contain thimerosal.

- Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed Tripedia[®] *Preservative Free*. The concentration of mercury (Hg) in this reformulated vaccine has been reduced to a trace level.
- Influenza Virus Vaccine, Fluzone[®] *Preservative-free* Pediatric Dose. Fluzone[®] *Preservative-free*, is the US-licensed influenza vaccine approved for immunization of infants and young children from 6 to 24 months of age. The concentration of mercury (Hg) in this reformulated vaccine has been reduced to a trace level.
- Diphtheria and Tetanus Toxoids Adsorbed USP (For Pediatric Use) *Preservative-free*. The concentration of mercury (Hg) in this reformulated vaccine has been reduced to a trace level.
- Meningococcal Polysaccharide Vaccine Groups A, C, Y and W-135 Combined, Menomune[®] – A/C/Y/W-135. Thimerosal has been removed from the diluent for the single dose presentation. The vial of diluent for the multi-dose presentation contains thimerosal.

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- Tetanus and Diphtheria Toxoids Adsorbed Vaccine (Td) (For Adult Use) contains thimerosal as a preservative.
- Influenza Virus Vaccine, Fluzone[®], multidose and 0.5mL syringe presentations contain thimerosal as a preservative.

Should you require any additional information, please address inquiries directly to Kenneth P. Guito, Director, Regulatory Policy and Intelligence, by telephone at (570) 839-4212, by facsimile at (570) 839-5529, or by email at ken.guito@aventis.com.

Sincerely,

A handwritten signature in cursive script that reads "Kenneth P. Guito".

f Luc Kuykens, MD, MPH, DTM
Vice President, Regulatory Affairs, North America
and Authorized Official

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