

Aventis Pasteur



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Karen Midthun, M.D. (HFM-400)
Office of Vaccines Research and Review
Division of Vaccines and Related Products Applications
Center for Biologics Evaluation and Research
Food and Drug Administration
c/o Document Control Center (HFM-99)
Woodmont Office Center, Suite 200N
1401 Rockville Pike
Rockville, MD 20852-1448

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DUPLICATE

27 September 2002

Dear Dr. Midthun,

Aventis Pasteur has reviewed the Citizen's Petition sent by Dr. J. Barthelow Classen to the Dockets Management Branch, Food and Drug Administration, on 2 August 2002. In this document, Dr. Classen requests the Commissioner of Food and Drugs to amend the product insert and/or labelling for Haemophilus vaccines.

Dr. Classen's request is based on the hypothesis that immunization with Haemophilus influenzae type b conjugate vaccine causes type 1 diabetes in children. To support his view, Dr. Classen presents data from his studies with non-obese diabetes prone mice, as well as analysis of the epidemiologic data on relationship between Haemophilus vaccinations and type 1 diabetes. In his letter, Dr. Classen also reviews the design of other studies on the same subject, which he feels are flawed and hide the association between vaccines and diabetes.

Three expert groups have recently reviewed scientific evidence on the link between Haemophilus vaccinations and risk of type 1 diabetes. These groups include The Institute of Vaccine Safety Diabetes Workshop, the European Vaccine Manufacturers' Working Group, and the Institute of Medicine's Immunization Safety Review Committee. All the above groups have concluded that no causal association between Haemophilus influenzae immunization and type 1 diabetes can be confirmed.

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Aventis Pasteur has reviewed the data presented in Dr. Classen's letter, as well as recent scientific publications on the subject. We conclude that there is no such data available that would suggest that Haemophilus influenzae vaccines would cause type 1 diabetes, and the conclusions of the above mentioned expert groups are valid.



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Based on this, we believe that no changes are warranted on the labelling components and package insert for these vaccines. Should you have any comments, or wish to discuss this issue further, please contact Kenneth P. Guito, Director, Regulatory Policy and Intelligence, directly at (570) 839-4212.

Sincerely,

A handwritten signature in black ink that reads "Kenneth P. Guito".

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

LK/KPG/kh