Aventis Pasteur

Aventis

1929 '03 APR 14 A8:01

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

Re: Docket No. 03N-0016
MedWatch: The FDA Medical Products Reporting Program, Forms FDA 3500 and FDA 3500A
[68 FR 6752, February 10, 2003]

11 April 2003

Dear Sir/Madam:

Aventis Pasteur Inc. of Swiftwater, Pennsylvania thanks the Food and Drug Administration (FDA) for the opportunity to comment on the above-referenced notice entitled "Agency Information Collection Activities; Proposed Collection; MedWatch: The FDA Medical Products Reporting Program; Comment Request" for input on the structure and use of the current forms (Form FDA 3500 and Form FDA 3500A).

We offer the following comments for your consideration as they apply to the biologics (vaccine) industry:

We believe it might be useful to add spaces in **Section C. Suspect medication(s)**, after **box 8**, on both FDA Forms 3500 and 3500A for:

1) History of Previous Event with same or related product

2) Immediate outcome (if known)

On behalf of Aventis Pasteur Inc., we appreciate the opportunity to comment on this information collection notice and thank you for your consideration of these comments. Should you like to discuss any of our comments or concerns further, please address inquiries directly to Kenneth P. Guito, Director, Regulatory Policy and Intelligence, by telephone at (570) 839-4212, or by facsimile at (570) 839-5529, or by e-mail at ken.guito@aventis.com.

Sincerely,

Kenneth P. Guito

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

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