Aventis Pasteur

Aventis

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16 September 2003

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

Re: Docket No. 03N-0059; Pharmaceutical Current Good Manufacturing Practices for the 21st Century: A Risk-Based Approach [68 Federal Register 9092, February 27, 2003]; **Progress Report of the Working Group on Product Specialists on Inspection Teams**

Dear Sir/Madam,

Aventis Pasteur Inc. of Swiftwater, Pennsylvania thanks the Food and Drug Administration (FDA) for the opportunity to further comment on the above-referenced report entitled, ***"Progress Report of the Working Group on Product Specialists on Inspection Teams."*** Aventis Pasteur Inc. is part of the Aventis Pasteur family of companies, which consists of the parent firm Aventis Pasteur SA, headquartered in Lyon, France, Aventis Pasteur Inc., and other subsidiaries (collectively Aventis Pasteur). In turn, Aventis Pasteur SA is a subsidiary of Aventis SA.

Aventis Pasteur is a world leader in vaccines and produces more than one billion doses of vaccines every year to immunize 400 million people around the world. Aventis Pasteur, in close consultation with the US public health establishment, including the FDA, and Centers for Disease Control and Prevention (CDC), strives to alleviate the suffering and death of vaccine-preventable diseases.

We offer the following comments for your consideration concerning the FDA's solicitation of responses as they apply to the Biologics (Vaccine) industry.

Aventis Pasteur emphatically supports the practice of including experienced CBER Product Specialists on Team Biologics CGMP inspections. The inclusion of CBER Product Specialists as an integral part of the *Team* during inspections of Vaccine Manufacturer sites has been a relatively common practice since the mid-1990's. We believe this represents *FDA Best Practices* that could be applied more broadly as part of the ongoing FDA GMP initiative.

Our experience has been that these Product Specialists provide a science-based expertise that facilitates the overall inspection process. Product Specialists who are familiar with the product or product class, the terms of the product license and the application and interpretation of biological testing that supports CGMP manufacturing, add measurably to the process and complement the inspection management expertise provided by the Office of Regulatory Affairs (ORA) and/or FDA Field Staff.

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Aventis Pasteur agrees with FDA's observation as noted in this Working Group Report that collaboration by various parts of the Agency improves regulatory effectiveness and consistency and helps to minimize technical disputes during these inspections. In addition, we believe that public health will be better served through the effective use of FDA resources and the application of risk management approaches to assess risk and to identify and prioritize real issues.

On behalf of Aventis Pasteur Inc., we appreciate the opportunity to comment on this Progress Report of the Working Group on Product Specialists on Inspection Teams and thank you for your consideration of these responses. Should you wish 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 email at ken.guito@aventis.com.

Sincerely,

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

LK/KPG/kh