

Aventis Pasteur



1 December 2004

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

Re: Docket No. 2004D-0443; Draft Guidance for Industry on Quality Systems Approach to Pharmaceutical Current Good Manufacturing Practice Regulations [69 Federal Register 59256, October 4, 2004]

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Pennsylvania thanks the Food and Drug Administration (FDA) for the opportunity to comment on the above-referenced draft guidance for industry entitled, "Quality Systems Approach to Pharmaceutical Current Good Manufacturing Practice Regulations." 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.

2004D-0443

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General Comment

The majority of the guidance document provides a high level assessment of what a quality unit must contain, the responsibilities of management in establishing quality systems, and the function of the quality system. The guidance document also reflects its ISO influence concerning the criticality of the role of management in the quality process.

Specific Comments

Aventis Pasteur agrees with the basic concepts of the guidance document, as well as the philosophy expressed in Lines 81 and 82:

Quality should be built into the product, and testing alone cannot be relied on to ensure product quality.

In Lines 98-103 the document states:

The FDA has concluded that modern quality systems, when coupled with manufacturing process and product knowledge, can handle many types of changes to facilities, equipment, and processes without the need for a regulatory submission. Manufacturers with appropriate process knowledge and a robust quality system should be able to implement many types of improvements without the need for a prior regulatory filing. In addition, an effective quality system, by lowering the risk of manufacturing problems, may result in shorter and fewer FDA inspections.

Aventis Pasteur notes that FDA has made some broad and powerful statements in this passage regarding changes that can be made to facilities, equipment and processes without the requirement of a prior regulatory filing. As this statement is so broad, it would be beneficial if FDA could provide some specific circumstances or examples in which a regulatory filing would not be required.

The guidance document indicates there will be a six-system inspection model (begins Line 239), with the Quality System being the main focus. However, little information is provided on the other five systems: Materials System, Laboratory Controls System, Facilities and Equipment System, Production System, and Packaging and Labeling System. It would be beneficial to make more specific information available on these systems, as well as on management of information and computer systems.

Aventis Pasteur



On behalf of Aventis Pasteur Inc., we appreciate the opportunity to comment on this draft guidance 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 Denise Rieker, Manager, Regulatory Policy and Intelligence, by telephone at (570) 895-3465, or by email at denise.rieker@aventis.com.

Sincerely,

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

Kenneth P. Guito
Global Head, Regulatory Policy and Intelligence

KPG/DR/kh