



sanofi aventis

September 22, 2005

Via fax and UPS

11267 5 SEP 26 P3:27

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

Re: Docket No. 2005D-0288

Draft Guidance for Industry on ICH Q9 Quality Risk Management

Dear Sir/Madam:

Sanofi-Synthelabo Inc. and Aventis Pharmaceuticals, members of the sanofi-aventis Group, appreciate the opportunity to comment on the above-referenced Draft Guidance entitled "ICH Q9 Quality Risk Management".

This draft guidance provides principles and examples of tools for quality risk management that can be applied to all aspects of pharmaceutical quality throughout the lifecycle of drug substances, drug products, and biological and biotechnological products.

We have evaluated the content of the draft guidance and offer the following comments and/or clarifications for your consideration.

GENERAL COMMENTS

- The guideline provides a comprehensive overview over the possibilities of quality risk management.
- The guideline is very general in nature. It would be helpful to develop an understanding from a theoretical perspective which steps could be applied and which tools used. In particular, Annex I provides an understanding of where to apply the guidance.
- It is not totally clear how the guidance will be interpreted and used by regulators.

2005D-0288

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SPECIFIC COMMENTS:**Section 3. PRINCIPLES OF QUALITY RISK MANAGEMENT**

As protection of the patient is the key principle, we suggest rewording the title specifically to: "*Pharmaceutical Quality Risk Management*".

Annex 1.3 Quality Risk Management as Part of Development

This section on Quality Risk Management (QRM) as Part of Development is not very detailed, however, there are other sections covering issues that relate to development (i.e. QRM for Facilities, Equipment and Utilities 1.4, QRM as Part of Materials Management 1.5) that do not seem to be geared towards development such as cleaning validation and providing appropriate consideration for ensuring the availability of pharmaceuticals. The development section should include differences for development or the particular sections should detail the differences.

Annex 1.4 Quality Risk Management for Facilities, Equipment and Utilities

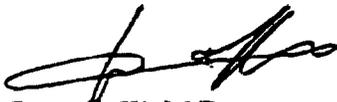
Under the subheading "*Computer systems and computer controlled equipment*", it specifies code review, however this is typically performed by the vendor. The client typically performs a verification through SAT and IQ/OQ. Therefore, we suggest rewording the next sentence to read:

To determine the extent of validation, *even when performed by the vendor*, e.g.

- identification of critical performance parameters;
- selection of the requirements and design;
- code review;
- the extent of testing and test methods;
- reliability of electronic records and signatures.

On behalf of Sanofi-Synthelabo Inc. and Aventis Pharmaceuticals, members of the sanofi-aventis Group, we appreciate the opportunity to comment on the *Draft Guidance for Industry ICH Q9 Quality Risk Management* and are much obliged for your consideration.

Sincerely,



Steve Caffé, M.D.
Vice President, US Deputy Head
Regulatory Development



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0314 5 SEP 27 10:43

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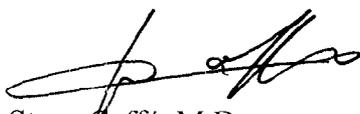
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