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European Commission
Pharmaceuticals Unit
Att.: entr-pharmaceuticals@ec.europa.eu

Chilly-Mazarin, December 18, 2009

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Sanofi-aventis and Sanofi Pasteur response on the public consultation paper "*Assessment of the functioning of the Clinical Trials Directive 2001/20/EC*"

Sanofi-aventis and Sanofi Pasteur appreciate the opportunity to comment on the public consultation on the functioning of the Clinical Trials Directive. Enclosed you will find our response to the public consultation paper.

Sanofi-aventis and Sanofi Pasteur welcome all efforts aiming at addressing and solving the issues identified with the implementation of the Clinical Trials Directive. Steps toward better harmonisation of authorisation of clinical trials and their follow-up are necessary. For ensuring that all clinical trials conducted in the Community are subject to the same criteria for the approval and supervision, we believe the requirements should be established and enforced by a Regulation. This would enable to homogenise evaluation process in the EU and to optimize timelines without decreasing the level of protection of patients. We believe as well that the nature/stringency of the requirements and obligations should not be driven by the status/identity of the sponsor.

We wish to inform you that we have contributed to, and support, the comments submitted by the European Federation of Pharmaceutical Industries and Associations (EFPIA).

In conclusion, sanofi-aventis and Sanofi Pasteur appreciate the opportunity to comment on various options for improving the functioning of the Clinical Trials Directive in order to strengthen medical research and optimal clinical trial implementation in the EU and hope the comments provided are useful in the legislative development process.

Sincerely,

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Associate Vice President, Europe Regulatory Policy & General Affairs
Corporate Regulatory Affairs

L'essentiel c'est la santé.

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