EXPLANATORY NOTE

(This note is not part of the Order)

These Regulations make consequential amendments to the references in the Good Laboratory Practice Regulations 1999, the Medicines and Healthcare Products Regulatory Agency Trading Fund Order 2003 and the Cosmetic Products (Safety) Regulations 2003 following the adoption of the European Parliament and Council Directives 2004/9/EC and 2004/10/EC. Those Codification Directives repealed and re-enacted Council Directive 87/18/EEC as amended by Commission Directive 1999/11/EC and Council Directive 88/320/EEC as amended by Commission Directive 1999/12/EC.

The Notification of New Substances Regulations 1993 are amended to update the definition of the "principles of good laboratory practice".

In addition these Regulations amend the Good Laboratory Practice Regulations 1999 definition of "regulatory study" to improve the clarity of the wording of the definition and make a minor amendment to Regulation 5(4) to correct a drafting error.

A Transposition Note in respect of Directives 2004/9/EC and 2004/10/EC has been placed in the libraries of both Houses of Parliament, and copies can be obtained from the Medicines and Healthcare products Regulatory Agency, Room 16-107, Market Towers, 1 Nine Elms Lane, London SW8 5NQ. These Regulations do not impose any cost on business.