SCHEDULE 1

GOOD LABORATORY PRACTICE PRINCIPLES **[**[F1](BASED ON SECTION II OF ANNEX I TO THE EUROPEAN PARLIAMENT AND COUNCIL DIRECTIVE 2004/10/EC)**]**

Textual Amendments

F1 Words in Sch. 1 heading substituted (27.4.2004) by The Good Laboratory Practice (Codification Amendments Etc.) Regulations 2004 (S.I. 2004/994), regs. 1, **2(d)**

PART I

TEST FACILITY ORGANISATION AND PERSONNEL

Study director's responsibilities

2.—(1) The study director is the single point of study control and has the responsibility for the overall conduct of the regulatory study and for its final report.

(2) These responsibilities should include, but not be limited to, the following functions. The study director should—

(a) approve the study plan and any amendments to the study plan by dated signature;

(b) ensure that the quality assurance personnel have a copy of the study plan and any amendments in a timely manner and communicate effectively with the quality assurance personnel as required during the conduct of the study;

(c) ensure that study plans and amendments and standard operating procedures are available to study personnel;

(d) ensure that the study plan and the final report for a multi-site study identify and define the role of any principal investigators and any test facilities and test sites involved in the conduct of the study;

(e) ensure that the procedures specified in the study plan are followed, and assess and document the impact of any deviations from the study plan on the quality and integrity of the study, and take appropriate corrective action if necessary; and acknowledge deviations from standard operating procedures during the conduct of the study;

(f) ensure that all raw data generated are fully documented and recorded;

(g) ensure that computerised systems used in the study have been validated;

(h) sign and date the final report to indicate acceptance of responsibility for the validity of the data and to indicate the extent to which the study complies with the principles of good laboratory practice;

(i) ensure that after completion (including termination) of the regulatory study, the study plan, the final report, raw data and supporting material are archived.

Changes to legislation:
There are currently no known outstanding effects for the The Good Laboratory Practice Regulations 1999, Paragraph 2.