SCHEDULE 1

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

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 II

QUALITY ASSURANCE PROGRAMME

General

1.—(1) The test facility should have a documented quality assurance programme to assure that regulatory studies performed are in compliance with the principles of good laboratory practice.

(2) The quality assurance programme should be carried out by an individual or by individuals designated by and directly responsible to management and who are familiar with the test procedures.

(3) This individual or these individuals should not be involved in the conduct of the regulatory study being assured.

Responsibilities of the quality assurance personnel

2. The responsibilities of the quality assurance personnel should include, but not be limited to, the following functions. They should—

(a) maintain copies of all approved study plans and standard operating procedures in use in the test facility and have access to an up-to-date copy of the master schedule;

(b) verify that the study plan contains the information required for compliance with the principles of good laboratory practice. The verification should be documented;

(c) conduct inspections to determine if all studies are conducted in accordance with the principles of good laboratory practice. Inspections should also determine that study plans and standard operating procedures have been made available to study personnel and are being followed. Inspections can be of three types, as specified by quality assurance programme standard operating procedures—

—study based inspections,

—facility based inspections,

—process based inspections,

and records of such inspections should be retained;

(d) inspect the final reports to confirm that the methods, procedures, and observations are accurately and completely described, and that the reported results accurately and completely reflect the raw data of the regulatory study;

(e) promptly report any inspection results in writing to management and to the study director, and to any principal investigator and the respective management, when applicable;

(f) prepare and sign a statement, to be included with the final report, which specifies the types of inspections and their dates, including the phase of a study inspected, and the dates inspection results were reported to management and the study director and any principal

investigators, if applicable. This statement would also serve to confirm that the final report reflects the raw data.

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