SCHEDULE 1

GOOD LABORATORY PRACTICE PRINCIPLES(BASED ON SECTION II OF THE ANNEX TO COUNCIL DIRECTIVE 87/18/EEC,AS AMENDED BY COMMISSION DIRECTIVE 1999/11/EC)

PART X

STORAGE AND RETENTION OF RECORDS AND MATERIALS

1.—(1) The following should be retained in the archives for the period specified by the appropriate regulatory authorities—

(a) the study plan, raw data, samples of test and reference items, specimens and the final report of each regulatory study;

(b) records of all inspections performed by the quality assurance programme, as well as master schedules;

(c) records of qualifications, training, experience and job descriptions of personnel;

(d) records and reports of the maintenance and calibration of apparatus;

(e) validation documentation for computerised systems;

(f) the historical file of all standard operating procedures;

(g) environmental monitoring records.

(2) In the absence of a required retention period, the final disposition of any study materials should be documented. When samples of test and reference items and speciments are disposed of before the expiry of the required retention period for any reason, this should be justified and documented. Samples of test and reference items and specimens should be retained only as long as the quality of the preparation permits evaluation.

2. Material retained in the archives should be indexed so as to facilitate orderly storage and retrieval.

3. Only personnel authorised by management should have access to the archives. Movement of material in and out of the archives should be properly recorded.

4. If a test facility or an archive contracting facility goes out of business and has no legal successor, the archive should be transferred to the archives of the sponsor of the regulatory study.