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 IX

REPORTING OF REGULATORY STUDY RESULTS

General

1.—(1) A final report should be prepared for each regulatory study. In the case of short-term studies, a standardised final report accompanied by a study specific extension may be prepared.

(2) Reports of principal investigators or scientists involved in the regulatory study should be signed and dated by them.

(3) The final report should be signed and dated by the study director to indicate acceptance of responsibility for the validity of the data. The extent of compliance with these principles of good laboratory practice should be indicated.

(4) Corrections and additions to a final report should be in the form of amendments. Amendments should clearly specify the reason for the corrections or additions and should be signed and dated by the study director.

(5) Reformatting of the final report to comply with the submission requirements of a national registration or regulatory authority does not constitute a correction, addition or amendment to the final report.

Content of the Final Report

2. The final report should include, but not be limited to, the following information—

Identification of the regulatory study, the test item and the reference item

(a) (i) a descriptive title,

(ii) identification of the test item by code or name (IUPAC, CAS number, biological parameters etc.),

(iii) identification of the reference item by name,

(iv) characterisation of the test item including purity, stability and homogeneity;

Information concerning the sponsor and the test facility

(i) name and address of the sponsor,

(ii) name and address of any test facilities and test sites involved,

(iii) name and address of the study director,

(iv) name and address of any principal investigators and the phase of the study delegated, if applicable,

(v) name and address of scientists having contributed reports to the final report;

(b)

Information concerning the sponsor and the test facility

(i) name and address of the sponsor,

(ii) name and address of any test facilities and test sites involved,

(iii) name and address of the study director,

(iv) name and address of any principal investigators and the phase of the study delegated, if applicable,

(v) name and address of scientists having contributed reports to the final report;

Dates

(c) experimental starting and completion dates;

Statement

(d) a quality assurance programme statement listing the types of inspections made and their dates, including the phases inspected, and the dates any inspection results were reported to management and to the study director and any principal investigators, if applicable. This statement would also serve to confirm that the final report reflects the raw data;

Description of materials and test methods

(e) (i) description of methods and materials used,

(ii) reference to OECD test guidelines or other test guidelines or methods;

Results

(f) (i) a summary of results,

(ii) all information and data required in the study plan,

(iii) a presentation of the results, including calculations and determinations of statistical significance,

(iv) an evaluation and discussion of the results and, where appropriate, conclusions;

Storage

(g) the location where the study plan, samples of test and reference items, specimens, raw data, and the final report are to be stored.