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 IX

REPORTING OF REGULATORY STUDY RESULTS

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;

(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.

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