SCHEDULE 1

PRINCIPLES OF GOOD LABORATORY PRACTICE (BASED ON ANNEX 2 TO THE DECISION OF 12TH MAY 1981 OF THE COUNCIL OF THE OECD ON THE MUTUAL ACCEPTANCE OF DATA FOR THE EVALUATION OF CHEMICAL PRODUCTS)

PART I

LABORATORY ORGANISATION AND PERSONNEL

The management's responsibilities

1.—(1) Laboratory management should ensure that the principles of good laboratory practice are complied with in laboratory premises.

(2) At a minimum it should—

(a) ensure that qualified personnel, appropriate facilities, equipment, and materials are available;

(b) maintain a record of the qualifications, training, experience and job description for each professional and technical individual;

(c) ensure that personnel clearly understand the functions they are to perform and, where necessary, provide training for those functions;

(d) ensure that health and safety precautions are applied according to national and/or international regulations;

(e) ensure that appropriate standard operating procedures are established and followed;

(f) ensure that there is a quality assurance programme with designated personnel;

(g) where appropriate, agree the study plan in conjunction with the sponsor;

(h) ensure that amendments to the study plan are agreed upon and documented;

(i) maintain copies of all study plans;

(j) maintain a historical file of all standard operating procedures;

(k) for each safety study ensure that a sufficient number of personnel is available for its timely and proper conduct;

(l) for each safety study designate an individual with appropriate qualifications, training, and experience as the study director before the safety study is initiated. If it is necessary to replace a study director during a safety study, this should be documented;

(m) ensure that an individual is identified as responsible for the management of the archives.

The study director's responsibilities

2.—(1) The study director has the responsibility for the overall conduct of the safety study and for its report.

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

(a) agreeing to the study plan;

(b) ensuring that the procedures specified in the study plan are followed, and that authorisation for any modification is obtained and documented together with the reasons for them;

(c) ensuring that all data generated are fully documented and recorded;

(d) signing and dating the final report to indicate acceptance of responsibility for the validity of the data and to confirm compliance with the principles of good laboratory practice;

(e) ensuring that after termination of the safety study, the study plan, the final report, raw data and supporting material are transferred to the archives.

Personnel responsibilities

3.—(1) Personnel should exercise safe working practices. Chemicals should be handled with suitable caution until their hazard has been established.

(2) Personnel should exercise health precautions to minimise risk to themselves and to ensure the integrity of the safety study.

(3) Personnel known to have a health or medical condition that is likely to have an adverse effect on the safety study should be excluded from operations that may affect the safety study.