SCHEDULE 2

INSPECTION PROCEDURES AND STUDY AUDITS (BASED ON ANNEX B TO THE GLP INSPECTION AND VERIFICATION DIRECTIVE)

PART II

STUDY AUDITS

16. Laboratory inspections will generally include *inter alia*(limited) study audits. These may be brief reviews of on-going or completed studies. When specific study audits are requested by regulatory authorities, the conduct and reporting of the study should be subjected to a detailed examination. Because of the wide variation in the types of studies which might be audited, only general guidance is appropriate, and inspectors and others taking part in study audits will always need to exercise judgment as to the nature and extent of their examinations. The objective should be to reconstruct the study from the study plan using relevant standard operating procedures, raw data and other archived material.

17. In some cases, inspectors may need assistance from other experts in order to conduct an effective study audit, e.g. where there is a need to examine tissue sections under the microscope.

18. When conducting a study audit, the inspector should—

— obtain names, job descriptions and summaries of training and experience for selected personnel engaged in the study(ies) such as the study director and principal scientists,

— check that there are sufficient staff trained in relevant areas for the study(ies) undertaken,

— identify individual items of apparatus or special equipment used in the study and examine the calibration, maintenance and service records for the equipment,

— review the records relating to the stability of the test substances, analyses of test substance and formulations, analyses of feed, etc.,

— attempt to determine, through the interview process if possible, the work assignments of selected individuals participating in the study to ascertain if these individuals had the time to accomplish the tasks specified in the study plan or report,

— obtain copies of all documentation concerning control procedures or forming integral parts of the study, including—

  (i) the study plan,

  (ii) standard operating procedures in use at the time the study was done,

  (iii) log books, laboratory notebooks, files, worksheets, print-outs of computer stored data, etc.,

  (iv) the final report.

19. In studies in which animals (i.e. rodents and other mammals) are used, the inspectors should follow a certain percentage of individual animals from their arrival at the laboratory to autopsy. They should pay particular attention to the records relating to—

— animal body weight, food/water intake, dose formulation and administration etc.,

— clinical observations and autopsy findings,

— clinical chemistry,

— pathology.