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 VI

TEST AND REFERENCE ITEMS

Receipt, handling, sampling and storage

1.—(1) Records including test item and reference item characterisation, date of receipt, expiry date, quantities received and used in regulatory studies should be maintained.

(2) Handling, sampling, and storage procedures should be identified in order that the homogeneity and stability are assured to the degree possible and contamination or mix-up are precluded.

(3) Storage containers should carry identification information, expiry date, and specific storage instructions.

Characterisation

2.—(1) Each test and reference item should be appropriately identified (eg code, chemical abstracts service registry number (CAS number), name, biological parameters etc.).

(2) For each regulatory study, the identity, including batch number, purity, composition, concentrations, or other characteristics to appropriately define each batch of the test or reference items should be known.

(3) In cases where the test item is supplied by the sponsor, there should be a mechanism, developed in co-operation between the sponsor and the test facility, to verify the identity of the test item subject to the study.

(4) The stability of test and reference items under storage and test conditions should be known for all regulatory studies.

(5) If the test item is administered or applied in a vehicle, the homogeneity, concentration and stability of the test item in that vehicle should be determined. For test items used in field studies (eg tank mixes), these may be determined through separate laboratory experiments.

(6) A sample for analytical purposes from each batch of test item should be retained for all regulatory studies except short-term studies.