SCHEDULE 1

Regulation 4(5)

REQUIREMENTS IN RESPECT OF PRODUCTS OTHER THAN IMMUNOLOGICAL PRODUCTS

1. The applicant shall comply with all the requirements set out in Parts 1 and 4 of Title I of the Annex to Council Directive 81/852/EEC.

2.—(1) Subject to sub-paragraphs (2) and (3) below, the applicant shall comply with the requirements set out in Part 2 of Title I of the Annex to Council Directive 81/852/EEC.

(2) Where at the request of the applicant a manufacturer of an active ingredient of the product submits details concerning the method of manufacture, quality control during manufacture and process validation directly to the Ministers, the applicant shall obtain from the manufacturer—

(a) all the data necessary for him to take responsibility for the product,

(b) written confirmation that the manufacturer will ensure batch to batch consistency and inform the applicant before he modifies the manufacturing process, and

(c) written confirmation that the manufacturer will supply to the Ministers all documents and particulars which may be required by them relating to any such modification,

and shall submit the data and confirmation received to the Ministers.

(3) Where the applicant refers to a specification in a monograph in a pharmacopoeia but the Ministers consider that such specification is insufficient to ensure the quality of the product, the applicant shall submit to the Ministers on request a more appropriate specification.

3. The applicant shall comply with the requirements set out in Part 3 of Title I of the Annex to Council Directive 81/852/EEC, and shall supply a copy of any certificate issued by a laboratory which carried out any such test certifying that the test was carried out in conformity with the principles of good laboratory practice as referred to in the second paragraph of Part 3.