SCHEDULE 1

CAPITAL FEES FOR APPLICATIONS FOR, AND VARIATIONS TO, LICENCES AND CERTIFICATES

PART III

CAPITAL FEES FOR APPLICATIONS FOR VARIATIONS OF LICENCES AND CERTIFICATES

Product licences

1. Subject to paragraphs 2, 3, 4, 11 and 12, the fee payable under regulation 7(a) in connection with an application for variation of a product licence shall be—

(a) in the case of any complex application, £8,500; and

(b) in any other case, £280.

2. Where a product licence has been granted in accordance with an application to which paragraph 5 of Chapter III of Part 3 of the Annex to Council Directive 75/318/EEC applies, the fee in connection with the first application for variation of that product licence made within 5 years of the date of the grant of that product licence, so as to authorise use of the medicinal product in a new therapeutic area, shall, in addition to the fee payable under regulation 7(a), be the difference between the fee paid in connection with the application for the grant of that licence and the fee which would have been payable had that application been a major application and the provisions of that paragraph had not applied.

3. The fee payable under regulation 7(a) in connection with an application for variation of a product licence (parallel import) which is a complex application, shall be the same as that payable in connection with an application for the grant of such a licence as specified in paragraph 1 of Part II of this Schedule.

4. The fee payable under regulation 7(a) in connection with an application for variation of a product licence shall be £80 in respect of each variation applied for which falls within one of the following paragraphs—

(a) a change of either or both of the name and the address of the holder of the licence;

(b) a change of either or both of the name and the address of a manufacturer, assembler, storer or distributor named in the licence where the change has been occasioned by the taking over of an existing business, whether by purchase, merger or otherwise and any change of address does not involve a change of the site of manufacture, assembly or storage or from which distribution takes place;

(c) the removal from the licence of details of one or more sites of manufacture, assembly or storage or from which distribution takes place;

(d) the removal from the licence of details of any of the activities to which the licence relates;

(e) the removal from the licence of details of any of the indications authorised for administration of the medicinal product;

(f) n relation to a product licence (parallel import), the removal from the licence of details of any of the medicinal products which the holder of the licence is authorised to import.

Manufacturers' licences

5. Subject to paragraphs 6 and 11, the fee payable under regulation 7(a) in connection with an application for variation of a manufacturer's licence shall be—

(a) in the case of a manufacturer's licence referred to in paragraph 6(2) of Part II of this Schedule, £80; and

(b) in any other case, £200.

6. The fee payable under regulation 7(a) in connection with an application for variation of a manufacturer's licence shall be £80 in respect of each variation applied for which consists of a change to the licence not requiring an inspection or medical, scientific or pharmaceutical assessment.

Wholesale dealers' licences

7. Subject to paragraphs 8 and 11, the fee payable under regulation 7(a) in connection with an application for variation of a wholesale dealer's licence shall be £200.

8. The fee payable under regulation 7(a) in connection with an application for variation of a wholesale dealer's licence shall be £80 in respect of each variation applied for which consists of a change to the licence not requiring an inspection or medical, scientific or pharmaceutical assessment.

Clinical trial certificates

9. Subject to paragraphs 10 and 11, the fee payable under regulation 7(a) in connection with an application for variation of a clinical trial certificate shall be £280.

10. Where an application is made for a variation to a provision of a clinical trial certificate and the variation applied for consists of no more than a change of either or both the name and address of the holder of the certificate, the fee payable under regulation 7(a) shall be £80.

Identical variations

11. Subject to paragraph 12 below, where more than one application is made at the same time by the same applicant for the variation of a product licence, a manufacturer's licence, a wholesale dealer's licence or a clinical trial certificate and where the applications are for identical variations, the fee payable under regulation 7(a)—

(a) in connection with the first application considered by the licensing authority shall be the appropriate amount specified in this Part of this Schedule;

(b) in connection with each of the other applications shall be 50% of that amount.

12. Where more than one complex application is made at the same time by the same applicant for the variation of a product licence, the fee payable under regulation 7(a)—

(a) in connection with the first application considered by the licensing authority shall be the appropriate amount specified in this Part of this Schedule;

(b) in connection with each of the other applications where the applications are for identical variations and in respect of which no further medical, scientific or pharmaceutical assessment is required shall be the amount which would be payable if the application was not a complex application.