STATUTORY INSTRUMENTS

1995 No. 1116

The Medicines (Products for Human Use — Fees) Regulations 1995

PART IV

CAPITAL FEES FOR APPLICATIONS FOR RENEWALS OF CLINICAL TRIAL CERTIFICATES AND FOR CERTAIN MANUFACTURER'S LICENCES AND FOR ASSOCIATED INSPECTIONS

Renewals of clinical trial certificates

10. Subject to regulations 19 and 23, in connection with an application under section 38(2) of the Act for renewal of a clinical trial certificate, there shall be payable by the applicant a fee of £2,405.

Renewals of certain manufacturer's licences

11.—(1) Subject to regulation 23, the fee payable in connection with an application for renewal of a manufacturer's licence which is limited solely to the manufacture or assembly of medicinal products the sale or supply of which does not require a marketing authorization or a product licence and to which article 2(2)(i)(e) (exemptions for certain special manufactured products) of the Medicines (Exemption from Licences) (Special and Transitional Cases) Order 1971(**1**) applies, shall be £85.

(2) In respect of any inspection made in connection with an application referred to in paragraph (1), the fee payable shall be that prescribed in paragraph 2(d) of Schedule 2.

Renewals in terms which are not identical to the existing authorization, licence or certificate

12. Where an applicant applies for renewal of a marketing authorization (other than a Community marketing authorization), a manufacturer's licence, a wholesale dealer's licence or a clinical trial certificate so as to contain provisions which are not identical to the provisions of that authorization, licence or certificate as in force at the date of that application, the fee payable under this Part of these Regulations shall be increased by an amount equal to the fee which would have been payable under Part III of these Regulations had he in addition made a separate application for variation of that authorization, licence or certificate in respect of each provision which is not identical.

(**1**) S.I.1971/1450; to which there are amendments not relevant to these Regulations.