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STATUTORY INSTRUMENTS

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**2004 No. 1031**

The Medicines for Human Use  
(Clinical Trials) Regulations 2004

PART 3

AUTHORISATION FOR CLINICAL TRIALS  
AND ETHICS COMMITTEE OPINION

**Request for authorisation to conduct a clinical trial**

17.—(1) A request for authorisation to conduct a clinical trial shall be made to the licensing authority by the sponsor of the trial.

(2) A request shall—

(a) be in writing and signed by or on behalf of the sponsor; and

(b) be accompanied by—

(i) the particulars and documents specified in Part 2 of Schedule 3, and

(ii) any fee which may be payable in connection with that application under the Medicines (Products for Human Use—Fees) Regulations 1995<sup>(1)</sup>.

(3) The request and any accompanying material shall be supplied in the English language.