
STATUTORY INSTRUMENTS

1996 No. 2194

MEDICINES

The Animal Test Certificates Regulations 1996

Made - - - - *21st August 1996*
Laid before Parliament *23rd August 1996*
Coming into force *13th September 1996*

THE ANIMAL TEST CERTIFICATES REGULATIONS 1996

1. Title and commencement
 2. Interpretation
 3. Applications for certificates
 4. Renewal of certificates
 5. Standard provisions for certificates
 6. Revocations
- Signature

SCHEDULE 1 — PARTICULARS TO BE CONTAINED IN AN APPLICATION FOR A CERTIFICATE

Part I— — Standard particulars

1. The name or proposed name of the product, or, if...
2. The name and address of the applicant, and of the...
3. Details of the manufacturer of the product, which—
4. The proposed duration of the certificate, if less than two...
5. Details of any certificate previously granted in respect of the...
6. Details of any application for, or grant of, a product...
7. For applications in respect of new molecules only, details of...
8. Drafts of the proposed labelling, and any proposed leaflet or...
9. A description of the proposed test including details of—

Part II— — Analytical information

1. Qualitative and quantitative particulars relating to the product, which shall...
2. The method of preparation of the product and of its...
3. Details of any substances of animal origin used in the...
4. Details of the in-process control tests to be carried out...
5. Proposals for a shelf-life and in-use shelf-life for the product...

Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

Part III— — **Safety information**

1. Details of any information relevant to the safety of the...
2. In the case of a product intended for administration in...

SCHEDULE 2 — STANDARD PROVISIONS FOR CERTIFICATES

1. The test shall be carried out in accordance with the...
2. Where such details were not submitted at the time of...
3. If the certificate holder wishes to alter any part of...
4. The parts of the approved dossier referred to in the...
5. If the certificate holder wishes to alter any part of...
6. The parts of the approved dossier referred to in the...
7. The certificate holder shall notify the licensing authority if the...
8. The certificate holder shall notify the licensing authority—

SCHEDULE 3 — REVOCATIONS

Explanatory Note