SCHEDULE 1 Regulation 3(4)

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 there is no name, some other designation which will adequately identify it.

2. The name and address of the applicant, and of the proposed certificate holder, if different, and any other name under which the applicant or proposed holder carries on business.

3. Details of the manufacturer of the product, which—

(a) for products which have not been imported, shall include the name and address of the person responsible for each stage of its manufacture and assembly, and the sites where manufacture and assembly takes place, or

(b) for imported products, shall mean the name and address of the manufacturer and assembler of the product in its imported form.

4. The proposed duration of the certificate, if less than two years.

5. Details of any certificate previously granted in respect of the product.

6. Details of any application for, or grant of, a product licence under the Act, or a marketing authorisation within the meaning of the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, in respect of the product.

7. For applications in respect of new molecules only, details of any application made and any approval given in respect of the testing or marketing of the product in another country.

8. Drafts of the proposed labelling, and any proposed leaflet or package insert, for the product.

9. A description of the proposed test including details of—

(a) the nature and purpose of the test,

(b) the species and maximum number of animals to be included in the test,

(c) the criteria to be used in the selection of animals for, or exclusion or withdrawal of animals from, the test,

(d) the proposals for monitoring the safety of the product during the test, including details of precautions to be followed by users of the product, and when the product is to be disposed of,

(e) the arrangements for the disposal of animals involved in the test,

(f) the proposed dosage for the product, and its duration, and the method, route and frequency of administration,

(g) the name and qualifications of the person who is to be responsible for the overall supervision of the test, and

(h) the address of every site at which the test is to be carried out and the number of animals involved in the proposed test at each site, but if these particulars are not known to the applicant at the time of application, they may be omitted, so long as the applicant gives an explanation why they are not known.

Part II—

Analytical information

1. Qualitative and quantitative particulars relating to the product, which shall include—

(a) the monograph name, or if none the specification, of each ingredient, whether active or not, but if there is no name or specification, details sufficient to identify and characterise each batch of each ingredient used in the product shall be given,

(b) a description of the product's container and its closures, and any special directions for storage or transport of the product, and

(c) the specification of the product, giving its qualitative and quantitative composition.

2. The method of preparation of the product and of its ingredients whether active or not.

3. Details of any substances of animal origin used in the manufacture of the active ingredient, including, for a biological product, details of the master seed and master cell-bank.

4. Details of the in-process control tests to be carried out during the manufacture of the product, and of the control tests to be carried out on the finished product.

5. Proposals for a shelf-life and in-use shelf-life for the product.

Part III—

Safety information

1. Details of any information relevant to the safety of the product, including a summary and evaluation of any studies carried out with the product or its ingredients which are necessary to establish the safety of the product for the purposes of the test.

2. In the case of a product intended for administration in the test to food-producing animals—

(a) details of any entry in Annexes I to IV of Council Regulation (EEC) No. 2377/90(**1**), in relation to the product or any of its ingredients, and

(b) a proposal and justification for a withdrawal period.

SCHEDULE 2

Regulation 5

STANDARD PROVISIONS FOR CERTIFICATES

1. The test shall be carried out in accordance with the approved dossier.

2. Where such details were not submitted at the time of the application, the certificate holder shall notify the licensing authority as soon as reasonably practicable of the address of every site at which the test is to be carried out and the number of animals involved in the proposed test at each site, and such details will be deemed to have been approved if the licensing authority has acknowledged the notification and has not notified the holder that it has not been approved within 30 days of the date of his notification.

3. If the certificate holder wishes to alter any part of the approved dossier described in paragraph 4 below, he shall make a written application to the licensing authority for a variation, which includes

(**1**) O.J. No. L224, 18.8.90, p.1.

a justification for the alteration, and he shall not make the alteration proposed until approval of the application has been given.

4. The parts of the approved dossier referred to in the preceding paragraph are:

(a) the maximum number of animals included in the test, where this is to be increased,

(b) the arrangements for disposal of treated animals, if the new arrangements involve the commencement of, or an increase in, animals or animal products being sent for human consumption,

(c) the approved withdrawal period,

(d) the dosage for the product, and its duration, and the frequency of administration, where any of these are to be increased, and

(e) the product's labelling, leaflet or package insert, where changes are required consequent on the alterations referred to in the preceding sub-paragraphs.

5. If the certificate holder wishes to alter any part of the approved dossier described in paragraph 6 below, he shall make a written application to the licensing authority for a variation, and his application will be deemed to have been approved if the licensing authority has acknowledged it and has not notified him that it has not been approved within 30 days of the date of the application.

6. The parts of the approved dossier referred to in the preceding paragraph are:

(a) any of the particulars referred to in paragraphs 1, 2, 3 or 9(a), (c), (d), (g) or (h) of Part I of Schedule 1,

(b) the species of animal included in the test,

(c) any of the particulars referred to in Part II of Schedule 1 where the proposed alteration will affect the product's bioavailability or stability, or the range or level of impurities it contains, and

(d) the product's labelling, leaflet or package insert, where changes are required other than as referred to in paragraph 4(e) above.

7. The certificate holder shall notify the licensing authority if the test is discontinued, giving an explanation for its discontinuance.

8. The certificate holder shall notify the licensing authority—

(a) within 15 days of his becoming aware of it of any suspected adverse reaction occurring during the test, which in the view of the holder was the cause of any increase in mortality or serious ill-health in the treated animals, and

(b) immediately of any other matter of which he becomes aware which may affect the safety of the product for the purposes of the test.

SCHEDULE 3

Regulation 6

REVOCATIONS

(1) *Regulations revoked*	(2) *References*	(3) *Extent of revocation*
The Medicines (Applications for Product Licences and Clinical Trial and Animal Test Certificates) Regulations 1971.	S.I. 1971/973.	The whole Regulations in so far as they relate to applications for animal test certificates.
The Medicines (Applications for Product Licences and	S.I. 1972/1201.	The whole Regulations in so far as they relate to

(1) *Regulations revoked*	(2) *References*	(3) *Extent of revocation*
Clinical Trial and Animal Test Certificates) Amendment Regulations 1972.		applications for animal test certificates.
The Medicines (Applications for Product Licences and Clinical Trial and Animal Test Certificates) Amendment Regulations 1975.	S.I. 1975/681.	The whole Regulations in so far as they relate to applications for animal test certificates.
The Medicines (Veterinary Drugs) (Renewal Applications for Licences and Animal Test Certificates) Regulations 1994.	S.I. 1994/3143.	The whole Regulations in so far as they relate to applications for renewal of animal test certificates.
The Medicines (Labelling) Regulations 1976.	S.I. 1976/1726.	The whole Regulations in so far as they relate to the labelling of containers and packages of medicinal products for administration in medicinal tests on animals, except for any medicinal test the subject of a certificate issued in respect of an application made in accordance with the Medicines (Applications for Product Licences and Clinical Trial and Animal Test Certificates) Regulations 1971.
The Medicines (Labelling) Amendment Regulations 1977.	S.I. 1977/996.	The whole Regulations in so far as they relate to the labelling of containers and packages of medicinal products for administration in medicinal tests on animals, except for any medicinal test the subject of a certificate issued in respect of an application made in accordance with the Medicines (Applications for Product Licences and Clinical Trial and Animal Test Certificates) Regulations 1971.
The Medicines (Labelling of Medicinal Products for Incorporation in Animal Feeding Stuffs and of Medicated Animal Feeding Stuffs) Regulations 1988.	S.I. 1988/1009.	The whole Regulations in so far as they relate to the labelling of containers and packages of medicinal products for administration in medicinal tests on

(1) *Regulations revoked*	(2) *References*	(3) *Extent of revocation*
		animals, except for any medicinal test the subject of a certificate issued in respect of an application made in accordance with the Medicines (Applications for Product Licences and Clinical Trial and Animal Test Certificates) Regulations 1971.