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 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.