Veterinary Medicines Directorate

VETERINARY MEDICINES DIRECTORATE
On behalf of the Secretary of State for the
Department for Environment, Food and Rural Affairs (Defra)

ISSUED BY:
VETERINARY MEDICINES DIRECTORATE
Woodham Lane, New Haw, Addlestone, Surrey, KT15 3LS
Tel: +44 (0)1932 336911; Website: www.gov.uk

Small Animal Manufacturers Authorisation

(Schedule 6 – Exemptions for Small Pet Animals)

SECTION 1A

1. Authorisation Number

SAM0020

2. Name and address of Authorisation Holder

Cloverleaf Industries Ltd, Stondon Farm, Ongar Road, Stondon Massey, Essex, CM15 0LD

3. Address(es) of manufacturing/importing site(s)
(All authorised sites should be listed if not covered by separate licences)

VMD SITE NUMBER:	SITE NAME:	ADDRESS:
S0579	Cloverleaf Industries Ltd	Stondon Farm, Ongar Road, Stondon Massey, Essex, CM15 0LD

4. Legally registered address of Authorisation Holder

Stondon Farm, Ongar Road, Stondon Massey, Essex, CM15 0LD

5. Scope of authorisation and dosage form

See ANNEX 1

6. Legal basis of authorisation

See Section 1B of licence.

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VETERINARY MEDICINES DIRECTORATE

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SECTION 1A (continued)

7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation

CONFIDENTIAL

8. Date

12 September 2018

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SECTION 1B

1. This authorisation covers the processes of manufacture and/or assembly and/or importation of veterinary medicinal products that fall within the scope of Schedule 6 (small animal exemption scheme) of the current Veterinary Medicines Regulations and are of the description or general classification at the premises specified and in accordance with the particulars set out in Section 3 by the authorisation holder named. All manufacturing and/or assembly and/or importation operations in respect of those products manufactured shall be conducted so as to ensure that the products shall conform to the standards of strength, quality and purity applicable to them in accordance with the specification made by the person to whose order they are manufactured and/or assembled and/or imported or the specification under which the products are sold or supplied.

   In relation to such products the authorisation holder shall either:

   a) provide and maintain such staff, premises and plant as are necessary for carrying out in accordance with such specification any tests of the strength, quality or purity as required by that specification, or
   b) make arrangements with a person approved by the Secretary of State for such tests to be carried out on his behalf by that person, and
   c) make arrangements for a Person(s) responsible for release of product on to the market to be available at all times for the purpose of checking that each batch of veterinary medicinal products has been manufactured and assembled in accordance with the appropriate provisions and to certify accordingly in a register.

2. The authorisation holder must inform the VMD, acting on behalf of the Secretary of State, in advance of any change to the details submitted or included in this authorisation. All changes must be approved by the Secretary of State prior to becoming effective. This includes any changes to named premises, persons, operations processes or structural alterations. If the business should change hands the new company or person must obtain a new authorisation prior to commencing operations. The manufacture and/or assembly and/or importation of any veterinary medicinal product pursuant to this authorisation shall not commence until a marketing authorisation has been granted naming the site named on this authorisation as being used for the manufacture of that product.

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SECTION 1B (continued

3. The names and addresses of holders of manufacturing authorisations for veterinary medicinal products together with addresses of authorised sites will be published on the EudraGMP database at www.eudragmp.ema.europa.eu.

4. Further information and specified guidelines may be obtained from the VMD website www.gov.uk.

5. Authorisation Structure

This authorisation is divided into three sections.

(a) Section 1 (this section) identifies the authorisation holder and holds the authorising name. This section would not usually be replaced during routine variations of the authorisation unless the authorisation holder details are varied.

(b) Section 2 lists variations to the authorisation. A replacement section 2 will be issued each time the authorisation is varied.

(c) Section 3 contains the details relating to each site named on the authorisation. Where there is more than one site there will be more than one part to Section 3. When a variation is made to the details of a site named in Section 3 the relevant part of Section 3 will be replaced.

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SECTION 3

ANNEX 1 - SITE INFORMATION

SCOPE OF AUTHORISATION

NAME AND ADDRESS OF SITE:	
SITE NAME:	Cloverleaf Industries Ltd
ADDRESS:	Stondon Farm, Ongar Road, Stondon Massey, Essex, CM15 0LD
VMD SITE NUMBER:	S0579

TYPE OF PRODUCTS HANDLED
Veterinary Medicinal Products

AUTHORISED OPERATIONS	
Manufacturing Operations (according to Part 1)	Not Authorised
Importation of Medicinal Products (according to Part 2)	Not Authorised

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ANNEX 1 – SITE INFORMATION (continued)

Part 1 – MANUFACTURING OPERATIONS

- authorised manufacturing operations include total and partial manufacturing (including various processes of dividing up, packaging or presentation), batch release and certification, importation, storage and distribution of specified dosage forms unless informed to the contrary;

- quality control testing and/or release and batch certification activities without manufacturing operations should be specified under the relevant items;

1.2	**Non-sterile products**	*Manufacture*
1.2.1	***Non-sterile products (list of dosage forms)***	
	1.2.1.1 Capsules, hard shell	Not Authorised
	1.2.1.2 Capsules, soft shell	Not Authorised
	1.2.1.5 Liquids for external use	Authorised
	1.2.1.6 Liquids for internal use	Not Authorised
	1.2.1.8 Other solid dosage forms	Authorised
	1.2.1.9 Pressurised preparations	Not Authorised
	1.2.1.11 Semi-solids	Not Authorised
	1.2.1.12 Suppositories	Not Authorised
	1.2.1.13 Tablets	Not Authorised
	1.2.1.16 Veterinary premixes	Not Authorised
	1.2.1.17 Other non-sterile medicinal products	Not Authorised
1.2.2	**Batch certification**	Authorised

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1.4	***Other products or manufacturing activity*** (any other relevant manufacturing activity/product type that is not covered above e.g. sterilisation of active substances, manufacture of biological active starting materials (when required by national legislation), medicinal gases, herbal or homeopathic products, bulk or total manufacturing, etc).	**Manufacture**
1.4.1	**Manufacture of:**	
	1.4.1.1 Herbal products	Not Authorised
	1.4.1.2 Homoeopathic products	Not Authorised
	1.4.1.3 Biological active starting materials	Not Authorised
	1.4.1.4 Other	Not Authorised
1.4.3	**Others**	Not Authorised

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1.5	***Packaging***	Manufacture
1.5.1	***Primary packing***	
	1.5.1.1 Capsules, hard shell	Not Authorised
	1.5.1.2 Capsules, soft shell	Not Authorised
	1.5.1.4 Impregnated matrices	Not Authorised
	1.5.1.5 Liquids for external use	Authorised
	1.5.1.6 Liquids for internal use	Not Authorised
	1.5.1.8 Other solid dosage forms	Authorised
	1.5.1.9 Pressurised preparations	Not Authorised
	1.5.1.11 Semi-solids	Not Authorised
	1.5.1.12 Suppositories	Not Authorised
	1.5.1.13 Tablets	Not Authorised
	1.5.1.16 Veterinary premixes	Not Authorised
	1.5.1.17 Other non-sterile medicinal products	Not Authorised
1.5.2	**Secondary packing**	Authorised

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1.6	**Quality control testing**	Manufacture
	1.6.1 Microbiological: sterility	Not Authorised
	1.6.2 Microbiological: non-sterility	Not Authorised
	1.6.3 Chemical/Physical	Authorised
	1.6.4 Biological	Not Authorised

Any restrictions or clarifying remarks related to the scope of these Manufacturing operations:

None