Annex IV: Documents to be enclosed for applying registration and license of veterinary disinfectants

Item	Documents to be enclosed	Manufactured disinfectants	Imported disinfectants
1	Five pieces of application form for registration and license of the manufactured (imported) veterinary drugs	○	○
2	Five pieces of label and insert pasting sheet	○	○
3	One name card of the veterinary disinfectant in both Chinese and another foreign language, or Chinese and English	○	○
4	Formulation basis	○	○
5	Two copies each of inspection specification, method, and report of the raw materials	○	○
6	Two copies each of inspection specification, method, and report of the finished product	○	○
7	Manufacturing and quality control information	○	○
8	Stability test information	○	○
9	One copy of the factory registration certificate	○	X
10	Manufacturing plant master file	X	○ Note 1
11	One copy of the license for trading veterinary drugs	X	○
12	The original and one copy of the power of attorney; the original will be returned	X	○
13	The original copy of the certificate of manufacture issued by the manufacturing country	X	○
14	The original copy of the certificate of free-sale issued by the manufacturing country	X	○
15	The original copy of the certificate of label and insert to be put on the market issued by the manufacturing country	X	○
16	Efficacy test	○ Note 2	○ Note 2
17	Single dose toxicity test	○ Note 3	○ Note 3
18	Residue test	○ Note 3	○ Note 3

Note:

1. This document is only required in the first application.
2. Applications of new veterinary disinfectants and those claiming to be effective against foot and mouth disease, swine vesicular disease, avian influenza, Newcastle disease, and classical swine fever must include this document.
3. Applications of new veterinary disinfectants that are applicable to the disinfect livestock houses and poultry houses must include this document.

Annotation:

I. ○: Documents are required. X: Documents are not required.

II. Please refer to the instructions in Annex 2 for the relevant provisions on the application form, label and insert pasting sheet draft, inspection reports of raw materials and finished products, (reference prescription), manufacturing plant master file, power of attorney, certificate of manufacture issued by the manufacturing country, certificate of free-sale issued by the manufacturing country, and the certificates of the text content on the label and insert to be put on the market issued by the manufacturing country.

III. If a new veterinary disinfectant with a new unit strength has the same application concentration as a registered veterinary disinfectant, the registration and license in the form of said new disinfectant is not required.

IV. A complete report of veterinary disinfectant on physical, chemical, efficacy, toxicity, residue, stability, and other research data shall be provided. According to the notice of the central competent authority, the raw data of the report may not be replaced by a general narrative, summary, or case reports.