Content

Title：	Enforcement Rules of Veterinary Drugs Control Act Ch
Date：	2017.01.03
Legislative：	1.Promulgated on November 21, 1975. 2.Amendment to all Articles promulgated on September 3, 1979. 3.Amendment to Appendix 2 of Article 55 promulgated on August 21, 1980. 4.Amendment to Appendices 2, 3, 4 of Article 55 promulgated on May 9, 1981. 5.Amendment to Article 55, Appendices of Article 55 promulgated on July 30, 1983. 6.Amendment to Article 55, Appendices of Article 55 promulgated on May 15, 1986. 7.Amendment to Article 10, Appendices 8, 9 of Article 10 promulgated on September 4, 1989. 8.Amendment to Article 55, Appendices of Article 55 promulgated on August 10, 1990. 9.Amendment to Article 55, Appendices of Article 55 promulgated on January 27, 1992. 10.Amendment to Article 23, Appendix 13 of Article 23 promulgated on September 15, 1993. 11.Amendment to Article 55, Appendices of Article 55 promulgated on April 22, 1995. 12.Amendment to Article 55, Appendices of Article 55 promulgated on August 31, 1995. 13.Amendment to Article 55, Appendices of Article 55 promulgated on April 25, 1996. 14.Amendment to Appendices of Article 55 promulgated on March 11, 1998. 15.Amendment to Appendices of Article 55 promulgated on August 11, 1999. 16.Amendment to Appendices of Article 55 promulgated on October 20, 1999. 17.Amendment to all Articles promulgated on May 31, 2001. 18.Amendment to all Articles promulgated on May 4, 2005. 19.Amendment to all Articles promulgated on September 17, 2008. 20.Amendment to Article 6 promulgated on January 29, 2010. 21.Amendment to Article 7 promulgated on June 28, 2012. 22.Amendment to all Articles promulgated on January 3, 2017.
Content：	Article 1 The Enforcement Rules are stipulated in accordance with Article 47 of the Veterinary Drugs Control Act (hereafter referred to as the Act). Article 2 The term “testing” in Article 4 and 6 of the Act refers to measures to: 2.1 inspect whether the veterinary drug is approved, is conformed to the original approval, and is secured with the seal of approval or not, 2.2 examine the veterinary drug’s characteristics, ingredients, quality, quantity, potency and relevant properties.

Article 3
The terms “without government approval” in Section 4.1 and “without a permit” in Section 5.1.2 of the Act refer to the situation that a veterinary drug is not approved in accordance with Section 12.1 of the Act.

Article 4
The central competent authority may invite experts and scholars to review documents and records of inspection and testing of a veterinary drug in accordance with of the Act.

Article 5
The competent authority may delegate its subordinate authorities, or commission administrative authorities with no relationship of administrative subordination, juristic persons or private entities to exercise a part of its powers for the following matters:
5.1 Testing and registration in Article 12 of the Act.
5.2 Changing the entries on registration in Article 13 of the Act
5.3 Renewal of veterinary drug license in Section 14.1 of the Act.
5.4 Sampling and inspection in Article 18 of the Act
5.5 Inspection of veterinary drug manufacturer in Article 25 of the Act.
5.6 Inspection of an entity (a veterinary drug manufacturer or dealer, veterinary care facility, farm of livestock, poultry or aquaculture, feed manufacturer or veterinary drug user, and sampling and testing of its veterinary drug in Article 26 of the Act.
5.7 Sampling and testing of suspicious counterfeit, banned or substandard veterinary drugs in Article 28 of the Act.

Article 6
To apply for repacking imported veterinary drugs into smaller sizes in accordance with Section 21.1 of the Act, the veterinary drug dealer shall submit two copies of application and the following documents to the central competent authority:
6.1 A copy of veterinary drug license.
6.2 A copy of customs import declaration.
6.3 A copy of certificate of analysis of the veterinary drug from the original manufacturer.
6.4 A copy of the agreement of the original manufacturer to repack.
6.5 A copy of the agreement of the re-packer and its veterinary drug manufacturer license.
6.6 One sample of each repack container (or container photography), label and package insert.

Article 7
To apply for an export license in accordance with Article 24 of the Act, the veterinary drug manufacturer shall file the application with the central competent authority for every batch. One must not begin to export the drug until the license is obtained.

Article 8
The original price, in Section 26.1 of the Act, means the wholesale price.

Article 9
The veterinary drug manufacturer, who is allowed to modify the substandard veterinary drug before a set deadline in accordance with Article 29 of the Act, shall notify the municipal or country (city) competent authority to send personnel to supervise the process 7 days prior to the modification.

Article 10
The recalled veterinary drugs and the inventory, whose veterinary drug licenses are annulled in accordance with Article 30 of the Act, shall be handled according to the following regulations:
10.1 The inventory of qualified veterinary drugs must not be sold until the municipal or county (city) competent authority check thoroughly the amount and affixes the “veterinary drug checkup stamp” to the label or the obvious place of the packaging of every bottle.
10.2 The recalled veterinary drugs and the inventory of counterfeit, banned or substandard veterinary drugs shall be sealed their final products, bulks, raw materials, labels and package inserts by the municipal or county (city) competent authority, and dealt with them in accordance with the Act.

Article 11
The veterinary drug, whose license is revoked, shall be handled in accordance with Section 10.1 of the Enforcement Rules.

Article 12
The Enforcement Rules take effect on the date of promulgation.