Regulation on Veterinary Drug Administration

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The "Regulation on Veterinary Drug Administration", which was adopted at the 45th executive meeting of the State Council on March 24, 2004, is hereby promulgated, and shall come into force on November 1, 2004.

Premier Wen Jiabao,

April 9, 2004

Regulation on Veterinary Drug Administration

Chapter I General Provisions

Article 1 The present Regulation is formulated in order to strengthen veterinary drug administration, guarantee veterinary drug quality, prevent and control animal diseases, promote the development of breeding industry, and maintain human health.

Article 2 The present Regulation shall apply to the research, production, operation, import, export, use or supervision of veterinary drugs inside the territory of the People's Republic of China.

Article 3 The responsibility to supervise veterinary drugs nationwide shall remain with the veterinary administration under the State Council.

The responsibility to supervise veterinary drugs within a certain jurisdiction shall remain with the veterinary administration under the local people's government at the county level or above.

Article 4 The state applies a system of administering veterinary drugs by classifying them into prescription veterinary drugs and non-prescription ones. The measures for classifying prescription veterinary drugs and non-prescription ones as well as the specific implementing procedures shall be formulated by the veterinary administration under the State Council.

Article 5 The state applies a veterinary drug reserve system.

In case of any major animal epidemic situation, disaster situation or any other unexpected incident, the veterinary administration under the State Council may urgently put the state-reserved veterinary drugs into use. If necessary, it may also put veterinary drugs other than the state-reserve ones into use.

Chapter II Research of New Veterinary Drugs

Article 6 The state encourages the research of new veterinary drugs, and protects the lawful rights and interests of the researchers in accordance with the law.

Article 7 Whoever researches a new veterinary drug shall have the suitable site, devices, equipment,

professionals, as well as safety management rules and measures.

Whoever researches a new veterinary drug shall subject it to safety appraisal. An entity engaging in safety appraisal of veterinary drugs shall be accredited by the veterinary administration under the State Council, and shall abide by the quality management rules on non-clinical research and clinical trial of veterinary drugs.

Article 8 Whoever researches a new veterinary drug shall, prior to the clinical trial, file an application to the veterinary administration under the people's government of the province, autonomous region, or municipality directly under the Central Government, and attach to it the safety appraisal report for the laboratory stage of the new veterinary drug and other pre-clinical research documents. The veterinary administration under the people's government of the province, autonomous region, or municipality directly under the Central Government shall, within 60 working days as of receipt of the application, notify the applicant in writing of the result of the examination.

If the new veterinary drug in research is a biological product, the researcher shall, prior to the clinical trial, file an application to the veterinary administration under the State Council. And the veterinary administration under the State Council shall, within 60 working days as of receipt of the application, notify the applicant in writing of the result of the examination.

Whoever needs to use the first category of pathogenic microorganism when researching a new veterinary drug shall, in addition, meet the conditions provided for by the veterinary administration under the State Council, and shall report to the veterinary administration under the State Council prior to the laboratory stage for approval.

Article 9 After the clinical trial is completed, the new veterinary drug researcher shall, when filing an application to the veterinary administration under the State Council for registration of the new veterinary drug, submit a sample of this new veterinary drug and the following information:
(1) the name, main components, physical and chemical characteristics;
(2) the research method, production process, quality standards and testing method;
(3) the result of pharmacological and toxicological trial, the clinical trial report and the stability trial report; and
(4) the environmental impact report and the measures for prevention and control of pollution.

If the researched new veterinary drug is a biological product, the researcher shall provide the relevant documents and information on culture (virus, worm seed) and cells, etc.. The culture (virus, worm seed) and cells shall be preserved by an institution designated by the veterinary administration under the State Council.

When researching a new veterinary drug for edible animals, the researcher shall carry out a trial on veterinary drug remnants in accordance with the provisions of the veterinary administration under the State Council, and shall provide such information as the withdrawal period, the maximum limitation of remnants, the methods of testing remnants and the basis thereof, etc.

The veterinary administration under the State Council shall, within 10 working days as of receipt of the application, deliver the documents on the new veterinary drug under acceptance to the veterinary drug review and adjudication office it has set up for review and adjudication, and deliver the sample of the new veterinary drug to its designated inspection office for re-check and inspection, and shall complete the examination within 60 working days as of receipt of the conclusion of the review and adjudication and the conclusion of the re-check and inspection. If it is examined as qualified, a new veterinary drug registration certificate shall be issued, and the quality standards on this veterinary drug shall be promulgated. Otherwise, the said veterinary administration shall notify the applicant in writing.

Article 10 The state protects the undisclosed trial data and other data of the lawfully registered veterinary drug containing new compound, which are submitted by any applicant who has obtained such data by himself.

If, within 6 years as of registration, any other applicant applies for a veterinary drug registration by using the data in the preceding paragraph without the consent of the applicant of such registered veterinary drug, the veterinary drug registration organ shall not register it, but the data obtained by the said other applicant himself which he submits shall be registered.

Except the following circumstances, no veterinary drug registration organ may disclose the data provided for in Paragraph 1 of the present Article:
(1) The data are needed for public benefits;
(2) The adopted measures could guarantee that such information would not be unjustly used for commercial purposes.

Chapter III Veterinary Drug Production

Article 11 Whoever intends to establish a veterinary drug production enterprise shall conform to the national development planning and policies of the veterinary drug industry, and shall meet the following conditions:
(1) Having a number of technicians in veterinary medicine, pharmaceutics or in the related specialties suitable for the production of veterinary drug;
(2) Having the plant and relevant facilities suitable for the production of veterinary drug;
(3) Having the offices, staff, apparatus and equipment for veterinary drug quality management and quality inspection suitable for the production of veterinary drug;
(4) Having a producing environment conforming to safety and sanitation requirements;
(5) Other production conditions provided for in veterinary drug production quality management rules.

An applicant may not file an application to the veterinary administration under the people's government of the province, autonomous region, or municipality directly under the Central Government unless meeting the conditions provided for in the preceding paragraph, and shall attach to it the documents proving that the conditions in the preceding paragraph have been met when filing the application. The veterinary administration under the people's government of the province, autonomous region, or municipality directly under the Central Government shall, within 20 working days as of receipt of the application, submit the opinions on verification and the relevant documents to the veterinary administration under the State Council.

The veterinary administration under the State Council shall complete the examination within 40 working days as of receipt of the opinions on verification and the relevant documents. If the application is examined as qualified, a veterinary drug production permit shall be issued. Otherwise, the said veterinary administration shall notify the applicant in writing. The applicant shall go through the formalities of industrial and commercial registration upon strength of the veterinary drug production permit.

Article 12 A veterinary drug production permit shall indicate the scope of production, producing location, validity period, and the name of legal representative, and domicile, etc.

The validity period for a veterinary drug production permit shall be 5 years. If, at expiry of the validity period, the production of the veterinary drug needs to be continued, the producer shall, 6 months prior to the expiry of the validity period for the permit, apply to the original permit issuing organ for issuance of a new veterinary drug production permit.

Article 13 Where a veterinary drug production enterprise modifies its scope of production or

producing location, it shall, in accordance with Article 11 of the present Regulation, apply for issuance of a new veterinary drug production permit. The applicant shall make industrial and commercial modification registration upon strength of the newly issued veterinary drug production permit. If it modifies the enterprise name or the name of the legal representative, it shall, within 15 working days after making the industrial and commercial modification registration, apply to the original permit issuing organ for issuance of a new veterinary drug production permit.

Article 14 A veterinary drug production enterprise shall organize the production in accordance with the veterinary drug production quality management rules formulated by the veterinary administration under the State Council.

The veterinary administration under the State Council shall supervise and inspect whether the veterinary drug production enterprises conform to the requirements in the veterinary drug production quality management rules, and shall promulgate the result of such inspection.

Article 15 A veterinary drug production enterprise shall, for the sake of producing veterinary drugs, obtain a product approval document number checked and issued by the veterinary administration under the State Council. The validity period for the product approval document number shall be 5 years. The measures for checking and issuing veterinary drugs' product approval document numbers shall be formulated by the veterinary administration under the State Council.

Article 16 A veterinary drug production enterprise shall carry out the production pursuant to the national standards on veterinary drugs and the production process approved by the veterinary administration under the State Council. If a veterinary drug production enterprise changes the production process that might affect the veterinary drug quality, it shall report to the original approval organ for verification and approval.

A veterinary drug production enterprise shall set up its production records, which shall be kept integral and accurate.

Article 17 The raw materials and auxiliary materials needed for producing a veterinary drug shall conform to the national standards or the quality requirements of the produced veterinary drug.

The packing materials and containers which are directly in contact with a veterinary drug shall meet the medicinal requirements.

Article 18 A veterinary drug shall be subject to the quality inspection before leaving factory, and the veterinary drug failing to conform to the quality standards shall not leave the factory.

A veterinary drug shall, when leaving factory, be attached with a certificate of product quality.

It is prohibited to produce fake or inferior veterinary drugs.

Article 19 Each batch of veterinary biological products produced by a veterinary drug production enterprise shall, before leaving factory, be examined and checked by an inspection office designated by the veterinary administration under the State Council, and random inspections may be carried out when necessary. Any veterinary biological product that has not been examined and checked or that is randomly inspected as unqualified shall not be sold.

The veterinary biological products needed in compulsory immunity shall be produced by enterprises designated by the veterinary administration under the State Council.

Article 20 The packing of a veterinary drug shall be printed or stuck with a label as provided, with instructions being attached, and shall be marked with the words "for veterinary use" at an eye-

catching position.

The label and instructions of a veterinary drug may not be put into use until they have been approved and promulgated by the veterinary administration under the State Council.

On the label or instructions of a veterinary drug shall be indicated in Chinese the generally used name, components and the content thereof, specifications, production enterprise, product approval document number (the registration certificate number of imported veterinary drug), product batch number, date of production, validity period, indications, functions, usage, dosage, withdrawal period, contraindication, ill response, points for attention, conditions for transport, storage or custody, as well as other contents which ought to be stated. The commodity name, if any, shall also be indicated.

Besides the contents in the preceding paragraph, the label or instructions of a prescription veterinary drug shall be printed with the warning contents as provided for by the veterinary administration under the State Council. For the veterinary narcotic drugs, psychotropic drugs, toxic drugs and radioactive drugs, the label or instructions shall be additionally printed with a particular mark as provided for by the veterinary administration under the State Council. For the non-prescription veterinary drugs, the label or instructions shall be additionally printed with a mark of non-prescription drug as provided for by the veterinary administration under the State Council.

Article 21 The veterinary administration under the State Council may, upon the needs for guaranteeing animal product quality safety and human health, set up a monitoring period of not more than 5 years for the new veterinary drugs. Within the monitoring period, no other enterprise shall be approved to produce or import this new veterinary drug. The production enterprise shall collect the information on curative effect, ill response, etc. of this new veterinary drug within the monitoring period, and shall timely submit such information to the veterinary administration under the State Council.

Chapter IV Operation of Veterinary Drugs

Article 22 An enterprise that operates veterinary drugs shall meet the following conditions:
(1) Having a number of veterinary drug technicians who are suitable for the veterinary drugs operated;
(2) Having a business site, the equipment, warehouses and facilities suitable for the veterinary drugs operated;
(3) Having a quality management office or such employees who are suitable for the veterinary drugs operated; and
(4) Other operational conditions provided for in veterinary drug operation quality management rules.

Only when the conditions in the preceding paragraph are met may the applicant file an application to the veterinary administration under the city or county people's government, and the documents proving that the conditions in the preceding paragraph have been met shall be attached. Whoever operates veterinary biological products shall file the application to the veterinary administration under the people's government of the province, autonomous region, or municipality directly under the Central Government, and the documents proving that the conditions in the preceding paragraph have been met shall be attached.

The veterinary administration under the local people's government at the county level or above shall complete the examination within 30 working days as of receipt of the application. If the application is examined as qualified, a veterinary drug operation permit shall be issued; otherwise, the said veterinary administration shall notify the applicant in writing. The applicant shall make industrial and commercial registration upon strength of the veterinary drug operation permit.

Article 23 A veterinary drug operation permit shall indicate such details as the scope of business, place of business, validity period, name of the legal representative, and domicile.

The validity period of a veterinary drug operation permit shall be 5 years. If, at expiry of the validity period, the operator needs to continue operating veterinary drugs, it shall, 6 months prior to the expiry, apply to the original permit issuing organ for issuance of a new veterinary drug operation permit.

Article 24 Where a veterinary drug operation enterprise modifies its scope of business or place of business, it shall, in accordance with Article 22 of the present Regulation, apply for issuance of a new veterinary drug operation permit. The applicant shall make industrial and commercial modification registration upon strength of the new veterinary drug operation permit. If it modifies the enterprise name or the legal representative, it shall, within 15 working days after making industrial and commercial modification registration, apply to the original permit issuing organ for issuance of a new veterinary drug operation permit.

Article 25 The veterinary drug operation enterprises shall abide by the veterinary drug operation quality management rules formulated by the veterinary administration under the State Council.

The veterinary administration under the local people's government at the county level or above shall supervise and inspect whether the veterinary drug operation enterprises meet the requirements in veterinary drug operation quality management rules, and shall promulgate the result of its inspections.

Article 26 A veterinary drug operation enterprise shall, when purchasing veterinary drugs, check whether the veterinary drug products are consistent with the product label or instructions, and the product quality certificate.

Article 27 A veterinary drug operation enterprise shall explain to the buyer the involved veterinary drug's functions, indications, usage, dosage, and points for attention. If it sells prescription veterinary drugs, it shall abide by the measures for the administration of prescription veterinary drugs.

A veterinary drug operation enterprise selling materials of Chinese traditional veterinary drugs shall indicate the place of origin.

Veterinary drug operation enterprises are prohibited from operating human drugs and fake or inferior veterinary drugs.

Article 28 A veterinary drug operation enterprise shall, when purchasing or selling a veterinary drug, set up records on purchase and sale. The records on purchase and sale shall indicate the veterinary drug's commodity name, general name, form, specifications, batch number, validity period, producer, purchaser and seller, quantity of purchase and sale, date of purchase and sale, as well as other details provided for by the veterinary administration under the State Council.

Article 29 A veterinary drug operation enterprise shall set up a veterinary drug custody system, and take necessary cold storage, anti-freezing, moisture-proof, worm resistant or mouse proof measures, etc., so as to maintain the quality of the veterinary drugs in operation.

Veterinary drugs entering or exiting the storeroom shall be under an inspection and acceptance system, and accurate records shall be kept.

Article 30 The operation of veterinary biological products needed in compulsory immunity shall conform to the provisions of the veterinary administration under the State Council.

Article 31 The contents in a veterinary drug advertisement shall be consistent with those in the veterinary drug instructions. Where a veterinary drug advertisement is published in any of the major media throughout the country, it shall be examined and approved by the veterinary administration under the State Council. And the examination and approval document number shall be obtained. If the veterinary drug advertisement is published in a local medium, it shall be examined and approved by the veterinary administration under the people's government of the province, autonomous region, or municipality directly under the Central Government. And the examination and approval document number shall be obtained. No veterinary drug advertisement shall be published without approval.

Chapter V Import and Export of Veterinary Drugs

Article 32 For the veterinary drugs exported to China for the first time, the exporter's office in China or the Chinese domestic agency it has authorized shall apply to the veterinary administration under the State Council for registration, and submit the following documents and articles:
(1) the documents on proof of production or sale, which were approved by the veterinary drug administration of the country (region) where the production enterprise is located;
(2) the proof documents on conformity to the veterinary drugs production quality management rules, which were issued by the veterinary drug administration of the country (region) where the production enterprise is located;
(3) the manufacturing method, production process, quality standards, testing method, results of pharmacological and toxicological trials, clinical trial report and stability trial report of the veterinary drug involved, as well as other relevant documents; the withdrawal period, the maximum limitation of remnants, and remnant-testing method for the veterinary drugs used for edible animals, as well as the basis thereof, etc.;
(4) the sample of label and instructions of the veterinary drug involved;
(5) the sample, contrast product and standard product of the veterinary drug involved;
(6) the environmental impact report and the measures for prevention and control of pollution; and
(7) other documents involving veterinary drug safety.

Whoever applies to export veterinary biological products to China shall provide the relevant documents on culture (virus, worm seed), cells, etc., in addition.

Article 33 The veterinary administration under the State Council shall organize the preliminary examination within 10 working days as of receipt of the application. If the application is preliminarily examined as qualified, the veterinary administration shall deliver the veterinary drug documents, which it has decided to accept, to the veterinary drug review and adjudication office it has set up for review and adjudication, and deliver the sample of this veterinary drug to its designated inspection office for re-check and inspection, and shall complete the examination within 60 working days as of receipt of the conclusions of review and adjudication and of re-check and inspection. If the documents are examined as qualified, the said veterinary administration shall issue a registration certificate for the imported veterinary drug, and promulgate the quality standards of this veterinary drug; otherwise, it shall notify the applicant in writing.

In the process of examination, the veterinary administration under the State Council may investigate whether the enterprises exporting veterinary drugs to China meet the requirements in the veterinary drug production quality management rules, and shall be entitled to require such enterprises to carry out safety and validity trial of the said veterinary drug in the institution designated by the veterinary administration under the State Council.

The veterinary drugs urgently needed in our country, a few veterinary drugs used in scientific research or the samples, contrast products and standard products of the registered veterinary drugs shall be imported in accordance with the provisions of the veterinary administration under the State Council.

Article 34 The validity period of a registration certificate for the imported veterinary drug shall be 5 years. If, at expiry of the validity period, the certificate holder needs to continue exporting veterinary drugs to China, it shall, 6 months prior to the expiry of the validity period, apply to the original certificate issuing organ for re-registration.

Article 35 Overseas enterprises are not permitted to sell veterinary drugs directly in China. Where an overseas enterprise intends to sell veterinary drugs in China, it shall lawfully set up a sales agency within the territory of China or authorize a Chinese domestic agency meeting the requirements.

Where any enterprise intends to import a veterinary biological product for which it has obtained the registration certificate for the imported veterinary drug in China, the Chinese domestic agency shall apply to the veterinary administration under the State Council for the proof documents on permitting the import of the veterinary biological product, and shall, upon strength of such proof documents, apply to the veterinary administration under the people's government at the port locality for the customs release list for imported veterinary drugs. Where any enterprise intends to import any other veterinary drug for which it has obtained the registration certificate for the imported veterinary drug in China, the Chinese domestic agency shall, upon strength of the registration certificate for the imported veterinary drug, apply to the veterinary administration under the people's government at the port locality for the customs release list for imported veterinary drugs. The customs shall release the drugs upon strength of the customs release list for imported veterinary drugs. The measures for the administration of veterinary drug import shall be formulated by the veterinary administration under the State Council jointly with the General Administration of Customs.

After a veterinary biological product is imported, it shall be subject to the examination, check and random inspection in accordance with Article 19 of the present Regulation. After any other veterinary drug is imported, the local veterinary administration shall notify the veterinary drug inspection office to make a random inspection on it.

Article 36 It is prohibited to import the following veterinary drugs:
(1) those whose effectiveness is uncertain, or whose ill response is heavy, or which might cause danger to the breeding industry or human health or which contain potential risks;
(2) veterinary biological products coming from epidemic areas which might cause an epidemic disease to disseminate within China;
(3) those whose production conditions are investigated as not conforming to the provisions; and
(4) those prohibited by the veterinary administration under the State Council from production, operation or use.

Article 37 Where, for exporting a veterinary drug outside China, the importer demands provision of the proof documents on export of the veterinary drug, the veterinary administration under the State Council or the veterinary administration under the people's government of the province, autonomous region, or municipality directly under the Central Government where the enterprise is located may issue such proof documents.

The veterinary administration under the State Council may restrict exporting the vaccines urgently needed in our country for epidemic prevention or prohibit them from being exported.

Chapter VI Use of Veterinary Drugs

Article 38 The veterinary drug using entities shall abide by the provisions formulated by the veterinary administration under the State Council on safe use of veterinary drugs, and shall set up records on the use of drugs.

Article 39 It is prohibited to use fake or inferior veterinary drugs, or the drugs or other compounds

prohibited by the veterinary administration under the State Council from use. The catalogue of the drugs and other compounds prohibited from use shall be formulated and promulgated by the veterinary administration under the State Council.

Article 40 When a veterinary drug having a withdrawal period is used on edible animals, the feeder shall provide the buyer or the slaughter with accurate and genuine records on the use of this drug. The buyer or the slaughter shall guarantee that the animals and their products will not be consumed as food within the drug-in-use period and withdrawal period.

Article 41 The responsibility to formulate and promulgate the catalogue of the varieties of medicinal forage additives permitted to be added to forage shall remain with the veterinary administration under the State Council.

It is prohibited to add hormonal drugs or other prohibited drugs provided for by the veterinary administration under the State Council to forage or animal drinking water.

A veterinary drug that is allowed upon approval to be added to forage may not be added until it has been manufactured by the veterinary drug production enterprise into medicinal forage additive. It is prohibited to add drug materials directly to forage or animal drinking water, or directly feed animals with drug materials.

It is prohibited to use human drugs on animals.

Article 42 The veterinary administration under the State Council shall formulate and organize the implementation of the national plan on monitoring and controlling the remnants of veterinary drugs for animals and animal products.

The veterinary administration under the people's government at the county level or above shall be responsible for organizing the test of veterinary drug remnants in animal products. The test result of veterinary drug remnants shall be promulgated by the veterinary administration under the State Council or the veterinary administration under the people's government of the province, autonomous region, or municipality directly under the Central Government according to their scope of power.

Where the producer or seller of the animal product has any objections to the test result, it may, within 7 working days as of receipt of the test result, file an application to the veterinary administration that organized the test of veterinary drug remnants or its superior veterinary administration for re-test. The veterinary administration that accepts the application shall designate an inspection office to carry out the re-test.

The standards for the limitation of veterinary drug remnants and the remnant testing methods shall be formulated and promulgated by the veterinary administration under the State Council.

Article 43 It is prohibited to sell edible animal products which contain illicit drugs or whose veterinary drug remnants exceed the standards for limitation.

Chapter VII Supervision over Veterinary Drugs

Article 44 The power to supervise veterinary drugs shall be exercised by the veterinary administration under the people's government at the county level or above.

The inspections on veterinary drugs shall be undertaken by the veterinary drug inspection office set up by the veterinary administration under the State Council and the inspection offices set up by the veterinary administrations under the people's government of all provinces, autonomous regions, and municipalities directly under the Central Government. The veterinary administration under the State

Council may, upon its needs, determine other inspection offices to make inspections on veterinary drugs.

Where a party has any objections to the result of the inspection on a veterinary drug, he may, within 7 working days as of receipt of the inspection result, apply to the office that carried out the inspection or the inspection office set up by the superior veterinary administration for re-inspection.

Article 45 Veterinary drugs shall meet the national standards for veterinary drugs.

The "Veterinary Pharmacopoeia of the People's Republic of China" drafted by the Commission of Chinese Veterinary Pharmacopoeia and promulgated by the veterinary administration under the State Council as well as other veterinary drug quality standards promulgated by the veterinary administration under the State Council shall be the national standards for veterinary drugs.

The responsibility to determine the standard products and contrast products under national standards for veterinary drugs shall remain with the veterinary drug inspection office set up by the veterinary administration under the State Council.

Article 46 If the veterinary administration finds any possible fake or inferior veterinary drug which can be proved with evidence when carrying out supervision or inspection in accordance with the law, it may take administrative compulsory sealing measures or distraining measure, and shall, within 7 working days as of taking the administrative compulsory measures, make a decision on whether the case shall be filed. If an inspection is needed, it shall, within 15 working days as of the day when the inspection report was sent out, make a decision on whether the case shall be filed. If the conditions for filing a case are not met, it shall rescind the administrative compulsory measure. If the production, operation or use needs to be suspended, the veterinary administration under the State Council or the veterinary administration under the people's government of the province, autonomous region, or municipality directly under the Central Government shall make a decision according to their scope of power.

Without the approval of the organ for deciding to take administrative compulsory measures or its superior organ, no one may discretionally transfer, use, destroy, or sell the sealed or distrained veterinary drugs or the relevant documents.

Article 47 The veterinary drugs under any of the following circumstances shall be fake:
(1) A non-veterinary drug is passed off as a veterinary drug or another kind of veterinary drug is passed off as one kind of veterinary drug; or
(2) The category or the name of the components contained in a veterinary drug fail to conform to the national standards for this veterinary drug.

Veterinary drugs under any of the following circumstances shall be treated as fake veterinary drugs:
(1) The veterinary drug is prohibited by the veterinary administration under the State Council from use;
(2) The veterinary drug is required by the present Regulation to be examined and approved but is produced or imported without being examined and approved, or is required by the present Regulation to be randomly inspected, examined and checked but is sold or imported without being randomly inspected, examined and checked;
(3) The veterinary drug is deteriorated;
(4) The veterinary drug is polluted; or
(5) The indicated indications or functions exceed the provided scope.

Article 48 Veterinary drugs under any of the following circumstances shall be inferior:
(1) The content of components fails to meet the national standards for the veterinary drug or no effective components are indicated;

(2) No validity period is indicated or the validity period is modified or has expired;
(3) No product batch number is indicated or the product batch number is modified; or
(4) Other circumstances under which the national standards for the veterinary drug are not met, while the veterinary drug is not fake.

Article 49 It is prohibited to divide the veterinary drug materials for sale or to sell veterinary drug materials to any entity or individual other than the veterinary drug production enterprises.

It is prohibited to sell, purchase or use the veterinary drugs controlled under the provisions of the veterinary administration under the State Council without the prescription issued by the veterinarian.

Article 50 The state applies a system of reporting ill responses of veterinary drugs.

A veterinary drug production or operation enterprise, a veterinary drug using entity or a veterinarian issuing a prescription shall, when finding any heavy ill response that might be related to the use of the veterinary drug, immediately report to the veterinary administration under the local people's government.

Article 51 Where a veterinary drug production or operation enterprise ceases its production or operation for more than 6 months or is closed, it shall be ordered by the original permit issuing organ to return its veterinary drug production permit or veterinary drug operation permit. And its industrial and commercial registration shall be modified or written off by the industrial and commercial administration.

Article 52 It is prohibited to purchase, sell, lease or lend any veterinary drug production permit, veterinary drug operation permit or documents proving approval of the veterinary drug.

Article 53 The charging items and rates for review and adjudication as well as inspection of veterinary drugs shall be formulated by the financial administration under the State Council jointly with the price administration under the State Council, and shall be announced.

Article 54 None of the veterinary administrations at all levels, their veterinary drug inspection offices and functionaries shall participate in veterinary drug production or operation activities, nor shall any of them supervise the production or sale of veterinary drugs in their own names.

Chapter VIII Legal Liabilities

Article 55 Where a veterinary administration or any of its functionaries, by taking advantage of its/his position to accept properties from others or to seek other benefits, issues a permit to an entity or individual not conforming to the statutory conditions, signs a consenting opinion on examination, fails to perform its/his supervision duties, or does not investigate or punish the illegal act it/he has found, and thus causes serious consequences, and a crime is constituted, it/he shall be prosecuted for criminal liabilities in accordance with the law. If no crime is constituted, it/he shall be imposed upon administrative sanctions in accordance with the law.

Article 56 Whoever violates the present Regulation by producing or operating a veterinary drug without the veterinary drug production permit or veterinary drug operation permit, or by producing or operating fake or inferior veterinary drugs although having a veterinary drug production permit or veterinary drug operation permit, or whichever veterinary drug operation enterprise violates the present Regulation by operating human drugs, shall be ordered to cease his/its production or operation, his/its raw materials, auxiliary materials and packing materials used in illegal production, the produced or operated veterinary drugs, as well as the illegal proceeds shall all be confiscated. And a fine of not less than twice but not more than five times the value of the illegally produced or operated veterinary drugs (including the veterinary drugs both sold and unsold, the same as below)

shall be imposed in addition. If the amount of the goods value is unable to be verified, a fine of not less than 100,000 Yuan but not more than 200,000 Yuan shall be imposed. If the circumstance of producing veterinary drugs without a veterinary drug production permit is serious, the production equipment shall be confiscated. If the circumstance of producing or operating fake or inferior veterinary drugs is serious, the veterinary drug production permit or veterinary drug operation permit shall be revoked. If a crime is constituted, the violator shall be prosecuted for criminal liabilities. If any loss is caused to others, the violator shall bear the compensation liabilities in accordance with the law. The main responsible person and directly liable persons-in-charge of the production or operation enterprises shall be prohibited from engaging in production or operation of veterinary drugs for life.

Whoever discretionally produces veterinary biological products needed in compulsory immunity shall be considered as producing veterinary drugs without a veterinary drug production permit for punishment.

Article 57 Where anyone violates the present Regulation by obtaining a veterinary drug production permit or veterinary drug operation permit, or documents proving approval of the veterinary drug in a way of providing false documents or sample or by other fraudulent means, its/his veterinary drug production permit or veterinary drug operation permit shall be revoked, or its/his documents proving approval of the veterinary drug shall be nullified. And a fine of not less than 50,000 Yuan but not more than 100,000 Yuan shall be imposed in addition. If any loss is caused to others, it/he shall bear the compensation liabilities in accordance with the law. The main responsible person and directly liable persons in charge shall be prohibited from engaging in import and export of veterinary drugs for life.

Article 58 Whoever purchases, sells, leases or lends the veterinary drug production permit or veterinary drug operation permit, or documents proving approval of the veterinary drug, the illegal proceeds shall be confiscated. And a fine of not less than 10,000 Yuan but not more than 100,000 Yuan shall be imposed in addition. If the circumstance is serious, its/his veterinary drug production permit or veterinary drug operation permit shall be revoked, or its/his documents proving approval of the veterinary drug shall be nullified. If a crime is constituted, it/he shall be prosecuted for criminal liabilities. If any loss is caused to others, it/he shall bear the compensation liabilities in accordance with the law.

Article 59 Where any entity for safety appraisal of veterinary drugs, any clinical trial entity, or any production or operation enterprise violates the present Regulation by failing to implement the rules on research trial of veterinary drugs, or the rules on production and operation quality management in accordance with relevant provisions, it shall be imposed upon a warning, and be ordered to make a correction within a time limit. If it fails to make a correction within the time limit, it shall be ordered to cease the veterinary drug research trial, production or operation activities, and a fine of not more than 50,000 Yuan shall be imposed in addition. If the circumstance is serious, its veterinary drug production permit or veterinary drug operation permit shall be revoked. If any loss is caused to others, it shall bear the compensation liabilities in accordance with the law.

Where any new veterinary drug researcher violates the present Regulation by discretionally using the first category of pathogenic microorganism without meeting the provided conditions or by failing to be approved prior to the laboratory stage, it shall be ordered to cease its experiment, and a fine of not less than 50,000 Yuan but not more than 100,000 Yuan shall be imposed in addition. If a crime is constituted, it/he shall be prosecuted for criminal liabilities. If any loss is caused to others, it/he shall bear the compensation liabilities in accordance with the law.

Article 60 Whoever violates the present Regulation by failing to have the label and instructions of a veterinary drug approved, shall be ordered to make a correction within a time limit. If it/he fails to make a correction within the time limit, it/he shall be considered as producing or operating fake

veterinary drugs for punishment. If it/he has a product approval document number for the veterinary drug, such number shall be nullified. If any loss is caused to others, it/he shall bear the compensation liabilities in accordance with the law.

Where the packing of a veterinary drug is not attached with the label or instructions, or the label or instructions are not consistent with the approved ones, the party concerned shall be ordered to make a correction within a time limit. If the circumstance is serious, it/he shall be punished in accordance with the preceding paragraph.

Article 61 Where an overseas enterprise violates the present Regulation by directly selling veterinary drugs in China, it shall be ordered to make a correction within a time limit. The directly sold veterinary drugs and illegal proceeds shall be confiscated. And a fine of not less than 50,000 Yuan but not more than 100,000 Yuan shall be imposed in addition. If the circumstance is serious, its registration certificate for the imported veterinary drug shall be revoked. If any loss is caused to others, it shall bear the compensation liabilities in accordance with the law.

Article 62 Whoever violates the present Regulation by failing to comply with the relevant provisions of the state on safe use of veterinary drugs when using a veterinary drug, or by failing to set up records on using veterinary drugs or by setting up records that are not complete or genuine, or by using drugs or other compounds prohibited from use, or by using human drugs on animals, shall be ordered to make a correction immediately, and carry out innocuous treatment for the animals and their products which have been fed with illicit drugs or the said other compounds. The law-breaking entity shall be imposed upon a fine of not less than 10,000 Yuan but not more than 50,000 Yuan. If any loss is caused to others, it shall bear the compensation liabilities in accordance with the law.

Article 63 Whoever violates the present Regulation by selling animals and their products which are still in the drug-in-use period or withdrawal period as food for consumption, or by selling animal products containing illicit drugs or animal products whose veterinary drug remnants exceed the limitation as food for consumption shall be ordered to carry out innocuous treatment of such said animal products. Its/his illegal proceeds shall be confiscated. And a fine of not less than 30,000 Yuan but not more than 100,000 Yuan shall be imposed in addition. If a crime is constituted, it/he shall be prosecuted for criminal liabilities. If any loss is caused to others, it/he shall bear the compensation liabilities in accordance with the law.

Article 64 Whoever violates the present Regulation by discretionally transferring, using, destroying or selling sealed or distrained veterinary drugs or the relevant documents, shall be ordered to cease the illegal act, be imposed upon a warning, and a fine of not less than 50,000 Yuan but not more than 100,000 Yuan shall be imposed in addition.

Article 65 Where any veterinary drug production or operation enterprise, veterinary drug using entity or any veterinarian who issues prescriptions violates the present Regulation by failing to report to the veterinary administration under the local people's government when finding any heavy ill response that might be related to the use of the veterinary drug, it/he shall be imposed upon a warning, and a fine of not less than 5,000 Yuan but not more than 10,000 Yuan shall be imposed in addition.

Where a production enterprise fails to collect or timely submit the documents on curative effect and ill response, etc. of a new veterinary drug within the monitoring period for this new veterinary drug, it shall be ordered to make a correction within a time limit, and a fine of not less than 10,000 Yuan but not more than 50,000 Yuan shall be imposed in addition. If the circumstance is serious, the product approval document number of this new veterinary drug shall be nullified.

Article 66 Whoever violates the present Regulation by selling, buying or using a prescription veterinary drug without the prescription issued by a veterinarian, shall be ordered to make a

correction within a time limit. Its/his illegal proceeds shall be confiscated. And a fine of not more than 50,000 Yuan shall be imposed. If any loss is caused to others, it/he shall bear the compensation liabilities in accordance with the law.

Article 67 Where any veterinary drug production or operation enterprise violates the present Regulation by selling drug materials to any entity or individual other than veterinary drug production enterprises, or any veterinary drug operation enterprise violates the present Regulation by dividing drug materials for sale, it shall be ordered to make a correction immediately, and be imposed upon a warning. Its illegal proceeds shall be confiscated. And a fine of not less than 20,000 Yuan but not more than 50,000 Yuan shall be imposed in addition. If the circumstance is serious, its veterinary drug production permit or veterinary drug operation permit shall be revoked. If any loss is caused to others, it shall bear the compensation liabilities in accordance with the law.

Article 68 Whoever violates the present Regulation by adding hormonal drugs or other prohibited drugs as provided for by the veterinary administration under the State Council to forage or animal drinking water shall be punished in accordance with the relevant provisions in the "Regulation on the Administration of Forage and Forage Additives". Whoever directly adds drug materials to forage or animal drinking water, or feeds animals with drug materials shall be ordered to make a correction immediately. And a fine of not less than 10,000 Yuan but not more than 30,000 Yuan shall be imposed in addition. If any loss is caused to others, it/he shall bear the compensation liabilities in accordance with the law.

Article 69 In case of any of the following circumstances, the veterinary drug's product approval document number shall be nullified, or the registration certificate for the imported veterinary drug shall be revoked:
(1) The veterinary drug was randomly inspected as unqualified for twice;
(2) The effectiveness of the drug is uncertain, its ill response is heavy, or it might cause danger to the breeding industry or human health or contains potential risks; or
(3) It is a veterinary drug prohibited by the veterinary administration under the State Council from production, operation or use.

A veterinary drug whose product approval document number has been nullified or an imported veterinary drug whose registration certificate has been revoked shall not be kept on being produced, imported, operated or used. Those having been produced or imported shall be destroyed under the supervision of the local veterinary administration, and the necessary expenses shall be borne by the law-breaker. If any loss is caused to others, the law-breaker shall bear the compensation liabilities in accordance with the law.

Article 70 The administrative penalties provided for in the present Regulation shall be decided by the veterinary administration under the people's government at the county level or above. While such administrative penalties as revocation of veterinary drug production permit or veterinary drug operation permit, nullification of documents proving approval of the veterinary drug, and ordering to cease veterinary drug research or trial, shall be decided by the original certificate issuing department or approval department.

The superior veterinary administration shall, with regard to the inferior veterinary administration's administrative act of violating the present Regulation, order it to make a correction within a time limit. If it fails to make a correction within the time limit, the superior veterinary administration shall be entitled to change or nullify such administrative act.

Article 71 The amount of goods value as provided for in the present Regulation shall be calculated according to the price marked on the illegally produced or operated veterinary drug. If there is no marked price, the said amount shall be calculated according to the market price of the same category of veterinary drug.

Chapter IX Supplementary Provisions

Article 72 The following terms in the present Regulation have their respective meanings as below:
(1) Veterinary drugs shall mean the substances used for preventing, treating, diagnosing animal diseases or purposively adjusting animal's physiological functions (including medicinal forage additives), mainly including: serum products, vaccines, diagnostic products, micro-ecological products, materials of Chinese traditional medicine, prepared Chinese traditional medicine, chemical drugs, antibiotics, bio-chemical drugs, radioactive drugs and external pesticides, disinfectant, and so on.
(2) Prescription veterinary drugs shall mean the veterinary drugs that may not be bought or used without the veterinarian's prescription.
(3) Non-prescription veterinary drugs shall mean the veterinary drugs promulgated by the veterinary administration under the State Council, which may be bought without any veterinarian's prescription and be used pursuant to the instructions.
(4) Veterinary drug production enterprises shall mean the enterprises specially or concurrently produces veterinary drugs, including those engage in the packing of veterinary drugs.
(5) Veterinary drug operation enterprises shall mean the enterprises specially or concurrently operates veterinary drugs.
(6) New veterinary drugs shall mean the veterinary drugs never sold in the markets within the territory of China. And
(7) Documents proving approval of the veterinary drug shall mean the veterinary drug's product approval document number, registration certificate for the imported veterinary drug, documents proving permission of import of the veterinary biological product, documents proving export of veterinary drugs, new veterinary drug registration certificates, and other similar documents.

Article 73 Such particular drugs as narcotic drugs, psychotropic drugs, toxic drugs and radioactive drugs, etc. for veterinary use shall be administered in accordance with the relevant provisions of the state.

Article 74 The responsibilities for the administrative penalties and supervision over the use of veterinary drugs in aquatic breeding, testing of veterinary drug remnants, as well as illegal use of veterinary drugs in the process of aquatic breeding, shall remain with the fishery administrative department under the people's government at the county level or above and the government's subordinate fishery supervision agency.

Article 75 The present Regulation shall come into force on November 1, 2004.