

DECREE

**AMENDMENTS TO CERTAIN ARTICLES OF DECREE NO. 35/2016/ND-CP
DATED MAY 15, 2016 OF THE GOVERNMENT OF VIETNAM ELABORATING
CERTAIN ARTICLES OF THE LAW ON VETERINARY MEDICINE**

Pursuant to the Law on Governmental Organization dated June 19, 2015; Law on amendments to the Law on Governmental Organization and the Law on Local Government Organization dated November 22, 2019;

Pursuant to the Law on Veterinary Medicine dated June 19, 2015;

At the request of the Minister of Agriculture and Rural Development;

The Government of Vietnam promulgates a Decree on amendments to certain Articles of Decree No. 35/2016/ND-CP dated May 15, 2016 of the Government of Vietnam elaborating certain Articles of the Law on Veterinary Medicine.

Article 1. Amendments to certain Articles of Decree No. 35/2016/ND-CP dated May 15, 2016 of the Government of Vietnam elaborating certain Articles of the Law on Veterinary Medicine

1. Amendments to Point a Clause 2 Article 14:

“a) Entities shall send 01 application for issuance of GMP Certificates to the Department of Animal Health via online media, by post or in person. Within 10 working days after receiving the application, the Department of Animal Health shall process it or send a written request for adjustment if the application does not meet the requirements;”

2. Amendments to Clause 1 Article 15:

“1. Entities shall send 01 application for GMP Certificate renewal to the Department of Animal Health via online media, by post or in person. The application includes the original copies of the following documents:

a) An application form for GMP re-inspection;

- b) A report on operations and changes of the facility in 05-year application of GMP; Description of information on the facility that has prepared environmental protection measures as prescribed by laws;
- c) A report on remedies for shortcomings in the previous inspection;
- d) A report on trainings of the facility;
- dd) A list of available equipment of the facility;
- e) A list of products being manufactured;
- g) A list of standard operating procedures;
- h) The latest minutes of self-inspection and evaluation of the facility (within 3 months) in terms of GMP application.

3. Amendments to Clause 1 Article 16:

“1. Application and procedures for GMP certificate renewal in case of loss, damage or wrong information; changes in information related to the applicant:

“a) The entity shall send 01 application for GMP Certificate renewal to the Department of Animal Health via online media, by post or in person. The application includes an original copy of the application form for renewal and original copy or a certified true copy or a copy bearing a certification seal of the facility of the documentary evidence of changes in information related to the applicant or the issued GMP Certificate, except for Certificate lost;

b) Within 03 working days after receiving the application, the Department of Animal Health shall send a written instruction for completing the inadequate application to the entity (if any);

c) Within 05 working days after receiving the adequate application, the Department of Animal Health shall renew the GMP Certificate or send a written reply with clear explanation in case of rejection.”

Article 2. Annulments and changes of certain points and clauses of Decree No. 35/2016/ND-CP dated May 15, 2016 of the Government of Vietnam elaborating certain Articles of the Law on Veterinary Medicine

1. Annulment of points b and k clause 1 Article 14.

2. Replacement of the phrase “Hồ sơ đăng ký kiểm tra GMP phải có trang bìa và mục lục, được sắp xếp theo đúng trình tự của mục lục, có phân cách giữa các phần” (“the application for GMP inspection must include a cover page and a table of contents,

arranged in the correct order of the table of contents, with a separation between sections”) to the phrase “Hồ sơ gồm bản chính tài liệu quy định tại các điểm a, c, d, đ, e, g và i khoản 1 Điều này; bản chính hoặc bản sao có chứng thực hoặc bản sao có đóng dấu xác nhận của Doanh nghiệp tài liệu quy định tại điểm h khoản 1 Điều này. Hồ sơ đăng ký kiểm tra GMP phải có trang bìa và mục lục, được sắp xếp theo đúng trình tự của mục lục, có phân cách giữa các phần” (“An application consists of an original copy specified at Points a, c, d, dd, e, g and i, Clause 1 of this Article; an original or a certified true copy or a copy bearing a certification seal of the facility of the documents specified at Point h, Clause 1 of this Article. The application for GMP inspection must have a cover page and a table of contents, arranged in the order of the table of contents, with a separation between sections” in clause 1 of Article 14.

Article 3. Entry into force

This Decree comes into force from the day on which it is signed.

Article 4. Transitional regulations

Applications received before the date on which this Decree takes effect shall comply with regulations in Decree No. 35/2016/NĐ-CP dated May 15, 2016 of the Government elaborating certain Articles of the Law on Veterinary Medicine.

Article 5. Responsibility for implementation

Ministers, Heads of ministerial agencies, Heads of Governmental agencies, Presidents of the People's Committees of provinces and central-affiliated cities, relevant organizations and individuals are responsible for implementation of this Decree.

**ON BEHALF OF. GOVERNMENT
OF VIETNAM
PP. PRIME MISNISTER
DEPUTY PRIME MINISTER**

Le Van Thanh

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