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Notification with regard to the follow-up works of the cancellations of two administrative approvals related to veterinary drugs

Dear Sir or Madam,

Please find below our update on the Notification with regard to the follow-up works of the cancellations of two administrative approvals related to veterinary drugs.

Kind regards,
CMS, China

The *Decision of the State Council on the Cancelation and Delegation of a Batch of Administrative Licensing Items* promulgated by the State Council on 27 February 2019 ("Decision Guo Fa [2019] No. 6") has cancelled 25 items of administrative approvals, among which, the following two approvals related to veterinary drugs have been cancelled:

(1) the approval of the clinical trial of new veterinary drug; and

(2) the permit of importation of biological veterinary drug.

Following the above Decision Guo Fa [2019] No.6, the Ministry of Agriculture and Rural Affaires of the People's Republic of China ("MOA") promulgated the *Notification with regard to the follow-up work of the cancellation of the administrative approval of new veterinary drug and other approvals* on 26 March 2019 ("Notification") for the purpose of implementation of the Decision Guo Fa [2019] No.6.

1. Cancellation of the approval of the clinical trial of new veterinary drug

According to the previous regulation, especially Article 8 of the *Regulation on Veterinary Drug Administration* revised and effective as of 6 February 2016, the applicant should file an application for the approval of the clinical trial with the competent veterinary administration authorities before starting its clinical trial.

According to the Decision Guo Fa [2019] No. 6, the approval of the clinical trial of new veterinary drug shall be cancelled as of 27 February 2019. Instead of an approval of the competent authority, the applicant shall file a recordal with the competent veterinary administration authority before starting its clinical trial.

The Notification further clarifies that the cancellation of approval is not applicable to clinical trial of the new biological veterinary drug. This implies that the prior approval of clinical trial for new biological veterinary drug is still required. According to the Notification, the applicant can file the recordal of clinical trial after the laboratory

study of the new veterinary drug is completed. After the recordal is made, the applicant can start the clinical trial right away.

The following documents are required for the recordal:

(1) The standard recordal form;

(2) Report of basic information of newly developed veterinary drug;

(3) Clinical trial plan;

(4) Clinical trial agreement between the applicant and unit which will conduct the clinical trial;

(5) Manufacturing of clinical trial plan, draft of quality standard, summary report and examination report of clinical trial; and

(6) Safety assessment report issued by a qualified institute.

It usually takes 10 working days for the competent authority to issue the recordal receipt provided that all the application documents are complete.

2. Cancellation of the permit for the importation of biological veterinary drug

According to Article 35 of the *Regulation on Veterinary Drug Administration*, to import biological veterinary drug to China, the import agent shall first obtain a permit of importation of the biological veterinary products with the MOA, in addition to the photocopy of the Imported Veterinary Drug Registration Certificate. With these two documents, the import agent can apply for the customs clearance form with the MOA to import such products.

According to the Decision Guo Fa [2019] No. 6, such prior permit for the importation of veterinary biological drug is no longer required as of 27 February 2019.

The Notification further clarifies that due to such cancellation, at the time of application for the permit of importation of the biological veterinary drug, the photocopy of the above permit for the importation of biological veterinary drug is no longer needed and the import agent only needs to apply for customs clearance form for the importation of the above veterinary drug with competent veterinary authorities.

In case you have questions or for further information, please contact the authors of this newsletter:

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