



A Pre-NDA meeting for the inhaled nitric oxide (trade name: INOMAX)

On August 20, 2019, a pre-NDA meeting for the inhaled nitric oxide (trade name: INOMAX) was held at the Drug Evaluation Center of the NMPA. Participants at the conference included Minister Ma Yunan, Vice Minister Wang Yamin, Yu Hong (senior reviewer), Liu Fuli (chief reviewer), Shi Jingfen, other reviewers and manufacturer representatives, Callie Gautreaux and Stacy Woepfel, as well as representatives from the registered agents of Zhaoke Pharmaceutical (Hefei) Co., Ltd., Dr. Dai Xiangrong, Dr. Huang Sijia, Shi Min, Li Dongmei, Wang Xuyu.

The meeting mainly focused on discussing the production process of and the technical requirements related to the import registration of INOmax. Before the meeting, the participants from both sides were introduced by Dr. Liu Fuli and Dr. Dai Xiangrong. Then, Shi Min, the project manager of Zhaoke Pharmaceutical, briefly introduced the basic information of the product, the summary of the pharmaceutical materials, related questions and answers through the presentation slides. Then, the manufacturer's representative, Callie, introduced the production process, filling system, gas cylinder transportation and recycling management of the product in detail, and gave detailed answers to the questions raised by the reviewers of the Drug Evaluation Center. In the end, both parties reached an agreement on all the issues raised. The communication of this meeting provided a sufficient pharmacy basis for the NDA application of INOmax.

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