State Food and Drug Administration

Notice on the Issuance of Good Supply Practice of Medical Devices &

Guidelines for On-site Inspection

SFDA〔2015〕No.239

Oct. 15, 2015

Food and drug administrations at all provinces, autonomous regions and municipalities, food and drug administration of Xinjiang Production and Construction Corps:

In order to strengthen supervision and management for operation quality of medical devices, standardize and guide the on-site inspection work of regulations for operation quality management of medical devices, China Food and Drug Administration drafted *Good Supply Practice of Medical Devices : Guidelines for On-site Inspection*(hereinafter referred to as Guideline) according to *Operation Quality Management Standards for Medical Devices*. Hereby printed and issued to you.

Guideline is applicable for the on-site verification of class-III medical device wholesale/retail companies' operation permit(including changing and continuity) by food and drug regulator, on-site verification of class-II medical device wholesale/retail companies after business record, and various supervision and inspection for medical device companies. During on-site inspection, inspection group shall inspect medical device company's implementation of *Operation Quality Management Regulations of Medical Devices* based on the inspection programs and corresponding key programs included in the Guideline. Medical device companies can determine their reasonable missing programs according to their operation mode, operation range and operation products characteristics, and issue written explanations, which shall be approved by inspection group.

In the on-site verification of class-III medical device wholesale/retail companies' operation permit (including changing and continuity), if applicable programs all meet the requirements, the company is marked with "pass inspection". If there're non-conformity key programs, or the percentage of non-conformity general programs exceeds 10%, the company shall be determined as "failed to pass inspection". Food and drug administration issues the written decision on whether to approve the permit according to the inspection.

To the companies whose key programs all meet the requirements and the percentage of non-conformity general programs is no more than 10%, they will be determined as "correction within prescribed timeframe". These companies shall complete correction within 30 days after on-site inspection and submit correction report to the former regulator. If all programs are reviewed meeting the requirements after correction, food and drug administration issues a written decision on approving permit. If these companies fail to submit correction report within 30 days, or non-conformity programs still exist after review, food and drug administration shall issue a written decision on not approving permit.

The percentage of non-conformity general programs described in the Guideline = number of non-conformity programs in general programs / (total number of general programs – number of reasonable missing programs in general programs) * 100%

In the various supervisions and inspections of medical device companies and on-site verification for the class-II medical device wholesale/retail companies after business record, if all applicable programs meet the requirements, the company is determined as "pass inspection". If there're non-conformity programs, the company is determined as "correction within prescribed timeframe".

Whoever violates related provisions of *Regulations for the Supervision and Management of Medical Devices* and *Regulations for the Operation and Supervision of Medical Devices* shall be punished according to laws and regulations.

After inspection, inspection group shall fill out On-site Inspection Sheet for Good Supply Practice of Medical Devices and On-site Inspection Report for Good Supply Practice of Medical Devices

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Good Supply Practice of Medical Devices: Guidelines for On-site Inspection.docx