Appendix :

Writing Specification for Periodic Risk Evaluation Report of Medical Devices

1. RECITALS

In order to guide and standardize medical device registrants and filers (hereinafter referred to as registrants) to write Periodic risk evaluation reports, this specification is formulated in accordance with the *Administrative Measures for Monitoring and Re-evaluation of Adverse Events of Medical Devices* (No.1 Order of the State Administration for Marketing Regulation and the People's Republic of China) (hereinafter referred to as the Measures). The registrant mentioned in this specification has the same connotation as the holder of medical device marketing license mentioned in the Measures.

This specification is a technical document guiding medical device registrants to draft and write periodic risk evaluation reports, and it is also an important basis for medical device adverse event monitoring institutions to evaluate periodic risk evaluation reports.

As a guiding document in principle, this Specification is formulated based on the current understanding of periodic risk evaluation reports and puts forward general requirements for writing. However, the actual situation is diverse, and it is difficult to cover all aspects. Specific issues not covered by this Specification should be studied and determined from reality. At the same time, with the accumulation of experience of medical device registrants summarizing medical device safety information regularly, the change of regulatory requirements, and the continuous development of science and technology, this specification will be adjusted in due course.

2. Basic requirements

2.1 on the submission of reports

2.1.1 For medical devices that have been approved for registration or filing for the first time, the registrant shall complete the periodic risk evaluation report of the previous year within 60 days after each full year. The registrant shall submit the Periodic Risk Evaluation Report of Class II and Class III medical devices through the National Medical Device Adverse Event

Monitoring Information System, fill in the submission form of Periodic Risk Evaluation Report online (see attached table 2), and upload the Periodic Risk Evaluation Report as an attachment of the submission form. The Periodic Risk Evaluation Report of Class I Medical Devices shall be kept by the filer for future reference.

2.1.2 The registrant shall complete the Periodic Risk Evaluation Report of this registration cycle when applying for renewal of registration for the Class II and Class III medical devices, and the registrant shall keep it for future reference. A periodic risk evaluation report is prepared every year for the first five years after the Class I medical device obtains the filing certificate, and there is no need to prepare a periodic risk evaluation report after that.

2.2 About data summary time

2.2.1 When the medical device is approved for registration for the first time, the data start date shall be consistent with the time when the registration certificate is obtained, and the data deadline shall be each full year after the start date.

2.2.2 For medical devices with renewal registration, the data start date shall be the deadline of the last risk information summary, and the data deadline shall be within 60 days before the next application for renewal registration.

2.2.3 In case of early renewal of registration in the first registration cycle, the Periodic Risk Evaluation Report of the current reporting period shall be completed according to the reporting requirements of the first registration cycle after the product has obtained renewal registration, and then it can be written according to the frequency requirements of renewal registration.

2.2.4 In the case of combined report writing, the enterprise may take the registration certificate time of any product as the data start date, but it must ensure the continuity of the data summary date of the combined report afterwards.

2.2.5 The data collection time should be continuous throughout the whole life cycle of medical devices.

2.3 About the writing format of the report

The Periodic Risk Evaluation Report includes three parts: cover, catalogue and main body.

2.3.1 The front cover includes product name, approval date of registration certificate/filing certificate, report type (first registration/renewal registration), number of report, report period, current domestic sales volume, current overseas sales volume, current adverse event report quantity, enterprise name, contact address, postal code, fax, department responsible for product safety, responsible person and contact information (including mobile phone, fixed