AIPLA
American Intellectual Property Law Association

June 14, 2018
2018 年 6 月 14 日

VIA EMAIL: ylqxzc@sina.cn
Director Jiao Hong
China Food and Drug Administration
16 Xuanwumen West Street, Building 2
Beijing 100053
P.R. China

通过邮件：ylqxzc@sina.cn
焦红局长
中国食品药物监督管理局
宣武门西街 16 号，2 号楼
北京 100053
中国

Re: **AIPLA Comments on the Draft Revised Special Approval Procedure for Innovative Medical Devices**

关于： **美国知识产权法律协会有关《创新医疗设备特别批准程序（修订稿）》的建议**

Dear Sirs/Madams:
尊敬的先生们/女士们：

The American Intellectual Property Law Association ("AIPLA") welcomes this opportunity to submit comments on the draft revised Special Approval Procedure for Innovative Medical Devices issued by the China Food and Drug Administration. The American Intellectual Property Law Association is a national bar association of approximately 13,500 members who are primarily lawyers engaged in private or corporate practice, in government service, and in the academic community. AIPLA members represent a wide and diverse spectrum of individuals, companies, and institutions involved directly and indirectly in the practice of patent, trademark, copyright, trade secret, and unfair competition law, as well as other fields of law affecting intellectual property. Our members represent both owners and users of intellectual property. Our mission includes helping to establish and maintain fair and effective global laws and policies that stimulate and reward invention while balancing the public's interest in healthy competition, reasonable costs, and basic fairness.

美国知识产权法律协会（“AIPLA”）十分欢迎能有机会对中国食品药物监督管理局发布的《创新医疗设备特别批准程序（修订稿）》提出建议。美国知识产权法律协会是一个全国性的法律组织，拥有约 13500 名成员，主要由从事私人或公司业务、政府服务以及学术研究的律师构成。美国知识产权法律协会成员来自广泛多元的、直接或间接涉及专利、商标、版权、商业机密、不正当竞争法及其他知识产权法领域的个人、公司和机构。我们的成员既代表知识产权的所有者、也代表使用者。我们的宗旨包括帮助建立和维持公平、有效的全球法律和政策，以促进、奖励发明，同时平衡良性竞争、合理成本和基本公平的公共利益。

As an initial matter, AIPLA commends the development of a Special Approval Procedure for Innovative Medical Devices. It can take a great deal of time to develop, test, and obtain regulatory approval before innovative medical devices can be made available to improve the healthcare of patients.
首先，美国知识产权法律协会对《创新医疗设备特别批准程序》法规的制定表以赞许。在创新医疗设备用于增进病人健康前，可能需要很多时间来发展、测试以及获得监管审批。

AIPLA does not comment on every article proposed in the draft revised Special Approval Procedure for Innovative Medical Devices. However, our decision not to do so should not be interpreted as agreement or acquiescence with the proposed article(s).
美国知识产权法律协会没有对《创新医疗设备特别批准程序（修订版）》进行逐条评论。然而，该决定不能被释义为对未评论条款的同意或默认。

Article II(i)
第二(i)条

Draft Article II(i) would create a five-year limit on the use of Chinese invention patents or published applications that could support qualification of a medical device, starting from the priority date of the patent or patent application. Only patents/applications first filed less than 5 years before the request to enter the Special Procedure could be used to support the request, which would be a challenge for many innovative products that are developed over more than five years. This would result in the regulation being unavailable to prioritize review of innovative medical devices that require substantial development, disadvantaging such devices relative to other devices that are either less innovative or otherwise easier to develop. Moreover, it may not be prudent to implement a revision that would press regulatory applicants to rush their research and testing procedures in order to take advantage of the expedited review. We would suggest not to put a time limit on patents or patent applications that could be used to qualify for the Special Procedure. However, in the event that it is essential to impose such a time limit, we suggest that a reasonable time be at least 10 years, and more preferably 15 years in order to provide a reasonable time for diligent manufacturers to perform careful studies prior to seeking approval of their products.
修订稿第二(i)条将对中国创新专利或已发布的、支持医疗设备资格的应用设立五年限制使用期，从专利或专利申请的优先日期开始计时。只有当最初专利/应用的申请日与申请“特别程序”的时间间隔不多于五年时，“特别程序”才能适用该申请。这将对很多研发期超过五年的创新产品构成挑战。该法规将使提前审查不能适用于

许多需要大量研究的创新医疗设备，它们将比其他创新性更低或更易研发的设备在审批程序上处于更加不利的地位。此外，实行一项要求合规申请者仓促完成其研究和测试过程以赶上加速审查程序的规定之举欠慎重。我们建议取消“特别程序”的专利或专利申请资质中的时间限制。然而，若有必要设立该时间限制，我们建议至少 10 年的合理时间长度，15 年更好，以便勤勉的制造商有充裕时间在申请审查前对其产品进行全面研究。

Article X
第十条

Draft Article X would limit the Special Procedure to a three-year period during which the registration application must be filed, after which the applicant can file a new application for the Special Procedure. The period before filing the registration application may include one or more clinical studies needed to support filing of the registration application, which may require more than three years to complete. It also may not be prudent to press regulatory applicants to rush clinical trials to support filing registration applications before the end of the three-year period. We would suggest that expiration of the Special Procedure for a medical device be limited to situations in which no action is being taken by the applicant to proceed with the application. In particular, medical devices under clinical investigation should not be dropped from the Special Procedure.
修订稿第十条规定“特别程序”只适用于三年内提交注册申请的申请者，否则申请者需重新申请。注册申请前，该步骤需一个或多个临床研究的支持，这些研究可能需要多于三年的时间。同时，要求合规申请者三年内仓促完成临床测试以支持注册申请的规定可能欠慎重。我们建议医疗设备“特别程序”的失效条件改成当申请者不采取任何推动申请行为。特别值得注意的是，不能从“特别程序”中取消正在临床调研的医疗设备。

Article XXII (iv) and (v)
第 22(iv)和(v)条

Article XXII (iv) provides for termination of the Special Procedure if the patent application for the core technological invention has been rejected or regarded as revoked. Article XXII (v) provides for termination of the Special Procedure if the patent rights or using rights of the product core technological invention have been lost. We request clarification of the condition for termination under either of these provisions to limit termination to situations where all patent or patent applications on core technological inventions have been ***finally*** rejected, revoked or lost where the applicant has either exhausted appeals or declined to appeal such rejection, revocation or loss.
第 22(iv)条表明若核心技术发明的专利申请被拒绝或被视为撤回，则“特别程序”终止。第 22(v)条表明若失去专利权利或产品核心技术发明的使用权力，则“特别程序”终止。我们认为应进一步澄清在此两种情况下的终止条件，限制条件为只有当所有

核心技术发明的专利或专利申请被最后拒绝、撤回或丧失、且申请者采取了全部上诉方式或放弃上诉此（专利或专利申请）拒绝、撤回或失去的决定。

AIPLA appreciates the opportunity to provide these comments in response to the draft revised Special Approval Procedure for Innovative Medical Devices. Please contact us if you would like us to provide additional information on any issues discussed above.
美国知识产权法律协会十分感激本次对《创新医疗设备特别批准程序（修订版）》提出以上建议的机会。若您希望我们对以上评论提供进一步信息，请随时联系我们。

Sincerely,
此致

Myra H. McCormack
President 主席
American Intellectual Property Law Association
美国知识产权法律协会