二零一八年六月十五日

100053
中国北京市西城区宣武门西大街 26 号院 2 号楼
国家药品监督管理局办公室
焦红局长

电子邮件信箱：ylqxzc@sina.cn

主题：《创新医疗器械特别审批程序(修订稿征求意见稿)》反馈意见

尊敬的焦局长您好：

美国知识产权所有人协会(下称“IPO 协会”)感谢国家药品监督管理局提供的对 2018 年 5 月 4 日发布的《创新医疗器械特别审批程序（修订稿征求意见稿）》(下称“创新程序修订稿”)提交意见的机会。

IPO 协会是一家代表各行业、各技术领域内拥有知识产权或相关权益的公司和个人的国际性行业协会。它拥有大约两百家公司会员以及超过一万两千多名个人会员。这些个人会员有些从属于公司会员或律所成员，有些是发明人、作者或律师会员。IPO 协会的会员遍及三十多个国家。

IPO 协会提倡有效和实惠的知识产权，为会员提供广泛的服务，包括支持会员在立法和国际事务中的利益、分析当前知识产权问题、提供教育和信息服务、以及向公众传播知识产权的重要性。

我们很高兴地看到国家药品监督管理局在国家市场监督管理总局的领导下，鼓励创新医疗器械以促进医疗卫生事业发展。我们知道经 2014 年 3 月起施行的创新医疗器械特别审批程序批准的创新医疗器械已经或即将使很多病人受益。

IPO 协会对创新程序修订稿的反馈意见主要集中在第二条第(一)点和第二十二条。

创新程序修订稿在第二条第(一)点中增加了“专利的申请日(有优先权的按优先权日)在创新医疗器械特别审批程序申请 5 年内”这一要求。我们迫切希望取消这一限制，理由是开发真正开创性的医疗新技术需要不止五

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年的时间。在研究和开发新的治疗病人的医疗器械过程中,发明专利申请往往从早期就会开始,并且随着研发的进行而持续。对一个医疗器械来说,它的核心技术可能早就被发明并申请了相关专利,而将这个医疗器械完善成为具有安全性和临床应用价值的产品却会需要远不止五年。我们担心五年期限的设立或许会迫使有些医疗器械得不到足够的安全性能开发时间,这将使公众利益受损,与国家药监局鼓励医疗器械安全性以使公众收益的宗旨相悖。IPO 协会强烈建议本条中不设专利申请日/优先权日限制。

创新程序修订稿在第二十二条中增加了几种国家药监局可终止创新医疗器械特别审批程序的情形,包括(四)核心技术发明专利申请被驳回或视为撤回的和(五)失去产品核心技术发明专利专利权或者使用权的。我们赞同增加这些情形,但希望能见到更清晰的语言表明“驳回”和“失去”指的是在司法终局判决下的驳回和失去，也就是指在申请人用尽所有司法程序或者放弃上诉权利的情况下的最终驳回和最终失去权力。IPO 协会建议将本条(四)和(五)修改如下：

(四)核心技术发明专利申请被**司法终局决定**驳回或视为撤回的；

(五)**被司法终局判决**失去产品核心技术发明专利专利权或者使用权的。

随信附上本信的翻译版本。IPO 协会再次感谢贵局给予此次机会提出反馈意见。我们也非常愿意与贵局进一步交流或能有机会为贵局修改创新程序修订稿的工作提供更多的信息。

此致
美国知识产权所有人协会谨启

Mark Lauroesch 马克·劳勒施
执行会长

附件：IPO 协会对《创新医疗器械特别审批程序(修订稿征求意见稿)》的反馈意见(英文版)

15 June 2018

Ms. Jiao Hong
Director
China Drug Administration
16 Xuanwumen West Street, Building 2
Beijing 100053
P.R.China

VIA EMAIL: ylqxzc@sina.cn

Re: Special Review and Approval Procedure for Innovative Medical Devices (Amended Draft for Comments)

Dear Director Jiao:

Intellectual Property Owners Association (IPO) appreciates the opportunity to respond to the request for comments on the Special Review and Approval Procedure for Innovative Medical Devices (Amended Draft for Comments) ("the Amended Draft") dated 4 May 2018.

IPO is an international trade association representing companies and individuals in all industries and fields of technology who own, or are interested in, intellectual property rights. IPO's membership includes about 200 companies and more than 12,000 individuals who are involved in the association either through their companies or as inventor, author, law firm, or attorney members. IPO membership spans over 30 countries.

IPO advocates for effective and affordable IP ownership rights and offers a wide array of services, including supporting member interests relating to legislative and international issues; analyzing current IP issues; providing information and educational services; and disseminating information to the public on the importance of IP rights.

IPO commends the China Drug Administration, now under the leadership of the State Administration for Market Regulation, for its effort in promoting innovative medical devices to improve healthcare. We understand that many patients have benefited, and will benefit, from the innovative medical devices approved through the Special Review and Approval Procedure for Innovative Medical Devices which was implemented in March 2014.

Our comments below address the revisions to Article 2(1) and Article 22.

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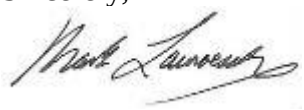
Article 2(1) of the Amended Draft added the requirement that "the patent application date (or priority date, if applicable) is within 5 years of the application date for the special review and approval procedure for innovative medical devices." We urge the removal of this requirement. This is because truly ground breaking medical technology typically takes more than five years to develop. Often, when developing new medical devices for treating patients, patent applications are filed very early in the research and development process and throughout the process. While the core technology might have been invented early on and associated patents might have been filed, a medical device using such core technology can take much longer than five years to become a product that is safe and has significant clinical value. Contrary to the China Drug Administration's interest in encouraging safety aspects of medical devices that will benefit the public, we believe that the proposed time limit would sometimes result in less time than necessary for the appropriate development of safety measures, which would instead be to detriment of the public. We strongly suggest that no time limit be placed on the patent application filing/priority date.

Article 22 of the Amended Draft added a number of scenarios under which the Administration can terminate the application process, including scenarios (4) "when the core technology invention patent application is rejected or deemed withdrawn" and (5) "when the Applicant losses its ownership or right to use the core technology invention patent." We agree with the inclusion of these scenarios, but would like to see it further clarified that the "rejection" and "loss" are under judicial final adjudication, meaning that the patent application has been finally rejected or the patent right finally lost where the Applicant has either exhausted or declined judicial appeals. We recommend amending Article 22(4) and (5) to read "when the core technology invention patent application is rejected or deemed withdrawn and remains rejected or deemed withdrawn having exhausted the judicial adjudication process" and "when the Applicant losses its ownership or right to use the core technology invention patent and it remains lost having exhausted the judicial adjudication process," respectively.

Attached please find this letter as translated. We again thank you for permitting IPO to provide comments and would welcome any further dialogue or opportunity to provide additional information.

Sincerely,



Mark Lauroesch 马克・劳勒施
Executive Director

Attachment