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CNIPA Issues the Revised Measures for the Registration of Pledge of Patent Rights

一、国家药监局规范医疗器械注册审批操作

2021.11.05

NMPA to Regulate the Approval of Domestic Medical Device Registration

日前，国家药品监督管理局印发《境内第二类医疗器械注册审批操作规范》（下称《规范》），自发布之日起施行。



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The National Medical Products Administration ("NMPA") has recently issued the *Good Operating Practice for Approval of the Registration of Domestic Class II Medical Devices* (the "*Operating Practice*"), effective from the date of issuance.

根据《规范》，境内第二类医疗器械注册审批包括受理、技术审评、行政审批和批件制作四个环节，变更备案包括受理和文件制作两个环节。其中，《规范》明确，注册审批过程中，技术审评机构应当自收到补充资料之日起 60 个工作日内完成技术审评。

According to the *Operating Practice*, the approval of registration of domestic Class II medical devices involves four processes, including acceptance, technical review, administrative examination and approval and document production while their record-filing for change involves two processes, namely, acceptance and document production. Among others, the *Operating Practice* makes clear that during the approval of registration, technical review institutions shall complete the technical review within 60 working days upon receipt of the supplementary materials.

《规范》要求，审评人员应根据申请人的申请，对其拟上市销售产品的安全性、有效性和质量可控性研究及其结果进行系统评价，确定注册内容是否符合医疗器械产品注册的相关规定，出具审评意见。

The *Operating Practice* also requires the review personnel to systematically assess the analysis result of the safety, effectiveness and quality controllability of the products to be marketed, and issue corresponding review opinions on whether the registration meets relevant provisions on medical device registration.

(Source:

<https://www.nmpa.gov.cn/xxgk/fgwj/gzwj/gzwjylqx/20211104142753166.html>)

二、国家网信办就《网络数据安全条例》征求意见

2021.11.15



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NMPA Clarifies Relevant Matters Concerning the Implementation of Administrative Measures for the Registration and Record-filing of Medical Devices

日前, 国家互联网信息办公室发出《网络数据安全条例(征求意见稿)》(下称《征求意见稿》), 现向社会征求意见, 意见反馈截止于 12 月 13 日。

The Cyberspace Administration of China ("CAC") has recently issued the *Administrative Regulations on Internet Data Security (Draft for Comment)* (the "*Draft for Comment*") to solicit public opinions by December 13, 2021.

《征求意见稿》规定, 国家建立数据分类分级保护制度。按照数据对国家安全、公共利益或者个人、组织合法权益的影响和重要程度, 将数据分为一般数据、重要数据、核心数据, 不同级别的数据采取不同的保护措施。国家对个人信息和重要数据进行重点保护, 对核心数据实行严格保护。

The *Draft for Comment* reiterates that China shall establish a category- and class-based data protection system. The data will be classified into common data, important data, and core data on account of its importance to national security, public interests, as well as the legitimate rights and interests of relevant individuals or organizations. Different protection measures will be imposed depending on the classifications. China will provide key protection for personal information and important data and strict protection for core data.

《征求意见稿》进一步明确, 数据处理者利用生物特征进行个人身份认证的, 应当对必要性、安全性进行风险评估, 不得将人脸、步态、指纹、虹膜、声纹等生物特征作为唯一的个人身份认证方式, 以强制个人同意收集其个人生物特征信息。

The *Draft for Comment* further specifies that data processors shall conduct risk assessment regarding the necessity and security when they perform personal identification by means of biometric features, and shall not take biometric data, such as



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face, gait, fingerprint, iris and vocal print, as an exclusive method for personal identification to coercively collect personal biometric information.

(Source: http://www.cac.gov.cn/2021-11/14/c_1638501991577898.htm)

三、国知局制发《商标审查审理指南》

2021.11.23

CNIPA Issues the Guide on Trademark Examination and Adjudication

日前，国家知识产权局发布《商标审查审理指南》（下称《指南》），自 2022 年 1 月 1 日起施行。

Recently, the China National Intellectual Property Administration ("CNIPA") has issued the *Guide on Trademark Examination and Adjudication* (the "*Guide*"), with effect on January 1, 2022.

《指南》涵盖上、下两编，分别对形式审查和事务工作以及商标审查审理加以规范。其中，商标审查审理编包括不以使用为目的的恶意商标注册申请的审查审理、不得作为商标标志的审查审理、商标显著特征的审查审理、商标相同近似的审查审理、三维标志商标的审查审理等内容。以“不以使用为目的的恶意商标注册申请的审查审理”为例，《指南》列明了法律依据、释义、适用要件、考虑因素、适用情形、典型案例等，旨在保障商标审查审理各环节法律适用统一和标准执行一致。

The *Guide* consists of two parts, respectively regulating the formality examination and trademark affairs as well as trademark examination and adjudication. Among them, the part "trademark examination and adjudication" includes the examination and adjudication of: (a) malicious trademark registration applications that are not intended for use, (b) marks that cannot be used as trademarks, (c) distinctive features of trademarks, (d) identical and similar trademarks, and (e) three-dimensional mark trademarks. With the "examination and adjudication of malicious trademark registration applications that are not intended for use" as an example, the *Guide* lists the legal basis,



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interpretation, applicable elements, consideration factors, applicable scenarios, typical cases, etc., with a view to ensuring the uniform application of laws and implementation of uniform standards in the whole process of trademark examination and adjudication.

(Source: https://www.cnipa.gov.cn/art/2021/11/22/art_74_171575.html)

四、国知局修改发布《专利权质押登记办法》

2021.11.17

CNIPA Issues the Revised Measures for the Registration of Pledge of Patent Rights

近日，国家知识产权局发出《专利权质押登记办法（2021年版）》（下称《办法》），自发布之日起施行。

The China National Intellectual Property Administration ("CNIPA") has recently issued the *Measures for the Registration of Pledge of Patent Rights (2021 Version)* (the "*Measures*") for implementation from the date of issuance.

《办法》对第六、第七、第十条等多个条款有较为重要的实质性修改，其他有关条款由于调整顺序、精简内容、规范表述等原因，进行了文字修改。主要条款修改内容如下：一是推行以承诺方式办理质押登记手续。二是减少不予办理登记的情形。三是压缩登记审查期限。四是优化登记相关服务。

The *Measures* propose material revisions to Articles 6, 7 and 10, which are of great significance. The texts of the remaining provisions are also revised for the purpose of adjusting orders, streamlining contents, and standardizing expressions. The revisions to the main provisions involve: (1) promoting the pledge registration procedures by means of commitment; (2) reducing the circumstances for unnecessary registration; (3) shortening the time limit required for registration review; (4) optimizing relevant registration services.

其中，《办法》明确当事人可以选择以承诺方式办理专利权质押登记相关手续，当事人提交相关承诺书的，无需提交身份证明、变更证明、注销证明等证明



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材料；国知局将加强事中事后监管，对于虚假承诺的，将按照相关规定采取失信惩戒措施。

Among others, the *Measures* specify that the party concerned may choose to register the pledge of a patent right by means of commitment, and when a commitment letter is submitted, identity certificate, certificate for change, certificate for deregistration, and other evidential materials are no longer required. The CNIPA will strengthen in-process and ex-post regulation and will lawfully impose disciplinary measures for dishonesty to those who make false commitment.

(Source: https://www.cnipa.gov.cn/art/2021/11/16/art_74_171449.html)

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