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NATIONAL MEDICAL PRODUCTS NEWSLETTER

中国食品药品国际交流中心
SERVIER
施维雅(天津)制药有限公司

Drugs

Center for Drug Evaluation of NMPA Announced on Issuing the Administrative Measures for Communication of Drug R&D and Technical Review

Pursuant to the *Announcement of NMPA on Issues Pertaining to Implementing the Provisions for Drug Registration* and the deployment of NMPA, to promote the drafting and formulation of related supporting normative documents and technical guidelines, the Center for Drug Evaluation organized the revision of the *Administrative Measures for Communication of Drug R&D and Technical Review*, which has, as per the requirements of the *Notice of the NMPA Comprehensive Department on Issuing the Release Procedures for Pharmaceutical Technical Guidelines*, been released with NMPA's examination and approval for implementation as from December 10, 2020. (December 11, 2020)

SAMR Released the Provisions for the Lot Release of Biological Products

To implement the newly formulated *Vaccine Administration Law* and the newly revised *Drug Administration Law*, and reinforce the supervision and administration of the lot release of biological products, NMPA drafted the *Provisions for the Lot Release of Biological Products* (hereinafter referred to as the Provisions). The Provisions has been adopted upon deliberation at the 11th Executive Meeting of the State Administration for Market Regulation on November 19, 2020, and shall go into effect as of March 1, 2021.

Vaccines are of great significance to people's health, public health safety and national security. General Secretary Xi Jinping requires to improve China's vaccine administration system and resolutely hold on to the bottom line of safety. During the revision process of the *Provisions*, drawing on the advanced experience of foreign lot release administration, the State Administration for Market Regulation and the NMPA resolutely implemented the "*Four Strictest*" requirements of the Party Central Committee and the State Council on the drug safety of vaccines, elaborated the principles and systems established by the *Vaccine Administration Law* and the *Drug Administration Law* in a practical way for solving problems, and further improved the administrative measures for determination of competent agencies for lot release of biologicals, as well as for the corresponding application, review and inspection processes, to effectively ensure the quality and supply of biological products. At the same time, strict approval administrative measures are adopted to fortify risk prevention and control, further consolidate the principal responsibility of drug marketing authorization holders, and reinforce the supervision and administration in this domain. These *Provisions* contain 48 Articles in eight Chapters, of which the major revisions include:

1. Clarifications of the assignment of responsibilities for lot release agencies, and improvement of the procedures for investigating and handling products with serious quality risks. Additional clauses provide that the provincial drug regulatory departments shall be responsible for the daily management of lot release

药品

国家药监局药审中心关于发布《药物研发与技术审评沟通交流管理办法》的通告

根据《国家药监局关于实施<药品注册管理办法>有关事宜的公告》，为推进相关配套规范性文件、技术指导原则起草制定工作，在国家药品监督管理局的部署下，药审中心组织修订了《药物研发与技术审评沟通交流管理办法》。根据《国家药监局综合司关于印发药品技术指导原则发布程序的通知》要求，经国家药品监督管理局审核同意，于2020年12月10日发布并实施。（2020-12-11）

市场监管总局发布《生物制品批签发管理办法》

为贯彻落实新制定的《疫苗管理法》和新修订的《药品管理法》，加强生物制品批签发工作监督管理，药监局起草修订了《生物制品批签发管理办法》（以下称《办法》）。2020年11月19日，国家市场监督管理总局2020年第11次局务会议审议通过《办法》，自2021年3月1日起实施。

疫苗关系人民群众健康，关系公共卫生安全和国家安全。习近平总书记要求完善我国疫苗管理体制，坚决守住安全底线。《办法》修订过程中，市场监管总局、药监局坚决贯彻落实党中央、国务院关于疫苗药品安全“四个最严”要求，细化《疫苗管理法》《药品管理法》确定的原则制度，突出问题导向，借鉴国外有关批签发管理的先进经验，进一步完善生物制品批签发机构确定、批签发申请与审核检验等管理举措，切实保障生物制品质量和供应。同时，严格审批管理，强化风险防控，进一步夯实药品上市许可持有人主体责任，强化生物制品批签发的监督管理。《办法》共八章48条，主要修改内容包括：

一是明确批签发职责分工和批签发机构等的职责，完善重大质量风险产品查处程序。增加规定省级药品监管部门负责本行政区域内批签发机构的日常管理，对企业生产过程中出现的可能影响产品质量的重大偏差进行调查。细

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agencies in the administrative area, while investigating major deviations that may affect product quality in the production process of the enterprise. The requirements for on-site inspection and handling in relation to lot release are specified, clarifying that if the drug regulatory department spots biological products with serious quality risks during the supervision and inspection, it should promptly notify the lot release agency based on the inspection results to reject or suspend the lot release of application by relevant drug marketing authorization holders and order for rectification .

2. Standardization of administrative requirements for lot release, clarifying the exemptions, inspection items and frequency requirements for lot release, and emphasizing control over production process deviations. According to the *Vaccine Administration Law*, vaccines that are urgently needed to prevent and control infectious diseases or respond to emergencies shall be exempted, with NMPA approval, from lot release. Detailed regulations have been made on the lot release methods, inspection items, and frequency for vaccines and other biological products, and it is required that the lot release of vaccines should be subject to dossier review and sampling inspection. It is stipulated that relevant dossiers such as production process deviation should be submitted while applying for lot release, to facilitate the competent agency's review and on-site inspections.

3. Implementation of the principal responsibilities of the marketing authorization holders, emphasizing life-cycle management requirements. Additional clauses provide that the drug marketing authorization holders should build up a complete production quality management system and deviation control; lot release products should be produced in accordance with approved processes and should meet national drug standards and drug registration standards; and the whole process of production should conform to drug GMP requirements. It is clarified that for products with quality problems or other safety hazards, the holders should take immediate measures such as stopping sales and use, and recalling defective products, etc. At the same time, the handling measures for violations of laws and regulations in the lot release process are clearly defined in accordance with the law, to implement the requirement of strictest supervision and strictest punishment.

In the next step, the NMPA will quickly formulate supporting documents to ensure that all regulations are fully implemented and that the biological products such as vaccines are safe and effective.

(December 21, 2020)

化批签发现场检查及处置工作要求，明确药品监督管理部门在监督检查中发现生物制品存在重大质量风险的，应当根据检查结果及时通知批签发机构对药品上市许可持有人的相关产品不予批签发或者暂停批签发并责令整改。

二是规范批签发管理要求，明确批签发豁免情形、检验项目和频次要求，强化生产工艺偏差管理。依照《疫苗管理法》规定，明确预防、控制传染病疫情或者应对突发事件急需的疫苗，经国家药监局批准，免予批签发。对疫苗产品和其他生物制品批签发方式、检验项目和频次分别作出细化规定，要求疫苗批签发应当逐批进行资料审核和抽样检验。规定在批签发申报时应当提交生产工艺偏差等有关资料，由批签发机构对相关资料进行审核、开展现场检查等。

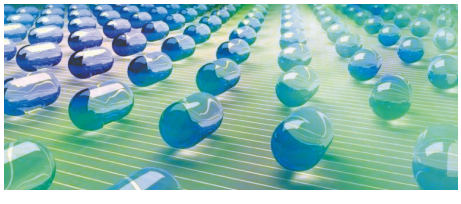
三是落实上市许可持有人主体责任，强化全生命周期管理要求。增加规定药品上市许可持有人应当建立完整的生产质量管理体系，持续加强偏差管理；批签发产品应当按照经核准的工艺生产，并应当符合国家药品标准和药品注册标准；生产全过程应当符合药品生产质量管理规范的要求。明确对存在质量问题或者其他安全隐患的产品，持有人应当采取停止销售、使用，召回缺陷产品等措施。同时，依法明确批签发过程中违法违规行为的处理措施，落实最严格监管和最严厉处罚要求。

下一步，国家药监局将抓紧制定配套文件，确保各项规定落到实处，切实保障疫苗等生物制品安全、有效。（2020-12-21）

NMPA Announcement on Issues Pertaining to Online Application for Drug Registration Affairs

As per the requirements of the *Notice of the General Office of the State Council on the Issuance of Implementation Program for Furtherance of the 'Internet + Government Affairs Service' and the 'One Network, One Door, One Time (One Network Online Service, One Door Offline Service and One Time On-Site Service)' Reform* and the *Guiding Opinions of the General Office of the State Council on Accelerating 'Cross-provincial Handling' of Government Affairs Services*, the NMPA has enabled and officially launched on January 1, 2021 the online application module for drug registration affairs.

Applicants for drug registration shall complete user registration and authorization-based binding of the drug business application system through the Online



国家药监局关于药品注册网上申报的公告

为落实《国务院办公厅关于印发进一步深化“互联网+政务服务”推进政务服务“一网、一门、一次”改革实施方案的通知》和《国务院办公厅关于加快推进政务服务“跨省通办”的指导意见》有关要求，国家药监局已开通药品注册事项网上申报功能，并于2021年1月1日正式上线运行。

药品注册申请人应当按照《药品业务应用系统企业操作指南》，通过国家药品监督管理局网上办事大厅（https://zwfw.nmpa.gov.cn/）完成用户注册及药品业务应用系统授权绑定操作，自2021年1月1日起可在网上办

Service Hall of the NMPA (https://zwfw.nmpa.gov.cn/) as per the *Operation Guidelines for Enterprises on Pharmaceutical Related Application System*. As of January 1, 2021, drug registration can be applied online. For the smooth and steady transition of drug registration, relevant drug registration applicants can continue to use the original drug registration application software to fill in the application after the Online Application Module is launched. As of April 1, 2021, application offers generated by the original drug registration application software shall no longer be handled. (December 28, 2020)

理药品注册业务。

为确保药品注册申报工作平稳过渡，网上申报功能上线后相关药品注册申请人仍可继续使用原药品注册申报软件填报申请表，自2021年4月1日起停止接收原药品注册申报软件生成的报盘文件。 (2020-12-28)

NMPA Announcement on Issuing the Provisions for the *Change Management of Post-approval Drugs (Interim)*

In accordance with the relevant provisions of the *Drug Administration Law*, to reinforce the management of changes of post-approval drugs, the NMPA organized to formulate of the *Provisions for Change Management of Post-approval Drugs (Interim)*, is hereby promulgated and shall go into effect as of January 12, 2021. The provisions of this present Announcement shall prevail over those previously announced.

Each provincial drug regulatory department shall implement the responsibility for supervision over change management of post-approval drugs at its administrative area, by specifying requirements, formulating working documents, and clarifying time limits. The cooperation between drug registration administration and production supervision should be consolidated for mutual support, to ensure the smooth and orderly implementation of change management of post-approval drugs. (January 13, 2021)

国家药监局关于发布《药品上市后变更管理办法（试行）》的公告

为贯彻《药品管理法》有关规定，进一步加强药品上市后变更管理，国家药监局组织制定了《药品上市后变更管理办法（试行）》，于1月12日发布并施行，此前规定与本公告不一致的，以本公告为准。

各省级药品监管部门应当落实辖区内药品上市后变更监管责任，细化工作要求，制定工作文件，明确工作时限，药品注册管理和生产监管应当加强配合，互为支撑，确保药品上市后变更监管工作平稳有序开展。 (2021-01-13)

NMPA Announcement on the Cancellation of Registration Certificates for Phenolphthalein Tablets and Phenolphthalein Buccal Tablets

According to Article 83 of the *Drug Administration Law of the People's Republic of China*, NMPA organized a post-marketing evaluation of phenolphthalein tablets and phenolphthalein lozenges, with the conclusion that these tablets have serious adverse reactions, rendering that the risk of use exceeds the benefit. The NMPA therefore decided the immediate cessation of production, sales and use of the two drugs in China with their registration certificates (drug approval number) revoked forthright. The two drugs that have been released on the market shall be recalled by the manufacturers. The recalled products shall be destroyed on-site under the supervision of the drug regulatory departments directly governing the manufacturers. (January 14, 2021)

国家药监局关于注销酚酞片和酚酞含片药品注册证书的公告

根据《中华人民共和国药品管理法》第八十三条规定，国家药品监督管理局组织对酚酞片和酚酞含片进行了上市后评价，评价认为酚酞片和酚酞含片存在严重不良反应，在我国使用风险大于获益，决定自即日起停止酚酞片和酚酞含片在我国的生产、销售和使用，注销药品注册证书（药品批准文号）。已上市销售的酚酞片和酚酞含片由生产企业负责召回，召回产品由企业所在地药品监督管理部门监督销毁。 (2021-01-14)

NMPA Announcement on Revising the Package Inserts of Sulfasalazine Preparations

To further protect public medication safety, the NMPA decided to revise the package inserts of Sulfasalazine Preparations. The relevant issues are hereby announced as follows:

1. All manufacturers of Sulfasalazine Preparations shall, in accordance with the *Provisions for Drug Registration* and relevant requirements, based on the instruction of the revised *Package Inserts*

国家药监局关于修订柳氮磺吡啶制剂说明书的公告

为进一步保障公众用药安全，国家药品监督管理局决定对柳氮磺吡啶制剂说明书进行修订。现将有关事项公告如下：

一、所有柳氮磺吡啶制剂生产企业均应

of Sulfasalazine Preparations, submit a supplementary application as such before April 12, 2021 to the Center for Drug Evaluation, NMPA or corresponding provincial drug regulatory department for filing.

If the modification relates to the label of the drug, the latter shall be modified together; the other content of the package insert and the label shall be consistent with the original approved ones. All the insert sheets and labels of ex-factory drugs shall be changed within 9 months after the record filing of the supplementary application.

The manufacturers of Sulfasalazine Preparations should conduct in-depth research on the occurrence mechanism of new adverse reactions, take effective measures to publicize the training on drug use and safety issues, and notify the drug distributors and end-user units in an appropriate and timely manner if the medication safety-related contents are changed, to guide the physician and pharmacist to use the medicine rationally.

2. The clinicians and pharmacists should carefully read the revised contents of the package inserts for Sulfasalazine Preparations. Drug options should be based on comprehensive benefit / risk analysis as per the new revisions.
3. The patients should carefully read the newly modified package inserts before use, and strictly comply with the medication orders.

(January 14, 2021)

依据《药品注册管理办法》等有关规定，按照柳氮磺吡啶制剂说明书修订要求，提出修订说明书的补充申请，于2021年4月12日前报国家药品监督管理局药品审评中心或省级药品监管部门备案。

修订内容涉及药品标签的，应当一并进行修订；说明书及标签其他内容应当与原批准内容一致。在补充申请备案后9个月内对所有已出厂的药品说明书及标签予以更换。

柳氮磺吡啶制剂生产企业应当对新增不良反应发生机制开展深入研究，采取有效措施做好使用和安全性问题的宣传培训，涉及用药安全的内容变更要立即以适当方式通知药品经营和使用单位，指导医师、药师合理用药。

二、临床医师、药师应当仔细阅读柳氮磺吡啶制剂说明书的修订内容，在选择用药时，应当根据新修订说明书进行充分的获益/风险分析。

三、患者应严格遵医嘱用药，用药前应当仔细阅读说明书。

特此公告。 (2021-01-14)

NMPA Announcement on the Application of ICH Guideline *E9 (R1): Estimands and Sensitivity Analysis in Clinical Trials*

To keep pace with the international technical standards for drug registration, the NMPA has decided to recommend the application of ICH Guideline *E9 (R1): Estimands and Sensitivity Analysis in Clinical Trials*. E9 (R1) will be applicable to clinical studies of drugs initiated after 12 months from the date of issuance of this Announcement on January 21, 2021.

The relevant technical guidelines may be accessed on the website of the Center for Drug Evaluation, NMPA. The Center for Drug Evaluation, NMPA shall be responsible for effective technical guidance in relation to the implementation of this Announcement.

(January 21, 2021)

国家药监局关于适用《E9（R1）：临床试验中的估计目标与敏感性分析》国际人用药品注册技术协调会指导原则的公告

为推动药品注册技术标准与国际接轨，经研究，国家药品监督管理局决定适用《E9（R1）：临床试验中的估计目标与敏感性分析》国际人用药品注册技术协调会（ICH）指导原则。自2021年1月21日发布公告之日起，12个月后启动的药物临床研究适用E9（R1）。

相关技术指导原则可在国家药品监督管理局药品审评中心网站查询。国家药品监督管理局药品审评中心负责做好本公告实施过程中的相关技术指导工作。 (2021-01-21)

Medical Devices

NMPA Announcement on Issuing of Two Registration Technical Review Guidelines Including the Guidelines for Technical Review of Clinical Evaluation of Ultrasound Diagnostic Imaging Equipment Based on Predicate Products

In order to strengthen the supervision and guidance over medical device registration and further improve the quality of registration review, the NMPA has organized to formulate 2 technical review guidelines for registration including the Guidelines for Technical Review of Clinical Evaluation of Ultrasound Diagnostic Imaging Equipment Based on Predicate Products, which are hereby promulgated on January 15, 2021.

(January 18, 2021)

医疗器械

国家药监局关于发布影像型超声诊断设备同品种临床评价技术审查指导原则等2项注册技术审查指导原则的通告

为加强医疗器械产品注册工作的监督和指导，进一步提高注册审查质量，国家药监局组织制定了影像型超声诊断设备同品种临床评价技术审查指导原则等2项注册技术审查指导原则，于2021年1月15日发布。

（2021-01-18）

NMPA Announcement on Issuing the *Catalogue of Medical Devices Exempt from Clinical Trials (Revised Second Batch)*

In September 2018, NMPA issued the *Announcement on the Issuance of the Newly Revised Catalogue of Medical Devices Exempt from Clinical Trials*, which comprehensively revised and summarized the previously published Catalog of medical devices (and in vitro diagnostic reagents) exempt from clinical trials. Consequently, the revised and summarized *Catalogue of Medical Devices Exempt from Clinical Trials* and *Catalogue of In Vitro Diagnostic Reagents Exempt from Clinical Trials* were issued respectively. On this basis, in December 2019, NMPA issued the *Announcement on the Issuance of the New and Revised Catalogues of Medical Devices Exempt from Clinical Trials*, and published the first batch of New and Revised Catalogues of Medical Devices (and in vitro diagnostic reagents) Exempt from Clinical Trials.

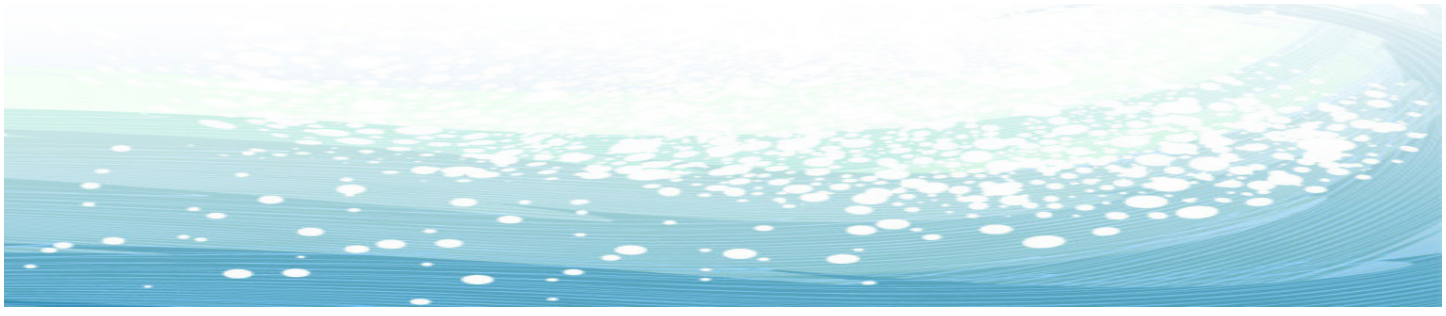
In order to implement the *Opinions on Deepening the Reform of Review and Approval System and Encouraging the Innovation of Drugs and Medical Devices* issued by the General Office of the Central Committee of the Communist Party of China and the General Office of the State Council and the requirements of the State Council for deepening the reform of "streamline administration, delegate power, strengthen regulation and improve services", in accordance with the *Regulations for the Supervision* and *Administration of Medical Devices*, the *Provisions for Medical Device Registration* and the *Provisions for In Vitro Diagnostic Reagent Registration*, the NMPA organized the addition and revision of the catalogue of the second batch of medical devices (including in vitro diagnostic reagents) exempted from clinical trials. It is promulgated and implemented as of January 14, 2021.

(January 19, 2021)

国家药监局关于发布免于进行临床试验医疗器械目录（第二批修订）的通告

2018年9月，国家药品监督管理局印发《关于公布新修订免于进行临床试验医疗器械目录的通告》，对前期已发布的免于进行临床试验的医疗器械（及体外诊断试剂）目录进行了全面修订和汇总，分别印发了修订汇总后的《免于进行临床试验的医疗器械目录》和《免于进行临床试验的体外诊断试剂目录》。在此基础上，2019年12月，国家药品监督管理局印发《关于公布新增和修订的免于进行临床试验医疗器械目录的通告》，公布了第一批新增和修订的免于进行临床试验的医疗器械（及体外诊断试剂）目录。

为贯彻落实中共中央办公厅、国务院办公厅《关于深化审评审批制度改革鼓励药品医疗器械创新的意见》和国务院深化“放管服”改革有关要求，进一步做好医疗器械注册管理工作，根据《医疗器械监督管理条例》《医疗器械注册管理办法》《体外诊断试剂注册管理办法》，国家药品监督管理局组织新增和修订了第二批免于进行临床试验医疗器械（及体外诊断试剂）目录。于2021年1月14日公布并施行。（2021-01-19）



NMPA Announcement on Issuing Three Guidelines for Technical Review of the Registration Including that of Mycoplasma Pneumoniae IgM/IgG Antibody Detection Reagents

To strengthen the supervision and guidance over the registration of medical device products and further improve the quality of registration review, NMPA has organized the formulation of and released on January 18, 2021 the *Guidelines for Technical Review of the Registration of Mycoplasma Pneumoniae IgM/IgG Antibody Detection Reagents*, *Guidelines for Technical Review of the Registration of Cryptococcus Capsular Polysaccharide Antigen Detection Reagents*, and *Guidelines for Technical Review of the Registration of Hereditary Hearing Loss Gene Mutation Detection Reagents*.

(January 19, 2021)

国家药监局关于发布肺炎支原体IgM/IgG抗体检测试剂等3项注册技术审查指导原则的通告

为加强医疗器械产品注册工作的监督和指导，进一步提高注册审查质量，国家药品监督管理局组织制定了《肺炎支原体IgM/IgG抗体检测试剂注册技术审查指导原则》《隐球菌荚膜多糖抗原检测试剂注册技术审查指导原则》和《遗传性耳聋相关基因突变检测试剂注册技术审查指导原则》，于2021年1月18日发布。 (2021-01-19)

Cosmetics

SAMR Issued the *Provisions for Registration and Notification of Cosmetics*

To implement the newly revised *Regulations on the Supervision and Administration of Cosmetics* (hereinafter referred to as the *Regulations*), reinforce the administration of cosmetics registration and notification, protect consumers' health rights, and standardize and promote the healthy development of the cosmetics industry, the NMPA drafted the *Provisions for Registration and Notification of Cosmetics* (hereinafter referred to as the *Provisions*). The Provisions has been adopted upon deliberation at the 14th Executive Meeting of the State Administration of Market Regulation on December 31, 2020, and shall go into effect as of May 1, 2021.

The revised *Regulations* has established a registration and notification administration system with the registration persons and notification persons as the subject of liability for quality and safety, clarified the procedures and requirements for the registration and notification of cosmetics and new cosmetic ingredients, and determined a series of new concepts, systems and mechanisms, which necessitate the formulation of supporting provisions to further elaborate cosmetics registration and notification administration. During the drafting of the *Provisions*, the NMPA held multiple symposiums, on-site surveys and special discussions, and extensively listened to the opinions and suggestions of local regulatory authorities, industry associations, enterprises, legal and technical experts from all social sectors. Emphasizing on the "Four Strictest" requirements in a practical way of problem orientation, the *Provisions* elaborates the principles and systems determined in the Regulations, with a view to strictly implementing review and approval as well as notification administration, reinforcing risk control, deepening the reform of "streamlining administration, delegating more powers to lower-level governments and society and improving regulation and optimizing services", encouraging R&D enterprises to innovate, optimizing the registration and notification procedures, and implementing the principal responsibilities and supervision responsibilities of various parties. With a total of 63 Articles in 6 Chapters, the *Provisions* covers:

1. The elaboration on the administration system for registration and notification persons to potentiate corporate principal responsibilities. In accordance with the related requirements of the *Regulations*, detailed provisions for responsibilities,

化妆品

市场监管总局发布《化妆品注册备案管理办法》

为贯彻落实新颁布的《化妆品监督管理条例》（以下简称《条例》），加强化妆品注册和备案管理，保障消费者健康权益，规范和促进化妆品行业健康发展，国家药监局起草了《化妆品注册备案管理办法》（以下简称《办法》）。2020年12月31日，国家市场监督管理总局2020年第14次局务会议审议通过《办法》，自2021年5月1日起实施。

修订后的《条例》建立了以注册人、备案人为质量安全责任主体的注册备案管理制度，明确了化妆品、化妆品新原料注册备案程序和要求，确定了一系列新理念、新制度、新机制，需要制定配套规章进一步细化注册备案管理工作规定。《办法》起草过程中，国家药监局多次召开座谈会、实地调研、专题讨论，广泛听取了地方监管部门、行业协会、企业及法律和技术专家等社会各界的意见建议。《办法》落实“四个最严”要求，突出问题导向，细化《条例》确定的原则制度，严格审批审评和备案管理，强化风险控制；深化“放管服”改革，鼓励研发企业创新，优化注册备案程序，落实各方主体责任和监管责任，共6章63条，主要内容包括：

一是细化注册人、备案人管理制度，强化企业主体责任落实。根据《条例》关于注册人、备案人的相关规定要求，细化落实化妆品、化妆品新原料注册人、备案人的责任义务及准入条件，加强对产品责任源头监管。建立新原料安全监测制度，对新原料注

obligations and access conditions are applied to registration and notification persons of cosmetics and new cosmetic ingredients to potentiate the supervision and liability of product at its source. A safety monitoring system for new cosmetic ingredients is established with detailed regulations on the safety monitoring obligations of registration and notification persons of cosmetics and new cosmetic ingredients.

2. The optimization of the registration and notification administration procedures and concretization of reform measures for the review and approval system. As per the relevant provisions of the *Regulations* and the reform of "streamlining administration, delegating more powers to lower-level governments and society and improving regulation and optimizing services", the registration and notification administration procedures are further clarified and optimized on the basis of summarizing the experience drew from the reform implemented in the previous stage, such as the transition from review and approval to notification of imported general cosmetics, and the adjustment of special cosmetics to the informing & pledging system for registration renewal.

3. The enhancement of supervision and administration of post-notification to ensure that the responsibilities for product quality and safety are in place. The responsibilities and requirements for the supervision and administration of post-notification are clarified, with stricter penalties for violations of laws and regulations on filed products, which are subject to classification management to rationally allocate supervision resources.

4. The establishment of an innovation-encouraging mechanism to serve the high-quality development of the industry. The relevant provisions of the *Regulations* on encouraging innovative development are further elaborated, clarifying that during the safety monitoring period, no cosmetics registration persons and notification persons can use the new cosmetic ingredient without the consent of its registration person or notification person so as to protect the enthusiasm of enterprises in new ingredient R&D; Greater efforts are made to construct the information technology for registration and notification, multi-functional information service platforms shall be built to improve the efficiency of registration and notification, so as to accelerate product marketing, and promote the steady improvement of the high-quality development of the cosmetics industry. (January 12, 2021)

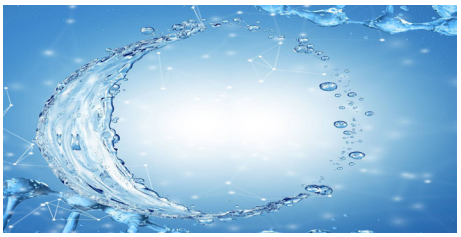
册人、备案人和化妆品注册人、备案人应当履行的安全监测义务进行了细化规定。

二是优化注册备案管理程序，落实审批制度改革措施。在总结前期已经实施的进口非特殊用途化妆品审批改备案、特殊用途化妆品延续告知承诺制审批等改革措施取得成效的基础上，根据"放管服"改革精神和《条例》相关规定，进一步明确和优化了注册备案管理程序。

三是加强备案后监督管理，确保产品质量安全责任落实到位。明确备案后监督管理责任落实和工作要求，加大对备案产品违法违规行为的惩处力度；实施备案产品分级管理，合理配置监管资源。

四是建立鼓励创新机制，服务产业高质量发展。深化落实《条例》关于鼓励创新发展的相关规定，明确安全监测中的新原料经新原料注册人、备案人同意后，化妆品注册人、备案人方可用于化妆品生产，保护新原料研发企业的积极性；加强注册、备案信息化建设，构建多功能信息服务平台，提升注册、备案工作效率，加快产品上市速度，促进化妆品产业高质量发展水平的稳步提升。

(2021-01-12)



General Information

The State Administration for Market Regulation, the National Medical Products Administration, and the China National Intellectual Property Administration Jointly Commend Advanced Collectives and Advanced Individuals in Fighting the COVID-19 Pandemic

On January 18, the State Administration for Market Regulation held the National Market Regulation Work Conference and announced the *Decision of the State Administration for Market Regulation, the National Medical Products Administration, and the China National Intellectual Property Administration on Commending Advanced Collectives and Advanced Individuals in the National Market Regulation System for Fighting the COVID-19 Pandemic*. 198 advanced collectives and 395 advanced individuals in the market regulation system were commended.

Approved by the CPC Central Committee and the State Council, the commendation was carried out by the SAMR in conjunction with the NMPA and CNIPA to honor the advanced models in the market regulation system that have emerged in the severe fight against the COVID-19 Pandemic, and to

综合信息

市场监管总局 国家药监局 国家知识产权局联合表彰抗击新冠肺炎疫情先进集体和先进个人

1月18日，市场监管总局召开全国市场监管工作会议，会议宣布了《市场监管总局 国家药监局 国家知识产权局关于表彰全国市场监管系统抗击新冠肺炎疫情先进集体和先进个人的决定》，全国市场监管系统198个先进集体和395名先进个人受到表彰。

此次表彰经党中央、国务院批准，由市场监管总局会同国家药监局、国家知识产权局开展，表彰在抗击新冠肺炎疫情严峻斗争中涌现出的市场监管系统先进典型，以进

further potentiate market supervisors' sense of responsibility, mission and honor.

The Conference emphasized that the current task of coordinating and promoting normalized epidemic prevention & control and socio-economic development remains arduous and heavy. Guided by Xi Jinping's Thought on Socialism with Chinese Characteristics for a New Era, the national market regulation system must enhance the "Four Consciousnesses", hold fast the "Four-sphere Confidence", and ensure the "Two Upholds"; take the commended advanced collectives and advanced individuals as examples, remain true to the original aspiration, keep the mission in mind, fulfill their duties and bravely shoulder important responsibilities, in order to make new and greater contributions to improving the modern level of market regulation and better serving the high quality socio-economic development. (January 18, 2021)

一步增强市场监管人员的责任感、使命感和荣誉感。

会议强调，当前统筹推进常态化疫情防控和经济社会发展的任务仍然艰巨繁重，全国市场监管系统要以习近平新时代中国特色社会主义思想为指导，增强"四个意识"、坚定"四个自信"、做到"两个维护"，以受表彰的先进集体和先进个人为榜样，不忘初心、牢记使命，恪尽职守、勇担重任，为提高市场监管现代化水平、更好地服务经济社会高质量发展作出新的更大贡献。（2021-01-18）

Notes: • All Chinese information in the Newsletter is extracted from newspapers and the Internet. All English articles are translations from the Chinese version.
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