2021. Volume 4

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

NMPA CDE Announcement on Issuing the *Guidance for Real-World Data Used to Generate Real-World Evidences (Interim)*

In order to further guide and regulate sponsors to use real-world data to generate real-world evidences to support drug R & D, the CDE has organized to formulate the *Guidance for Real-World Data Used to Generate Real-World Evidences (Interim)*, which was issued for implementation on April 13 upon review and approval by NMPA.

(April 13, 2021)

NMPA Announcement on Revising the Package Inserts of 14 Drug Varieties Including Paracetamol, Pseudoephedrine Hydrochloride and Dextromethorphan Hydrobromide Oral Solution

In order to further protect the medication safety for the public, NMPA decided to revise the package inserts of 14 drug varieties including the Paracetamol, Pseudoephedrine Hydrochloride and Dextromethorphan Hydrobromide Oral Solution, Paracetamol, Pseudoephedrine Hydrochloride and Dextromethorphan Hydrobromide Syrup, Pediatric Paracetamol and Amantadine Hydrochloride Granules, Paracetamol, Pseudoephedrine Hydrochloride and Chlorpheniramine Maleate Chewable Tablets, Pediatric Compound Paracetamol and Amantadine Hydrochloride Tablets, Pediatric Paracetamol, Caffein, Artificial Cow-bezoar and Chlorphenamine Maleate Granules, Paracetamol, Amantadine Hydrochloride, Artificial Cow-bezar and Chlorphenamine Mdeate Granules, Paraceramol Caffeine Guaifenfsin and Chlorphenamine Maleate Solution, Pediatric Compound Paracetamol and Phenylephrine Tablets, Paracetamol, Caffeine, Artificial Cow-Bezoar, Chlorphenamine Maleate Oral Solution, Paracetamol, Pseudoephedrine Hydrochloride and Chlorphenamine Maleate Dispersible Tablets (III), Compound Paracetamol and Chlorphenamine Tablets for Infant, Pediatric Paracetamol, Artificial Cow-bezoar and Chlorphenamine Maleate Tablets, and Pediatric Paracetamol, Artificial Cow-bezoar and Chlorphenamine Maleate Granules.

(April 21, 2021)

NMPA CDE Announcement on Issuing the *Guidance for Clinical Trials of Biosimilars of Pertuzumab Injection*

In order to encourage the R & D of biosimilars, further standardize and guide the design and endpoint selection of biosimilars of pertuzumab injection and provide a technical specification that can be referred to, under the deployment of NMPA, CDE has organized to formulate the *Guidance for Clinical Trials of Biosimilars of Pertuzumab Injection*, which was issued for implementation on April 21 upon review and approval by NMPA. (April 21, 2021)

药品

国家药监局药审中心关于发布《用于产生真实世界证据的真实世界数据指导原则(试行)》的通告

为进一步指导和规范申办者利用真实世界数据生成真实世界证据支持药物研发，药审中心组织制定了《用于产生真实世界证据的真实世界数据指导原则(试行)》，经国家药品监督管理局审查同意，于4月13日发布并施行。 (2021-04-13)

国家药监局关于修订氨酚麻美口服溶液等14个品种药品说明书的公告

为进一步保障公众用药安全，国家药品监督管理局决定对氨酚麻美口服溶液、氨酚麻美糖浆、小儿氨酚烷胺颗粒、氨酚伪麻那敏咀嚼片、小儿复方氨酚烷胺片、小儿氨咖黄敏颗粒、氨金黄敏颗粒、氨咖愈敏溶液、儿童复方氨酚肾素片、氨咖黄敏口服溶液、氨酚伪麻那敏分散片（III）、小儿氨酚那敏片、小儿氨酚黄那敏片、小儿氨酚黄那敏颗粒等14个品种药品说明书进行修订。 (2021-04-21)

国家药监局药审中心关于发布《帕妥珠单抗注射液生物类似药临床试验指导原则》的通告

为鼓励生物类似药研发，进一步规范和指导帕妥珠单抗生物类似药的临床试验设计和终点选择，提供可参考的技术规范，在国家药品监督管理局的部署下，药审中心组织制定了《帕妥珠单抗注射液生物类似药临床试验指导原则》，经国家药品监督管理局审查同意，于4月21日发布并施行。 (2021-04-21)

Published by
China Center for Food and Drug International Exchange
Servier (Tianjin) Pharmaceutical Co., Ltd.

NMPA CDE Announcement on Issuing the *Guidance for Clinical Trials of Biosimilars of Tocilizumab Injection*

In order to encourage the R & D of biosimilars, further standardize and guide the design and endpoint selection of biosimilars of *Tocilizumab Injection* and provide a technical specification that can be referred to, under the deployment of NMPA, CDE has organized to formulate the *Guidance for Clinical Trials of Biosimilars of Tocilizumab Injection*, which was issued for implementation on April 21 upon review and approval by NMPA.

(April 21, 2021)

国家药监局药审中心关于发布《托珠单抗注射液生物类似药临床试验指导原则》的通告

为鼓励生物类似药研发，进一步规范和指导帕妥珠单抗生物类似药的临床试验设计和终点选择，提供可参考的技术规范，在国家药品监督管理局的部署下，药审中心组织制定了《托珠单抗注射液生物类似药临床试验指导原则》，经国家药品监督管理局审查同意，于4月21日发布并施行。 （2021-04-21）

NMPA Announcement on the Applicability of ICH Guidelines *M9: Biopharmaceutics Classification System-based Biowaivers* and Q&A *Document thereof* and Q5D *Derivation and Characterisation of Cell Substrates Used for Production of Biotechnological/Biological Products*

In order to promote the technical standards of drug registration in line with international standards, upon study, NMPA decided to apply the ICH Guidelines M9 Biopharmaceutics Classification System-based Biowaivers and Q&A document thereof and Q5D Derivation and Characterisation of Cell Substrates Used for Production of Biotechnological/Biological Products. On April 28, 2021, relevant matters were announced as follows:

I. Applicants are required to carry out the study in accordance with the ICH Guidelines as early as possible based on current technical requirements. For relevant studies that start 6 months after the issuance date of this Announcement (based on the time point of the trial record), the above ICH Guidelines shall apply.

II. The relevant technical guidelines may be accessed on the website of the Center for Drug Evaluation of NMPA. The Center for Drug Evaluation of NMPA shall be responsible for relevant technical guidance during the implementation of this Announcement.

(May 7, 2021)

国家药监局关于适用M9及问答文件和Q5D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《M9：基于生物药剂学分类系统的生物等效性豁免》及问答文件和《Q5D：用于生物技术产品及生物制品生产的细胞基质的来源和鉴定》国际人用药品注册技术协调会（ICH）指导原则。于2021年4月28日就有关事项公告如下：

一、申请人需在现行技术要求基础上，尽早按照ICH指导原则的要求开展研究。本公告发布之日起6个月后开始的相关研究（以试验记录时间点为准），适用上述ICH指导原则。

二、相关技术指导原则可在国家药监局药审中心网站查询。国家药监局药审中心负责做好本公告实施过程中的相关技术指导工作。 （2021-05-07）

NMPA Announcement on Issuing the *Good Pharmacovigilance Practice*

According to the *Drug Administration Law of the People's Republic of China* and *the Vaccine Administration Law of the People's Republic of China*, NMPA has organized to formulate the *Good Pharmacovigilance Practice* to standardize and guide drug marketing authorization holders and drug registration applicants to conduct pharmacovigilance activities, which was issued on May 7. The issues related to the implementation of the *Good Pharmacovigilance Practice* are hereby announced as follows:

I. The *Good Pharmacovigilance Practice* will come into force as of December 1, 2021.

II. Drug marketing authorization holders and drug registration applicants shall actively prepare for the implementation of the *Good*

国家药监局关于发布《药物警戒质量管理规范》的公告

根据《中华人民共和国药品管理法》《中华人民共和国疫苗管理法》，为规范和指导药品上市许可持有人和药品注册申请人的药物警戒活动，国家药监局组织制定了《药物警戒质量管理规范》，于5月7日予以公布，并就实施《药物警戒质量管理规范》有关事宜公告如下：

一、《药物警戒质量管理规范》自2021年12月1日起正式施行。

Pharmacovigilance Practice, establish and continuously improve the pharmacovigilance system and conduct pharmacovigilance activities in a standardized manner.

III. Drug marketing authorization holders shall complete information registration at the National ADR Monitoring System within 60 days upon issuance of this Announcement.

IV. All the provincial medical products administration shall supervise and urge the drug marketing authorization holders within their respective administrative areas to actively make preparations, cooperate with relevant publicity and interpretation, supervise and guide drug marketing authorization holders to implement the *Good Pharmacovigilance Practice* as required by strengthening routine inspection and other activities, and in a timely manner collect and feedback relevant questions and comments.

V. The National Center for ADR Monitoring shall organize and coordinate the publicity, training and technical guidance for the *Good Pharmacovigilance Practice* in a unified manner and set a special column of the *Good Pharmacovigilance Practice* on its official website to reply to questions and comments in a timely manner.

(May 13, 2021)

二、药品上市许可持有人和药品注册申请人应当积极做好执行《药物警戒质量管理规范》的准备工作，按要求建立并持续完善药物警戒体系，规范开展药物警戒活动。

三、药品上市许可持有人应当自本公告发布之日起60日内，在国家药品不良反应监测系统中完成信息注册。

四、各省级药品监督管理部门应当督促本行政区域内的药品上市许可持有人积极做好相关准备工作，配合做好有关宣贯和解读，通过加强日常检查等工作监督和指导药品上市许可持有人按要求执行《药物警戒质量管理规范》，及时收集和反馈相关问题和意见。

五、国家药品不良反应监测中心统一组织和协调《药物警戒质量管理规范》的宣贯培训和技术指导工作，在官方网站开辟《药物警戒质量管理规范》专栏，及时解答相关问题和意见。 (2021-05-13)

NMPA Announcement on the Cancellation of Registration Certificates for 283 Drugs including Megestrol Acetate Dispersible Tablets

According to the Regulations for the Implementation of the Drug Administration Law of the People's Republic of China and the *Provisions for Drug Registration*, NMPA has decided to cancel the registration certificate of 283 drugs including Megestrol Acetate Dispersible Tablets.

(May 24, 2021)

国家药监局关于注销醋酸甲地孕酮分散片等283个药品注册证书的公告

根据《中华人民共和国药品管理法实施条例》和《药品注册管理办法》的有关规定，国家药品监督管理局决定注销醋酸甲地孕酮分散片等283个药品注册证书。 (2021-05-24)

NMPA Announcement on Adding the Medication Information for Children to the Package Inserts of Haloperidol Tablets and Other Varieties

In order to better meet the clinical medication needs of children, upon the study and demonstration, package inserts of Haloperidol Tablets and other varieties may be added with the children users and dosage and usage for children according to the requirements. On May 28, relevant issues are hereby announced as follows:

I. The marketing authorization holders of relevant varieties may, based on the *Provisions for Drug Registration* and in accordance with corresponding revision suggestions, submit the supplementary application to the Center for Drug Evaluation of NMPA, revise the [Indications] and [Usage and Dosage] of the package insert, and simultaneously improve the safety information and other relevant contents in the package insert. If revision relates to the drug label, the latter shall be modified together.

II. After the approval of corresponding supplementary application is obtained, the marketing authorization holders of relevant varieties shall collect and report the ADR information in time, and conduct risk control and pharmacovigilance for pediatric medication.

(May 31, 2021)

国家药监局关于氟哌啶醇片等品种说明书增加儿童用药信息的公告

为更好满足儿童临床用药需求，经研究论证，氟哌啶醇片等药品的说明书可以按要求增加儿童使用人群及用法用量。于5月28日将有关事项公告如下：

一、相关品种的上市许可持有人可依据《药品注册管理办法》等有关规定，按照相应修订建议，向国家药监局药品审评中心提出补充申请，修订说明书【适应症】和【用法用量】项有关内容，并同时完善说明书安全性信息等相关内容。修订内容涉及药品标签的，应当一并进行修订。

二、相应补充申请批准后，相关品种的上市许可持有人应及时收集并报告不良反应信息，做好儿童用药的风险控制及药物警戒工作。 (2021-05-31)

Announcement of NMPA and General Administration of Customs on the Establishment of Changchun Airport as a Drug Import Port

According to the *Drug Administration Law of the People's Republic of China*, upon approval of the State Council, NMPA and General Administration of Customs agree to establish Changchun Airport as a drug import port. On June 7, 2021, relevant matters are hereby announced as follows:

I. As of the date of issuance of this Announcement, except for the drugs specified in Article 10 of the *Provisions for Drug Importation* (hereinafter referred to as the *Provisions*), other imported drugs (including narcotic drugs and psychotropic drugs) may be imported through Changchun Airport.

II. Jilin Medical Products Administration is added as the port drug regulatory authority, which shall undertake the specific drug import filing at Changchun Airport.

III. Jilin Institute for Drug Control is added as the port drug testing institute. As of the date of issuance of this Announcement, Jilin Institute for Drug Control starts to undertake the drug port testing at Changchun Airport.

(June 15, 2021)

国家药监局 海关总署关于增设长春空港口岸为药品进口口岸的公告

根据《中华人民共和国药品管理法》，经国务院批准，国家药品监督管理局、海关总署同意增设长春空港口岸为药品进口口岸。于2021年6月7日将有关事宜公告如下：

一、自本公告发布之日起，除《药品进口管理办法》（以下简称《办法》）第十条规定的药品外，其他进口药品（包括麻醉药品、精神药品）可经由长春空港口岸进口。

二、增加吉林省药品监督管理局为口岸药品监督管理部门，由其承担长春空港口岸药品进口备案的具体工作。

三、增加吉林省药品检验研究院为口岸药品检验机构。自本公告发布之日起，吉林省药品检验研究院开始承担长春空港口岸的药品口岸检验工作。（2021-06-15）

Medical Devices

NMPA Announcement on Issuing the Principles for the Classification Defining of Recombinant Collagen Products

In order to strengthen the supervision and administration of recombinant collagen products and promote the high-quality development of the industry, NMPA has organized to formulate the *Principles for the Classification Defining of Recombinant Collagen Products*, which was issued on April 13. (April 13, 2021)

医疗器械

国家药监局关于发布重组胶原蛋白类医疗产品分类界定原则的通告

为进一步加强重组胶原蛋白类医疗产品监督管理，推动产业高质量发展，国家药监局组织制定了《重组胶原蛋白类医疗产品分类界定原则》，于4月13日发布。

（2021-04-13）

NMPA Announcement on Issuing the Working Procedures for Dynamic Adjustment of Classification Catalogue for Medical Devices

In order to strengthen the classification management of medical devices and standardize the dynamic adjustment of the *Classification Catalogue for Medical Devices*, according to the *Regulations for the Supervision and Administration of Medical Devices* and the *Classification Rules for Medical Devices*, NMPA has organized to formulate the *Working Procedures for Dynamic Adjustment of Classification Catalogue for Medical Devices*, which was issued on April 27. (May 8, 2021)

国家药监局关于发布医疗器械分类目录动态调整工作程序的公告

为加强医疗器械分类管理，规范《医疗器械分类目录》动态调整工作，根据《医疗器械监督管理条例》《医疗器械分类规则》，国家药监局组织制定了《医疗器械分类目录动态调整工作程序》，于4月27日发布。（2021-05-08）

NMPA Announcement on Issuing 5 Technical Review Guidances for Registration

To strengthen the supervision and guidance of medical device registration and further improve the quality of registration review, NMPA has organized to formulate the *Guidance for Package Insert Update and Technical Review of Oncology Companion Diagnostic Reagents Based on Similar Therapeutic Products, the Technical Review Guidance for the Registration of Real-time Fluorescence PCR Analyzer, the Technical Review Guidance for the Registration of Rotavirus Antigen Test Reagents, the Technical Review Guidance for the Registration of Group B Streptococcus Nucleic Acid Test Reagents,* and the *Technical Review Guidance for the Registration of Human Parvovirus B19 IgM/IgG Antibody Test Reagents*, which were issued on April 7. (April 15, 2021)

国家药监局关于发布基于同类治疗药物的肿瘤伴随诊断试剂说明书更新与技术审查等5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《基于同类治疗药物的肿瘤伴随诊断试剂说明书更新与技术审查指导原则》《实时荧光PCR分析仪注册技术审查指导原则》《轮状病毒抗原检测试剂注册技术审查指导原则》《B群链球菌核酸检测试剂注册技术审查指导原则》和《人细小病毒B19 IgM/IgG抗体检测试剂注册技术指导原则》，于4月7日发布。 (2021-04-15)

NMPA Announcement on Approving the Registration of 139 Medical Devices

In April 2021, NMPA approved the registration of a total of 139 medical devices. Among them, there are 100 domestic Class III medical devices, 19 imported Class III medical devices, 19 imported Class II medical devices, and 1 medical device from Hong Kong, Macao and Taiwan. (May 24, 2021)

国家药监局关于批准注册139个医疗器械产品的公告

2021年4月，国家药品监督管理局共批准注册医疗器械产品139个。其中，境内第三类医疗器械产品100个，进口第三类医疗器械产品19个，进口第二类医疗器械产品19个，港澳台医疗器械产品1个。 (2021-05-24)

NMPA Announcement on Implementing Relevant Matters of the Regulations for the Supervision and Administration of Medical Devices

The revised *Regulations for the Supervision and Administration of Medical Devices* (State Council Order No.739, hereinafter referred to as the *Regulations*) will be implemented as of June 1, 2021. NMPA is organizing the formulation and revision of supporting regulations, normative documents and technical guidances, which will be released one after another in accordance with procedures. The matters related to implementation of the new Regulations are hereby announced as follows:

I. Full Implementation of the Medical Device Registrant and Filing Applicant System

As of June 1, 2021, the enterprises and the medical device R & D institutions, which have obtained the medical device registration certificate or have filed Class I medical devices, shall fulfill the obligations of medical device registrant and filling applicant respectively, strengthen the quality management over the whole life cycle of medical devices, and bear responsibilities for the safety and effectiveness of medical devices in the process of R & D, manufacture, distribution and use in accordance with the new Regulations.

II. Registration and Filing of Medical Devices

As of June 1, 2021, prior to the issuance and implementation of relevant provisions on registration and filing supporting the new *Regulations*, medical device registrants and filing applicants shall

国家药监局关于贯彻实施《医疗器械监督管理条例》有关事项的公告

新修订的《医疗器械监督管理条例》（国务院令第739号，以下简称新《条例》），将于2021年6月1日起施行。国家药监局正在组织制修订配套规章、规范性文件和技术指导原则等，将按照程序陆续发布。现就贯彻实施新《条例》有关事项公告如下：

一、关于全面实施医疗器械注册人、备案人制度

自2021年6月1日起，凡持有医疗器械注册证或者已办理第一类医疗器械备案的企业、医疗器械研制机构，应当按照新《条例》规定，分别履行医疗器械注册人、备案人的义务，加强医疗器械全生命周期质量管理，对研制、生产、经营、使用全过程中医疗器械的安全性、有效性依法承担责任。

二、关于医疗器械注册、备案管理

自2021年6月1日起，在新《条例》配套的注册、备案相关规定发布实施前，医疗

continue to apply for registration and conduct filing in accordance with the current provisions. The requirements for clinical evaluation of medical devices shall be implemented in accordance with Article III of this Announcement. Medical products administration shall carry out the registration and filing in accordance with the currently specified procedures and time limits.

III. Clinical Evaluation Management of Medical Devices

As of June 1, 2021, medical device registrants and filing applicants shall carry out clinical evaluation in accordance with the new *Regulations*. Clinical evaluation may be exempted for those complying with the provisions for exemption from clinical evaluation in the new *Regulations*; for the purpose of performing clinical evaluation, it is feasible to prove the safety and effectiveness of the medical device by carrying out clinical trials according to the product characteristics, clinical risks and the existing clinical data or by performing analysis and evaluation on the clinical literatures and clinical data of predicate medical devices; clinical trials shall be carried out for medical devices whose safety and effectiveness cannot be proved by the existing clinical literatures and clinical data. Prior to the issuance and implementation of relevant documents on exemption from clinical evaluation, the current Catalogue of Medical Devices Exempted from Clinical Trials shall be referenced for the Catalogue of Medical Devices Exempted from Clinical Evaluation.

IV. Production Licensing and Filing Management of Medical Devices

Prior to the issuance and implementation of relevant provisions on production licensing and filing supporting the new *Regulations*, medical device registrants and filing applicants shall handle the production licensing, filing and entrusted production in accordance with the existing rules and normative documents.

V. Distribution Licensing and Filing Management of Medical Devices

Medical device sold by its registrant and filing applicant at their residence or manufacturing site may not apply for medical device distribution licensing or filing, but shall comply with the specified distribution conditions; for Class II and Class III medical devices stored and sold at other sites, application for medical device distribution licensing or filing shall be made as required.

NMPA has drafted a Catalogue of Class II Medical Devices Exempted from Distribution and Filing, for which public comments are currently solicited. After being issued, the Catalogue shall be executed.

VI. Investigation and Punishment of Illegal Acts of Medical Devices

Where an illegal act of medical device occurs before June 1, 2021, the Regulations before revision shall apply. However, if the act is not considered illegal or the punishment is relatively light according to the new *Regulations*, the new *Regulations* shall apply. Where an illegal act occurs after June 1, 2021, the new *Regulations* shall apply.

It is hereby announced.

(May 31, 2021)

器械注册申请人、备案人继续按照现行规定申请注册和进行备案。有关医疗器械临床评价要求，按照本公告第三条执行。药品监督管理部门按照现行规定的程序和时限开展注册、备案相关工作。

三、关于医疗器械临床评价管理

自2021年6月1日起，医疗器械注册申请人、备案人根据新《条例》规定开展临床评价。符合新《条例》规定的免于临床评价情形的，可以免于临床评价；进行临床评价，可以根据产品特征、临床风险、已有临床数据等情形，通过开展临床试验，或者通过对同品种医疗器械临床文献资料、临床数据进行分析评价，证明医疗器械安全、有效；已有临床文献资料、临床数据不足以确认产品安全、有效的医疗器械，应当开展临床试验。在免于临床评价的相关文件发布实施前，免于进行临床评价医疗器械目录参照现行免于进行临床试验医疗器械目录执行。

四、关于医疗器械生产许可、备案管理

在新《条例》配套的生产许可、备案相关规定发布实施前，医疗器械注册人、备案人办理生产许可、备案和委托生产按照现有规章和规范性文件执行。

五、关于医疗器械经营许可、备案管理

医疗器械注册人、备案人在其住所或者生产地址销售其注册、备案的医疗器械，无需办理医疗器械经营许可或者备案，但应当符合规定的经营条件；在其他场所贮存、销售第二、三类医疗器械的，应当按照规定办理医疗器械经营许可或者备案。

国家药监局已起草有关免于经营备案的第二类医疗器械产品目录，目前正在公开征求意见。产品目录发布后，按目录执行。

六、关于医疗器械违法行为的查处

医疗器械违法行为发生在2021年6月1日以前的，适用修订前的《条例》，但依据新《条例》认为不违法或者处罚较轻的，适用新《条例》。违法行为发生在2021年6月1日以后的，适用新《条例》。

特此公告。 (2021-05-31)

Cosmetics

Announcement on Issuing the *Technical Guidelines for Submitting Registration and Notification Dossier of Cosmetics (Interim)*

In order to guide registrants and filing applicants of cosmetics and new raw materials to carry out registration and notification and submit relevant documents in a standardized manner, according to the *Regulations for the Supervision and Administration of Cosmetics,*

化妆品

国家药监局关于发布化妆品注册备案资料提交技术指南（试行）的通告

为指导化妆品和新原料注册人、备案人规范开展注册备案和提交注册备案资料，依据《化妆品监督管理条例》《化妆品注

Provisions for Registration and Notification of Cosmetics, Provisions for Registration and Notification Dossier of Cosmetics, Provisions for Registration and Notification Dossier of New Cosmetic Raw Materials and other relevant provisions, NMPA has organized to formulate the *Technical Guidelines for Submitting Registration and Notification Dossier of Cosmetics (Interim)*, which was issued on April 12. (April 25, 2021)

册备案管理办法》《化妆品注册备案资料管理规定》《化妆品新原料注册备案资料管理规定》等相关规定，国家药监局组织制定了《化妆品注册备案资料提交技术指南（试行）》，于4月12日发布。 (2021-04-25)

NMPA Announcement on Issuing the Working Procedures for the Administration of Supplementary Test Methods of Cosmetics and the Technical Guidelines for the Study and Drafting of Supplementary Test Methods of Cosmetics

In order to standardize the management of supplementary test methods for cosmetics, the *Working Procedures for the Administration of Supplementary Test Methods of Cosmetics* and the *Technical Guidelines for the Study and Drafting of Supplementary Test Methods of Cosmetics* were issued on April 23 in accordance with the Regulations for the Supervision and Administration of Cosmetics. (April 28, 2021)

国家药监局关于发布化妆品补充检验方法管理工作规程和化妆品补充检验方法研究起草技术指南的通告

为规范化妆品补充检验方法管理工作，依据《化妆品监督管理条例》，于4月23日发布《化妆品补充检验方法管理工作规程》和《化妆品补充检验方法研究起草技术指南》。 (2021-04-28)

NMPA Announcement on Issuing the *Catalogue of Used Cosmetic Raw Materials (Edition 2021)*

In order to further standardize the management of cosmetic raw materials, according to the *Regulations for the Supervision and Administration of Cosmetics*, NMPA has organized the revisions to the *Directory of Used Cosmetic Raw Materials* (*Edition 2015*) and formed the *Catalogue of Used Cosmetic Raw Materials* (*Edition 2021*), which was issued on April 27, and takes effect as of May 1, 2021. (April 30, 2021)

国家药监局关于发布《已使用化妆品原料目录（2021年版）》的公告

为进一步规范化妆品原料管理，依据《化妆品监督管理条例》相关规定，国家药监局组织对《已使用化妆品原料目录名称（2015版）》进行修订，形成了《已使用化妆品原料目录（2021年版）》，于4月27日公布，自2021年5月1日起施行。 (2021-04-30)

NMPA Announcement on Updating the Catalogue of Raw Materials Banned for Cosmetics

In order to further strengthen the administration of cosmetic raw materials and ensure the quality and safety of cosmetics, according to the *Regulations for the Supervision and Administration of Cosmetics*, NMPA has organized the revisions to the Banned Components for Cosmetics (Table 1) and Banned Plant (Animal) Components for Cosmetics (Table 2) in the *Technical Specification for the Safety of Cosmetics* (Edition 2015) (hereinafter referred to as the Specification) and formed the *Catalogue of Raw Materials Banned for Cosmetics and Catalogue of Plant (Animal) Raw Materials Banned for Cosmetics*, which have been adopted in the plenary meeting of the Expert Committee of Cosmetics Standards and issued and implemented as of May 26, replacing the original tables of banned components and included in the corresponding chapters of the *Specification* respectively. As of the date of promulgation of the Announcement, cosmetic registrants and filing applicants shall not manufacture or import cosmetics with the banned raw materials in the

国家药监局关于更新化妆品禁用原料目录的公告

为进一步加强化妆品原料管理，保证化妆品质量安全，依据《化妆品监督管理条例》相关规定，国家药品监督管理局组织对《化妆品安全技术规范（2015年版）》（以下简称《规范》）第二章中的《化妆品禁用组分（表1）》《化妆品禁用植（动）物组分（表2）》进行了修订，形成了《化妆品禁用原料目录》《化妆品禁用植（动）物原料目录》，经化妆品标准专家委员会全体会议审议通过，于5月26日发布并施行，分别替代原有禁用组分表，并纳入《规范》相应章节。自公告发布之日起，化妆品注册人、备案人不得生

product formula as specified in the *Catalogue of Raw Materials Banned for Cosmetics* and *Catalogue of Plant (Animal) Raw Materials Banned for Cosmetics*.

(May 28, 2021)

产、进口产品配方中使用了《化妆品禁用原料目录》《化妆品禁用植（动）物原料目录》规定的禁用原料的化妆品。（2021-05-28）

NMPA Announcement on Issuance and Implementation of the *Measures for the Administration of Cosmetics Labels*

In order to strengthen the supervision and administration of cosmetics labels, standardize the use of cosmetics labels and protect the legitimate rights and interests of consumers, according to the *Regulations for the Supervision and Administration of Cosmetics*, NMPA has drafted the *Measures for the Administration of Cosmetics Labels* (hereinafter referred to as the *Measures*), which are hereby promulgated. On May 31, matters related to implementation of the *Measures* are hereby announced as follows:

Cosmetics registrants and filing applicants are encouraged to label and mark cosmetics according to the *Measures* from the date of promulgation of this Announcement. As of May 1, 2022, cosmetics under application for registration or filing must comply with the Measures; as for the cosmetics for which application or filing has been previously made and labeling and marking fails to comply with the *Measures*, the cosmetics registrants and filing applicants must complete the update of product labels prior to May 1, 2023, so as to make them comply with the *Measures*.

(June 3, 2021)

国家药监局关于发布实施《化妆品标签管理办法》的公告

为加强化妆品标签监督管理，规范化妆品标签使用，保障消费者合法权益，依据《化妆品监督管理条例》，国家药监局组织起草了《化妆品标签管理办法》（以下简称《办法》），现予公布。于5月31日将《办法》实施有关事宜公告如下：

鼓励化妆品注册人、备案人自本公告发布之日起，按照《办法》规定对化妆品进行标签标识。自2022年5月1日起，申请注册或者进行备案的化妆品，必须符合《办法》的规定和要求；此前申请注册或者进行备案的化妆品，未按照本《办法》规定进行标签标识的，化妆品注册人、备案人必须在2023年5月1日前完成产品标签的更新，使其符合《办法》的规定和要求。（2021-06-03）

Notes: • All Chinese information in the Newsletter is extracted from newspapers and the Internet. All English articles are translations from the Chinese version.
• For electronic version of the Newsletter please visit http://www.ccfdie.org

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