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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

NMPA Announcement on Adopting ICH Guidelines S5 (R3) and S11

To keep pace with the international technical standards for drug registration, the NMPA has decided to adopt two guidelines of ICH (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use), including S5 (R3): *Detection of Reproductive and Developmental Toxicity for Human Pharmaceuticals* and S11: *Nonclinical Safety Testing in Support of Development of Pediatric Pharmaceuticals* (hereinafter referred to as S5 (R3) and S11).

Guidelines S5 (R3) and S11 shall be applicable to the non-clinical studies starting upon issuance of this Announcement. The designation of the starting date of non-clinical study shall be in accordance with the relevant provisions specified in the Good Laboratory Practice.

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

It is hereby announced. (2021-01-25)

NMPA Announcement on Adopting ICH Guideline E9 (R1)

To keep pace with the international technical standards for drug registration, the NMPA has decided to adopt the ICH (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use) Guideline E9 (R1): *Addendum on Estimands and Sensitivity Analysis in Clinical Trials*. E9 (R1) shall be applicable to the drug clinical studies starting 12 months upon the issuance of this Announcement.

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

It is hereby announced. (2021-01-25)

NMPA Announcement on Regulating Weian Capsules as Non-prescription Drugs

According to the *Provisions for the Classification Management of Prescription and Non-prescription Drugs* (*Interim*), after the demonstration and review organized by the NMPA, the Weian Capsules are approved to be regulated as non-prescription drugs.

Before April 25, 2021, the drug marketing authorization holder shall, in accordance with the *Provisions for Drug Registration*

药品

国家药监局关于适用S5（R3）和S11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《S5（R3）:人用药物生殖与发育毒性检测》和《S11:支持儿科药物开发的非临床安全性评价》（以下简称：S5（R3）和S11）国际人用药品注册技术协调会（ICH）指导原则。

自本公告发布之日起开始的非临床研究适用S5（R3）和S11指导原则。非临床研究起始日期的认定遵照《药物非临床研究质量管理规范》中相关规定执行。

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。

特此公告。 (2021-01-25)

国家药监局关于适用E9（R1）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。本公告发布之日起，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。

特此公告。 (2021-01-25)

国家药监局关于胃安胶囊转换为非处方药的公告

根据《处方药与非处方药分类管理办法（试行）》的规定，经国家药品监督管理局组织论证和审定，胃安胶囊由处方药转化为非处方药。

药品上市许可持有人在2021年4月25日前，

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and other relevant provisions, submit the revised package insert of drug to the provincial drug regulatory department for filing and in a timely manner inform relevant medical institutions, drug distributors and other units of the revised content in the package insert of drug.

For the content in the package insert of drug other than that specified in the template of the package insert of non-prescription drugs shall be revised in accordance with original approval document. Drug labels involving content related to the above revision shall be revised together. For drugs produced since the date of filing, the original package insert shall not be used any more.

(2021-02-01)

依据《药品注册管理办法》等有关规定将修订的药品说明书报省级药品监督管理部门备案，并将说明书修订的内容及时通知相关医疗机构、药品经营企业等单位。

非处方药说明书范本规定内容之外的说明书其他内容按原批准证明文件执行。药品标签涉及相关内容的，应当一并修订。自备案之日起生产的药品，不得继续使用原药品说明书。（2021-02-01）

NMPA Announcement on Cancellation of 8 Certification Items

As per the *Notice of the General Office of the State Council on Effective Clearance of Certification Items*, to further reduce redundant certification for the convenience of the people and optimize governmental service, the NMPA decided to cancel 8 certification items, and the Announcement is hereby issued. The certification items listed in the attachments cease to be required as of the date of issuance of this Announcement.

(2021-02-05)

国家药监局关于取消8项证明事项的公告

根据《国务院办公厅关于做好证明事项清理工作的通知》要求，为进一步减证便民、优化服务，国家药品监督管理局决定取消8项证明事项，现予以发布。附件所列证明事项自本公告发布之日起停止执行。

(2021-02-05)

序号 Serial No.	证明文件 Certification Document	用途 Purpose	依据 Basis	取消后的办理方式 Handling Way after Cancellation
1	新药证书 New Drug Certificate	放射性药品 上市注册审批 For the registration of radioactive pharmaceuticals	《放射性药品管理办法》 Provisions for Radioactive Pharmaceuticals	不再要求申请人提交 Applicants are no longer required to submit such item
2	企业营业执照 Business License for Enterprise	申请出具药品出口证明 Applying for the issuance of drug export license	《药品出口销售证明管理规定》、《国家食品药品监督管理总局关于出口欧盟原料药证明文件有关事项的通知》 Provisions for the Administration of Export License and Selling of Drugs; Notice of CFDA on Issues concerning the Certificate for Pharmaceutical Substances Exported to EU	不再要求申请人提交，改为网络核验 Applicants are no longer required to submit such item and it is changed into online verification
3	药品生产许可证 Drug Manufacturing Certificate	申请出具药品出口证明 Applying for the issuance of drug export license	《药品出口销售证明管理规定》、《国家食品药品监督管理总局关于出口欧盟原料药证明文件有关事项的通知》 Provisions for the Administration of Export License and Selling of Drugs; Notice of CFDA on Issues concerning the Certificate for Pharmaceutical Substances Exported to EU	不再要求申请人提交，改为内部核查 Applicants are no longer required to submit such item and it is changed into internal verification
4	药品上市许可持有人证明文件 Certification Document of Drug MAH	申请出具药品出口证明 Applying for the issuance of drug export license	《药品出口销售证明管理规定》 Provisions for the Administration of Export License and Selling of Drugs	不再要求申请人提交，改为内部核查 Applicants are no longer required to submit such item and it is changed into internal verification
5	生物制品批签发合格证 Certificate for the Lot Release of Biological Products	申请出具药品出口证明 Applying for the issuance of drug export license	《药品出口销售证明管理规定》 Provisions for the Administration of Export License and Selling of Drugs	不再要求申请人提交，改为内部核查 Applicants are no longer required to submit such item and it is changed into internal verification
6	企业营业执照 Business License for Enterprise	申请出具医疗器械产品出口销售证明 Applying for the issuance of export and selling license for medical devices	《国家食品药品监督管理总局关于发布医疗器械产品出口销售证明管理规定的通告》 Announcement of CFDA on Issuing the Provisions for Administration of Export License and Selling of Medical Devices	不再要求申请人提交，改为网络核验 Applicants are no longer required to submit such item and it is changed into online verification

7	医疗器械生产许可证 Manufacturing Certificate for Medical Device	申请出具医疗器械产品出口销售证明 Applying for the issuance of export and selling license for medical devices	《国家食品药品监督管理总局关于发布医疗器械产品出口销售证明管理规定的通告》 Announcement of CFDA on Issuing the Provisions for Administration of Export License and Selling of Medical Devices	不再要求申请人提交，改为内部核查 Applicants are no longer required to submit such item and it is changed into internal verification
8	医疗器械生产备案凭证 Manufacture Filing Certificate of Medical Devices	申请出具医疗器械产品出口销售证明 Applying for the issuance of export and selling license for medical devices	《国家食品药品监督管理总局关于发布医疗器械产品出口销售证明管理规定的通告》 Announcement of CFDA on Issuing the Provisions for Administration of Export License and Selling of Medical Devices	不再要求申请人提交，改为内部核查 Applicants are no longer required to submit such item and it is changed into internal verification

NMPA Announcement on Approval of Adding the Filing Function for the First Importation of Chemicals to the Chongqing Municipal Medical Products Administration

According to the *Provisions for Drug Importation*, the *Notice of the China Food and Drug Administration and General Administration of Customs on Printing and Issuing Principles and Standards for the Newly Establishment of Drug Import Ports*, the *Notice of the China Food and Drug Administration and General Administration of Customs on Printing and Issuing the Evaluation and Assessment Scheme for the Newly Establishment of Drug Import Ports*, the *Notice of the Comprehensive Department of National Medical Products Administration on Printing and Issuing the Evaluation Criteria for the Ports for the First Drug Importation* and other relevant regulations, upon the on-site evaluation and assessment, the NMPA has approved the application of the Chongqing Municipal Medical Products Administration for adding the filing function for the first importation of chemicals, and this Announcement was hereby issued on February 2 as follows:

I. Chongqing Municipal Medical Products Administration is approved to add the filing function for the first import of chemicals. As of the date of printing and issuing this Announcement, the Chongqing Municipal Medical Products Administration can handle the filing of the first importation of chemicals.

II. The Chongqing Institute for Food and Drug Control is responsible for the port inspection for filing the first importation of chemicals.

III. The Chongqing Municipal Medical Products Administration and Chongqing Institute for Food and Drug Control shall continue to strengthen the self-constructions and continuously improve the management capacity and technical level to guarantee a steady development of drug import. National Institutes for Food and Drug Control shall strengthen the technical guidance for relevant work.

(2021-02-07)

国家药监局关于同意重庆市药品监督管理局增加化学药品首次药品进口备案职能的公告

根据《药品进口管理办法》和《食品药品监管总局 海关总署关于印发增设允许药品进口口岸的原则和标准的通知》、《食品药品监管总局办公厅 海关总署办公厅关于发布增设允许药品进口口岸工作评估考核方案的通知》、《国家药监局综合司关于印发首次药品进口口岸评估标准的通知》等有关规定，经现场评估和考核，国家药品监督管理局批准重庆市药品监督管理局关于增加化学药品首次药品进口备案职能的申请，于2月2日公告如下：

一、同意重庆市药品监督管理局增加化学药品首次药品进口备案职能。自本公告印发之日起，重庆市药品监督管理局可办理化学药品首次药品进口备案手续。

二、重庆市食品药品检验检测研究院负责化学药品首次药品进口备案的口岸检验工作。

三、重庆市药品监督管理局和重庆市食品药品检验检测研究院应持续加强自身建设，不断提高管理能力和技术水平，保障药品进口管理工作的顺利开展。中国食品药品检定研究院加强对相关工作的技术指导。

（2021-02-07）

NMPA Announcement on Revising the Package Insert of Methimazole Preparations

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

I. The marketing authorization holder of this product shall, in accordance with the Provisions for Drug Registration and the revision requirements for the package insert of methimazole preparations, submit

国家药监局关于修订甲巯咪唑制剂说明书的公告

为进一步保障公众用药安全，国家药品监督管理局决定对甲巯咪唑制剂说明书进行修订。现将有关事项公告如下：

一、本品的上市许可持有人应依据《药品注册管理办法》等有关规定，按照甲巯咪

a supplementary application as such before May 3, 2021 to the Center for Drug Evaluation of NMPA or provincial drug regulatory department for filing.

If the revision involving the drug label, the label shall be revised together; the other content of the package insert and the label shall be consistent with the original approved ones. For drugs produced since the date of filing, the original package insert shall not be used any more. All the package inserts and labels of ex-factory drugs shall be changed within 9 months after the said revision had been filed by the drug marketing authorization holder .

II. The drug marketing authorization holder shall 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 distributor and end-user units in an appropriate and timely manner if the medication safety-related content are changed, to guide the physician and pharmacist to use the medicine rationally.

III. The clinicians and pharmacists shall carefully read the revised content of the package inserts for methimazole preparations. Drug options should be based on comprehensive benefit / risk analysis as per the new revisions.

IV. The patients should carefully read the package inserts before medication, and strictly comply with the medication orders.

V. Provincial drug regulatory departments shall urge the drug marketing authorization holders of the product within their respective jurisdiction to revise the package inserts, change the labels and package inserts as required and impose severe punishment in accordance with law if violations of laws and regulations happen.

It is hereby announced. (2021-02-09)

唑制剂说明书修订要求，提出修订说明书的补充申请，于2021年5月3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。在备案之日起生产的药品，不得继续使用原药品说明书。药品上市许可持有人应当在备案后9个月内对所有已出厂的药品说明书及标签予以更换。

二、药品上市许可持有人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。

三、临床医师、药师应当仔细阅读甲巯咪唑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。

四、患者用药前应当仔细阅读说明书，应严格遵医嘱用药。

五、省级药品监督管理部门应当督促行政区域内本品的药品上市许可持有人按要求做好相应说明书修订和标签、说明书更换工作，对违法违规行为依法严厉查处。

特此公告。 (2021-02-09)

NMPA Notice on Issuing the Requirements for Change Items of Marketed Chemicals and Application Dossier

To cooperate with the implementation of the *Provisions for Drug Registration*, the NMPA has organized to formulate the Requirements for Change Items of Marketed Chemicals and Application Dossier, which has been issued and implemented on February 3, 2021.

(2021-02-10)

国家药监局关于发布已上市化学药品变更事项及申报资料要求的通告

为配合药品注册管理办法实施，国家药品监督管理局组织制定了《已上市化学药品变更事项及申报资料要求》，于2021年2月3日发布并实施。 (2021-02-10)

NMPA Announcement on Issuing the Catalogue of Reference Preparations of Generic Drugs (Thirty-eighth Batch)

On February 20, the Catalogue of Reference Preparations of Generic Drugs (Thirty-eighth Batch) was issued, upon review and determination by the NMPA Experts Committee of Quality and Efficacy Consistency Evaluation of Generic Drugs.

(2021-02-23)

国家药监局关于发布仿制药参比制剂目录（第三十八批）的通告

经国家药品监督管理局仿制药质量和疗效一致性评价专家委员会审核确定，于2月20日发布仿制药参比制剂目录（第三十八批）。 (2021-02-23)

NMPA Notice on Issuing the *Requirements for Change Items of Marketed Traditional Chinese Medicines and Application Dossiers*

To cooperate with the implementation of the Provisions for Drug Registration, the NMPA has organized to formulate the *Requirements for Change Items of Marketed Traditional Chinese Medicines and Application Dossiers*, which has been issued and implemented on February 23.

(2021-02-24)

国家药监局关于发布《已上市中药变更事项及申报资料要求》的通告

为配合《药品注册管理办法》实施，国家药品监督管理局组织制定了《已上市中药变更事项及申报资料要求》，于2月23日发布并实施。 (2021-02-24)

NMPA Announcement on Revising the Package Insert of Misoprostol Tablets for Obstetrical and Gynecological Application

To further protect public medication safety, the NMPA decided to revise the package insert of Misoprostol Tablets for obstetrical and gynecological application. Relevant issues are hereby announced as follows:

I. The marketing authorization holders of this product shall, in accordance with relevant provisions such as the Provisions for Drug Registration, submit the supplementary application for revising the package insert according to the requirements for revising the package insert of Misoprostol Tablets for obstetrical and gynecological application, and report to the Center for Drug Evaluation of NMPA or provincial drug regulatory authorities for filing prior to May 24, 2021.

Where the content of revision involve the drug label, the label shall be revised along with all the others; the package insert and other contents of the label shall be consistent with those originally approved. For the drugs manufactured as of the date of filing, the original package insert of the drug shall not be used any more. The drug marketing authorization holder shall replace all the package inserts and labels of ex-factory drugs within 9 months after filing.

II. The drug marketing authorization holder shall 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 immediately notify the drug distributor and user facilities in an appropriate manner if the medication safety-related contents are changed, to guide physicians and pharmacists to use the drug rationally.

III. Clinicians and pharmacists shall carefully read the revised content in the package insert of Misoprostol Tablets for obstetrical and gynecological application; in the selection of drugs, comprehensive benefit/risk analysis shall be made based on the newly revised package insert.

IV. Patients shall carefully read the package insert prior to medication, and strictly comply with the medical orders.

V. Provincial drug regulatory departments shall urge the drug marketing authorization holder of this product within their jurisdiction to revise the package insert and replace the labels and package insert as required, and shall severely investigate and punish the violations of laws and regulations in accordance with law.

It is hereby announced.

(2021-02-26)

国家药监局关于修订妇产科用米索前列醇片说明书的公告

为进一步保障公众用药安全，国家药品监督管理局决定对妇产科用米索前列醇片说明书进行修订。现将有关事项公告如下：

一、本品的上市许可持有人应依据《药品注册管理办法》等有关规定，按照妇产科用米索前列醇片说明书修订要求，提出修订说明书的补充申请，于2021年5月24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。在备案之日起生产的药品，不得继续使用原药品说明书。药品上市许可持有人应当在备案后9个月内对所有已出厂的药品说明书及标签予以更换。

二、药品上市许可持有人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。

三、临床医师、药师应当仔细阅读妇产科用米索前列醇片说明书的修订内容，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。

四、患者用药前应当仔细阅读说明书，应严格遵医嘱用药。

五、省级药品监督管理部门应当督促行政区域内本品的药品上市许可持有人按要求做好相应说明书修订和标签、说明书更换工作，对违法违规行为依法严厉查处。

特此公告。

(2021-02-26)

Medical Devices

NMPA Notice on Issuing the Guidance for Technical Review of Clinical Evaluation of Equivalent Devices of Medical Magnetic Resonance Imaging Systems (Revision 2020)

To strengthen the supervision and guidance of medical device registration and further improve the quality of registration review, the NMPA organized to formulate the Guidance (Revision 2020) for Technical Review of Clinical Evaluation of Equivalent Devices of Medical Magnetic Resonance Imaging Systems which was issued on January 27, 2021.

(2021-02-01)

医疗器械

国家药监局关于发布医用磁共振成像系统同品种临床评价技术审查指导原则（2020年修订版）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医用磁共振成像系统同品种临床评价技术审查指导原则（2020年修订版），于2021年1月27日发布。（2021-02-01）

Cosmetics

NMPA Announcement on Issuing the *Rules for Registration and Notification Dossiers of New Cosmetic Ingredients*

In order to implement the *Provisions for Registration* and Notification of Cosmetics and standardize and guide the registration and notification of new cosmetic ingredients, the NMPA has developed the *Rules for Registration and Notification Dossiers of New Cosmetic Ingredients*, which is hereby issued and shall take effect as of May 1, 2021.

(2021-03-04)

化妆品

国家药监局关于发布《化妆品新原料注册备案资料管理规定》的公告

为贯彻落实《化妆品注册备案管理办法》，规范和指导化妆品新原料注册与备案工作，国家药监局制定了《化妆品新原料注册备案资料管理规定》，现予公布，自2021年5月1日起施行。（2021-03-04）

NMPA Announcement on Issuing the *Rules for Registration and Notification Dossiers of Cosmetics*

In order to implement the *Provisions for Registration and Notification of Cosmetics* and standardize and guide the registration and notification of cosmetics, the NMPA has developed the *Rules for Registration and Notification Dossiers of Cosmetics*, which is hereby issued and shall take effect as of May 1, 2021.

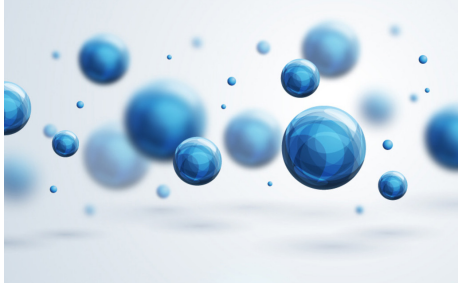
(2021-03-04)

国家药监局关于发布《化妆品注册备案资料管理规定》的公告

为贯彻落实《化妆品注册备案管理办法》，规范和指导化妆品注册与备案工作，国家药监局制定了《化妆品注册备案资料管理规定》，现予公布，自2021年5月1日起施行。（2021-03-04）

NMPA Announcement on Issues about Implementing the Rules for Registration and Notification Dossiers of Cosmetics

In order to implement the *Regulations for the Supervision and Administration of Cosmetics* and the *Provisions for Registration and Notification of Cosmetics* and further standardize the administration on registration and notification of cosmetics, the issues about implementing the *Rules for the Registration and Notification Dossiers of Cosmetics*



国家药监局关于实施《化妆品注册备案资料管理规定》有关事项的公告

为贯彻落实《化妆品监督管理条例》《化妆品注册备案管理办法》相关规定，进一步规范化妆品注册备案管理工作，现就实施《化妆品注册备案资料管理规定》（以下简称《规定》）有关事项公告如下：

一、关于化妆品注册备案信息服务平台

为方便企业提前做好化妆品注册备案准备工作，自2021年4月1日起，境内的化妆

(hereinafter referred to as the Rules) is hereby announced as follows:

I. About the Information Service Platform of Cosmetics Registration and Notification

In order to facilitate enterprises to make good preparation for the registration and notification of cosmetics in advance, as of April 1, 2021, domestic cosmetic registration persons, notification persons, domestic responsible persons and cosmetic manufacturers may submit relevant documents and apply for the user account for registration and notification at the Information Service Platform of Cosmetics Registration and Notification(hereinafter referred to as the new platform) according to the requirements in the Rules through the NMPA Online Service Hall (https://zwfw.nmpa.gov.cn), a national integrated online government service platform. As of May 1, 2021, cosmetic registration persons, notification persons and domestic responsible persons shall apply for the registration of special cosmetics or file notification of the general cosmetics through the new platform.

As of May 1, 2021, the original administrative licensing and filing information management system for cosmetics (hereinafter referred to as the original platform) shall no longer accept the registration application of special cosmetics or notification filing of general cosmetics. For registration applications of special cosmetics submitted and accepted at the original platform but with no approval decision made, such review and approval shall be continued at the original platform.

II. For products registered and filed notification at the original platform

In order to protect the safety in cosmetics use and legitimate rights and interests of consumers, for cosmetics with the registration or notification completed in the original platform, the registration and notification persons shall submit the product standards and product label samples, fill in the product formula of domestic general cosmetics and upload the label picture of the sales packages of special cosmetics prior to May 1, 2022.

III. Reporting of the safety related information of cosmetic ingredients

As of May 1, 2021, in case of registration or notification, registration and notification persons shall fill in the sources and trade names of the ingredients in product formula. For the ingredients of which quality specification are required in the Technical Specification for the Safety of Cosmetics, the quality specification certificate or safety-related information of the ingredients shall also be submitted.

As of January 1, 2022, in case of registration or notification, registration or notification persons shall provide safety-related information of the ingredients with functions of preservative, sunscreen, colorant, hair dye, spot corrector and whitening in accordance with the Rules.

As of January 1, 2023, in case of registration or notification, registration or notification persons shall provide safety-related information of all the ingredients in accordance with the Rules. For the cosmetics with registration or notification already completed, registration or notification persons shall supplement safety-related information of all the ingredients in the product formula prior to May 1, 2023.

IV. Efficacy evaluation and test report of cosmetics for spot correcting, whitening and preventing hair loss

As of January 1, 2022, for the registration application of cosmetics for spot correcting, whitening and preventing hair loss, registration persons shall submit the human efficacy test report conforming to the requirements in accordance with the Rules.

品注册人、备案人、境内责任人和化妆品生产企业，可以通过全国一体化在线政务服务平台国家药监局网上办事大厅（https://zwfw.nmpa.gov.cn），按照《规定》的要求在化妆品注册备案信息服务平台（以下简称新注册备案平台）提交相关资料，办理注册备案用户账号；自2021年5月1日起，化妆品注册人、备案人、境内责任人，应当通过新注册备案平台申请特殊化妆品注册或者进行普通化妆品备案。

自2021年5月1日起，原化妆品行政许可和备案信息管理系统（以下简称原注册备案平台）不再接收特殊化妆品注册申请或者普通化妆品备案。此前已在原注册备案平台提交并受理，但尚未作出审批决定的特殊化妆品注册申请，继续在原注册备案平台开展审评审批。

二、关于原注册备案平台已注册和备案的产品

为保障化妆品使用安全和消费者合法权益，在原注册备案平台已经取得注册或者完成备案的化妆品，注册人、备案人应当通过新注册备案平台，在2022年5月1日前提交产品执行的标准和产品标签样稿、填报国产普通化妆品的产品配方、上传特殊化妆品销售包装的标签图片。

三、关于化妆品原料安全相关信息的报送

自2021年5月1日起，注册人备案人申请注册或者进行备案时，应当填报产品配方原料的来源和商品名信息，其中涉及《化妆品安全技术规范》中有质量规格要求的原料，还应当提交原料的质量规格证明或者安全相关信息。

自2022年1月1日起，注册人备案人申请注册或者进行备案时，应当按照《规定》的要求，提供具有防腐、防晒、着色、染发、祛斑美白功能原料的安全相关信息。

自2023年1月1日起，注册人备案人申请注册或者进行备案时，应当按照《规定》的要求，提供全部原料的安全相关信息。此前已经取得注册或者完成备案的化妆品，注册人、备案人应当在2023年5月1日前补充提供产品配方中全部原料的安全相关信息。

四、关于祛斑美白和防脱发化妆品功效评价检验报告

自2022年1月1日起，申请祛斑美白、防脱发化妆品注册时，注册申请人应当按照规定，提交符合要求的人体功效试验报告。

2021年5月1日前申请并取得注册的祛斑美白、防脱发化妆品，注册人应当在2023年

For the cosmetics for spot correcting, whitening and preventing hair loss with the application submitted and registration completed prior to May 1, 2021, registration persons shall submit the human efficacy test report prior to May 1, 2023.

For the cosmetics for spot correcting, whitening and preventing hair loss with the application submitted and registration completed between May 1 and December 31, 2021, registration persons shall submit the human efficacy test report conforming to the requirements prior to May 1, 2022.

V. Annual report of general cosmetics

As of January 1, 2022, an annual reporting system shall be implemented for the general cosmetics filed notification through the original and new platforms. The notification persons shall submit the annual report of general cosmetics that have been filed notification for a full year through the new platform during each January 1 to March 31.

(2021-03-05)

5月1日前补充提交人体功效试验报告。

2021年5月1日至12月31日期间申请并取得注册的祛斑美白、防脱发化妆品，注册人应当于2022年5月1日前补充提交符合要求的人体功效试验报告。

五、关于普通化妆品年度报告

自2022年1月1日起，通过原注册备案平台和新注册备案平台备案的普通化妆品，统一实施年度报告制度。备案人应当于每年1月1日至3月31日期间，通过新注册备案平台，提交备案时间满一年普通化妆品的年度报告。（2021-03-05）

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

备 注： • Newsletter中所有中文信息摘自报刊及网络。英文均系中文翻译。
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