NATIONAL MEDICAL PRODUCTS NEWSLETTER

中国食品药品国际交流中心

Drugs

NMPA Announcement on Issuing the *Requirements for Change Items and Application Dossiers of Marketed Biological Products*

To cooperate with the implementation of the *Provisions for Drug Registration*, the NMPA has organized to formulate the *Requirements for Change Items and Application Dossiers of Marketed Biological Products*, which has been issued and implemented on June 17.

(June 18, 2021)

药品

国家药监局关于发布《已上市生物制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《已上市生物制品变更事项及申报资料要求》，于6月17日发布并实施。

(2021-06-18)

NMPA Announcement on the Revision of the Package Insert of the Oxiracetam Preparations

In accordance with the results of adverse drug reaction evaluation, to further protect drug safety for the people, the NMPA decided to modify the items of [Adverse reactions], [Contraindications] and [Precautions] in the package inserts of oxiracetam preparations. On June 22, relevant issues are hereby announced as follows:

I. The marketing authorization holder of the product shall, in accordance with the *Provisions for Drug Registration* and the revision requirements for the package insert of oxiracetam preparations, file a report as such before September 21, 2021 to provincial drug regulatory authority.

Where the contents of revision involve the drug label, the label shall be revised along with all the others; the other contents of the label and insert sheets shall be consistent with those originally approved. For the drugs produced from 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 marketing authorization holder of drug.

II. The marketing authorization holder of drug 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, to guide the physician, pharmacist and patient to use the medicine rationally.

Ⅲ. The clinicians and pharmacists shall carefully read the revised contents of the package inserts for oxiracetam 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 for prescription drugs.

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

(June 24, 2021)

国家药监局关于修订奥拉西坦制剂说明书的公告

根据药品不良反应评估结果，为进一步保障公众用药安全，国家药品监督管理局决定对奥拉西坦制剂说明书【不良反应】、【禁忌】、【注意事项】等项目进行统一修订。于6月22日将有关事项公告如下：

一、上述药品的上市许可持有人均应依据《药品注册管理办法》等有关规定，按照相应附件要求修订说明书，于2021年9月21日前报省级药品监督管理部门备案。

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，采取有效措施做好药品使用和安全性问题的宣传培训，指导医师、药师或患者合理用药。

三、临床医师、药师应当仔细阅读上述药品说明书的修订内容，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药品说明书，使用处方药的，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上述药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。

(2021-06-24)

Published by
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NMPA Announcement on the Revision of the Package Insert of Somatostatin for Injection

In accordance with the results of adverse drug reaction evaluation, to further protect drug safety for the people, the NMPA decided to modify the items of [Adverse reactions], [Precautions] and [Drug Interactions] in the package inserts of somatostatin for injection. On June 22, relevant issues are hereby announced as follows:

I. The marketing authorization holder of the product shall, in accordance with the *Provisions for Drug Registration* and the revision requirements for the package insert of somatostatin for injection, submit a supplementary application as such before September 21, 2021 to provincial drug regulatory authority for filing.

Where the contents of revision involve the drug label, the label shall be revised along with all the others; the other contents of the label and insert sheets shall be consistent with those originally approved. For the drugs produced from 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 marketing authorization holder of drug.

II. The marketing authorization holder of drug 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, to guide the physician, pharmacist and patient to use the medicine rationally.

III. The clinicians and pharmacists shall carefully read the revised contents of the said package inserts. 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 for prescription drugs.

V. Provincial drug regulatory authorities shall urge the drug marketing authorization holders of the product within their respective jurisdiction to revise the package inserts and replacement of the labels and package inserts as required and impose severe punishment in accordance with the law for violations of laws and regulations. (June 24, 2021)

国家药监局关于修订注射用生长抑素说明书的公告

根据药品不良反应评估结果，为进一步保障公众用药安全，国家药品监督管理局决定对注射用生长抑素说明书【不良反应】、【注意事项】、【药物相互作用】等项目进行统一修订。于6月22日将有关事项公告如下：

一、上述药品的上市许可持有人均应依据《药品注册管理办法》等有关规定，按照相应附件要求修订说明书，于2021年9月21日前报省级药品监督管理部门备案。

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，采取有效措施做好药品使用和安全性问题的宣传培训，指导医师、药师或患者合理用药。

三、临床医师、药师应当仔细阅读上述药品说明书的修订内容，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药品说明书，使用处方药的，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上述药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。

(2021-06-24)

NMPA Announcement on Issuing the Catalogue of Reference Preparations of Generic Drugs (Forty-two Batch)

On June 22, the Catalogue of Reference Preparations of Generic Drugs (Forty-two Batch) was issued, upon review and determination by the NMPA Experts Committee of Quality and Efficacy Consistency Evaluation of Generic Drugs.

(June 25, 2021)

国家药监局关于发布仿制药参比制剂目录（第四十二批）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6月22日发布仿制药参比制剂目录（第四十二批）。(2021-06-25)

Announcement of National Medical Products Administration and National Intellectual Property Administration on the Issuance of the Measures for the Implementation of the *Mechanism for Early Settlement of Drug Patent Disputes (Interim)*

In accordance with the *Patent Law of the People's Republic of China*, the National Medical Products Administration and the China National Intellectual Property Administration formulated the *Measures for the Implementation of the Mechanism for Early Settlement of Drug Patent Disputes (interim)*, which will be promulgated and put into effect on July 4 with the approval by the State Council.

(July 4, 2021)

国家药监局 国家知识产权局关于发布《药品专利纠纷早期解决机制实施办法（试行）》的公告

根据《中华人民共和国专利法》，国家药监局、国家知识产权局组织制定了《药品专利纠纷早期解决机制实施办法（试行）》，经国务院同意，于7月4日发布并施行。

（2021-07-04）

NMPA Announcement on the Issues Related to the Implementation of the *Measures for the Implementation of the Mechanism for Early Settlement of Drug Patent Disputes (interim)*

In order to complete the implementation of the *Measures for the Implementation of the Mechanism for Early Settlement of Drug Patent Disputes (interim)* (hereinafter referred to as the Measures), relevant issues are hereby announced on July 4 as follows:

I. As of today, the China's Patent Information Registration Platform for Marketed Drugs is officially put into operation. Marketing authorization holders of relevant drugs are required to complete the registration and voluntary disclosure of relevant drug patent information on the China's Patent Information Registration Platform for Marketed Drugs in advance as required. Any change to relevant information registered and disclosed in the previous period shall be updated by marketing authorization holders in time. Relevant patent information that has been registered and disclosed shall be used as the basis for the patent declaration made by the applicants for marketing registration of chemical generics, traditional Chinese medicine of the same name and formula and biosimilars. Registration platform and operation instructions can be found in the China's Patent Information Registration Platform for Marketed Drugs at the website of the Center for Drug Evaluation of the National Medical Products Administration (https://zldj.cde.org.cn/home).

II. As of today, in case of filing the application for marketing registration of chemical generics, traditional Chinese medicine of the same name and formula and biosimilars, applicants shall submit the patent declaration in accordance with the requirements of the Measures by contrasting relevant drug patent information registered at the China's Patent Information Registration Platform for Marketed Drugs, and notify the marketing authorization holders of the declaration and basis for the declaration. Where the patent declaration has not been submitted, the application shall not be accepted until the patent declaration is supplemented. The requirements related to the filling, printing and uploading of patent declaration are detailed in the Enterprises Operation Instructions in the Pharmaceutical Business Application System at the Online Service Hall of the NMPA (https://zwfw.nmpa.gov.cn/).

(July 4, 2021)

国家药监局关于实施《药品专利纠纷早期解决机制实施办法（试行）》相关事宜的通告

为做好《药品专利纠纷早期解决机制实施办法（试行）》（以下简称《办法》）实施工作，于7月4日就有关事宜通告如下：

一、即日起，中国上市药品专利信息登记平台正式运行。请相关药品上市许可持有人根据需要提前在中国上市药品专利信息登记平台完成相关药品专利信息登记与主动公开。前期已登记并公开的相关信息如需变更，请上市许可持有人及时更新。已登记并公开的相关专利信息作为化学仿制药、中药同名同方药、生物类似药上市注册申请人作出专利声明的依据。登记平台以及操作说明详见国家药监局药品审评中心网站—中国上市药品专利信息登记平台（网址：https://zldj.cde.org.cn/home）。

二、即日起，申请人提交化学仿制药、中药同名同方药、生物类似药上市注册申请时，应当对照已在中国上市药品专利信息登记平台公开的相关药品专利信息，按《办法》要求提交专利声明，并将声明及声明依据通知上市许可持有人。未提交专利声明的，补正后方予以受理。专利声明填写、打印以及上传的相关要求详见国家药监局网上办事大厅—药品业务应用系统中的企业操作指南（网址https://zwfw.nmpa.gov.cn/）。

（2021-07-04）

NMPA Announcement on the Revision of the Package Insert of Metoclopramide

In accordance with the results of adverse drug reaction evaluation, to further protect drug safety for the people, the NMPA decided to modify the items of [Adverse reactions], [Contraindications] and [Precautions] in the package inserts of Metoclopramide. On June 29, relevant issues are hereby announced as follows:

I. The marketing authorization holder of the product shall, in accordance with the *Provisions for Drug Registration* and the revision requirements for the package insert of metoclopramide, submit a supplementary application as such before September 28, 2021 to provincial drug regulatory authority for filing.

Where the contents of revision involve the drug label, the label shall be revised along with all the others; the other contents of the label and insert sheets shall be consistent with those originally approved. For the drugs produced from 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 marketing authorization holder of drug.

II. The marketing authorization holder of drug 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, to guide the physician, pharmacist and patient to use the medicine rationally.

III. The clinicians and pharmacists shall carefully read the revised contents of the said package inserts. 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 for prescription drugs.

V. Provincial drug regulatory authorities shall urge the drug marketing authorization holders of the product within their respective jurisdiction to revise the package inserts and replacement of the labels and package inserts as required and impose severe punishment in accordance with the law for violations of laws and regulations. (July 5, 2021)

国家药监局关于修订甲氧氯普胺说明书的公告

根据药品不良反应评估结果，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氧氯普胺说明书【不良反应】、【禁忌】、【注意事项】等项目进行统一修订。于6月29日将有关事项公告如下：

一、上述药品的上市许可持有人均应依据《药品注册管理办法》等有关规定，按照相应附件要求修订说明书，于2021年9月28日前报省级药品监督管理部门备案。

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，采取有效措施做好药品使用和安全性问题的宣传培训，指导医师、药师或患者合理用药。

三、临床医师、药师应当仔细阅读上述药品说明书的修订内容，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药品说明书，使用处方药的，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上述药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。

(2021-07-05)

NMPA Announcement on Guidance for the Classification Defining of AI-Based Medical Software Products

In order to strengthen the supervision and administration of AI-based medical software products and promote the high-quality development of the industry, the NMPA has organized to formulate the *Principles for the Classification Defining of AI-Based Medical Software Products*, which was issued on July 1. (July 8, 2021)

国家药监局关于发布人工智能医用软件产品分类界定指导原则的通告

为进一步加强人工智能医用软件类产品监督管理，推动产业高质量发展，国家药监局组织制定了《人工智能医用软件产品分类界定指导原则》，于7月1日公布。 (2021-07-08)

NMPA Announcement on the Revision of the Package Insert of the Propranolol Tablets

In accordance with the results of adverse drug reaction evaluation, to further protect drug safety for the people, the NMPA decided to modify the items of [Precautions] in the package inserts of propranolol tablets. On July 15, relevant issues are hereby announced as follows:

I. The marketing authorization holder of the product shall, in accordance with the *Provisions for Drug Registration* and the revision requirements for the package insert of propranolol preparations, submit a supplementary application as such before October 14, 2021 to provincial drug regulatory authority for filing.

Where the contents of revision involve the drug label, the label shall be revised along with all the others; the other contents of the label and insert sheets shall be consistent with those originally approved. For the drugs produced from 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 marketing authorization holder of drug.

II. The marketing authorization holder of drug 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, to guide the physician and pharmacist to use the medicine rationally.

III. The clinicians and pharmacists shall carefully read the revised contents of the said package inserts. 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 for prescription drugs.

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

(July 20, 2021)

国家药监局关于修订普萘洛尔片剂说明书的公告

根据药品不良反应评估结果，为进一步保障公众用药安全，国家药品监督管理局决定对普萘洛尔片剂说明书【注意事项】等项目进行统一修订。于7月15日将有关事项公告如下：

一、上述药品的上市许可持有人均应依据《药品注册管理办法》等有关规定，按照相应附件要求修订说明书，于2021年10月14日前报省级药品监督管理部门备案。

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，采取有效措施做好药品使用和安全性问题的宣传培训，指导医师、药师合理用药。

三、临床医师、药师应当仔细阅读上述药品说明书的修订内容，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药品说明书，使用处方药的，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上述药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。

（2021-07-20）

NMPA Announcement on Issuing the Catalogue of Reference Preparations of Generic Drugs (Forty-three Batch)

On July 22, the Catalogue of Reference Preparations of Generic Drugs (Forty-three Batch) was issued, upon review and determination by the NMPA Experts Committee of Quality and Efficacy Consistency Evaluation of Generic Drugs.

(July 23, 2021)

国家药监局关于发布仿制药参比制剂目录（第四十三批）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7月22日发布仿制药参比制剂目录（第四十三批）。

（2021-07-23）

NMPA Announcement on the Revision of the Package Insert of the Vitamin B_6 Injection

In accordance with the results of adverse drug reaction evaluation, to further protect drug safety for the people, NMPA decided to modify the items of [Adverse reactions] and [Contraindications] in the package inserts of Vitamin B_6 injection. On July 22, relevant issues are hereby announced as follows:

I. The marketing authorization holder of the product shall, in accordance with the *Provisions for Drug Registration* and the revision requirements for the package insert of Vitamin B_6 injection, submit a supplementary application as such before October 21, 2021 to provincial drug regulatory authority for filing.

Where the contents of revision involve the drug label, the label shall be revised along with all the others; the other contents of the label and insert sheets shall be consistent with those originally approved. For the drugs produced from 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 marketing authorization holder of drug.

II. The marketing authorization holder of drug 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, to guide the physician and pharmacist to use the medicine rationally.

III. The clinicians and pharmacists shall carefully read the revised contents of the package inserts for Vitamin B_6 injection. 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 authorities shall urge the drug marketing authorization holders of the product within their respective jurisdiction to revise the package inserts and replacement of the labels and package inserts as required and impose severe punishment in accordance with the law for violations of laws and regulations.

(July 27, 2021)

国家药监局关于修订维生素B_6注射剂说明书的公告

根据药品不良反应评估结果，为进一步保障公众用药安全，国家药品监督管理局决定对维生素B_6注射剂说明书【不良反应】、【禁忌】等项目进行统一修订。于7月22日将有关事项公告如下：

一、上述药品的上市许可持有人均应依据《药品注册管理办法》等有关规定，按照相应附件要求修订说明书，于2021年10月21日前报省级药品监督管理部门备案。

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，采取有效措施做好药品使用和安全性问题的宣传培训，指导医师、药师合理用药。

三、临床医师、药师应当仔细阅读上述药品说明书的修订内容，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药品说明书，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上述药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。

（2021-07-27）

Medical Devices

NMPA Announcement on Issuing 2 Guidance including the Technical Review Guidance for the Registration of Vision Screeners and Mammography Systems

To strengthen the supervision and guidance of medical device registration, and further improve the quality of registration review, the NMPA organized to formulation of the *Guidelines for Technical Review of Vision Screener Registration* and the *Guidelines for Technical Review of Mammography System Registration*, which were published on June 24.

(June 29, 2021)

医疗器械

国家药监局关于发布视力筛查仪和乳腺X射线系统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，国家药品监督管理局组织制定了《视力筛查仪注册技术审查指导原则》和《乳腺X射线系统注册技术审查指导原则》，于6月24日发布。

（2021-06-29）

NMPA Announcement on Issuing the *Catalogue of Distribution of Class II Medical Devices Exempted from Filing*

In order to implement the *Regulations on the Supervision and Administration of Medical Devices*, the NMPA organized to formulate the *Catalogue of Distribution of Class II Medical Devices Exempted from Filing*, which was issued on June 28.

(June 30, 2021)

国家药监局关于公布《免于经营备案的第二类医疗器械产品目录》的公告

为贯彻实施《医疗器械监督管理条例》，国家药监局组织制定了《免于经营备案的第二类医疗器械产品目录》，于6月28日公布。

（2021-06-30）

NMPA Announcement on Issuing 6 Guidance including the Guidance for Nomenclature of the Generic Names of Medical Rehabilitation Devices

To further standardize the generic names of medical devices and strengthen the whole life cycle management for them, the NMPA has organized to formulate the *Guidance for Nomenclature for Generic Names of Medical Rehabilitation Devices, Guidance for Nomenclature for Generic Names of Equipment Used in Traditional Chinese Medicine*, *Guidance for Nomenclature for Generic Names of Radiotherapy Devices*, *Guidance for Nomenclature for Generic Names of Medical Software*, *Guidance for Nomenclature for Generic Names of Respiratory*, *Anaesthesia and First Aid Instruments and Guidance for Nomenclature for Generic Names of Obstetrics and Gynecology*, *Assisted Reproduction and Contraceptive Devices*, which are issued on July 12.

(July 15, 2021)

国家药监局关于发布医用康复器械通用名称命名指导原则等6项指导原则的通告

为进一步规范医疗器械通用名称，加强医疗器械全生命周期管理，国家药品监督管理局组织制定了《医用康复器械通用名称命名指导原则》《中医器械通用名称命名指导原则》《放射治疗器械通用名称命名指导原则》《医用软件通用名称命名指导原则》《呼吸、麻醉和急救器械通用名称命名指导原则》和《妇产科、辅助生殖和避孕器械通用名称命名指导原则》，于7月12日发布。

（2021-07-15）

NMPA Notice on Matters Concerning the Registration of Drug-device Combination Products

With the view to strengthening registration management of drug-device combination products, in accordance with relevant provisions for registration management of drugs and medical devices, matters concerning the registration of drug-device combination products are hereby announced on July 23 as follows:

I. Drug-device combination products refer to medical products composed of drugs and medical devices and produced as a single entity.

II. Drug-led drug-device combination products shall be registered in accordance with the relevant requirements for drugs, and device-led drug-device combination products shall be registered in accordance with the relevant requirements for medical devices. Where the drug or medical device contained in a drug-device combination product has been approved for marketing in China or country (region) of origin, the corresponding marketing approval document shall be submitted at the time of registration application. For the requirements for application dossiers of drug-device combination products, please refer to the relevant documents and guidance.

III. The Applicant shall fully evaluate the attributes of the drug-device combination products to be applied for. For the drug-device combination products whose attribute cannot be determined, the applicants shall apply for attribute definition to Center for Medical Device Standards Management, NMPA

国家药监局关于药械组合产品注册有关事宜的通告

为加强药械组合产品的注册管理，根据药品、医疗器械注册管理的有关规定，于7月23日就药械组合产品注册有关事宜通告如下：

一、药械组合产品系指由药品与医疗器械共同组成，并作为一个单一实体生产的医疗产品。

二、以药品作用为主的药械组合产品，应当按照药品有关要求申报注册；以医疗器械作用为主的药械组合产品，应当按照医疗器械有关要求申报注册。对于药械组合产品中所含药品或者医疗器械已获我国或者生产国（地区）批准上市销售的，相应的上市销售证明文件应当在申报注册时一并提交。药械组合产品的申报资料要求可参考相关文件和指导原则。

三、申请人应当充分评估其拟申报药械组合产品的属性。对于药械组合产品不能确定管理属性的，申请人应当在申报注册前向

(hereinafter referred to as the "CMDSM") prior to registration application.

IV. The CMDSM shall review the dossiers for accepted attribute definition application of drug-device combination products, propose opinions on attribute definition as per the procedure, inform the applicants in the Information System for Attribute Definition of Drug-Device Combination Products, and in a timely manner issue the attribute definition results of drug-device combination products to the public on website.

V. Applicants shall submit drug or medical device registration application to NMPA based on determination results on product attribute, and indicate "drug-device combination products" in the application form.

VI. Center for Drug Evaluation, NMPA, has established coordination mechanism together with Center for Medical Device Evaluation. For the drug-device combination products applied as drugs, Center for Drug Evaluation shall lead the evaluation. Where a joint evaluation is required, registration application dossier shall be transferred to Center for Medical Device Evaluation for synchronized evaluation; for the drug-device combination products applied as medical devices, Center for Medical Device Evaluation shall lead the evaluation, where a joint evaluation is required, registration application dossier shall be transferred to Center for Drug Evaluation for synchronized evaluation. For a drug-device combination product under joint evaluation, the CDE and the CMDE shall cooperate to carry out the communication and consultation of the product under application; both parties shall issue an evaluation report for the safety, effectiveness and quality controllability of the corresponding part and clarify the evaluation conclusion respectively, and the leading unit shall summarize it, make an overall evaluation and issue the overall evaluation conclusion, and then transfer to corresponding department of NMPA for administrative approval.

VII. Where the management attributes have been clearly specified in relevant regulations and documents, such provisions shall prevail.

VIII. The Notice shall be implemented as of the date of issuance. *The Notice on Matters Concerning the Registration of Drug-device Combination Products (Former CFDA Notice [2009] No. 16)* and the *Notice on Matters Concerning the Adjustment of Attribute Definition of Drug-device Combination Products (NMPA Notice [2019] No. 28)* shall be simultaneously abolished. (July 27, 2021)

国家药品监督管理局医疗器械标准管理中心（以下简称标管中心）申请药械组合产品属性界定。

四、标管中心对受理的药械组合产品属性界定申请资料进行审查，按程序提出属性界定意见，在药械组合产品属性界定信息系统中告知申请人，并及时在其网站对外公布药械组合产品属性界定结果。

五、申请人根据产品属性界定结果，向国家药品监督管理局申报药品或者医疗器械注册申请，并在申请表中注明“药械组合产品”。

六、国家药品监督管理局药品审评中心与医疗器械技术审评中心建立协调机制。按照药品申报注册的药械组合产品，由药品审评中心牵头进行审评，需要联合审评的，注册申报资料转交医疗器械技术审评中心同步进行审评；按照医疗器械注册申报的药械组合产品，由医疗器械技术审评中心牵头进行审评，需要联合审评的，注册申报资料转交药品审评中心同步进行审评。对于联合审评的药械组合产品，药品审评中心与医疗器械技术审评中心应当协同开展申报产品的沟通咨询等工作；双方分别对相应部分的安全性、有效性及质量可控性出具审评报告，并明确审评结论，由牵头单位进行汇总并做出总体评价，出具总体审评结论后转入国家药品监督管理局相应业务司进行行政审批。

七、相关法规、文件中已有明确管理属性规定的，按其规定执行。

八、本通告自发布之日起实施，《关于药械组合产品注册有关事宜的通告》（原国家食品药品监督管理局通告2009年第16号）和《关于调整药械组合产品属性界定有关事项的通告》（国家药品监督管理局通告2019年第28号）同时废止。（2021-07-27）

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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