君合研究简讯

JUNHE

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医药卫生领域法律热点问题

国家食品药品监督管理总局下放三项医疗器械审批行政职责至省级食品药品监督管理部门

为进一步深化医疗器械行政审批制度改革，依据《国务院办公厅关于印发国家食品药品监督管理总局主要职责内设机构和人员编制规定的通知》（国办发〔2013〕24 号，以下简称“**国家食药总局三定方案**”）要求，国家食品药品监督管理总局（以下简称“**国家食药总局**”）于 2013 年 6 月 21 日发布《国家食品药品监督管理总局关于部分医疗器械变更审批和质量管理体系检查职责调整有关事宜的通知》（食药监械管〔2013〕28 号，以下简称“**《通知》**”），决定将由国家食药总局承担的部分职责调整至省级食品药品监督管理部门。

一、 职责调整范围

（一） 自 2013 年 10 月 1 日起，将国家食药总局依据《医疗器械注册管理办法》（国家食品药品监督管理局令第 16 号，以下简称“**第 16 号令**”）第 38 条规定开展的**下述境内第三类医疗器械注册证书变更审批事项**，调整至省级食品药品监督管理部门实施：

1. 生产企业实体不变，企业名称改变；
2. 生产企业注册地址改变；
3. 生产地址的文字性改变。

（二） 自 2013 年 10 月 1 日起，将国家食药总局依据《体外诊断试剂注册管理办法（试行）》（国食药监械〔2007〕229 号，以下简称“**229 号文件**”）第 63 条开展的**下述境内第三类体外诊断试剂登记事项变更审批**，调整至省级食品药品监督管理部门实施：

1. 变更生产企业名称；
2. 变更生产企业注册地址；
3. 对境内第三类体外诊断试剂生产地址文字性变更的审批，参照变更生产企业注册地址方式，一并调整至省级食品药品监督管理部门实施。

（三） 自 2013 年 7 月 1 日起，将原国家食药总局药品认证管理中心（以下简称“**认证管理中心**”）组织开展的**下述医疗器械和第三类体外诊断试剂质量管理体系检查（考核）工作**，调整至省级食品药品监督管理部门实施：

1. 部分医疗器械：心脏起搏器、人工心脏瓣膜、血管内支架及导管、一次性使用塑料血袋、动物源医疗器械和同种异体医疗器械。
2. 部分第三类体外诊断试剂：与致病性病原体抗原、抗体以及核酸等检测相关的试剂；与血型、组织配型相关的试剂；与变态反应（过敏原）相关的试剂。

二、 医疗器械变更审批职责调整有关工作要求

（一） 事项界定

第 16 号令第 38 条中“生产企业实体不变，企业名称改变”系指生产企业因收购、重组、股份转让等原因需改变企业名称，但产品生产地址、标准、生产工艺、工序等没有发生改变的情形。

（二） 属地管辖

自 2013 年 10 月 1 日起，生产企业申请有关事项变更的，应向**生产企业所在地**省级食品药品监督管理部门递交申请。

（三） 递交资料要求

境内第三类医疗器械注册证书有关变更申请，生产企业应依据第 16 号令附件十和省级食品药品监督管理部门有关医疗器械注册证书变更规定递交申请材料。其中，生产企业名称变更应提交原注册批准时的产品标准复印件和标准修改单各两份。

境内第三类体外诊断试剂有关登记事项变更和生产地址的文字性变更申请，生产企业应依据 229 号文件附件二和省级食品药品监督管理部门有关体外诊断试剂登记事项变更规定递交有关材料。生产地址的文字性变更参照 229 号文件附件二中变更生产企业注册地址的要求提交申请材料。

同时，生产企业还须提交申请材料真实性自我保证声明，保证有关申请材料与原注册申请和审查批准的材料相同。必要时，省级食品药品监管部门可对申报材料真实性进行核查 。

（四） 审批工作程序与时限

各省级食品药品监督管理部门应按照第 16 号令第 39 和 40 条要求、229 号文件第 69 条以及本省境内第二类医疗器械注册证书变更、体外诊断试剂登记事项变更工作程序和时限开展有关审查工作。

（五） 信息公开和存档要求

各省级食品药品监督管理部门应根据信息公开有关规定，对相关审批过程和审批结果予以公示，同时应每半个月将变更后的医疗器械注册证书或医疗器械变更申请批件（体外诊断试剂）复印件及电子信息汇总后，按照境内第一、二类医疗器械注册数据信息报送要求报送至国家食药总局，相关信息将通过国家食药总局网站对外发布。

各省级食品药品监督管理部门应按照本省档案管理要求做好相关资料存档工作，存档资料应长期或永久保管，期限不得低于 16 年。

三、 过渡期的处理

关于产品变更申请的调整将于 2013 年 10 月 1 日起实施，此前国家食药总局已受理的有关医疗器械注册证书变更、体外诊断试剂登记事项变更申请，继续按程序审查审批。

关于产品质量管理体系的调整将于 2013 年 7 月 1 日起实施，此前（含 6 月 30 日）各省级食品药品监督管理部门对已受理的部分医疗器械和部分第三类体外诊断试剂质量管理体系检查（考核）申请，将于五个工作日内转寄认证管理中心，继续由该中心按现有工作程序和要求完成相关工作。

四、 简评

此次的职责调整，**涉及到的医疗器械产品类别**是原来归属国家食药总局及药品认证管理中心监管范围的境内第三类医疗器械和体外诊断试剂产品；**涉及到的行政许可事项**包括医疗器械注册证书变更、体外诊断试剂登记事项变更，以及质量体系检查（考核）。

《通知》内容是对于国家食药总局三定方案中以下两项下放规定的落实：(1) 将医疗器械质量管理规范认证职责下放省级食品药品监督管理部门；(2) 将国产第三类医疗器械不改变产品内在质量的变更申请行政许可职责下放省级食品药品监督管理部门。《通知》是国家食药总局发布的重组后的首个关于行政职责调整的文件，迈出了深化医疗器械行政审批制度改革、不断提高审批效率的坚实的一步，但职责调整之后的后续监管和衔接工作还有待具体文件进一步细化和规范。

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JUN HE BULLETIN

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Medical and Health

A Further Step to Reform in CFDA – Delegation of Power

On June 21, 2013, China Food and Drug Administration ("**CFDA**") issued the *Circular on Issues regarding Adjustment of Responsibilities of Approval of Certain Medical Device related Changes and Inspection of Quality Management System* (Shi Yao Jian Xie Guan [2013] No. 28, the "**Circular**"). This Circular is deemed as a further step to implement the *Circular of the General Office of the State Council on Issuance of Provisions on Main Responsibilities, Internal Institutions and Staffing Structure of China Food and Drug Administration* (the "**Three-Decisions Scheme**"), which policies have been considered as the signal to strengthen the reform in the area of medical device administrative system. Through this Circular, CFDA will delegate part of its responsibilities down to the provincial-level food and drug administration department ("**Local FDA**") to handle, which would be expected a further step to release its control over the medical device administration and supervision.

I. Delegation of Power

1. From October 1, 2013, approval authority for change of domestic Class III Medical Device Registration Certificate listed below (currently handled by CFDA pursuant to Article 38 of *Administrative Measures for Medical Device Registration* ("**Decree No. 16**")) will be delegated to Local FDA,

   (i) Change of the name of the production enterprise, but without changing the actual manufacturer;

   (ii) Change of the registered address of the production enterprise; and

   (iii) Literal change of the production address.

2. From October 1, 2013, approval authority for change of the registration items of domestic Class III in vitro diagnostic reagent listed below (currently handled by CFDA pursuant to Article 63 of Measures on Administration of Registration of In vitro Diagnostic Reagent (Trial Implementation) ("Document No. 229")) will be delegated to Local FDA,

   (i) Change of the name of the production enterprise;

   (ii) Change of the registered address of the production enterprise; and

   (iii) Examination and approval of literal change of the production address of domestic Class III in vitro diagnostic reagent will be performed by the local FDA by referring to change of the registered address of the production enterprise.

3. From July 1, 2013, inspection (examination) of quality management system of medical device and Class III In vitro Diagnostic Reagent listed below (currently organized and carried out by the former Center for Certification of Drug, State Food and Drug Administration ("CCD")) shall be carried out by Local FDA,

(i) Certain medical device: cardiac pacemaker, cardiac valve prosthesis, endovascular stent and catheter, disposal plastic blood bag, animal derived medical device and allogeneic medical device; and

(ii) Certain Class III In vitro Diagnostic Reagent: reagents relating to detection of pathogenic pathogens antigen, antibody and nucleic acid and so on; reagents relating to blood type, tissue typing; reagents relating to allergic reaction (allergen).

II. Requirements

1. Interpretation of Article 35 of Decree No.16

   "Change of the name of the production enterprise, but without changing the actual manufacturer" provided by Article 35 of Decree No. 16 refers to the situation where the production enterprise changes its name due to acquisition, restructure, transfer of shares etc, without changing the production address, standards, production technique, process and so on.

2. Territorial Jurisdiction

   From October 1, 2013, the production enterprise applying for changes of relevant items shall submit the application to the Local FDA in the place where the production enterprise is located.

3. Requirements of Submitting Materials

   With respect to application for change of domestic Class III Medical Device Registration Certificate, the production enterprise shall submit the application materials in accordance with Appendix 10 of Decree No. 16 and relevant provisions for change of Medical Device Registration Certificate of the Local FDA. The enterprise applying for change of the name of the production enterprise shall submit two copies of product standard and two standard modification documents.

   With respect to application for change of registration items and literal change of the production address of domestic Class III in vitro diagnostic reagent, the production enterprise shall submit relevant materials in accordance with Appendix 2 of Document No. 229 and relevant provisions of for change of the registration items of in vitro diagnostic reagent of the local FDA. The enterprise applying for literal change of the production address shall submit the application material by referring to requirements for change of the registered address of the production enterprise in Appendix 2 of Document No. 229.

   Meanwhile, the production enterprise shall submit a warranty statement of authenticity of application materials to ensure that the relevant application materials are identical with those submitted for initial registration and examination and approval. The Local FDA may check the authenticity of the application materials if it deems necessary.

4. Procedure and Timeline of Examination and Approval

   Each Local FDA shall carry out relevant examination in accordance with the requirements of Article 39 and 40 of Decree No. 16, Article 69 of Document No. 229 as well as the procedures and timeline for change of domestic Class II Medical Device Registration Certificate, and change of the registration items of in vitro diagnostic reagent of that province.

5. Information Disclosure and Requirements of Filing

   Each Local FDA shall publish related process and results of examination and approval in accordance with relevant provisions of information disclosure and at

the same time shall collect and submit the copies of the updated Medical Device Registration Certificate or the approval documents for medical device (in vitro diagnostic reagent) related changes and digital information to the CFDA in accordance with the requirements of submitting data information of registration of domestic Class I, II medical device. Relevant information shall be made public through the website of the CFDA.

Each local FDA shall keep the relevant material in the archives. The filing materials shall be kept for no less than 16 years.

III. Transition Period

The adjustments of application for changes of the products shall be implemented from October 1, 2013, relevant application for change of Medical Device Registration Certificate and change of the registration items of in vitro diagnostic reagent accepted by the CFDA before October 1 shall be continued to be examined and approved by the CFDA pursuant to applicable procedures.

The adjustments of product quality management system will be implemented from July 1, 2013, before which time (including June 30) application for inspection (examination) of quality management system of certain medical device and certain Class III in vitro diagnostic reagent accepted by every Local FDA, shall be forwarded to CCD within five working days and completed by CCD pursuant to current working procedure and requirements.

IV. Comments

The categories of medical device products involved in the delegation of power are domestic Class III medical device and in vitro diagnostic reagent products currently administered and supervised by CFDA and CCD. The administrative and approval items involved include change of Medical Device Registration Certificate, registration items of in vitro diagnostic reagent and inspection (examination) of quality system.

The Circular is the first regulation relating to delegation of powers issued by the CFDA after its restructuring. It is to implement the Three-Decisions Scheme in the aspects of (i) to delegate the certification authority for medical device quality management practices to the Local FDA; and (ii) to delegate the approval authority for change of domestic Class III medical device to the Local FDA, provided, however, that such change shall not touch the internal quality of the products.

This Circular moves a small step to implement the reform against the medical device administrative system. However, as the first circular regulating the implementation of policy-level regulations, we see a concrete step forward made by the authority.

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