医疗健康法律简讯

JUNHE

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本 期 要 目

- **《医疗器械标准管理办法》出台**
- **食品安全追溯体系建立**

一、《医疗器械标准管理办法》出台

2017 年 4 月 26 日，国家食品药品监督管理总局（以下简称“**食药监总局**”）发布《医疗器械标准管理办法》（国家食品药品监督管理总局令第 33 号）（以下简称“**《办法》**”），适用于中国境内医疗器械标准的制定、修订、实施及监督管理。《办法》将于 2017 年 7 月 1 日起施行。2002 年 1 月 4 日食药监总局发布的《医疗器械标准管理办法（试行）》（原国家药品监督管理局令第 31 号，以下简称“**《试行办法》**”）同时废止。

（一）《办法》出台的背景

2000 年 4 月 1 日，《医疗器械监督管理条例》开始实施，作为其配套规章，食药监总局于 2002 年 1 月 4 日发布《《试行办法》，规定了国家标准、行业标准和注册产品标准组成的医疗器械三级标准体系，医疗器械标准工作步入法制化轨道。

2014 年 3 月 7 日，国务院修订《医疗器械监督管理条例》，同年 7 月 30 日，食药监总局发布《医疗器械注册管理办法》，该两项规定取消“注册产品标准”，确定了“产品技术要求”的法律地位，形成国家标准和行业标准二级标准体系。随后，国务院于 2015 年 3 月 11 日印发《深化标准化工作改革方案》，提出整合精简强制性标准，优化完善推荐性标准等要求和措施，并于 2015 年 8 月 9 日印发《关于改革药品医疗器械审评审批制度的意见》，提出了改革医疗器械审批方式、及时修订医疗器械标准等要求。

在前述背景下，为加强医疗器械标准管理，食药监总局组织对《试行办法》进行修订，形成了目前发布的《办法》文本。

（二）重要概念解析

1、 医疗器械标准-定义

《办法》规定，医疗器械标准是指由食药监总局组织制修订，依法定程序发布，在医疗器械研制、生产、经营、使用、监督管理等活动中遵循的统一的技术要求。

2、 医疗器械标准-分类

《办法》删除了《试行办法》中关于“注册产品标准”的全部内容，明确医疗器械标准分为国家标准和行业标准。

医疗器械标准按照其效力分为强制性标准和

推荐性标准。

- 对保障人体健康和生命安全的技术要求，应当制定医疗器械强制性国家标准和强制性行业标准；
- 对满足基础通用、与强制性标准配套、对医疗器械产业起引领作用等需要的技术要求，可以制定为医疗器械推荐性国家标准和推荐性行业标准。

3、 “产品技术要求”的法律地位

与 2014 年发布的《医疗器械监督管理条例》和《医疗器械注册管理办法》保持一致，《办法》取消“注册产品标准”，代之以“产品技术要求”并进一步明确其与强制性标准和推荐性标准之间的关系。

根据《医疗器械注册管理办法》，拟注册或备案医疗器械的申请人或者备案人应当编制医疗器械的产品技术要求，在办理医疗器械备案或者注册时由相应的食品药品监督管理部门对产品技术要求进行备案或者核准。《办法》中对于产品技术要求做出进一步规定：

- 医疗器械产品技术要求不得低于产品适用的强制性国家标准和强制性行业标准；
- 医疗器械企业应当严格按照经注册或者备案的产品技术要求组织生产，保证出厂的医疗器械符合强制性标准以及经注册或者备案的产品技术要求；
- 医疗器械推荐性标准被法律法规、规范性文件及经注册或者备案的产品技术要求引用的内容应当强制执行。

(三) 标准管理职责及制修订程序

1、 标准管理职责

《办法》中分别规定了食药监总局、医疗器械标准管理中心、医疗器械标准化技术委员会、医疗器械标准化技术归口单位、地方食品药品监督管理部门、医疗器械研制机构、生产经营企业和使用单位在医疗器械标准管理中的职责与义务。

2、 标准制订修订程序

《办法》规定医疗器械标准制订修订程序包括标准立项、起草、征求意见、技术审查、批准发布、复审和废止等，并针对每一程序作出了具体要求，其中，如下要点值得关注：

- 快速程序。对医疗器械监管急需制订修订的标准，可以按照食药监总局规定的快速程序开展；
- 提高社会参与度。立项阶段，食药监总局审核通过的医疗器械标准计划项目，应当向社会公示；起草阶段，医疗器械生产经营企业、使用单位、监管部门、检测机构以及有关教育科研机构、社会团体等，可以向医疗器械标准化技术委员会提出起草相关医疗器械标准的申请，医疗器械标准化技术委员会择优选定起草单位；征求意见阶段，医疗器械标准征求意见稿在医疗器械标准管理中心网站向社会公开征求意见，征求意见的期限一般为两个月；
- 批准发布。相关医疗器械标准由医疗器械标准化技术委员会进行技术审查、医疗器械标准管理中心审核、并经食药监总局审查通过之后，国家标准送国务院标准化行政主管部门批准、发布，行业标准由食药监总局以公告形式发布；国家标准和行业标准均应公开并供公众查阅；
- 复审。医疗器械标准化技术委员会应当对已发布实施的医疗器械标准，根据科学技术进步、

产业发展以及监管需要对其有效性、适用性和先进性及时组织复审，提出复审结论。复审结论分为继续有效、修订或者废止。复审周期原则上不超过 5 年。

二、食品安全追溯体系建立

2017 年 3 月 28 日，食药监总局发布了《关于食品生产经营企业建立食品安全追溯体系的若干规定》（以下简称“《规定》”）。

（一）背景

2015 年 4 月 24 日，《中华人民共和国食品安全法》发布，在我国正式确立食品安全追溯制度。随后，国务院及食药监总局分别出台《国务院办公厅关于加快推进重要产品追溯体系建设的意见》（国办发〔2015〕95 号）和《食品药品监管总局关于推动食品药品生产经营者完善追溯体系的意见》（食药监科〔2016〕122 号），提出了落实食品安全追溯制度的总体性指导意见。

基于上述背景，食药监总局出台《规定》，旨在明确食品生产经营企业建立食品追溯体系的具体要求，启动各地食药监局的食品安全追溯体系试点。

（二）《规定》主要内容

1、 适用范围

《规定》适用于食品（不包括特殊食品[1]）生产、经营企业，后者包括食品（含食用农产品）销售、运输、贮存企业及餐饮企业。《规定》进一步明确，其不适用于食品（含食用农产品）销售企业销售自制食品，及餐饮企业销售非预包装食品，但上述不适用的食品生产经营主体和行为，可参照《规定》建立食品安全追溯体系。

2、 追溯信息内容

《规定》详细列出了食品生产经营企业在食品的生产到流通等各个环节中（包括生产、销售、餐饮、运输、贮存及交接等）应当记录信息的具体范围，为食品生产经营企业进行信息追溯和记录提供了系统化标准。以生产环节为例，根据《规定》，生产企业应当记录的信息包括产品信息、原辅材料信息、生产信息、销售信息、设备信息、设施信息、人员信息、召回信息、销毁信息及投诉信息等。

3、 信息记录、保存和衔接的要求

为确保信息追溯体系的有效运行，《规定》对信息记录、保存和衔接提出了具体要求，其中包括，食品生产经营企业应通过采取保存原始记录并由记录和审核人员复核签名等方式确保所记录信息真实有效；信息记录和凭证保存期限不得少于产品保质期满 6 个月，没有明确保质期的，保存期限不得少于 2 年。

4、 试点实施的总体方针及目标

《规定》指出，省级食品药品监管部门应考虑不同品种食品的生产经营特点、具体企业的生产经营实际情况及追溯方式可能给生产经营带来的成本等多方因素，在一类或几类食品（特别是高风险食品）中选择代表性企业先行试点，稳步推进，争取尽快基本实现大米、小麦粉、食用植物油、白酒等重点食品安全可追溯。

（三）影响

《规定》是食品生产经营企业建立追溯体系的第一个系统性指南，使食品生产经营企业建立食品安全追溯体系有章可循。未来，各地食药监局将如何据此进行试点值得密切关注。

[1]根据《食品安全法》，特殊食品包括保健食品、特殊医学用途配方食品和婴幼儿配方食品等。

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LIFE SCIENCES & HEALTH CARE BULLETIN

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You will find under this bulletin

- Release of the Medical Device Standards Administrative Measures
- Formation of Food Safety Tracing Systems

Release of the Medical Device Standards Administrative Measures

On April 26, 2017, the China Food and Drug Administration ("**CFDA**") released the *Measures on the Administration of Medical Device Standards (Order No. 33 of the CFDA)* (the" **Measures**"), which applies to the enactment, revision, enforcement, supervision and administration of medical device standards within the territory of the People's Republic of China. The Measures will come into force on July 1, 2017, and the *Measures on Administration of Medical Device Standards (for trial implementation)* (the former order No. 31 of the CFDA) released on January 4, 2002 shall be abolished simultaneously.

I. Background

On April 1, 2000, the *Regulations on the Supervision and Administration of Medical Devices* took effect, and as its supporting rules, on January 4, 2002, the CFDA released the *Measures on the Administration of Medical Device Standards (for trial implementation)* (the "**Measures for Trial Implementation**"), which specified the national standard, industry standard and registered products standard as a three-level standard system for medical devices.

On March 7, 2014, the State Council revised the *Regulations on the Supervision and Administration of Medical Devices*; during the same year, on July 30th, the CFDA released the *Measures on the Administration of Registration of Medical Devices.* These two regulations cancelled the "registered product standards" and defined the "product technical requirements" and its legal position, as such the two-level standard system (i.e., the national standard and industry standard) was formed.

Later, on March 11, 2015, the State Council released the *Plan for Deepening the Reform of Standardization Work*, requiring consolidation and streamlining of the compulsory standards and improving and optimizing the recommended standards; and then the State Council issued the *Opinions on Reform of the Review and Approval System for Drugs and Medical Devices* on August

9, 2015, requiring reform of the approval methods for medical devices and to promptly amend the medical device standards.

Under the foregoing background, in order to strengthen the administration of medical device standards, the CFDA organized to revise the Measures for Trial Implementation and the current version of the Measures is therefore formed.

II. Essential Concepts

Definition of medical device standards

According to the Measures, the medical device standards refer to the uniform technical requirements which shall be enacted and revised under the organization of the CFDA, released in accordance with legal procedures, and shall be followed during the course of the research and development, production, operation, use, supervision and administration of medical devices.

Categories of medical device standards

The Measures have deleted all the context regarding registered product standards under the Measures for Trial Implementation, and expressly specified that the medical device standards are categorized into national standards and industry standards.

In addition, according to their enforcement, the medical device standards are categorized into compulsory standards and recommended standards. Specifically,

- with respect to those technical requirements to guarantee the safety of human health and life, the compulsory national standards and compulsory industry standards shall be enacted;
- with respect to those technical requirements to satisfy fundamental and common use, affiliated to the compulsory standards and leading the medical device industry, the recommended national standards and recommended industry standards may be enacted.

Legal position of product technical requirements

Consistent with the *Regulation on the Supervision and Administration of Medical Devices* and the *Measures on the Administration of Registration of Medical Devices* released in 2014, the Measures replace the registered product standard with the product technical requirements, and further specify the relationship among the product technical requirements, compulsory standards and recommended standards.

According to the *Measures on the Administration of Registration of Medical Devices*, an applicant applying for registration or filing of a medical device shall prepare the product technical requirements for the medical device and submit to the food and drug authority for filing or approval. The Measures make further clarifications with respect to the product technical requirements:

- The product technical requirements shall not be lower than the compulsory national standards and compulsory industry standards;

- Medical device enterprises shall strictly obey the registered or filed product technical requirements during manufacturing, and make sure that the medical devices manufactured are in compliance with the compulsory standards and the registered or filed product technical requirements;
- The recommended standards of medical devices shall become mandatory when being cited by the laws, regulations, rules, and registered or filed product technical requirements.

III. Standard Administration Duties and Procedures for Enactment and Revision of Standards

Standards administration duties

The Measures have expressly stated the duties and obligations of the CFDA, the Administration Center for Medical Device Standards, the Standardization Technology Committee for Medical Devices, the entities undertaking the standardization technology related work for medical devices, local Food and Drug Administration, R&D institutes for medical devices, producers, operators and users of medical devices, respectively during the administration of medical device standards.

Procedures of enactment and revisions of the standards

According to the Measures, the procedures for the enactment and revision of medical device standards should consist of project initiation, drafting, release for public comments, technical examination, approval and issuance, revisiting, abolishment, and so on. Amongst those procedures, we summarized the following bullet points which are worth attention:

- Expedited procedures. As to the medical device standards for which there is an urgent need to enact or revise, the enactment or revisions thereof may follow the expedited procedures provided by the CFDA;
- Improvement of public participation. During the phase of project initiation, the contemplated project of medical device standards reviewed and approved by the CFDA shall be released to the public; during the stage of drafting, the producers, operators or users of the medical devices, the administration departments, the examining institutes, the related educational and research institutes, social entities, and so on, may apply to draft the related medical device standards, and the Standardization Technology Committee for Medical Devices will select the best entity to work on the drafting; in addition, the draft version of the medical device standards shall be released for public comments on the website of the Administration Center for Medical Device Standards, generally for two months;
- Approval and issuance. After being examined by the Standardization Technology Committee for Medical Devices, reviewed by the Administration Center for Medical Device Standards, and approved by the CFDA, the national standards will be submitted to the

Administration of Standardization of the State Council for final approval and issuance; while the industry standards will be issued by the CFDA. Both the national standards and industry standards shall be open to the public for review. The Standardization Technology Committee for Medical Devices shall revisit the effectiveness, feasibility and advancement of the issued medical device standards based on the progress of scientific technology, industry development, and the need for supervision, and upon revisiting, decide to keep such standards effective, or revise or abolish such standards. In general, the term for the revisit shall be no longer than 5 years.

Formation of Food Safety Tracing Systems

On March 28, 2017, the China Food and Drug Administration (the "**CFDA**") released the *Several Provisions in Respect of the Establishment of Food Safety Tracing Systems by Food Production and Operation Enterprises* (the "**Provisions**").

I. Background

On April 24, 2015, the circulation of the *Food Safety Law of the People's Republic of China* marked the official establishment of food safety tracing systems in China. Subsequently, the State Council and the CFDA successively issued the *Opinion on Accelerating the Construction of Important Product Tracing Systems* ([2015] No. 95 Document issued by the General Office of the State Council) and the *Opinion on Promoting the Improvement of Food Tracing Systems by Food and Drug Manufacturers and Operators* ([2016] No. 122 Document issued by the CFDA), putting forward the general guidance on the implementation of food safety tracing systems.

II. Overview

1. Scope of application

The Provisions apply to food (exclusive of special food[1]) production and operation enterprises, with the latter including food (inclusive of edible agricultural products) sales, transportation, storage enterprises and catering enterprises. It is further clarified under the Provisions that homemade products sold by food sales (including edible agricultural products) enterprises and the non-prepackaged food sold by catering enterprises shall be excluded although such food production or operation entities may adopt a food tracing system by reference to the Provisions.

2. Tracing information content

The Provision stipulates in detail the specific scopes of the information required to be recorded by food production and operation enterprises for each process during the entire course of food production and circulation (inclusive of production, sales, catering, transportation, storage and transfer, and so on), establishing a systematic standard for food production or operation enterprises to trace and record information. Taking the process for food production as an example, under the Provisions, a production enterprise shall record information on, among other areas, products, raw and auxiliary materials, production, sales, equipment, facility, personnel, recall, destruction and complaints.

3. Requirements for information recording, preservation and connection

In order to ensure the effective operation of tracing systems, the Provisions provides detailed requirements for information recording, preservation and connection, among which include that a food production or operation enterprise shall take actions such as preserving original records and requiring that all records be jointly signed by the personnel who record the information and who are responsible for reviewing the information so as to ensure that the

[1] Pursuant to the Food Safety Law, special food includes health food, formula food for special medical purposes, and formula food for infants.

information recorded is true and valid; and the retention period for records and vouchers shall not be less than six months after the expiration of the shelf life of products; or shall not be less than two years for products without a clear shelf life.

4. General principles and objectives for pilots

The Provisions point out that the food and drug regulatory departments at the provincial level shall, by taking into account multiple factors, including the characteristics for the production and operation of food in different categories, the actual business and operation situation of the specific enterprises, and the cost of such tracing systems for manufacturers and operators, carry out pilots in selected representative enterprises of one or several certain types of food (especially high-risk food) and make progress in a steady manner, with the aim of the basic realization of the traceability of food safety of rice, wheat flour, infant formula milk powder, edible vegetable oil, liquor and other food in key areas as early as practical.

III. Implications

The Provisions are the first systematic guidance in respect of the establishment of tracing systems by food production and operation enterprises, setting out clear requirements of the tracing systems for the food production or operation enterprises to follow. It is worth paying close attention to how the local Food and Drug Administration will conduct pilots in practice accordingly.

If you have any questions or comments, please contact

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