Regulatory Insights

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Government Agency
China FDA

Revision to <Measures for the Registration and Filling of Health Food> (Draft)

关于修改保健品注册备案管理办法的决定(征求意见稿)

China FDA is planning to revise, "Measures for the Registration and Filling of Health Food". Below are listed the changed wording followed by the original wording.

Article 7, Paragraph 2
The applicant of health food registration and recording must be responsible for the authenticity, integrity and traceability of the application materials, take the initiative to submit scientific research and experimental evidence about the functional claims, and take the legal responsibility of the authenticity.

Original:
The applicant of health food registration and recording must be responsible for the authenticity, integrity and traceability of the application materials, and take the legal responsibility of the authenticity.

Article 16, Paragraph 1
Review board should evaluate the application materials, conduct on-site inspection and retest as needed. The review process will be finished within 60 days. The review board will submit the review results and comments to CFDA.

Original:
Review board should organize review experts to evaluate the application materials, conduct on-site inspection and retest as needed. The review process will be finished within 60 days. The review board will submit the review results and comments to CFDA.

Article 32, Paragraph 1
Health food with approved registration needs renewal prior to the expiration date. The applicant needs to apply for the renewal 6 months before the expiration date. If the applicant fails to submit the renewal 6 months before the expiration date, the renewal will still be accepted; however, the manufacturer should stop production if they did not get application re-approval prior to the expiration date. *

For products' non-conformity with new regulations result from legislative changes, applicant should apply for amendment and supplement relevant materials regarding new regulations.

*HPA-China Commentary: If manufacturer summits 6 months prior to expiration, CFDA will approve before expiration, so that there is no time of non-approval on record.

Original:
Health food with approved registration needs renewal after the expiration date. The applicant needs to apply for the renewal 6 months before the expiration date.

Article 38
Review board should review application of amendment or extension, and make the decision of approval or rejection regarding article 36 and article 37 within 10 workdays, accepting institution should deliver the decision to applicant.

If the extension application is submitted more than 6 months before expiration date, review board should make the final decision before expiration date, if not, it will be recognized as approval.

If the extension application is submitted within 6 months before expiration date, review board should make the final decision within 6 months after receiving application.

Original:
FDA have to make the final decision before the registration expired. If no decisions have been made within the expiration date, it will be recognized as approved to be renewed.

Article 55
The label and instruction content cannot be related to prevention or treatment of disease, also the label must state the following: “This product cannot be used to replace drugs for the prevention or treatment of disease”.

For products without human trails, the function claim should add “this product only passed animal trail”; For products with human trails, the function claim should add “this product passed human consumption evaluation”

Original:
The label and instruction content cannot be related with disease prevention and treatment, have to claim that “This product cannot be used instead of drugs.”

Article 75
The electronic health food registration certificate has the equal legal effect as the printed certificate.

The above is a new article, so there is no “original”.

This regulation goes into effect on XX,XX,201X
The revised version of <Measure for the Registration and Filling of Health Food> will be released separately in the future according to this draft.

**CFDA requires comments submitted before January 29, 2018, please give us your feedback before January 25, 2018 to leave us some time for gathering, translating and summarizing.*

Original Chinese Document listed Below

国家食品药品监督管理总局关于修改《保健食品注册与备案管理办法》的决定（征求意见稿）

国家食品药品监督管理总局决定对《保健食品注册与备案管理办法》作如下修改：

一、将第七条第二款修改为：“保健食品注册申请人或者备案人应当对所提交材料的真实性、完整性、可溯源性负责，主动公开与产品功能相关的科学文献和试验依据，并对提交材料的真实性承担法律责任。”

二、将第十六条第一款修改为：“审评机构应当组织对申请材料进行审查，并根据实际需要组织查验机构开展现场核查，组织检验机构开展复核检验，在60个工作日内完成审评工作，并向国家食品药品监督管理总局提交综合审评结论和建议。”

三、将第三十二条第一款修改为：“已经生产销售的保健食品注册证书有效期届满需要延续的，保健食品注册人应当在有效期届满6个月前申请延续；未在有效期届满6个月前申请延续，且在注册证书有效期内的，保健食品注册人可以申请延续注册，但延续注册申请受理后，原注册证书有效期届满时，企业应停止生产，待作出准予注册决定后方可恢复生产。

增加一款，作为第三十二条第二款：因法律法规和食品安全标准变化，产品不符合新的规定的，保健食品注册人应当及时申请变更，并补充完善符合新法规要求的相关材料。”

四、将第三十八条修改为：“审评机构组织对保健食品变更注册或者延续注册申请材料进行审查，按照第三十六条和第三十七条的规定，作出准予注册或者不予注册的决定，并应当自作出决定之日起10个工作日内，由受理机构向注册申请人发出保健食品注册证书或者不予注册决定。

保健食品注册人在有效期届满6个月前提出延续注册申请的，审评机构应当在保健食品注册证书有效期届满前作出是否准予延续的决定。逾期未作出决定的，视为准予延续注册。

保健食品注册人未在有效期届满6个月前申请延续，但在注册证书有效期内申请延续的，审评机构应当自受理之日起6个月内作出是否准予延续的决定。”

五、将第五十五条修改为：保健食品的标签、说明书主要内容不得涉及疾病预防、治疗功能，并声明“本品不能代替药物的疾病预防、治疗作用”。

未经人群食用评价的，保健功能声称的限定用语应增加“本品仅经动物实验评价”；经人群食用评价的，保健功能声称的限定用语应增加“本品经人群食用评价”。

六、在第七十四条后增加一条，作为第七十五条：“食品药品监督管理部门制作的保健食品注册电子证书与印制的保健食品注册证书具有同等法律效力。”

本决定自2017年 月 日起施行。

《保健食品注册与备案管理办法》根据本决定作相应修改并对条文序号作相应调整，重新公布。