

China Calls for Submissions of New Health Claims

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On August 6, 2024, the Chinese State Administration for Market Regulation (SAMR) issued a notice calling for the submission of new health claims for health foods[1], with a deadline of December 31, 2024. China published the *Implementation Rules of Technical Evaluation of New Health Food Products and the Functions (Trial)* (“Implementation Rules”) to apply for new health claims[2] in August 2023. SAMR’s call to submit new health claims will create momentum for the industry to use the process and bring more health claims into the market.

Health foods in China include foods that make health claims and foods sold as nutrient supplements, such as vitamins and minerals. All health foods must be pre-approved by SAMR before being sold in China. Historically, industry is only allowed to use the specific health claims that are included in the *Catalogue of Permissible Functional Claims for Health Foods - Non-Nutrient Supplements (2023 Edition)*[3]. Any claim beyond this Catalogue is not allowed to be used unless it is evaluated and approved by SAMR through the above Implementation Rules. A more detailed discussion regarding the management of health foods in China can be found in our article – [Health Foods in China: New Rules Approving Functional Claims](#).

According to the SAMR notice, through this call for submissions, new health claims beyond the Catalogue are encouraged to be submitted and reviewed by the agency through a dedicated program. An application for a new health claim should be prepared in accordance with the Implementation Rules, which involve extensive data preparation, e.g., working with at least one qualified Chinese institution or clinical trial organization to validate the new claim as well as the methodology. Under the Implementation Rules, any company or individual can file an application with SAMR seeking approval of a new health claim for food. New health claims are categorized into three types, i.e., “*supplementing nutritional substances in the diet*,” “*maintaining or improving health conditions of the human body*,” and “*reducing the risk of incurring diseases*.”

We also should point out that SAMR permits a “joint-review” mechanism addressing both the new claim and the health food product together, i.e., when one seeks evaluation on the new claim, it also may submit an application for the approval of the health food (i.e., blue-hat approval) bearing the new claim simultaneously. Under this scenario, a health food application alone requires a range of safety and efficacy data. Since it takes time to contract testing and generate local data in China to satisfy the requirements, it may be challenging for enterprises to pursue the “joint-review” pathway, given SAMR’s upcoming December 2024 deadline. Nevertheless, companies may still submit the proposed new health claims alone without seeking approval for the finished health food bearing the new claim, as SAMR now adopts a collective approach and has established a dedicated project to review applications for new claims.

SAMR’s call for submissions demonstrates their commitment to help industry promote new health claims for foods sold in China and presents a valuable opportunity for enterprises that produce health foods with claims currently not permitted in China but are accepted in other markets.

[1] https://www.samr.gov.cn/hd/zjdc/art/2024/art_2819b280868d4ea4a6c0e24131612410.html

[2] https://www.gov.cn/zhengce/zhengceku/202308/content_6900636.htm

[3] https://www.samr.gov.cn/zw/zfxxgk/fdzdgknr/tssps/art/2023/art_bfffccd97e6e4dfaa9d353318487e670.html

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