**The Turkish Medicines and Medical Devices Agency Publishes New Draft Guidelines**

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On June 7, 2022, the Turkish Medicines and Medical Devices Agency ("*Agency*") published the Draft Guidelines on Packaging Information and Legibility of Foods for Special Medical Purposes ("*Legibility Guidelines*")[1] and the Draft Guidelines on New Health Claim Applications (*"Application Guidelines"*)[2].

The Legibility Guidelines is indicated to be based on the Regulation on the Licensing of Foods for Special Medical Purposes, and aims to provide the rules and procedures of services and operations to be carried out regarding packaging information and legibility in food license applications for special medical purposes. It defines foods for special medical purposes as all foods that are specially formulated and obtained by industrial methods to be used under medical supervision in order to regulate patient diets (including infants) who have limited, decreased or impaired capacity to take in, digest, absorb, metabolize and remove nutrients or metabolites from the body and whose dietary management cannot be achieved through a normal diet.

The Legibility Guidelines classifies the common technical documentation format in two main modules, consisting of (i) information on packaging and foods for special medical purposes and (iv) the legibility of the packaging information. In the first section, the Legibility Guidelines provides general information on the replacement and specification of foods for special medical purposes, components, warnings and storage. In the second section the Legibility Guidelines lays out information regarding outer and inner packaging. Accordingly, the packaging information of the product should be in line with the specified articles before notifying the Agency.

The Agency has invited concerned parties to submit their comments for the Legibility Guidelines through the e-mail address tıbbi.beslenme@titck.gov.tr until June 27, 2022.

The Application Guidelines, on the other hand, aims to provide the rules and procedures regarding a new health claim application in accordance with the provisions of the Regulation

[1] https://www.titck.gov.tr/duyuru/ozel-tibbi-amacli-gidalarin-ambalaj-bilgilerine-ve-okunabilirliklerine-iliskin-kilavuz-taslagi-07062022160747 (last access: June 13, 2022)
[2] https://www.titck.gov.tr/duyuru/yeni-saglik-beyani-basvuru-kilavuz-taslagi-07062022160232 (last access: June 13, 2022)

on the Use of Health Claims which is still in its draft form. It covers natural and legal persons applying for new health claim permits.

Per the Application Guidelines, the application must be conveyed in compliance with the table specified in Annex-1 and submitted to the Agency with the Application Form in Annex-2. In order to fulfill a valid application, the Application Guidelines provides a set of requirements. Accordingly, each application should be made for only one relationship between a single declared effect and a nutrient, other elements, food or food group; to indicate the regulation to which the health claim is related. For scientific data, the applicant must submit a summary of the relevant data, and specify whether it is from an appropriate human study or non-human study. The applicant must disclose the cause and effect relationship between the food and the consumption. It is also required to demonstrate the level of representation of the specific working groups from which the evidence and data is obtained. Finally, the Agency provides information and guidelines to companies and natural persons for a new health claim application and the required information and its legibility for packaging.

The Agency has invited concerned parties to submit their comments for the Application Guidelines through the e-mail address bdud.saglikbeyani@titck.gov.tr until June 24, 2022.

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