China Announces New Draft Regulations on Health Foods

Recently, the China Food and Drug Administration (CFDA) promulgated three draft regulations on health foods for public comment: (1) Regulation on Health Food Function Claim Catalog and Ingredient Catalog; (2) Regulation on the Registration and Notification for Health Foods; and (3) Regulation on Health Food Labeling. The draft regulations are intended to implement the new requirements on health foods set forth in the recently published China Food Safety Law (FSL). Specifically, under Article 75 of the FSL, CFDA is charged with compiling, revising and publishing a catalog for health food ingredients and a catalog for health function claims. Article 76 of the FSL further sets forth two regulatory paths for health foods, i.e., pre-market registration and notification. This represents significant progress from the current registration-only system for health foods, as it helps to ease the regulatory burden on industry without compromising the quality and safety of health food products. The following is a summary of the three draft regulations.

1. Regulation on Health Food Function Claim Catalog and Ingredient Catalog

The draft Regulation sets forth detailed standards and procedures for a health function claim or an ingredient to be included in the corresponding catalog. Specifically, the health function claim catalog refers to a list of permitted health function claims on health foods. The claims are based on test methods and criteria that have been systematically evaluated and verified. The ingredient catalog refers to a list of functional ingredients that can be used in health foods whose safety and functionality already have gone through evaluation. The catalog provides information on the name of each functional ingredient, its compatibility with other ingredients, use levels, permitted health function claims, quality standard, active components, testing methods, etc. It is intended to be used as an accompanying document to determine whether a health food is subject to registration or notification. (See Section (2) below for a discussion on notification vs. registration requirements.) The ingredient catalog also contains a special sub-catalog of nutritional substances, including vitamins and minerals. While vitamins and minerals listed in the catalog can be freely used together to produce multi-vitamin/mineral supplements, for the remaining ingredients on the catalog, the use of two or more ingredients in one health food product must have sufficient scientific justification as well as a history of use.

2. Regulation on the Registration and Notification for Health Foods

The health food ingredient catalog will be used to determine whether a health food product needs pre-market registration or only notification. According to the draft Regulation on the Registration and Notification for Health Foods, pre-market registration with CFDA is required under two scenarios: 1. health foods using functional ingredients not listed in the ingredient catalog, and 2. health foods imported into China for the first time (except for imported nutritional substances, such as vitamins and minerals on the ingredient catalog). The pre-market registration process for health foods has already been in place in China since 1996. In addition, the Regulation on the Registration for Health Foods (Experimental) was promulgated by CFDA in 2005. The notification process, which is intended to ease the regulatory burden that typically is experienced under the pre-market registration process, was recently introduced into the new FSL. According to the draft Regulation, notification is required (as opposed to pre-market registration) for nutritional substances such as supplemental vitamins and minerals imported into China for the first time, and for domestically made health foods where all functional ingredients are listed in the ingredient catalog. In other words, imported health foods, unlike domestically produced health foods, are not, unfortunately, eligible for the new notification process, unless the foreign health foods are supplemental vitamins and minerals. Further, an imported health food must be marketed in the producing country for at least one year.
ast one year before it can be registered or notified in China. (3) Regulation on Health Food Labeling Compared with the existing health food labeling regulations, the draft Regulation specifies more detailed and stringent labeling requirements, such as compliance with GM labeling rules and food recall procedures. Specifically, under Article 35, when a health food manufacturer recalls its products due to non-compliant labels, it can continue selling the products as long as it takes remedial action and is able to guarantee product safety. However, the manufacturer must clearly indicate to customers the remedial measures that are being taken. Notably, the draft Regulation adds a mandatory disclaimer requirement for health food products for which registration is not required, i.e., “This product has not been evaluated by the CFDA authorities.” Currently, registered health foods are permitted to use the “blue hat” logo on their labels. It is subject to further confirmation as to whether health food products that are only subject to notification also are eligible to bear the blue hat logo. We will provide further updates as the regulations develop. The existing health food regulations, such as the Regulation on Health Foods (1996), the Regulation on Health Food Registration (Trial) (2005), and the Rules on Health Food Labels (1996) will likely be superseded after the above-discussed regulations are adopted.

1 http://www.sda.gov.cn/WS01/CL0780/125502.html

2 http://www.sda.gov.cn/WS01/CL0780/125503.html