USA New Guidance for NDIs

The US Food and Drug Administration (FDA) has recently published its long-awaited draft guidance on New Dietary Ingredient (NDI) notifications, and is currently inviting comment on its content.

A 'new dietary ingredient, under the federal Food Drug and Cosmetic Act (FDCA) is defined as a dietary ingredient not marketed in the US prior to October 15th 1994. A 'dietary ingredient' is defined as a vitamin, mineral, herb or other botanical, amino acid, dietary substance for use by man to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract or combination of any of the above.

The FDCA requires manufacturers/distributors of an NDI or supplement that contains an NDI to submit a pre-market notification to FDA at least 75 days before introducing the supplement into interstate commerce, unless the NDI and any other dietary ingredients in the supplement 'have been present in the food supply as an article used for food in a form in which the food has not been chemically altered'.

An NDI notification must include a history of use or other evidence of safety for the ingredient. FDA then determines whether it will file the notification, ask further questions or refuse to file it. However, until now, there has been little guidance on what 'present in the food supply' means, or the type and quality of safety data the agency requires to file the notification without further questions.

The draft guidance proposes a number of definitions and clarifications:

- 'Marketing' and 'evidence of marketing' are defined. (Importantly, the presence of an ingredient on an industry list of 'grandfathered' dietary ingredients is insufficient evidence that the ingredient is not an NDI.)
- Changes in manufacturing processes that would attract an NDI are defined
- 'Use in food' includes the world food supply. However, the guidance also defines what chemical alteration of an article previously used in food would trigger an NDI notification
- NDI submissions are supplement specific, not ingredient specific. Thus each notification must contain information about the supplement in which the NFI is to be used, including dosage, uses and other ingredients – unless these are substantially equivalent (also defined) to a previous application. Also, because the Agency will be evaluating the supplement as a whole, safety data on all other ingredients, colourings, flavourings, etc. in the supplement must be submitted.
- Botanicals, amino acids, probiotics, esters are defined, as are special conditions relating to them – and whether or not they can be regarded as dietary ingredients.
- The requirement for a comprehensive safety profile and safety narrative.

- A description of the types of evidence the agency will require (i.e., 25 years widespread use is the minimum requirement to establish a history of safe use, without need for further safety data).

Initial response to the new document from industry has been to welcome it for the additional clarity if offers on existing regulation, whilst noting that it does not constitute new regulation. However, all associations are drawing the attention of their members to the comprehensive and complex nature of the guidance, and urging them to undertake close scrutiny its requirements in relation to their current and proposed products. Associations have also scheduled a number of seminars to examine the document in detail, and there have also been requests for an extension of the time period for comment.

Source: AHPA, CRN US, UNPA