

FDA Accepts Use of Existing Labels

The FDA has agreed to accept requests by processors to use existing labels after the trans fat labeling effective date.

By Leslie Krasny, Contributing Editor

The deadline for implementation of allergen labeling and trans fat labeling is January 1, 2006, although the triggers are different. The Food Allergen Labeling and Consumer Education Act of 2004 (FALCPA) requirements apply to any food product that is “labeled on or after January 1, 2006,” and the trans fat labeling requirements are based on “the initial introduction into interstate commerce.”

The inconsistent triggers were considered burdensome, given that many companies will be affected by both requirements, and there is also great uncertainty concerning the interpretation of “initial introduction into interstate commerce.”

Interstate commerce is defined under section 201(b) of the federal Food, Drug and Cosmetic Act as “commerce between any state or territory and place outside thereof, and commerce within the District of Columbia or within any other Territory not organized with a legislative body.” A narrow interpretation of “initial introduction into interstate commerce” would require movement of finished product across state boundaries, but under a broader view, the requirement could be satisfied by the movement of product to a different intrastate location — such as to a third-party facility — if the activity could be said to affect interstate commerce.

The scope of Congressional power under the Commerce Clause is controversial. A June 2005 U.S. Supreme Court decision

on medical marijuana endorsed a broad interpretation: *Gonzales v. Raich* held that Congress has the power under the Commerce Clause to criminalize the noncommercial use of medical marijuana pursuant to the federal Controlled Substances Act, based on the regulation of purely local activities that are part of an economic class of activities having a substantial effect on interstate commerce.

But without an official position from the FDA regarding a definition of “initial introduction into interstate commerce” in the context of compliance with the trans fat effective date, some companies are reluctant

Enforcement Factors

The FDA intends to consider the following factors when deciding whether to exercise enforcement discretion: (1) whether the products contain 0.5 g or less trans fat per serving; (2) the reason why the request is being made; (3) the number of existing labels the company is requesting to use; (4) the dollar amount associated with the number of existing labels to be used; and (5) the estimate of the amount of time needed (not exceeding 12 months), to exhaust the number of existing labels the company is requesting to use. It appears that the “0.5 g or less trans fat per serving” criterion is based on the quantity of trans fat as rounded for purposes of nutrition labeling.

to rely on a broad interpretation. In January, a letter signed by 14 food industry trade associations requested the FDA harmonize the two new labeling requirements so that the effective dates are triggered the same way that is based on the date of labeling (the allergen labeling effective date is statutory and cannot be changed by FDA). However, FDA has not harmonized the requirements.

The FDA plans to issue a guidance document on procedures for requesting an extension of the trans fat labeling deadline. The requests will be considered at any time before or after January 1, 2006, but it will cease to grant trans fat labeling extensions after two years.

In recent months, some manufacturers had advised the FDA of difficulties in revising labels in time to meet the compliance date for trans fat labeling, and requested permission to continue using old labels after January 1, 2006. Based on those communications, the FDA decided to implement procedures for handling such requests.

On September 1, the FDA published a notice in the Federal Register announcing it would consider, on a case-by-case basis upon an appropriate showing, whether to exercise enforcement discretion with respect to the January 1, 2006, effective date for trans fat labeling for companies meeting specified criteria. Companies granted extensions would have the option of using some or all of their existing label stock that does not comply with the trans fat requirements. FDA plans to issue a guidance document on procedures for companies to use in requesting an extension of the trans fat labeling deadline.

The requests will be considered at any time before or after January 1, 2006, but the FDA will cease to grant trans fat labeling extensions after two years (January 1, 2008) because by that time it is unlikely that any older labeling will remain. The FDA

stated in the Federal Register notice that, although companies of all sizes are eligible to request extensions, small companies and very small companies are most likely to be able to

demonstrate a need for an extension of the trans fat labeling deadline.

The FDA plans to respond to extension requests in writing — hopefully before January 1, 2006. However, the FDA also stated that if it is not able to respond by that date, companies requesting extensions are expected to comply with the trans fat labeling requirements by the deadline. Based on the small number of extension requests received prior to the publication of the notice, the FDA estimated only 56 requests would be received in year one, and 28 requests in year two.

As a practical matter, if the FDA is deluged with requests, and the period for reviewing submissions is lengthy, many companies requesting extensions may be unable to wait for a response and still be assured of complying. ❁



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