PLMA
PRIVATE LABEL MANUFACTURERS ASSOCIATION

October 1, 2001

Dockets Management Branch (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane, Rm 1601
Rockville, MD 20852

(Re: Docket No. 00P-13221)
Food Safety and Food Labeling;
Presence and Labeling of
Allergens in Food

Dear FDA:

This letter contains our comments regarding the FDA's call for public and industry input on the Presence and Labeling of Allergens in Foods, and the possible need for additional regulations to protect the consuming public from potentially harmful contraindications resulting from the ingestion of such foods.

The Private Label Manufacturers Association (PLMA) is a major trade association representing both manufacturers and marketers of a full range of grocery, dairy, frozen/refrigerated, baked goods, beverages, snack foods, and other everyday foods and non-foods purchased by consumers at retail outlets.

Many of the food products are sold under the private label brands of major national, regional, and local supermarket chains and independent stores. These retailer owned brands currently account for approximately 20% of supermarket sales nationwide, and came to about $38 Billion last year in supermarkets alone (nearly $50 Billion overall).

Our members -- some of whom are large, nationally known companies and others of whom are medium sized and smaller manufacturers -- supply virtually thousands of different food products under hundreds of different retailer owned brands.

Because of this considerable market share nationwide for store brands and the wide range of foods with which our members are involved (including all eight of the food and food groups/derivatives that FDA finds are most often implicated in allergic responses), we are very concerned about the problems and issues at hand, and the expedient and sensible resolution of these food safety matters.

We therefore support the FDA's current efforts to obtain public and industry input and information. At the same time, we feel the responsibility to inform the FDA of certain significant issues that are unique to the private label industry, and hope these will be given due consideration as proposed rules and regulations are promulgated.

We attended the FDA's Public Meeting on August 13, and learned that a group called the Food Allergy Issues Alliance submitted a "Food Allergen Labeling Guidelines" document to the FDA.

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Subsequent to the August 13 meeting, we have reviewed the Alliance's "Guidelines," and, with minor reservations, we generally support these labeling and related proposals. Nonetheless, as the store brand people, we feel we must emphasize to the FDA our very serious concerns over implementation and compliance issues that are not addressed in the Alliance's guidelines, and that only our Association can enunciate – because they are unique to the 20% of the retail food sales market that store brands command.

Our concerns are parallel to those we expressed to FDA/CFSAN in the early 1990s, as the NLEA rules and compliance dates were being developed. Basically, they center on two major issues. One is the understanding and subsequent favorable consideration by the FDA of the fact that changing private label brand (retailer brand) labels – whether for one given type of food or for all categories of store brands sold – is more difficult, expensive, and takes far longer than it does for national brands.

For example, if Kellogg's Corn Flakes needs a new label to comply with new allergen label declaration rules, the Kellogg Co. has essentially one label to redesign – and, because it is the brand owner of that label, all reviews, "approvals," and so on are internal; that is, fully under Kellogg's control. The result is that Kellogg can meet any virtually reasonable compliance deadline with relative ease.

On the other hand, if the Kroger Co., America's largest supermarket chain, needs to comply with new labeling rules, it may have to change thousands of its Kroger brand labels on a multitude of different food products.

Similarly, the manufacturers of these different store brands for Kroger and many other retailers are often asked by their retail customers to help in bringing their labels into compliance; very often, they have to oversee changing hundreds of different private brand labels for the same exact product (corn flakes, in this example).

Remember, too, that when private brand manufacturers are asked to oversee these multiple changes, they must submit, revise, and resubmit the work over and over again to the stores for interim and final approval, because they are the latter's brands, <u>not</u> brands owned outright by the manufacturer (e.g. Kellogg).

PLMA, as well as individual supermarkets and food manufacturers, had no choice nearly a dozen years ago other than to petition Congress to intervene and grant a extension of 18 months to FDA's previously published compliance deadline for most foods under the new NLEA rules.

This need was ultimately recognized during the NLEA round of label revisions and an extension was granted. We want to introduce it early enough in this go-round to hopefully bypass the need to petition the Congress to get involved at the eleventh hour once again.

Our second major concern is that any new or amended allergen rules requiring label revisions provide for a reasonable "grandfathering" period wherein previously printed labels can continue to be used while the new labels are printed and introduced into retail commerce.

Here again, it is very important to understand that retailers generally do not change their store brand labels nearly as often as do the makers of the national brands. So it is not as simple as saying: "They can just make the allergen declarations the next time they change their labels to add words like 'New' or 'Improved'," which the national brands tend to do every few months, if not more often.

During the years that the NLEA and its amendments were being developed, PLMA met with Congressional subcommittees, FDA officials and others to make the above points.

During one such meeting with then-CFSAN Director Dr. Edward F. Scarborough, we brought along an executive of one of the largest label printers in the U.S., who explained that printers simply could not get the changeovers done in the initially mandated time frame, even if they worked three shifts, 24 hours a day, seven days a week – that there were just too many jobs to handle, all begging to be done at the same time.

PLMA is well aware that this current potential for label changes is not nearly as extensive as was the NLEA. Nonetheless, it would still require a fair compliance deadline for all who must do the job, particularly the private label community, for all of the reasons stated previously.

Past experience tells us that a minimum one-year lead time is necessary to get new private brand labels into interstate commerce; and at least that long to allow for the working-off of existing label inventories.

Thank you for this opportunity to express our views and concerns regarding this very important subject. If our Association can provide additional information, please contact me or Ken Clarfield, PLMA's Director of Industry Relations, at (212) 972-3131; fax (212) 983-1382.

Sincerely,

BRIAN SHAROFF
President

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