KELLEN COMPANY



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August 9, 2000

TO: Dr. Susan Thompson, FDA CFSAN Ver C2128

FROM: Rick Cristol, President

RE: Your Fax of 8/7/00

Dr. Thompson, your fax asks for clarification of NAMM's comments endorsing a criterion of not more than 2 g of saturated fat for a 'trans fat free" claim and our acceptance for a disclosure level of 1 gram or more for saturated fat when a "trans fat free" claim is made.

It is my understanding that there is nothing in the existing statutes or regulations that requires that disqualifying and disclosure levels must be the same for a particular nutrient content claim. In fact, inherently it would seem impossible. If a claim is disqualified there would be no claim presented for which to require any type of disclosure.

NAMM believes that a "trans fat free" claim should be permitted for a product with up to and including 2 grams of saturated fat, providing the product meets the definition of "trans fat free". However, NAMM recognizes that FDA has constituencies to serve who will take a more conservative approach. Therefore, in an effort to achieve acceptance of the 2 gram saturated fat criterion among these constituencies NAMM indicated it would not object to a referral statement, as now set forth in 21 CFR § 101.13(h)(1), associated with "trans fat free" claim. Alternatively, although less appealing than a referral statement, NAMM indicated it would not object to a disclosure of a level of saturated fat of 1 gram or more in immediate proximity to the "trans fat free" claim.

I hope this clarifies our position. If not, I would be pleased to hear from you so we can talk it through to your satisfaction.

Thank you for the opportunity to provide additional clarifying input on our comments.





FOOD AND DRUG ADMINISTRATION OFFICE OF NUTRITIONAL PRODUCTS, EB 22 AND :04 LABELING AND DIETARY SUPPLEMENT (ONPLDS) 200 C STREET SW (HFS-800) WASHINGTON, DC 20204

ONPLDS Fax: 202 205 55 32 ONPLDS Voice:____

DATE: 3 7 00 Total Pages (Including Cover)
TO: <u>Richard Cristal</u> re Docket * 948-0036 *C 2128
FAX NUMBER: 202 223 9741 VOICE NUMBER:
FROM: Susan Thompson
Hi
I'm reading the comments on trans
tally acids. I notice that on p. 10 of your
<u>comment</u> you recommend that "tions fat-free" should a criterion of not move than 2 g of saturated
should a critzrion of not move than 2 g of saturated
fat. On p. 14 you state that sat fat could
be disclosed by a transfat free claim when ig a
more of sat fat is present. Please changy - one
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these 2 separate recommendations + the 2-g limit your first choice? thanks Thompson . Supon Thompson
Suson thought