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July 30, 2002

Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20857

Re: Docket 02N-0209
Labeling Restrictions and Compliance with 1st Amendment Case Law

Dear Sir:

A notice appearing the Federal Register of May 16, 2002 requested comments to help assure that FDA regulations continue to comply with governing 1st Amendment case law.

I would like to bring to the Administration's attention a specific restriction relating to communicating the cholesterol content of foods appearing at 21 CFR 101.62(d).

That regulation prohibits cholesterol free, low cholesterol, or reduced cholesterol claims on foods that have more than 2g of saturated fat per serving. That restriction is based on a belief that such statements would be misleading because the advantage of having no, low or reduced cholesterol might be counterbalanced to some extent by the effect saturated fat intake is assumed to have on the natural formation of cholesterol in the body.

Certainly it would be reasonable to require a statement adjacent to any such cholesterol claim directing the purchaser to see the nutrition information for the saturated fat content (and perhaps soon, also the trans fat content). Such a statement would make sure consumers considered that factor when making a decision to purchase and consume such product. However, to absolutely prohibit calling attention to true and factual information about the cholesterol content of the food is an unnecessary and unreasonable restraint of truthful speech which denies the consumer relevant information.

The adverse impact of this restriction on both consumers and manufacturers becomes especially apparent when considering new technology capable of removing the cholesterol from milkfat.

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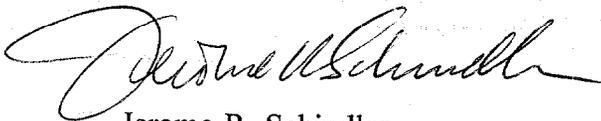
A serving of cholesterol free ice cream with 5g of saturated fat is a better dietary choice for many people than a serving of ice cream with 30mg cholesterol and 5g of saturated fat. However, since pointing out the cholesterol advantage of such a product on its label is prohibited, there is no incentive for a manufacturer to incur the added expense of using that cholesterol free milkfat.

Even if the fat were reduced by as much as 50%, no cholesterol statement could be made as the remaining saturated fat would still exceed 2g per serving.

Should the Administration determine that the basic statute and/or good public policy requires continuation of such a restriction, at a minimum the FDA should increase the saturated fat content threshold so that at least reduced fat dairy products utilizing a cholesterol stripped source of milkfat would be able to advise consumers of that cholesterol content advantage.

Consumers are far wiser about nutritional matters than they were ten years ago when NLEA was first implemented. They need and deserve the information necessary to make choices. Regulations that for all practical purposes deny a market to a nutritionally superior cholesterol stripped milkfat are inconsistent with a goal of improving the overall quality of the American diet.

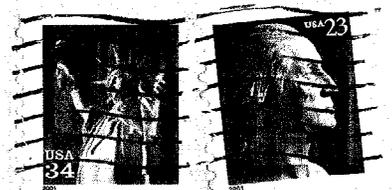
Sincerely,

A handwritten signature in cursive script, appearing to read "Jerome R. Schindler".

Jerome R. Schindler

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