Gerber

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March 19, 2001

Dockets Management Branch, (HFA-305)
Food and Drug Administration, Room 1061
5630 Fishers Lane
Rockville, MD 20852

Response of Gerber Products Company to:

[Docket Number: 00D-1598], Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering,
66 Federal Register 4839, January 18, 2001

Dear Sir or Madam:

Gerber Products Company (Gerber) is a leading manufacturer of infant and baby foods with over $1 billion in annual sales and over 70% share of the baby food market in the United States. Honoring its commitment to help parents raise happy, healthy babies, Gerber maintains extremely high quality standards. This includes the stringent requirement for factual and non-misleading information Gerber provides to parents about good nutrition for their children. As a result Gerber has the highest level of trust of any brand in the US[1]. Gerber is committed to providing useful, helpful and accurate information to consumers on issues such as agricultural biotechnology. It is with this commitment along with our expertise in consumer communication that we provide comments to FDA on the industry guidance document about labeling of foods developed using bioengineering.

Gerber appreciates the opportunity to participate in this rulemaking and commends the FDA for their efforts in this area.

Labeling for the Absence of Biotechnology Derived Ingredients
FDA outlines, in some detail, guidance for the use of terminology about the absence of biotechnology derived ingredients in a food product. FDA asserts that terms such as "Genetically Modified", "GMO" and "GMO-Free" among others would be misleading to consumers because they imply conditions about the food that are fundamentally not correct. The guidance is also based on information about the lack of consumer understanding of this terminology and therefore, the great potential for such terms to be misleading.

Gerber agrees with FDA and commends FDA for providing clear guidance on this topic that will result in better information for consumers.

Labeling for the Absence of the Use of Ingredients from Bioengineered sources
FDA indicates that descriptions of the process for obtaining foods from non-bioengineered sources would be appropriate as long as they did not suggest "zero" presence. In the context of describing why the use of the term "free" is misleading FDA indicates that it "...does not have

[1] Advertising Age, 10/5/98, "WPP brand study ranks Gerber 1st in U.S. market"

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information with which to establish a threshold level of bioengineered constituents of ingredients in foods for the statement 'free of bioengineered material'". In the context of describing the substantiation of claims with regard to bio-engineered food content, FDA regards the practices and record keeping that substantiate the "certified organic" statement would be sufficient to substantiate a claim that a food was not produced using bioengineering.

Gerber is the largest producer of organic baby food in the US. As a result Gerber has had to obtain crops that not only meet the certification requirements for organic but also meet the expectations of consumers about the content of the organic ingredients. Gerber has found that certified organic crops may contain substantial quantities of the indicators of bioengineered crops as a result of "adventitious" contamination. The amount present may be significant to consumers. Table I outlines the content of recombinant DNA (rDNA) as an indicator of the presence of bioengineered corn in 17 lots of Certified Organic corn reported in 1999 and 2000.

Table 1 - rDNA content of Certified Organic corn

Number of lots per test result	Test result - % rDNA measured by PCR
4	None detected
3	< 0.1%
5	0.1% to 1.0%
5	> 1.0%

In many cases the practice of use of documentation such as organic certification to substantiate a label statement about the non-use of bioengineered foods would be misleading to consumers since they would likely believe that such a process precludes the presence of bioengineered ingredients in the product. The data presented here indicate that contamination of organic ingredients is not only possible, but reasonably likely. In addition to being misleading to the consumer, the potential exists for third parties to test food products thus labeled, find bioengineered material and call into question the efficacy of the FDA label guidelines.

Gerber believes FDA should establish a content standard to be required in addition to process documentation to substantiate a claim that bioengineered crops were not used to make a given food product. Since FDA has indicated that establishing a content standard is not possible at this time, Gerber requests FDA not allow this claim at this time.

FDA enforcement of the label guidelines for bioengineered foods

FDA describes in detail the basis of its authority to regulate the information content of food labels particularly with regard to label claims that are misleading.

Gerber believes FDA will and should ensure consumers continue to have clear accurate information about their food products by ensuring that misleading claims with respect to bioengineering are not allowed. Gerber urges FDA to use its authority to the fullest extent when any claims that FDA has outlined as being misleading with respect to bioengineering are made.

Sincerely,

Kathleen C. Reidy, Dr. P.H., R.D.
Director - Regulatory Affairs

Nicholas W. Hether, Ph.D.
Director - Product Safety

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