

June 26, 2003

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

4218
03
-1
P1

Re: Docket No. 95N-0309: Current Good Manufacturing Practice, Quality Control Procedures, Quality Factors, Notification Requirements, and Records and Reports for the Production of Infant Formula

Dear Sir or Madam:

On behalf of its 700,000 members in the United States, the Center for Science in the Public Interest (CSPI)¹ urges the Food and Drug Administration (FDA) to expand the scope of its proposed infant formula rule to take into account the FDA's recent discovery of acrylamide in some infant formulas. The FDA should immediately test every brand of infant formula to determine whether it contains detectable levels of acrylamide and should then convene a workshop to make recommendations to the FDA on how to reduce, if not eliminate, acrylamide in all infant formulas.

I. Background

As detailed in the attached petition that CSPI submitted on June 4, 2003, acrylamide has recently been detected in varying levels in many common foods. In December 2002, the FDA announced the results of its exploratory survey of 18 classes of food. Of special relevance to this proceeding is the FDA's detection of acrylamide in two out of 12 brands of infant formula tested: Enfamil Milk-Based Infant Formula with Iron (powdered) and Similac Infant Formula with Iron (powdered).

As explained in the attached petition in sections III.A. and III.F., acrylamide has been recognized as dangerous by both the Environmental Protection Agency (EPA) and the FDA. In 1991, the EPA concluded that human consumption of acrylamide can cause damage to the nervous system, paralysis, and cancer. The EPA therefore requires that a water supplier ensure that the amount of uncoagulated acrylamide monomer in water is less than 0.5 parts per billion (ppb). In June 2002, the FDA termed acrylamide "a recognized neurotoxin" and established the safe daily intake of acrylamide as 12 micrograms per person.

II. The FDA Should Set Especially Protective Acrylamide Limits and Quality Factors for Infant Formula.

Although the amount of acrylamide that the FDA found in two infant formulas was less than 10 ppb, the government and academic experts supporting CSPI's June 4 petition have said that even small amounts of acrylamide may be harmful to infants (see attached June 4, 2003

95N-0309 **C19**
¹ CSPI, a nonprofit organization based in Washington, D.C., is supported by its members and subscribers to its *Nutrition Action Healthletter*. CSPI has been working to improve the nation's health through better nutrition and safer food since 1971.

letter to Commissioner McClellan). That is because:

- Babies rely on infant formula for a substantial portion of their overall diets during their crucial first year. Most babies do not begin to eat solids until four or six months, and so their diets consist exclusively of breastmilk or infant formula in their first critical months.
- Babies tend to consume more food in proportion to their body weights than adults.
- Babies may be more sensitive to the carcinogenic action of acrylamide. Recently proposed EPA guidance suggests that exposures to mutagenic carcinogens in the first two years of life should be assumed to pose ten times the risk per unit dose as those for adults.²
- Babies may be more sensitive to the neurotoxic impact of acrylamide because of their immature nervous systems.

Because of both the possible dangers to babies from ingesting even small amounts of acrylamide in their infant formula and the FDA's statutory responsibility to be especially protective of infants, CSPI requests that the FDA immediately take the following actions:

A. The FDA Should Test all Infant Formula Currently Available on the Market.

In order to properly assess how widespread the problem of acrylamide in infant formula is, the FDA should immediately test every brand of infant formula on the market to determine whether it contains detectable levels of acrylamide.³ Results of these tests will clarify whether acrylamide is present only in certain types of formulas (*e.g.*, powdered formula with iron) or whether acrylamide is present in other types and brands of formula as well. The FDA should immediately post the results of its tests on its website.

B. The FDA Should Convene a Workshop to Determine Acceptable Levels of Acrylamide in Infant Formula.

The FDA should immediately convene a workshop of doctors, scientists, infant formula manufacturers, and consumer groups to analyze the results of its tests. Doctors and scientists should offer recommendations on the amount of acrylamide, if any, that can be safely allowed in infant formula.⁴ Manufacturers should explain how they could achieve that goal and estimate how difficult the required changes could be and the cost to infant formula producers. Based on

² Supplemental Guidance for Assessing Cancer Susceptibility from Early-Life Exposure to Carcinogens, External Review Draft EPA/630/R-03/003 (February 2003). See also section 408(b)(2)(C) of the Federal Food, Drug, and Cosmetic Act, which directs the FDA to apply an additional tenfold margin of safety for infants and children when assessing the safety of pesticide chemical residues.

³ The FDA could also test all baby foods and put the results of its tests on its website, as it found acrylamide in 16 of the 23 baby foods it tested last year.

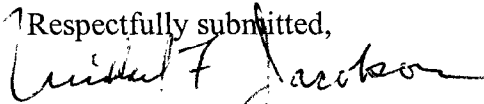
⁴ The FDA could also invite baby food manufacturers to this workshop and broaden its scope to include recommendations on the amount of acrylamide, if any, that can safely be allowed in baby foods.

that information, the FDA should then propose quality factors to ensure that unsafe acrylamide levels do not result from the production of infant formula.

III. Conclusion

Out of concern for those most vulnerable, Congress provided in section 412 of the Federal Food, Drug, and Cosmetic Act for more strict regulation of infant formula than any other food (see section V.D.1. of our June 4 petition).⁵ The FDA should therefore treat its discovery of acrylamide in infant formula with great concern, immediately assess the danger, and establish stringent quality factors to ensure the safety of all infant formulas.

Respectfully submitted,



Michael F. Jacobson, Ph.D.
Executive Director



Aliza Sperling
Staff Attorney

attachments

⁵ As explained by a Court of Appeals in 1985, the specific impetus for congressional action in 1980 was the revelation that two infant formulas lacked an essential nutrient, chloride. *Formula v. Heckler*, 779 F.2d 743, 745 (D.C. Cir. 1985). The current statutory provision, as amended in 1986, clearly provides for the FDA to consider both the absence of nutrients and the presence of contaminants by directing the FDA to “establish requirements for quality factors for infant formulas to the extent possible consistent with current scientific knowledge...” Thus, the FDA has now asked for comment on whether it should set a microbiological requirement for *Enterobacter sakazakii* following an April 2001 outbreak involving 10 infants in a Tennessee hospital. 68 Fed. Reg. 22341 (April 28, 2003).