United States Breastfeeding
COMMITTEE
PROTECTING • PROMOTING • SUPPORTING

July 21, 2009

Joshua M. Sharfstein, MD
Principal Deputy Commissioner
Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Sharfstein:

Thank you for giving pediatricians the opportunity to advise you on how the Food and Drug Administration might advance the health needs of children. The United States Breastfeeding Committee is especially concerned about the criteria for determining the safety and efficacy of infant formula. In particular, new ingredients are added to infant formula without adequate prior testing. The FDA should insist these ingredients undergo rigorous scrutiny before the products containing them are marketed or sold.

The FDA should review the procedures whereby it evaluates and approves new formula ingredients. Meticulous post-marketing surveillance for adverse reactions to these products is also needed, and such reactions should be made a matter of public record.

The United States Breastfeeding Committee also requests that the FDA critically evaluate the materials submitted by the formula companies in support of their new products. It must carefully monitor the claims of formula manufacturers with respect to the putative benefits of new infant formula products. Any claims found not to be supported by sound research should be repudiated.

Finally, consumers should be advised that powdered formula is not a sterile product. Those purchasing such formula must be made aware of the dangers of contamination and instructed in the appropriate manner of preparation, as recommended by the World Health Organization.

Sincerely,

Joan Younger Meek

Joan Younger Meek, MD, MS, RD, FAAP, FABM, IBCLC
Chair
United States Breastfeeding Committee

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