

October 15, 2018

Douglas Balentine, Ph.D.  
Director, Office of Nutrition and Food Labeling  
U.S. Food and Drug Administration  
Silver Spring, MD 20993

Dear Dr. Balentine,

As organizations committed to improving nutrition and health for mothers and children in the U.S. and around the world, we write to urge that the U.S. Government prioritize the well-being of infants and toddlers in its deliberations on the Review of the Codex Standard for Follow-Up Formula. The upcoming Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) in Berlin, Germany from November 26-30, 2018, as well as the regional meetings that the U.S. Department of Agriculture is holding in advance of CCNFSDU, are important opportunities for the U.S. Government to reiterate its stated commitment to breastfeeding—a practice that has the potential to save the lives of over 800,000 young children every year.

The World Health Organization (WHO) and the United Nations Children's Fund (UNICEF) recommend that breastfeeding be initiated within one hour of birth, that it continue with no other foods or liquids for the first six months of life and that it be continued together with complementary feeding—i.e. breastfeeding with other age-appropriate foods—until *at least 24 months of age*. WHO and UNICEF recommend children be breastfed for at least 24 months because doing so protects against child mortality, child obesity and life-threatening illnesses in women. The benefits of breastfeeding to 24 months are summarized in the attached brief from Helen Keller International.

The U.S. Government should note that WHO considers all follow-up formulas, i.e. breast-milk substitutes that are marketed for use in children from 6 months to 36 months, unnecessary. Furthermore, WHO has indicated that the consumption of follow-up formulas replaces—and does not complement—the intake of breast milk, thereby having the effect of undermining optimal breastfeeding practices as set forth in the global guidelines offered by WHO and UNICEF. Since the decisions reached by CCNFSDU are often either directly adopted by countries or used by governments to develop their own legislation and regulation, the U.S. Government should facilitate strong policy coherence between Codex and the World Health Assembly—the highest global health policy-setting body—and support Member State consensus around the need to protect the health of infants, young children and their mothers by protecting breastfeeding.

Moreover, the U.S. Government should consider that follow-up formulas for older infants and for children 12-36 months are branded, labeled, marketed, and positioned in a confusingly similar manner to infant formula—a product that is specifically designed to serve the unique nutritional needs of infants 0-6 months. There is emerging research that shows that the ways in which these products are labeled and identified leads to the misuse of these products, endangering the health of infants and young children.

It is therefore critical that as the Codex Follow-up Formula Standard is updated, changes are made to better provide consumers with clear and accurate information about these products, free

from misleading claims and packaging. The U.S. Government should ensure that CCNFSDU, as part of its mandate to protect consumer health, takes care not to add to the existing and pervasive confusion on the part of parents and caregivers who are purchasing and, in some cases, misusing follow-up formula products.

Considering the above, we request that the U.S. Government support and advance the following positions in the lead up to and at the CCNFSDU:

**1. Establish one single Follow-up Formula Standard for all products that aligns with policy recommendations from the World Health Organization.**

The CCNFSDU has agreed to have one Standard for Follow-up Formulas with two categories of products: one for older infants 6 to 12 months and one for young children 12 to 36 months of age. There is no justification to reopen the discussion on this issue as both categories of products are follow-up formulas that, while different in composition, are not different in how they *function* with respect to replacing—rather than complementing—breastmilk. Separating the standard under discussion into two standards creates an unnecessary and arbitrary age break at 12 months that has no basis in evidence as to what a child needs for optimal health and development. The proposal to do so appears to be driven by commercial interests rather than what is in the best interest of infants and young children. It is evident that having two different standards (rather than one standard with two categories of product) would benefit manufacturers of these follow-up formulas as they could claim, despite the lack of evidence, that follow-up formulas for children 12 month to 36 months are not breast-milk substitutes and therefore not subject to national laws and regulations based on the International Code of Marketing of Breast-Milk Substitutes and subsequent resolutions (hereafter referred to as “the Code”).

**2. Align the Follow-up Formula Standard with the Code, including World Health Assembly Resolution 69.9, and relevant accompanying WHO guidance.**

It is essential that the standards and text put forward by the CCNSFDU support, and do not contradict or undermine, the policy frameworks agreed to by Member States at the World Health Assembly (WHA) in the form of resolutions as well as recommendations from WHO. For this reason, the U.S. Government should seek to ensure that the Follow-up Formula Standard aligns with WHA 69.9 and accompanying guidance. Specifically, the preamble for the Standard and/or the scope of each category of product should make specific reference to WHA 69.9 and/or the labelling text of the Standard must include the labelling recommendations in the WHO Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children.

Referring to the Code and WHA 69.9 will ensure that the Codex Standard for Follow-Up Formula acknowledges the unique needs of older infants and young children and the fact that breastfeeding is a critical *health behavior* that must be protected. Because protecting the health of consumers—in this case, older infants and young children for whom breastfeeding provides a unique and important source of nutrition—is part of the mandate of Codex, references to the Code, including WHA 69.9, should in fact be considered within the scope of the Standard. Moreover, the U.S. Government should recall that WHA Resolution 34.22 in 1981 requests that the FAO/WHO Codex Alimentarius commission “give full consideration,

within the framework of its operational mandate, to action that it might take to improve the quality standards of infant foods, and to support and promote the implementation of the...Code”.

**3. State unequivocally that follow-up formulas are breast-milk substitutes, irrespective of whether the products are for 6-12 month old infants or 12-36 month old children, and that they are not complementary food.**

At issue is the *function* of follow-up formula. Follow-up formulas function as breast-milk substitutes because their consumption replaces, rather than complements, the intake of breastmilk. Because they both replace a young child’s consumption of breastmilk and are consumed as the liquid part of a young child’s diet, follow-up formula should in no way be considered a complementary food.

Accordingly, the definitions text of the Standard must directly refer to these products as breast-milk substitutes. In addition, the text in the labelling section of the Standard should be written so as to ensure that all elements of the Code and WHO Guidance are incorporated.

Strengthening the protection of breastfeeding, improving the health and nutrition of infants and young children, and ensuring consumers have the information they need to make informed choices about what they feed their children should guide the U.S. Government’s position on the Follow-up Formula Standard as well as its engagement with other Member States before and during CCNFSDU.

We stand ready to work with you to re-affirm the U.S. Government’s stated commitment to breastfeeding and advance its efforts to address malnutrition and end preventable child deaths. We would appreciate a response to our letter and we would be pleased to meet with to discuss our request in further detail. If you have any questions, kindly direct your inquiries to Lucy M. Sullivan, Executive Director of 1,000 Days.

Sincerely,

**1,000 Days  
Action Against Hunger  
Alive & Thrive  
CARE USA  
Catholic Relief Services  
Church World Service  
Food for the Hungry  
Helen Keller International  
The Hunger Project  
John Snow, Inc.  
The Manoff Group, Inc.  
March of Dimes  
Public Citizen  
United States Breastfeeding Committee  
Women of the Evangelical Lutheran Church in America**