August 1, 2014

The Honorable Margaret Hamburg, MD
Commissioner
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2012-N-1210 and RIN 0910-AF22

Dear Commissioner Hamburg,

The undersigned organizations who are committed to the health and wellbeing of women, infants, children, and families appreciate the opportunity to comment on the proposed rule, "Food Labeling: Revision of the Nutrition and Supplement Facts Labels," as published in the *Federal Register* on March 3, 2014 (Docket No. FDA-2012-N-1210). We commend the Food and Drug Administration's (FDA) effort to update nutrition information on food labels to better assist consumers in maintaining healthy dietary practices, but would like to convey our profound concern with the changes as they relate to folate and folic acid.

As proposed, the new labels will lead to public confusion and limit the ability to monitor intake and safety, and could negatively impact birth outcomes. We urge FDA to ensure that consumers can continue to determine the amount of folic acid contained in conventional food and supplements based on the U.S. Public Health Service (USPHS) recommendation of 400 mcg daily to prevent neural tube defects (NTDs). We believe declaring the amount of folic acid in micrograms along with the percent of daily value (based on the USPHS recommendation) must be included on both the Nutrition and Supplement Facts labels.

The discovery that folic acid could prevent neural tube defects led to a recommendation in 1992 by the U.S. Public Health Service (USPHS) that all women capable of becoming pregnant should consume 400 micrograms (mcg) of synthetic folic acid per day.[1] In 1998, the Institute of Medicine (IOM) established 400 micrograms Dietary Folate Equivalents (mcg DFE) as the Recommended Dietary Allowance (RDA) for folate.[2] While these numbers appear to be identical, they are in fact functionally different, using two separate units of measurement. Dietary Folate Equivalents, as defined by the IOM, adjust for the nearly 50 percent lower bioavailability of food folate compared with that of synthetic folic acid.

The proposed rule would amend section 101.9(c)(8)(iv) such that mcg DFE would be used to declare the amount of total folate, and labels would only provide information on folate that is applicable to the IOM's Recommended Daily Allowance. Because of the difference between measuring folate/folic acid in DFEs versus micrograms, this means the RDA is lower than the USPHS recommendation for intake among women of childbearing age. As a result, a food product or dietary supplement that stated it contained 100% Daily Value of Folate (400 mcg DFE) would not contain 100% of the USPHS-recommended level of folic acid for the prevention of neural tube defects (400 mcg folic acid). As the proposed rule states, "a dietary supplement that now declares 400 mcg of folic acid would declare the

[1] Recommendations for the use of folic acid to reduce the number of cases of spina bifida and other neural tube defects. MMWR Recomm Rep 1992; 41:1-7.
[2] Institute of Medicine. Dietary Reference Intakes for Thiamin, Riboflavin, Niacin, Vitamin B6, Folate, Vitamin B12, Pantothenic Acid, Biotin, and Choline. Food and Nutrition Board. Washington DC: National Academy Press, 1998.

same amount as 680 mcg DFE or 170 percent of the RDI." For over two decades, folic acid educational campaigns and materials have taught consumers to check the label to be sure it contains 100% of the daily value (DV) of folic acid. Under the proposed rule, there would be virtually no way for a woman to realize that, even though a label stated that she was receiving 100% of the RDA for folic acid, that amount did not in fact meet recommended standards for preventing NTDs. This failure to inform women accurately on the optimal intake of folate as it relates to NTDs could severely impact NTD prevention.

We would note that the adoption of the mcg DFE measurement would not allow the Centers for Disease Control and Prevention to continue its efforts to monitor the number of women meeting the daily recommended intake of folic acid for the prevention of NTDs. It would also no longer be possible to measure how many people are exceeding the Tolerable Upper Intake Level (UL) for folic acid. This information is obtained through the National Health and Nutrition Examination Survey (NHANES), which uses food labels to collect information on the type and amount of micronutrients (including. folic acid) contained in food products.

In conclusion, we strongly recommend that folic acid intake levels necessary to prevent NTDs should continue to be reflected on both Nutrition and Supplement Facts labels. In addition, any changes to labeling should be accompanied by robust education efforts to assist with consumer understanding of the changes. If we may provide further information or answer questions, please contact March of Dimes Director of Federal Affairs Emil Wigode at ewigode@marchofdimes.org or 202-659-1800.

Sincerely,
American Association on Health and Disability
American Academy of Pediatrics
American Congress of Obstetricians and Gynecologists
American Thrombosis and Hemostasis Network
Association of Maternal & Child Health Programs
Association of State and Territorial Health Officials
Association of Women's Health, Obstetric and Neonatal Nurses
Birth Defects Research & Education Foundation Inc.
Centering Healthcare Institute
Family Voices Indiana
First Focus
March of Dimes
Missouri Association of Local Public Health Agencies
National Association of County and City Health Officials
National Association of Pediatric Nurse Practitioners
National Birth Defects Prevention Network, Inc
National Council of La Raza
National Healthy Mothers, Healthy Babies Coalition
National Preconception Health and Health Care Initiative
New England Regional Spinal Cord Injury Center, Boston Univ. School of Public Health
Spina Bifida Association
Teratology Society
The Arc
Washington State Department of Health