Renee R. Jenkins, MD FAAP President American Academy of Pediatrics Department of Federal Affairs Homer Building, Suite 400 N 601 13<sup>th</sup> Street, NW Washington, DC 20005

Dear Dr. Jenkins,

Thank you very much for your comments related to Federal Register Notice released on June 18, 2008 (73 FR 34702) announcing the data collection for the Evaluation of the Birth Month Breastfeeding Changes to the WIC Food Package. We greatly appreciate your support for the study.

We have reviewed your letter carefully and took its points under careful consideration. Below we provide you with feedback to your specific recommendations.

1) "The evaluation...should focus on tracking postpartum women who choose partial breastfeeding and determine whether the women continue partial breastfeeding, or if they switch to fully formula feeding or fully breastfeeding after the first month postpartum. The tracking must occur on a monthly basis for the child's first year of life."

We will be tracking food package choices of WIC participants for the first six months postpartum, both prior to and after the Interim Rule is implemented. We chose this time period because, at six months, research indicates that currently 78% of WIC participants had discontinued breastfeeding. Given the need to make findings available as soon as possible, we believe that tracking food package changes for six months postpartum will be sufficient; over that time period the study is likely to capture use of the partial and full breastfeeding packages for the vast majority of WIC participants.

We will be interviewing WIC participants about their breastfeeding behaviors during their first 60 days postpartum, as opposed to spreading the sample over six months (or one year). We decided to limit the sample to the first 60 days postpartum because the study has limited resources. Data from WIC Participant Characteristics (2006) indicate that, among infants who were ever breastfed, 22% were weaned in a week or less; 50% were weaned in 6 weeks or less; and 65% were weaned in 13 weeks or less. We believe that therefore we are likely to detect the greatest impacts of the first-month food package changes on both the intensity and duration of breastfeeding within the first 60 days postpartum and have maximized our ability to detect these effects by limiting the sample to this time period.

2) "Further, the study should document current baseline feeding practices and correlate them to patterns of weight gain, hyperbilirubinemia, hospitalization due to dehydration, and failure to thrive, and compare the data to the occurrences after the new policy is implemented."

The purpose of the study is to determine the effects of the changes in the WIC breastfeeding food packages on breastfeeding behaviors. Therefore, we will be interviewing WIC participants about their feeding practices prior to when the Interim Rule is implemented as well as after it is implemented. It is beyond the scope of the study, however, to determine the effects of these changes on infants' health status.

3) "Given the known ethnic and racial difference in breastfeeding initiation and continuation rates, the study must also measure any differential effects of food package changes to ensure children and mothers of all races and ethnicities have equal access to the best nutritional practices possible."

We have stratified our site selection to ensure that the sample includes LWAs that serve WIC participants who are predominantly (at least 60 percent) non-Hispanic black, predominantly non-Hispanic white, predominantly white, and all other. We will gather data about local agency efforts to support WIC participants' breastfeeding practices. It also may be possible to detect differences in outcomes among WIC participants with different racial and ethnic backgrounds; however, due to the sample size of 1600 participants, these differences will need to be large in order to be detected.

4) "In addition, the Interim Rule evaluation should address the impact of food package changes on women who may wish to fully breastfeed but unable to do so. The study should examine the reasons why mothers discontinue fully breastfeeding, including returning to work or school, or whether these women have adequate access to breast pumps and support services that may be necessary to comply with the food package changes."

These issues are addressed by the study.

5) "The evaluation should also obtain data on prenatal care and the prevalence of prenatal breastfeeding education to measure the influences of such initiatives."

We will collect information from WIC participants about the information that they received related to breastfeeding and the source(s) of that information including staff from WIC, doctors' offices, health clinics, hospitals, etc. However, it is beyond the scope of the study to measure the prevalence of breastfeeding education.

6) "Finally, a review of WIC clinic staff training should be conducted."

We will collect detailed information about training of WIC staff as it relates to the breastfeeding food package changes. As part of the contextual information gathered through state and local interviews, we will also collect general information about WIC clinic staff training related to breastfeeding. However, this study does not do a thorough review of staff training to support WIC participant breastfeeding, as it is beyond the scope of this study. FNS currently has another

related study in the field, the WIC Peer Counseling study. For that effort, FNS is conducting a full review of training to support breastfeeding to WIC peer counselors and related staff.

Thank you again for your support for the study. We agree with you that it is important to understand if the changes to the WIC birth month breastfeeding packages have the intended effects of improving breastfeeding rates among WIC participants.

If you have any further questions, please do not hesitate to contact me at (703-305-2121).

Sincerely,

Theodore F. Macaluso, Ph.D., Chief Special Nutrition Evaluation Branch Office of Research and Analysis Food and Nutrition Service, USDA 3101 Park Center Drive Alexandria, VA 22302