



December 8<sup>th</sup>, 2003

Ms Patricia Daniels, Director,  
Supplemental Food Programs Division,  
Food and Nutrition Service,  
USDA, 3101 Park Center Drive,  
Room 520,  
Alexandria, Virginia 22302.

Re: Comment, "Revisions to the WIC Food Packages", Federal Register of September 15, 2003 (Volume 68, Number 178), Proposed Rules, Page 53903-53910.

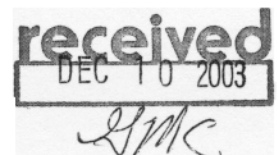
Summary of comments:

(1) WIC Food Package 1, iron-fortified infant formula, 7 CFR 246.10(c)(1)(i). The existing minimum requirement of 10 mg iron / liter should be revised to a minimum of 6 or 8 mg iron / liter in accord with the FDA/LSRO Expert Panel Assessment of Nutrient Requirements for Infant Formulas. There appears to be no scientific justification for the existing 10 mg/L WIC minimum iron content. The LSRO finds that there is "little or no advantage to an iron fortification at a level greater than 8 mg/L (1.2mg/100Kcal)", - a level that is beneath WIC's current 'minimum' 10 mg/L iron content requirement. The LSRO actually recommends a maximum iron content in formula of 1.65mg/100 Kcal (11 mg/L), - which includes about a 35% overage to allow for possible processing concerns

Reducing the WIC minimum iron content as suggested would be consistent with contemporary science, still allow for uniform iron-fortified WIC formulas and also allow for innovated cost-effective formulas to be available under WIC.

(2) Include in 7 CFR 246.10(c)(1)(i) a requirement that WIC infant formula should contain between 1.5 mcg and 5.0 mcg/100 Kcal of selenium to be consistent with the above noted LSRO Expert Panel recommendations. Our comment here is meant to address the addition of an essential nutrient not yet found in the CFR relative to minimum nutritional formula content requirements for infant formula, (typical US formulas already contain this amount of selenium in advance of regulations to do so). Referenced LSRO recommendation is attached.

(continued)





Dear Ms Daniels;

PBM Products and Bright Beginnings Nutritionals, a division of PBM, is a company dedicated to providing cost-effective high quality liquid and powder milk and soy infant formulas throughout the United States. Our infant formulas are produced by Wyeth Laboratories and are of course duly registered with and comply with FDA requirements. Manufacturing is routinely inspected by FDA, among other authoritative government agencies, for compliance with various requirements. Product samples are routinely obtained and analyzed by FDA to further assure compliance with requirements. Additionally, our manufacturing has been and is produced under an ISO (International Standards Organization) 9001 Certified Quality System for over a decade.

In this context, PBM is offering comments relative to 'Revisions to the WIC Food Packages' as referenced above. Our comments focus on iron and selenium in infant formula.

The main support for our comments will come from The Life Sciences Research Organization (LSRO), 'Assessment of Nutrient Requirements For Infant Formulas'. This independent expert assessment was done under contract by the Food and Drug Administration. It represents the most thorough science-based review specific to infant formula nutritional content done to date anywhere in the world. The American Academy of Pediatrics (AAP) as well as The National Academy of Sciences (NAS) assisted with the LSRO Expert Panel assessments.

Information explaining this expert panel and it's approach is appended as Attachment #1. Note that the Panel included comprehensive published toxicology, clinical, safe marketing history and similar data as the main part of their reviews. Unlike some previous formula content reviews that were based upon theoretical data or breast milk composition, this Panel's approach included those aspects as well as food technology issues, ingredient bioavailability, matrix, infant physiologic performance and related concerns.

(1) Our first comment concerns the present requirement for a minimum infant formula content of 10 mg/L iron under 7 CFR 246.10 (c)(1)(i). (here forth referred to as 7 CFR 246).



All infant formulas must comply with the nutritional requirements of the Infant Formula Act and 21 CFR 107.100. The Infant Formula Act requires that formula must contain between 0.15 mg / 100 Kcal and 3.0 mg / 100 Kcal of iron. This is a broad range that was set about 1980. The lower level of iron permitted by 21 CFR 107.100 requires labeling wherein a consumer would need to be advised that supplemental iron should be provided the infant. This current broad range for iron is being reviewed by FDA and others largely based upon the LSRO and other recent authoritative recommendations that all infant formula should be iron-fortified.

It appears that this later concern may be the genesis of the requirement in 7 CFR 246 for a minimum iron content in WIC eligible formula and with good reason as witnessed by recent AAP recommendations that all infant formulas should be iron fortified.

However, in addition to supplying formula compliant with FDA's minimum nutritional requirements, manufacturers have continued to scientifically innovate and improve their formulas so that formulas now contain nutrients in addition to those minimally required by law. These additional nutrients are generally recommended by contemporary expert authorities. Additions are based upon scientific evaluation to assure safety and typically are accompanied by formula matrix modifications to either better accommodate the change, reflect contemporary science or both.

Within the above, PBM Products/Bright Beginnings Nutritionals recently began distribution of highly cost-competitive milk and soy-based infant formulas that are supplemented with the very long chain polyunsaturated fatty acids (LCPUFA) Docosahexaenoic and Arachidonic acids (DHA and AA respectively).

Our DHA/AA-supplemented formulas, while fully compliant with FDA/IFA requirements, and consistent with expert contemporary nutrient recommendations for infant formula, are excluded from WIC consideration because their iron content is below the minimum prescribed for WIC eligibility. In current 7 CFR 246, WIC requires a 'minimum' iron content of 1.4 mg/100 Kcal (10 mg/L). Our DHA/AA supplemented formulas contain 1.2 mg / 100 Kcal (8 mg/L) of iron.

The level of iron in our DHA formulas however complies with both FDA requirements as well as the LSRO maximum recommendations for iron. We therefore see no scientific justification for the current WIC level for iron that excludes our formulas from WIC eligibility.

Attachment 2 is a copy of the deliberations of the LSRO Panel with respect to iron content in infant formula. Note the very wide range of published and other data that were



considered by the Expert Panel as well as the thorough scientific process followed in their deliberations. This may have been due in some measure to the large amount of data on the highly important role of iron in pediatric nutrition and development.

The LSRO expert panel concluded that *"there was little or no advantage to an iron fortification at a level greater than 8 mg / L (1.2 mg/100 Kcal)"*. The LSRO has set *maximum* iron content for infant formula at 1.65 mg / 100 Kcal (11 mg/L) which includes about a 35% processing overage to their actual recommendation for iron.

The level of iron prescribed by LSRO is precisely the level of iron in our DHA/AA-supplemented formulas (8 mg/L). In fact, our formulas were purposefully developed with this iron level in order to comply with the LSRO recommendation.

It is especially noteworthy that the LSRO recommended 'maximum' is actually below the 'minimum' level of iron required by 7 CFR 246. In considering the extensive deliberations of the LSRO Expert Panel, no scientific justification for the current WIC minimum requirement of 10 mg/L is apparent. However we do note that there could be a sound rationale supporting the retention of an iron minimum content in WIC formula, - but a minimum consistent with the LSRO science-based assessments of about 8 mg/L. This is because such a minimum would conform to authoritative recommendations for all formulas to be iron fortified but at levels more consistent with the LSRO's findings.

**PBM Products therefore requests that the current minimum iron requirement of 10 mg/L (1.4 mg/100Kcal) in 7 CFR 246.10(c)(1)(i) be changed to a minimum of 6 or 8 mg / L (1.0 mg/100 Kcal, 1.2 mg /100Kcal).**

**We believe such a reduction is scientifically warranted, could be availed by all manufacturers and, more importantly, would reflect the most modern pediatric nutritional research regarding the composition of infant formula.**

(2) PBM Products' second comment pertains to the selenium content in infant formulas.

We are not in the habit of requesting new regulations however we feel that the LSRO deliberations and assessment as regards selenium in the diet of infants warrants a selenium content in WIC formulas. We therefore request that selenium content between 1.3 mcg / 100 Kcal and 5.0 mcg / 100 Kcal be added to the requirements for WIC formulas under 7 CFR 246.



Attachment #3 is a copy of the LSRO's assessment of selenium in infant formula. As regards safety and efficacy levels, the Expert Panel concludes that a level between 1.5 mcg /100 Kcal (10 mcg/L) and 5 mcg /100 Kcal (33 mcg/L) is recommended for infant formula. Attachment #3 should be referred to for the scientific data and associated support for this position.

PBM feels that selenium represents a special case in creating a required level of this mineral in WIC formulas. This is because selenium has attained essential status in infant nutrition as evidenced by the Institute of Medicine's selenium RDA for infants.


In this context, although selenium has not been formally incorporated into FDA's minimum essential compositional requirements for infant formula as yet, the recognized authoritative recommendations for selenium have been sufficient as to be acknowledged by FDA within the framework of existing regulations.

Manufacturers, with FDA acceptance, have been supplementing their formulas with selenium at levels commensurate with LSRO recommendations for several years. FDA has allowed this supplementation and has allowed the selenium to be declared in the restricted and reserved labeling declaration section for infant formula's required quantitative nutrient labeling, (selenium is found between the minerals iodine and sodium in infant formula labeling). Only nutrients deemed essential by appropriate authoritative recommendations may be declared in that product labeling section.

**PBM therefore requests WIC to list a requirement under 7 CFR 246 for a selenium content in WIC formulas. We are suggesting a range of between 1.5 mcg/100 Kcal and 5.0 mcg / 100 Kcal consistent with the LSRO Expert Panel's recommendations.\***

Sincerely and respectfully submitted

PBM Products, Inc  
Bright Beginnings Nutritionals

  
Raymond J. Maggio  
Vice-President,  
Nutritional R&D, RA, & QA  
204 North Main Street  
Gordonsville, VA. 22942



\*{To prevent possible confusion with our above selenium recommendation, we wish to point out that other nutrients voluntarily added to formula (nucleotides, taurine, etc) may not have attained the level of authoritative recognition accorded selenium and so may not be appropriate to consider including in 7 CFR 246 in like manner as selenium at this time.}

Three attachments enc: