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December 15, 2003

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

RE: REVISIONS TO THE WIC FOOD PACKAGES

Dear Ms. Daniels:

We propose that flavored cod liver oil (which meets European purity standards) and a children's multivitamin-mineral supplement containing trace metals (including selenium), be added to the WIC food packages for children 6 months to 5 years of age. Use of these nutritional supplements has the potential to improve the health of young children while decreasing their medical costs for upper respiratory illnesses, for both doctor visits and prescription drugs. This proposal is based on our research, as summarized below. Cod liver oil is not available through Medicaid and does not have a National Drug Code (NDC) number. The children's vitamins available through Medicaid that we have located in New York City do not contain trace metals.

Copies of the following materials are enclosed:

Published Paper:

1. Linday LA, Dolitsky JN, Shindledecker RD, Pippenger CE. Lemon-flavored cod liver oil and a multi-vitamin/mineral supplement for the secondary prevention of otitis media in young children: Pilot research. *Annals of Otolaryngology & Laryngology* 2002;111:642-652.

Presented Abstract:

2. Linday LA, Shindledecker RD, Tapia-Mendoza J, Dolitsky JN. Daily cod liver oil and a multivitamin-mineral with selenium decreases upper respiratory pediatric visits by young, inner-city, Latino children. Poster Presentation; Section on Food, Nutrition, and Physical Activity: **The Second International Conference on Urban Health, October 16, 2003**, New York, New York.

Manuscripts Submitted for Publication:

3. Linday LA, Shindledecker RD, Tapia-Mendoza J, Dolitsky JN. Effect of daily cod liver oil and a multivitamin-mineral with selenium on upper respiratory pediatric visits by young, inner-city, Latino children: Randomized pediatric sites. Submitted for publication. (This is the full paper of the above abstract.)
4. Linday LA, Dolitsky JN, Shindledecker RD. Nutritional supplements as adjunctive therapy for children with chronic/recurrent sinusitis: Pilot research. Submitted for publication.

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Research Summary

Our published paper (#1, above) reports the results of two studies. We obtained blood samples from 44 children undergoing ambulatory surgery (most of whom were undergoing placement of tympanostomy tubes). These children had lower levels than adults of eicosapentaenoic acid (EPA; an anti-inflammatory, omega-3 fatty acid), vitamin A (the "anti-infective" vitamin, which also has anti-inflammatory properties), and selenium (a trace metal that is an intrinsic component of glutathione peroxidase, which decreases reactive oxygen species). We then performed a small, open-label, supplementation study using lemon-flavored cod liver oil (which contains both EPA and vitamin A) and a children's multivitamin-mineral supplement containing selenium. Participating children were treated with antibiotics for otitis media for 12% fewer days during supplementation than before (in the same fall/winter period).

We then performed a larger clinical study, as summarized in our presented abstract (#2) and submitted manuscript (#3). Two private pediatric offices with similar demographics, located in upper Manhattan, New York City, were randomized to a Supplementation Site and a Medical Records Control Site. The study enrollment period was 10/21/02-12/12/02; the follow-up/supplementation period was 12/13/02-5/1/03. Ninety-four children (47 at each site), aged 6 months to 5 years, were enrolled. The mean age of the Supplementation Group was 2.03 years (± 1.04 SD); that of the Control Group was 2.08 years (± 1.10 SD). Participants were Latino children from low-income families; their mothers were predominantly Spanish-speaking, unmarried, immigrants from the Dominican Republic. Children ≥ 1 year of age in the Supplementation Group received 1 teaspoon of lemon-flavored cod liver oil/day and $\frac{1}{2}$ tablet of a children's multivitamin-mineral (MVM); the starting dose was halved for children < 1 year. Supplements were given from enrollment through 5/1/03. The primary outcome measure was the number of upper respiratory visits during the follow-up/supplementation period; other illness visits during the same time period were a secondary outcome measure.

The Supplementation Group had a statistically significant decrease in the mean number of upper respiratory visits over time ($p = 0.042$; $r = 0.893$; $y = 0.602 - 0.002x$); the Medical Records Control Group had no change in this parameter ($p = 0.999$; $r = 0.0006$; $y = 0.259 + 1.43 \cdot 10^{-6}x$). Supplements were well-tolerated; 70% of children completed the 5-6 month course of cod liver oil.

Our final paper (#4 above), summarizes our experience using these supplements in children with chronic/recurrent sinusitis. One of the children dropped out for administrative reasons. Four, six, and eight weeks after beginning study supplements, the three responders had decreased sinus symptoms, fewer episodes of acute sinusitis, and fewer doctor visits for acute illnesses. They had also begun to recover from upper respiratory illnesses without complications, which was unusual for these children.

Given the link between sinusitis and asthma, as well as the fact that exacerbations of asthma in children are often precipitated by an upper respiratory infection, we believe these supplements may be useful as adjunctive therapy in children with asthma, and are pursuing this new area of research.

Supplements

Cod liver oil also contains docosahexaenoic acid (DHA), a major component of the brain and eye, as well as vitamin D. The Norwegian National Council on Nutrition and Physical Activity recommends supplementation with cod liver oil from four weeks of age, both for its vitamin D content (for the prevention of rickets) and for its omega-3 fatty acid content.

The children's multivitamin-mineral supplement used in our research also contains iron, vitamin C, folic acid, zinc, vitamin B6 and magnesium.

We have found that use of a flavored cod liver oil is essential for compliance.

Hispanic Children

These nutritional supplements were highly acceptable to the young Hispanic children in our study and to their parents. This is relevant to the population served by WIC; per the Federal Register request for comments, the percentage of Hispanic enrollees in WIC has risen to 35.3%, while the percentages of black and white (non-Hispanic) enrollees have decreased.

Cost of Supplements

These supplements can be purchased in a pharmacy or health foods store without a prescription. A bottle of flavored cod liver oil (containing 170 ml) has a retail cost of approximately \$4.50. Our usual dose was 5 ml/day; the bottle therefore contains 34 doses, or approximately a one-month supply. A year's supply for one child is approximately 12 bottles, and the retail cost would be \$54.00.

A bottle of the children's multivitamin-mineral supplement used in this research contains 60 tablets and has a retail cost of \$6.60. Our usual dose was one tablet per day; it therefore contains 60 doses or a two-month supply. A year's supply for one child is six bottles and the retail cost would be approximately \$40.

These costs may pose an excessive financial burden for a poor family. However, volume discounts are undoubtedly available on the wholesale level.

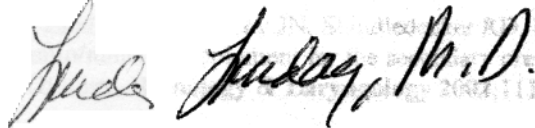
Cost/Benefit Analysis

Use of these nutritional supplements has the potential to improve the health of young children while decreasing their medical costs for upper respiratory illnesses, for both doctor visits and prescription drugs. Cod liver oil is not available through Medicaid and does not have a National Drug Code (NDC) number. We therefore hope that these supplements will be added to the WIC food packages for children 6 months to 5 years of age.

Please do not hesitate to contact me as above should you have any questions regarding this proposal.

Thank you for your attention. I look forward to your reply.

Sincerely,



Linda A. Linday, M.D.

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Enc.

SA: WIC 2003-12-15