NURITIONAL FORMULA CONTAINING HYDROLYZED PROTEIN AND A FIBER BLEND

This application is a continuation-in-part of U.S. patent application Ser. No. 08/816,286 filed on Mar. 13, 1997 now abandoned.

The present invention generally relates to liquid nutritional products that contain fiber, and more particularly, to infant formulas with hydrolyzed protein which contain a fiber blend that is useful in the management of infantile colic. The invention also relates to medical nutritional products that contain hydrolyzed protein and/or amino acids, and high levels of total dietary fiber that are useful in the management of diarrhea and other maladies.

BACKGROUND

Fiber is an important component in the treatment of humans with colic, diarrhea, short gut syndrome, impaired bowel function, Chron's disease, gastrointestinal intolerance and malabsorption.

Colic is one of the most confusing subjects facing pediatrics today. In the absence of a standard definition of "colic," it is difficult to compare one study on "colicky infants" with another. Furthermore, given the absence of a standard definition, studies assessing the causes and/or management of colic undoubtedly involve a heterogeneous group of infants with both a variety of problems as well as no problems at all.

Numerous reports in pediatric literature suggest that colic occurs in at least 10% to as high as 30% of both breast-fed and formula-fed infants. Colic is often described as unexpected episodes of crying or fussing which generally occur in the evening hours. While neither an organic or physical cause nor a non-organic etiology has been confirmed, several relatively diverse therapies are nevertheless employed in attempts to treat colic. To those who believe that colic is somehow related to a food allergy to intact protein, certain formulas incorporate hydrolysates, wherein the protein in the formula is broken down to reduce the allergenic response. Another current therapy often employs sedative or anti-spasmodic drugs. Still another therapy used in the treatment of colicky infants involves the use of mechanical rocking or vibrating devices. Unfortunately, each of these treatments is often ineffective.

Fiber is a normal dietary constituent once solid foods become part of the infant's diet, generally at 4 to 6 months of age. Fiber is introduced into the infant's diet only after the infant is consuming foods such as cereals, fruits and vegetables. As such, dietary fiber would not normally be a constituent of the diet of infants who experience colic.

Prior to the present invention, fiber has not been intentionally incorporated into an infant formula with hydrolyzed protein. Typical hydrolyzed protein or hypoallergenic formulas are prone to phase separation upon standing for a short period of time and the addition of dietary fiber only aggravates the stability problem due to the inherent insolubility of numerous fibers. Further, fibers increase viscosities such that incorporation of the dietary fiber at physiologically effective levels produces a liquid of high viscosity that is not suitable for nipple or tube feeding.

The physical stability of the hydrolyzed formula is important as phase separation may result in the recipient receiving an improper balance of nutrients. Phase separation during bottle feeding can also result in rejection of the formula by the infant due to changes in the flavor of the formula. The

present invention, in part, relates to a method of incorporating a fiber blend into a formula that contains hydrolyzed protein without resulting in increased phase separation or a product that is too viscous to feed through a nipple or a feeding tube. Formulas produced in accordance with the present invention will be useful in the management of colic, infantile diarrhea and other gastrointestinal conditions where dietary fiber can have a positive impact.

Constipation and diarrhea are problems in a substantial percentage of adult patients receiving enteral feedings. In addition to patient discomfort, diarrhea can severely compromise patient health because of depletion in fluid, electrolytes and other nutrients. The problem is aggravated when the patient requires an elemental or hydrolyzed enteral nutritional formula due to impaired bowel function, surgery or the like. Control of diarrhea in these patients is especially important.

The use of fiber to control or manage diarrhea is well known. Dietary fiber has been included in enteral nutritional formulas such as Ensure® with Fiber, Jevity® and PediaSure® with Fiber. All of these products are marketed by the Ross Products Division of Abbott Laboratories, Columbus, Ohio. A major problem with the inclusion of physiologically effective levels of dietary fiber in hydrolyzed or elemental medical nutritionals is product stability. Hydrolyzed or elemental medical nutritionals are inherently prone to phase separation. Inclusion of dietary fiber only aggravates the product's instability due to the insoluble character of certain fibers. Also, various fibers, at physiologically effective levels, produce products that are of high viscosity and therefore not useful for tube feeding. Thus, there is a need for dietary fiber containing products that possess enhanced shelf life or emulsion stability while avoiding excessive viscosities that would preclude tube feeding and nipple feeding.

U.S. Pat. No. 5,416,077 to Hwang, et al., discloses liquid nutritionals with improved physical stability. The nutritionals having limited sedimentation contain 50 to 1000 parts per million of iota-carrageenan and optionally, kappa carrageenan at a concentration of less than 25% of the total concentration of iota and kappa-carrageenan. This patent does not address the special problems of hydrolyzed formulas wherein the protein component has been hydrolyzed to the degree that it no longer provides stability to the product emulsion.

U.S. Pat. No. 5,492,899 to Masor, et al., discloses an infant formula containing specified levels and ranges of four (4) nucleotides. This patent also suggests that diarrhea can be controlled and the immune system enhanced through consumption of the formula according to the invention. The teachings of U.S. Pat. No. 5,492,899 are incorporated herein by reference.

U.S. Pat. No. 4,670,268 to Mahmoud discloses a hypoallergenic formula that contains carbohydrates, lipids, protein hydrolysates, vitamins and minerals and a starch modified by octenyl succinic anhydride. This patent is concerned with the physical stability of infant formula with hydrolyzed protein but fails to address the additional problem of adding fiber to such a product.

U.S. Pat. No. 5,085,883 to Garleb, et al., teaches a blend of dietary fiber for nutritional products. The blend contains by weight 5 to 50% of a fiber which is both soluble and fermentable; 5 to 20% of a fiber which is both soluble and non-fermentable; and 45 to 80% of a dietary fiber which is both insoluble and non-fermentable. Gum arabic, sodium carboxymethylcellulose and oat hull fiber are disclosed as