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**McEwen et al.**

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- (54) **ELEMENT ENTERAL NUTRITIONAL PRODUCT**
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- 5,547,927 8/1996 Cope et al. .
- 5,550,146 8/1996 Acosta et al. .
- 5,661,180 8/1997 DeMichele et al. .
- 5,695,803 12/1997 Sharp et al. .
- 5,723,446 3/1998 Gray et al. .
- 5,728,678 3/1998 Trimbo et al. .

**OTHER PUBLICATIONS**

Kenler, et al., "Early Enteral Feeding in Postsurgical Cancer Patients," *Annals of Surgery* 1996, vol. 223, No. 3, pp. 316-333.

Swails, et al., "Effect of a Fish Oil Structured Lipid-Based Diet on Prostaglandin Release From Mononuclear Cells in Cancer Patients After Surgery," *Journal of Parental and Enteral Nutrition*, 1997, vol. 21, No. 5, pp. 266-274.

Haumann, "Structured Lipids Allow Fat," *Inform*, Oct., 1997, vol. 8, No. 10, pp. 1004-1011.

"Perative™ Specialized Liquid Nutrition for Metabolically Stressed Patients," Ross Laboratories Product Brochure, May 1992.

"Immun-Aid™ Advanced Metabolic Formulation," McGaw Package Insert, 1992.

"Reabilan HN," O'Brien KMI, Product Brochure.

"Crucial® Complete Elemental Diet for Critically Ill Patients," Clintec Nutrition Company Product Brochure, 1994.

"Vivonex® Plus," Novartis Nutrition Corporation Product Brochure.

"Criticare HN®," Mead Johnson Product Brochure, Bristol-Myers Squibb Company, Evansville, Indiana, 1992.

"Peptamen® and Peptamen VHP® Oral Elemental Diets," Clintec Nutrition Company Product Brochure, 1994.

"Vital® High Nitrogen, Nutritionally Complete, Partially Hydrolyzed Diet," Ross Laboratories Product Brochure, Jan., 1989.

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(\*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

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**Related U.S. Application Data**

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- (51) **Int. Cl.**<sup>7</sup> ..... **A61K 35/78**; A61K 38/00; A23L 1/30; A23J 1/00
- (52) **U.S. Cl.** ..... **424/757**; 514/2; 514/21; 514/23; 426/72; 426/648; 426/654; 426/656; 426/657; 426/658
- (58) **Field of Search** ..... 514/2, 21, 23; 426/72, 648, 654, 656, 657, 658; 424/195.1, 757

(56) **References Cited**

**U.S. PATENT DOCUMENTS**

- 4,100,024 7/1978 Alder-Nissen .
- 4,670,268 6/1987 Mahmoud .
- 4,752,618 6/1988 Mascioli et al. .
- 4,871,768 10/1989 Bistran et al. .
- 4,897,384 1/1990 Janoff et al. .
- 4,913,896 4/1990 Harvey .
- 4,963,380 10/1990 Schroeder et al. .
- 5,059,591 10/1991 Janoff et al. .
- 5,084,294 1/1992 Schroeder et al. .
- 5,085,883 2/1992 Garleb et al. .
- 5,196,198 3/1993 Shaw et al. .
- 5,221,668 6/1993 Henningfeld et al. .
- 5,223,263 6/1993 Hostetler et al. .
- 5,223,285 6/1993 DeMichele et al. .
- 5,260,336 11/1993 Forse et al. .
- 5,308,832 5/1994 Garleb et al. .
- 5,403,826 4/1995 Cope et al. .
- 5,444,054 8/1995 Garleb et al. .
- 5,514,655 5/1996 DeWille et al. .

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(57) **ABSTRACT**

The present invention is directed to an elemental liquid nutritional product useful for providing nutrition to a patient having a malabsorption condition by enterally feeding to the patient a nutritionally effective amount of the liquid nutritional products of the present invention. One nutritional product of the present invention includes a protein system in which at least 65 w/w % of said proteins have a molecular weight of less than 5,000 daltons. The proteins system includes soy protein hydrolysate, and partially hydrolyzed caseinate. The preferred products further include a structured lipid formed from marine oil and medium chain triglyceride oil. Palatability of elemental nutritional products has been improved by keeping caloric density in a range from 0.60 kcal/ml to about 1.05 kcal/ml and incorporating sufficient amounts of selected palatability enhancers.

**22 Claims, No Drawings**