US006849595B2

(12) **United States Patent**
Mark et al.

(10) **Patent No.: US 6,849,595 B2**
(45) **Date of Patent: Feb. 1, 2005**

(54) **CALORICALLY DENSE NUTRITIONAL COMPOSITION**

(75) Inventors: **David A. Mark**, Oak Park, IL (US); **Diana Twyman**, Chicago, IL (US); **Tom Michalski**, Grayslake, IL (US)

(73) Assignee: **Nestec S.A.**, Vevey (CH)

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

(21) Appl. No.: **09/759,037**

(22) Filed: **Jan. 10, 2001**

(65) **Prior Publication Data**

US 2001/0049352 A1 Dec. 6, 2001

Related U.S. Application Data

(63) Continuation of application No. 09/025,363, filed on Feb. 18, 1998.

(51) **Int. Cl.**[7] **A61K 38/01**; A61K 33/00

(52) **U.S. Cl.** **514/2**; 514/21; 514/23; 514/547; 514/474; 514/494; 424/600; 424/641; 424/681; 426/72

(58) **Field of Search** 514/2, 494, 547, 514/21, 23, 474; 424/600, 702, 535, 641, 681; 426/72

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,112,123	A	9/1978	Roberts	
4,358,465	A	11/1982	Brule et al.	
4,361,587	A	11/1982	Brule et al.	
4,427,658	A	1/1984	Maubois et al.	
4,495,176	A	1/1985	Brule et al.	
4,670,268	A	6/1987	Mahmoud	
4,740,462	A	4/1988	Brule et al.	
4,753,963	A	6/1988	Jandacek et al.	
4,816,398	A	3/1989	Brule et al.	
4,920,098	A	4/1990	Cotter et al.	
4,931,300	A	6/1990	Monte	
4,980,450	A	12/1990	Brule et al.	
5,028,589	A	7/1991	Brule et al.	
5,053,387	A	10/1991	Alexander	
5,055,446	A	10/1991	Alexander et al.	
5,156,875	A	10/1992	Monte	
5,166,189	A	11/1992	Trimbo et al.	
5,221,668	A	6/1993	Henningfield et al.	
5,223,285	A	6/1993	DeMichele et al.	
5,260,279	A	11/1993	Greenberg	
5,340,603	A	8/1994	Neylan et al.	
5,422,127	A	6/1995	Dube et al.	
5,438,042	A	8/1995	Schmidl et al.	
5,480,872	A	1/1996	Cope et al.	
5,504,072	A	4/1996	Schmidl et al.	
5,547,927	A	8/1996	Cope et al.	
5,549,905	A	8/1996	Mark et al.	
5,574,065	A	11/1996	Trimbo	
5,589,468	A	12/1996	Lin et al.	
5,635,199	A	6/1997	Trimbo et al.	
5,661,123	A	8/1997	Stalker et al.	
5,700,782	A	12/1997	Cope et al.	
5,700,837	A	12/1997	Trimbo	
5,714,472	A	2/1998	Gray et al.	
5,723,446	A	3/1998	Gray et al.	
5,733,884	A	3/1998	Barbul et al.	
5,766,621	A	6/1998	Trimbo et al.	
6,200,950	B1 *	3/2001	Mark et al.	514/2

FOREIGN PATENT DOCUMENTS

EP	0 189 160	7/1986
EP	0 721 742	7/1996
WO	97/16079	5/1997

OTHER PUBLICATIONS

Brochure entitled "Respalor" by Mead Johnson & Company, 1994.

Brochure entitled "Pulmocare" by Ross Products Division, Abbott Laboratories, 1993.

Brochure entitled "Fresubin 750 MCT High–Caloric Formula for Oral and Tube Feeding" by Fresenius AG, 1989.

Culpepper–Morgan et al. article entitled "Using Enteral Nutrition Formulas" *The Gastroenterologist,* vol. 1, No. 2, Jun. 1993, pp. 143–156.

Ziegler et al. article entitled "Pharmacokinetic assessment of an oligopeptide–based enteral formula in abdominal surgery patients" *Am. J. Clin. Nutr.,* 1998 vol. 67, pp. 124–128.

Ziegler et al. article entitled "Present Knowledge in Nutrition" *International Live Sciences Institute,* 1996, pp. 38–40.

Alexander et al., "Beneficial Effects of Aggressive Protein Feeding in Severly Burned Children", Ann. Surg., vol. 192, No. 4, 1980, pp. 505–517.

Anderson et al., "Intestinal Protein Loss During Enteral Alimentation in Critically Ill Patients", J. Parenter Enteral Nutr., vol. 14 (Suppl), No. 1, 1990, p. 24, Abstract.

August et al., "Determination of Zinc and Copper Absorption at Three Dietary Zn–Cu Ratios by Using Stable Isotope Methods in Young Adult and Elderly Subjects", Am. J. Clin. Nutr., vol. 50, 1989, pp. 1457–1463.

Austin, "Water: Guidelines for Nutritional Support", Nutritional Support Services, vol. 6, No. 9, 1986, pp. 27–29.

Belcher et al., "Determinants of Urinary Nitrogen Excretion in Burned Patients", Burns, vol. 14, No. 4, 1988, pp 303–307.

(List continued on next page.)

Primary Examiner—Russell Travers
Assistant Examiner—Shahnam Sharareh
(74) *Attorney, Agent, or Firm*—Bell, Boyd & Lloyd LLC

(57) **ABSTRACT**

The present invention provides an enteral composition and method for providing nutrition to metabolically stressed patients. Pursuant to the present invention, the enteral composition has an increased caloric density of approximately 1.4 to 1.8 kcal/mL. The enteral composition includes a peptide based protein source, a lipid source, and a carbohydrate source.

17 Claims, No Drawings