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(54) **METHOD FOR REDUCING OR PREVENTING SYSTEMIC INFLAMMATION**

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See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

5,705,160	A	1/1998	Bruce et al.	
5,804,179	A	9/1998	Bruce et al.	
6,156,320	A *	12/2000	Izvekova et al.	424/197.11
6,180,100	B1	1/2001	Bruce et al.	
6,331,140	B1	12/2001	Mollet et al.	
6,358,521	B1 *	3/2002	Izvekova et al.	424/439
6,399,055	B1	6/2002	Postaire et al.	
6,479,051	B1	11/2002	Bruce et al.	
6,797,266	B2	9/2004	Naidu	
7,090,840	B2	8/2006	Cho	
7,125,963	B2	10/2006	Naidu	
2002/0006432	A1	1/2002	Collins et al.	
2003/0091549	A1	5/2003	Collins et al.	
2003/0092163	A1	5/2003	Collins et al.	
2003/0113306	A1	6/2003	Collins et al.	
2003/0166257	A1	9/2003	Collins et al.	
2003/0170217	A1	9/2003	Collins et al.	
2003/0215467	A1	11/2003	Collins et al.	
2004/0115178	A1	6/2004	Schiffrin et al.	
2004/0208863	A1	10/2004	Versalovic et al.	
2005/0074441	A1	4/2005	Collins et al.	
2005/0084482	A1	4/2005	Collins et al.	
2005/0100531	A1	5/2005	Bienenstock	
2005/0180962	A1	8/2005	Raz et al.	
2005/0214272	A1	9/2005	Collins et al.	
2005/0244392	A1	11/2005	Pei et al.	
2006/0002908	A1	1/2006	Collins et al.	
2006/0078547	A1	4/2006	Collins et al.	
2006/0088514	A1	4/2006	O'Mahony et al.	
2006/0233752	A1	10/2006	McMahon et al.	
2006/0233762	A1	10/2006	McMahon et al.	
2006/0292133	A1	12/2006	Collins et al.	
2007/0031393	A1	2/2007	Trejo et al.	

FOREIGN PATENT DOCUMENTS

WO	WO 97/00078	*	1/1997
WO	20060124630	*	11/2006
WO	WO 2006124630 A2	*	11/2006

OTHER PUBLICATIONS

Kaila et al, "Viable ver. inativ. lactobacillus strain GG in acute rotavirus diarrhoea", Archives of Disease in Childhood, 1995; 72: 51-53.*

International Search Report of the International Searching Authority for application No. PCT/US2008/054710, International filing date Feb. 22, 2008. Date of mailing Jun. 23, 2008.

Zhang, L., et al., *Alive and Dead Lactobacillus rhamnosus GG Decrease tumor necrosis Factor-α-induced Interleukin-8 Production in Caco-2 Cells*, Journal of Nutrition, Wistar Institute of Anatomy and Biology, vol. 135, No. 7, Jul. 1, 2005, pp. 1752-1758.

Kankaanpaa, P., et al., *Homogenates derived from probiotic bacteria provide down-regulatory signals for peripheral blood mononuclear cells*, Food Chemistry, Elsevier Science Publishers Ltd., vol. 83, No. 2, Nov. 1, 2003, pp. 269-277.

Zhang, L., et al., *Lactobacillus rhamnosus GG Decreases Lipopolysaccharide-induced Systemic Inflammation in a Gastrostomy-fed Infant Rat Model*, Jour. of Ped. Gastroenterology and Nutr., vol. 42, No. 5, May 1, 2006, pp. 545-552.

Jeschke, et al., *Insulin Attenuates the Systemic Inflammatory Response to Thermal Trauma*, Mol. Med. 8(8):443-450 (2002).

Murch, S.H., *Toll of Allergy Reduced by Probiotics*, Lancet, 357:1057-1059 (2001).

(Continued)

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(57) **ABSTRACT**

The present disclosure is directed to a novel nutritional formula for treating or preventing systemic inflammation in a subject. The nutritional formula comprises a therapeutically effective amount of inactivated *Lactobacillus rhamnosus* GG (LGG).

20 Claims, 6 Drawing Sheets