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(54) STABLE FIXED DOSE PHARMACEUTICAL COMPOSITION COMPRISING MOMETASONE AND OLOPATADINE

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See application file for complete search history.

(56) References Cited

U.S. PATENT DOCUMENTS

4.071.065		10/1000	T T 4 1
4,871,865		10/1989	· · · · · · · · · · · · · · · · · · ·
4,923,892	A	5/1990	Lever, Jr. et al.
5,837,699	A	11/1998	Sequeira et al.
6,127,353	A	10/2000	Yuen et al.
6,841,146	B2	1/2005	Haslwanter et al.
7,977,376	B2	7/2011	Singh et al.
8,399,508	B2	3/2013	Singh et al.
9,078,923	B2 *	7/2015	Dhuppad A61K 9/0043
9,370,483	B2	6/2016	Dhuppad et al.
9,750,754	B2 *	9/2017	Dhuppad A61K 31/58
10,016,443	B2 *	7/2018	Khairatkar-Joshi A61K 31/58
2004/0097474	A1	5/2004	Cagle et al.
2006/0110328	A1	5/2006	Cagle et al.
2007/0099883	A1	5/2007	Calis et al.
2008/0058296	A1	3/2008	Chaudry
2012/0121653	A1	5/2012	Jenkins et al.
2013/0252929	A1	9/2013	Lee et al.
2015/0099725	A1	4/2015	Khairatkar-Joshi et al.
2015/0272966	A1	10/2015	Khairatkar-Joshi et al.

FOREIGN PATENT DOCUMENTS

WO	WO-1995020393 A1	8/1995		
WO	WO-2001026658	4/2001		
WO	WO-2006057769 A2	6/2006		
WO	WO-2007095041 A2	8/2007		
WO	WO-2008012338 A2	1/2008		
WO	WO-2009003199 A1	12/2008		
WO	WO-2010025236 A1	3/2010		
WO	WO-2010042701 A2	4/2010		
	(Conti	(Continued)		

OTHER PUBLICATIONS

Avicel® RC-591, Product Specification Bulletin, Feb. 2009. (Continued)

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(57) ABSTRACT

The present invention relates to a stable fixed dose aqueous pharmaceutical composition (e.g., contained in a container) for nasal administration to a human, comprising mometasone or its salt, olopatadine or its salt. The composition may further include a hydrocolloid. The invention also relates to a process for preparing the pharmaceutical composition, and the use of the pharmaceutical composition in the treatment of rhinitis in a subject.

33 Claims, No Drawings