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(12) United States Patent
Dhuppad et al.**(10) Patent No.: US 10,561,672 B2****(45) Date of Patent: *Feb. 18, 2020****(54) STABLE FIXED DOSE PHARMACEUTICAL COMPOSITION COMPRISING MOMETASONE AND OLOPATADINE**31/4174; A61K 31/519; A61K 31/5415;
A61K 31/58; A61K 9/0043; A61K
9/0048; A61K 31/00; A61K 31/192;
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See application file for complete search history.

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Chaux-de-Fonds (CH)**(*) Notice:** Subject to any disclaimer, the term of this
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This patent is subject to a terminal dis-
claimer.**(21) Appl. No.: 15/703,780****(22) Filed: Sep. 13, 2017****(65) Prior Publication Data**

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(2013.01)**(58) Field of Classification Search**CPC .. A61K 2300/00; A61K 45/06; A61K 31/167;
A61K 31/19; A61K 31/335; A61K**(56) References Cited**

U.S. PATENT DOCUMENTS

4,871,865 A 10/1989 Lever, Jr. et al.
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 A61K 31/58
9,750,754 B2 9/2017 Dhuppad et al.
2004/0097474 A1 * 5/2004 Cagle A61K 9/0043
514/171
2006/0110328 A1 * 5/2006 Cagle A61K 31/00
424/45
2007/0099883 A1 5/2007 Calis et al.
2008/0058296 A1 * 3/2008 Chaudry A61K 9/0043
514/169
2012/0121653 A1 * 5/2012 Jenkins A61K 9/145
424/400
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

(Continued)

OTHER PUBLICATIONS

Avicel® RC-591, Product Specification Bulletin, Feb. 2009.
Austin, et al., Mometasone Furoate is a Less Specific Glucocorticoid
than Fluticasone Propionate, Eur Respir J, 2002, 20:1386-1392.
Baja, et al., Benefits of Skin Prick Tests for Allergic Rhinitis, The
Internet Journal of Otorhinolaryngology, 2006, 6:1.
International Search Report for International Application PCT/
IB2014/064251 dated Nov. 19, 2014, pp. 1-13.
Johnson, M., Ph.D., Development of Fluticasone Propionate and
Comparison with Other Inhaled Corticosteroids, J Allergy Clin
Immunol, Apr. 1998, 101:4:P2:S434-S439.

(Continued)

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(74) Attorney, Agent, or Firm — Blank Rome LLP**(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 mometa-
sone 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.**22 Claims, No Drawings**