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(54) FORMULATIONS OF TESTOSTERONE AND METHODS OF TREATMENT THEREWITH

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(58) Field of Classification Search

None

See application file for complete search history.

(56) References Cited

U.S. PATENT DOCUMENTS

5,756,071 A 5/1998 Mattern et al. 6,280,770 B1 8/2001 Pather et al. (Continued)

FOREIGN PATENT DOCUMENTS

WO 2006113505 * 10/2006 WO WO 2006/113505 10/2006 WO WO 2011/129812 10/2011

OTHER PUBLICATIONS

"Natesto (testosterone) nasal gel CIII", dated May 1, 2014, from www.accessdata.fda.gov/drugstatfda_docs/label/201/205488s0001bl. pdf (retrieved on Jan. 19, 2018).

(Continued)

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(57) ABSTRACT

The present disclosure relates to novel pharmaceutical composition for the administration of testosterone or testosterone derivatives. The present disclosure also provides methods of treatment of diseases and disorders associated with fear and anxiety, a decrease in libido, or hypogonadism.

19 Claims, 7 Drawing Sheets

