(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

G00002

(43) International Publication Date
20 June 2002 (20.06.2002)

PCT

(10) International Publication Number
WO 02/047693 A3

(51) International Patent Classification[7]: A61K 31/567, 31/565, 31/569, 47/26, A61P 5/30

(21) International Application Number: PCT/US01/48862

(22) International Filing Date:
13 December 2001 (13.12.2001)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/255,669 14 December 2000 (14.12.2000) US

(71) Applicant: **ORTHO-MCNEIL PHARMACEUTICAL, INC.** [US/US]; US ROUTE 202, RARITAN, NJ 08869-0602 (US).

(72) Inventors: **SCHULTZ,, Thomas**; 91 Matthew Circle, Richboro, PA 18954 (US). **CLARK,, Bradley, A.**; 17846 Pond Ridge Circle, Gurnee, IL 60031 (US). **FALZONE, Angela**; 1024 Colby Avenue, Raritan, NJ 08869 (US).

(74) Agents: **JOHNSON, Philip, S.** et al.; Johnson & Johnson, One Johnson & Johnson Plaza, New Brunswick, NJ 08933 (US).

(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZM, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*

(88) Date of publication of the international search report:
7 November 2002

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

162162

WO 02/047693 A3

(54) Title: STEROID HORMONE PRODUCTS COMPRISING A STABILIZING AGENT IN NON-CRYSTALLINE FORM

(57) Abstract: The present invention relates to steroid hormone products, such as oral contraceptive products, including at least one steroid active ingredient mixed with an excipient and having improved dissolution and release rate properties. The invention further relates to methods for making such steroid hormone products, wherein a mixture of the hormone and the excipient is subjected to sufficient mechanical energy to form a powder blend wherein the hormone is stabilized by the excipient in substantially non-crystalline form.