ANDA 76-737

JAN 27 2006

Watson Laboratories, Inc.
Attention: Christine M. Woods
Associate Director, Regulatory Affairs
311 Bonnie Circle
Corona, CA 92880

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated May 13, 2003, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Testosterone Gel 1%.

Reference is also made to your amendments dated September 17, September 21, and November 2, 2004; March 23, September 19, and December 13, 2005; and January 9, 2006.

We have completed the review of this ANDA and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the ANDA is approved. The Division of Bioequivalence has determined your Testosterone Gel, 1%, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug, AndroGel®, 1%, of Unimed Pharmaceuticals, Inc.

The reference listed drug (RLD) upon which you have based your ANDA, AndroGel® 1% of Unimed Pharmaceuticals (Unimed), is subject to a period of patent protection. As noted in the Agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), U.S. Patent No. 6,503,894 (the '894 patent) expires on August 30, 2020.

Your ANDA contains a certification under section 505(j)(2)(A)(vii)(IV) of the Act stating that this patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Testosterone Gel 1% under this ANDA. You have informed the Agency that Unimed initiated a patent infringement suit against Watson Laboratories in the United States District Court [redacted] (b)(4)

(b)(4)

(b)(4) . Although this litigation remains ongoing, the 30-month period identified in section 505(j)(5)(B)(iii) of the Act, during which time FDA was precluded from approving your ANDA, has expired.

With respect to 180-day generic drug exclusivity, we note that Watson was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification to the '894 patent. Therefore, with this approval Watson is eligible for 180 days of generic drug exclusivity for Testosterone Gel 1%. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act,[1] will begin to run from the earlier of the commercial marketing or court decision dates identified in section 505(j)(5)(B)(iv). Please submit correspondence to this ANDA informing the Agency of the date the exclusivity begins to run.

Under section 506A of the Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert(s) directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705

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[1] Because your ANDA was filed before the date of enactment of the Medicare Prescription Drug, Improvement and Modernization Act (MMA)(Public Law 108-173) on December 8, 2003, this reference to the 180-day exclusivity provision is to the section of the Act as in effect prior to December 8, 2003. See MMA § 1102(b)(1).

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Division of Drug Marketing, Advertising, and Communications with a completed Form FDA 2253 at the time of their initial use.

Sincerely yours,

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research