DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-489/S-013 **APPROVAL LETTER**

Watson Laboratories, Inc.
Attention: Kevin Barber, Ph.D., RAC, PMP
Director, Regulatory Liaison
577 Chipeta Way
Salt Lake City, UT 84108

Dear Dr. Barber:

Please refer to your supplemental new drug application dated November 21, 2005, received November 22, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Androderm® (testosterone transdermal system).

We acknowledge receipt of your submission dated December 5, 2005.

This "Changes Being Effected in 30 days" supplemental new drug application provides for the following:

- Revision of PRECAUTIONS sections of the Package Insert (PI) and Patient Package Insert (PPI) as requested by the Agency.
- Revision of excipient name and testing requirements for excipient due to revision of National Formulary (NF) monograph.

We completed our review of this application, as amended, and it is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling.

The final printed labeling (FPL) must be identical to the enclosed labeling that were submitted November 21, 2005, for the package insert and patient package insert.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA.* Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 20-489/S-013**." Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call John C. Kim, R.Ph., J.D., Regulatory Health Project Manager, at (301) 796-0932.

Sincerely,

{See appended electronic signature page}

Daniel Shames, M.D., F.A.C.S.
Director
Division of Reproductive and Urologic Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure: Agreed-upon labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Daniel A. Shames
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