DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020489/S-025

SUPPLEMENT APPROVAL

Watson Laboratories, Inc.
Attention: Wendy DeSpain, B.S., M.B.A., R.A.C.
Associate Director, Regulatory Liaison
Proprietary Regulatory Affairs
577 Chipeta Way
Salt Lake City, UT 84108

Dear Ms. DeSpain:

Please refer to your Supplemental New Drug Application (sNDA) dated and received December 22, 2010, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Androderm® (testosterone transdermal system).

We acknowledge receipt of your amendments dated February 2, April 21, 29, June 29, July 28, August 25, September 6, 12, 19, 21, 22, October 7 and 18, 2011.

This "Prior Approval" supplemental new drug application proposes new strengths of Androderm® (testosterone transdermal system) of 2 mg and 4 mg.

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert and text for the patient package insert), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

CARTON AND IMMEDIATE CONTAINER LABELS

We acknowledge your October 7, 2011, submission containing final printed carton and container labels.

Please submit these labels electronically according to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)." Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 020489/S-025**." Approval of this submission by FDA is not required before the labeling is used.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
5901-B Ammendale Road
Beltsville, MD 20705-1266

You must submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at http://www.fda.gov/opacom/morechoices/fdaforms/cder.html; instructions are provided on page 2 of the form. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

REPORTING REQUIREMENTS

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

We also request that you submit additional quarterly safety reports based on all postmarketing reports of the following product quality issues for Androderm 2 mg and 4 mg patches:

1. **Tight release**: (i.e. patches that were difficult to peel apart from the release liner)
2. **Adhesion failures**:
    a. Full adhesion failure: (i.e. patch fell off)
    b. Partial adhesion failure: (i.e. patch not fully adhering to skin [e.g. wrinkling of patches, lifting on edges])
    c. Secondary exposures of Androderm to nonpatients including pets
3. **Adhesive issues**:
    a. Pre-application adhesive transfer: (i.e. complaints relating to transfer of adhesive from the packaging components [pouch, liner, etc] or to patients/caregiver fingers)
    b. Post application adhesive transfer: (i.e. adhesive remains on skin after removing patch from skin)
4. **Torn patches**: (i.e. patches being torn during application and removal)

    The quarterly safety report should also include:

    a. For each case, a description of any associated adverse event(s) reported and lot information (if available).
    b. For each category of report(s) or complaint(s) received, present the number of patches exhibiting these issues.

c. Include all cases involving more than one category of product quality issues (e.g., number of cases involving both tight release and adhesive transfer) in a clear and concise presentation.

We request that you submit these additional quarterly safety reports for a period of at least 3 years following launch of the Androderm 2 mg and 4 mg patches in the US.

If you have any questions, please call Jeannie Roule, Regulatory Health Project Manager, at (301) 796-3993.

Sincerely,

{See appended electronic signature page}

Audrey Gassman, M.D.
Acting Deputy Director
Division of Reproductive and Urologic Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

ENCLOSURES:
Content of Labeling
Carton and Container Labeling

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

/s/

AUDREY L GASSMAN
10/20/2011