DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022309/S-011

SUPPLEMENT APPROVAL

AbbVie, Inc.
Attention: Gennadiy Koev, Ph.D.
Associate Director, Regulatory Affairs
1 N. Waukegan Road
Dept PA77, Bldg. AP30-1E
North Chicago, IL 60064

Dear Dr. Koev:

Please refer to your Supplemental New Drug Application (sNDA) dated and received May 15, 2014, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for AndroGel® (testosterone gel) 1.62%.

We acknowledge receipt of your amendments dated July 2 and 28, October 22 and November 12, 2014, and your risk evaluation and mitigation strategy (REMS) assessment statement dated October 22, 2014.

We also refer to our Prior Approval Supplement Request letter dated February 10, 2014, notifying you that the Agency had become aware of reports of patients applying AndroGel® (testosterone gel) to sites on the body other than the approved sites that could potentially increase the likelihood of secondary exposure to women and children. These reports were identified following a review of postmarketing safety after 18 months and 10,000 patient uses of AndroGel® (testosterone gel) 1.62% in accordance with Title IX, Section 915 of the Food and Drug Administration Amendments Act of 2007.

This supplemental new drug application provides for revisions that include a new application site diagram in the labeling and the Medication Guide and proposed modifications to the approved AndroGel® (testosterone gel) 1.62% risk evaluation and mitigation strategy (REMS), consistent with our February 10, 2014 letter. It also provides for revisions to the Pharmacokinetics section of the labeling based on the results of the recently completed required post-marketing hand-washing study.

APPROVAL & LABELING

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.

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, Medication Guide, 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 that includes labeling changes 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).

We request that the labeling approved today be available on your website within 10 days of receipt of this letter.

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.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for AndroGel® (testosterone gel) 1.62% was originally approved on April 29, 2011, and REMS modifications were approved on September 7, 2012, May 20, 2013, and last modified on June 19, 2014. The REMS consists of a Medication Guide, and a timetable for submission of

assessments of the REMS. Your proposed modifications to the REMS consist of a revised Medication Guide containing a new application site diagram.

Your proposed modified REMS, submitted on July 28, 2014 to the original prior approval labeling supplement submitted May 15, 2014, and appended to this letter, is approved.

The timetable for submission of assessments of the REMS will remain the same as that approved on April 29, 2011.

There are no changes to the REMS assessment plan described in our April 29, 2011, letter.

In addition to the assessments submitted according to the timetable included in the approved REMS, you must submit a REMS assessment when you submit a supplemental application for a new indication for use as described in section 505-1(g)(2)(A) of the FDCA.

If the assessment instruments and methodology for your REMS assessments are not included in the REMS supporting document, or if you propose changes to the submitted assessment instruments or methodology, you should update the REMS supporting document to include specific assessment instrument and methodology information at least 90 days before the assessments will be conducted. Updates to the REMS supporting document may be included in a new document that references previous REMS supporting document submission(s) for unchanged portions. Alternatively, updates may be made by modifying the complete previous REMS supporting document, with all changes marked and highlighted. Prominently identify the submission containing the assessment instruments and methodology with the following wording in bold capital letters at the top of the first page of the submission:

NDA 022309 REMS CORRESPONDENCE
(insert concise description of content in bold capital letters, e.g.,
UPDATE TO REMS SUPPORTING DOCUMENT - ASSESSMENT METHODOLOGY)

Prominently identify the submission containing the REMS assessments or proposed modifications of the REMS with the following wording in bold capital letters at the top of the first page of the submission as appropriate:

NDA 022309 REMS ASSESSMENT

NEW SUPPLEMENT FOR NDA 022309
PROPOSED REMS MODIFICATION

NEW SUPPLEMENT (NEW INDICATION FOR USE)
FOR NDA 022309
REMS ASSESSMENT
PROPOSED REMS MODIFICATION (if included)

If you do not submit electronically, please send 5 copies of REMS-related submissions.

REPORTING REQUIREMENTS

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 Meredith Alpert, M.S., Safety Regulatory Project Manager, at (301) 796-1218.

Sincerely,

{See appended electronic signature page}

Christine P. Nguyen, M.D.
Deputy Director for Safety
Division of Bone, Reproductive and Urologic Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

ENCLOSURES:
Content of Labeling
REMS

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

/s/

CHRISTINE P NGUYEN
11/14/2014