CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

210821Orig1s000

OTHER ACTION LETTERS

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 210821

COMPLETE RESPONSE

Valeant Pharmaceuticals Ireland
c/o Paragon BioTeck Inc.
Attention: Jeremy Brace
VP of Regulatory Affairs, Point Guard Partners LLC
400 N Ashley Drive, Suite 2150
Tampa, FL 33602

Dear Mr. Brace:

Please refer to your New Drug Application (NDA) dated and received February 22, 2018, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for tetracaine hydrochloride ophthalmic solution, 0.5%.

We have completed our review of this application, as amended, and have determined that we cannot approve this application in its present form. The methods to be used in, and the facilities and controls used for, the manufacture, processing, packing, or holding of the drug substance or the drug product must comply with the current good manufacturing practice regulations in 21 CFR 210 and 211. During a recent inspection of the Bausch & Lomb Inc. (FEI 1000113778) manufacturing facility for this application, our field investigators conveyed observations to the representative of the facility. These observations were not consistent with current good manufacturing practice regulations. Compliance with current good manufacturing practice regulations is required of all manufacturing facilities before this application may be approved.

We reserve comment on the proposed labeling until the application is otherwise adequate. We encourage you to review the attached draft package insert and labeling review resources on the *PLR Requirements for Prescribing Information* and *Pregnancy and Lactation Labeling Final Rule* websites, including regulations and related guidance documents and the Selected Requirements for Prescribing Information (SRPI) − a checklist of important format items from labeling regulations and guidances. Please submit a revised package insert, draft carton and container labeling that is consistent with the attached labeling.

When you respond to the above deficiency, please include a safety update as described at 21 CFR 314.50(d)(5)(vi)(*b*). Within one year after the date of this letter, you are required to resubmit or take other actions available under 21 CFR 314.110. If you do not take one of these actions, we may consider your lack of response a request to withdraw the application under 21 CFR 314.65. You may also request an extension of time in which to resubmit the application.

A resubmission must fully address the deficiency listed in this letter and should be clearly marked with "**RESUBMISSION**" in large font, bolded type at the beginning of the cover letter of the submission. The cover letter should clearly state that you consider this resubmission a complete response to the deficiency outlined in this letter. A partial response to this letter will not be processed as a resubmission and will not start a new review cycle.

You may request a meeting or teleconference with us to discuss what steps you need to take before the application may be approved. If you wish to have such a meeting, submit your meeting request as described in the draft FDA Guidance for Industry, "Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products," December 2017 at https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM590547.

If you have any questions, call Eithu Lwin, Regulatory Project Manager, at (301) 796-0728.

Sincerely,

{See appended electronic signature page}

Wiley A. Chambers, MD
Deputy Director
Division of Transplant and Ophthalmology Products
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURE: Proposed Package Insert

5 Page(s) of Draft Labeling have been Withheld in Full as b4 (CCI/TS) immediately following this page

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This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

WILEY A CHAMBERS
11/20/2018