



NDA 208090/S-009

**SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING
REQUIREMENT**

Collegium Pharmaceutical, Inc.
100 Technology Center Drive
Stoughton, MA 02072

Attention: Liz Stuart, PharmD, RAC
Director, Regulatory Affairs

Dear Dr. Stuart:

Please refer to your Supplemental New Drug Application (sNDA) dated and received June 26, 2018, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for XTAMPZA ER (oxycodone) extended-release capsules.

This supplement proposes the addition of component limit of lead specifications for oxycodone base, stearyl polyoxyl-32 glycerides, magnesium stearate, and Vcap capsules for XTAMPZA ER (oxycodone) extended-release capsules.

APPROVAL

We have completed our review of this supplemental new drug application. This supplement is approved.

FULFILLMENT OF POSTMARKETING REQUIREMENT

We have received your submission dated June 26, 2018, reporting on the following postmarketing requirement listed in the May 21, 2018, ACKNOWLEDGE REVISED POSTMARKETING REQUIREMENT MILESTONES AND COMMUNICATE GOOD CAUSE letter.

- 2966-14 Conduct a study to characterize the levels of lead in the final drug product formulation and propose a release specification to adequately control lead in the drug product.

Final Report Submission: 06/2018

We have reviewed your submission and conclude that the above requirement was fulfilled.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

We remind you that there are postmarketing requirements listed in our April 26, 2016, and May 12, 2017, letters that are still open.

If you have any questions, call Selma Kraft, Regulatory Project Manager, at (240) 402-9700.

Sincerely,

{See appended electronic signature page}

Joshua Lloyd, MD
Deputy Director
Division of Anesthesia, Analgesia, and
Addiction Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

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/

JOSHUA M LLOYD
10/26/2018