DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 208090

TENTATIVE APPROVAL

Collegium Pharmaceuticals, Inc.
780 Dedham Street
Suite 800
Canton, MA 02021

Attention: Jack Weet, PhD
Vice President, Regulatory Affairs and Quality Assurance

Dear Dr. Weet:

Please refer to your New Drug Application (NDA) dated and received December 12, 2014, submitted pursuant to Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA), for XTAMPZA ER (oxycodone) extended-release Capsules: 9 mg, 13.5 mg, 18 mg, 27 mg, 36 mg.

We also refer to our tentative approval letter dated November 6, 2015, which contained the following error: inclusion of a patent that is not listed in the Orange Book.

This replacement tentative approval letter incorporates the correction of the error. The effective tentative approval date will remain November 6, 2015, the date of the original tentative approval letter.

We acknowledge receipt of your amendments dated December 17, 18, and 30, 2015, January 21, February 6, 11, and 23, March 6 (2), 11, 18 (2) and 24, April 6, 17, and 24, May 1, 15, and 28, June 8, and 16, July 8, 24, and 29, August 3,7(2), 10, 11, and 26, September 2, 22(2), 23, 24, and 25, and October 2, 5(2), 6, 7, 13, 14, 15, and 26, November 2, and 3, 2015.

This new drug application provides for the use of XTAMPZA ER for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

We have completed our review of this application, as amended. It is tentatively approved under 21 CFR 314.105 for use as recommended in the amended enclosed labeling text for the package insert, Medication Guide, and immediate container labels submitted October 5, 2015. This determination is based upon information available to the Agency at this time, [i.e., information in your application and the status of current good manufacturing practices (cGMPs) of the facilities used in the manufacture and testing of the drug product]. This determination is subject to change on the basis of any new information that may come to our attention.

The listed drug upon which your application relies is subject to a period of patent protection and therefore final approval of your application under Section 505(c)(3) of the FDCA [21 U.S.C. 355(c)(3)] may not be made effective until the period has expired.

Your application contains certifications to each of the patents under Section 505(b)(2)(A)(iv) of the FDCA stating that the patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of, this drug product under this application ("Paragraph IV certifications").

Section 505(c)(3)(C) of the FDCA provides that approval of a new drug application submitted pursuant to Section 505(b)(2) of the FDCA shall be made effective immediately, unless an action is brought for infringement of one or more of the patents that were the subject of the paragraph IV certifications. This action must be taken prior to the expiration of forty-five days from the date the notice provided under Section 505(b)(3) is received by the patent owner/approved application holder. You notified us that you complied with the requirements of Section 505(b)(3) of the FDCA.

In addition, you have notified the Agency that the patent owner and/or approved application holder has initiated a patent infringement suit against you with respect to patent 7,674,799, 7,674,800, and 7,683,072, in the United States District Court for the District of Delaware. Therefore, final approval cannot be granted until:

1. a. Expiration of the 30-month period provided for in Section 505(c)(3)(C) beginning on the date of receipt of the 45-day notice required under Section 505(b)(3), unless the court has extended or reduced the period because of the failure of either party to reasonably cooperate in expediting the action, or

   b. The date the court decides that the patents are invalid or not infringed as described in section 505(c)(3)(C)(i), (ii), (iii,) or (iv) of the Act, or,

   c. The listed patents have expired, and

2. We are assured there is no new information that would affect whether final approval should be granted.[1]

To obtain final approval of this application, submit an amendment two or six months prior to the: 1) expiration of the patent(s) and/or exclusivity protection or 2) date you believe that your NDA will be eligible for final approval, as appropriate. In your cover letter, clearly identify your amendment as **"REQUEST FOR FINAL APPROVAL"**. This amendment should provide the legal/regulatory basis for your request for final approval and should include a copy of any relevant court order or judgment settlement, or licensing agreement, as appropriate. In addition to a safety update, the amendment should also identify changes, if any, in the conditions under

[1] We need not determine at this time whether approval of your 505(b)(2) NDA for XTAMPZA ER would otherwise be blocked by any other drug's marketing exclusivity expiring before termination of the 30-month stay.

which your product was tentatively approved, i.e., updated labeling; chemistry, manufacturing, and controls data; and risk evaluation and mitigation strategy (REMS). If there are no changes, clearly state so in your cover letter. Any changes require our review before final approval and the goal date for our review will be set accordingly.

Until we issue a final approval letter, this NDA is not deemed approved.

Please note that this drug product may not be marketed in the United States without final agency approval under Section 505 of the Act. The introduction or delivery for introduction into interstate commerce of this drug product before the final approval date is prohibited under Section 501 of the FDCA and 21 U.S.C. 331(d).

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 in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We note that if this application is ultimately approved, you will need to meet these requirements.

POSTMARKETING REQUIREMENTS UNDER 505(o)

(b) (4)

[redacted]

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(b) (4)

If you have any questions, call Ayanna Augustus, PhD, RAC, Sr. Regulatory Project Manager, at (301) 796-3980.

Sincerely,

{See appended electronic signature page}

Sharon Hertz, MD
Director
Division of Anesthesia, Analgesia, and
Addiction Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of Labeling
Carton and Container Labeling
REMS

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

/s/

SHARON H HERTZ
11/06/2015