DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 202088/Original #2

NDA APPROVAL

Citius Pharmaceuticals, LLC
Attention: Steven A. Kates, Ph.D.
Vice President
63 Great Road
Maynard, MA 01754

Dear Dr. Kates:

Please refer to your New Drug Application (NDA) dated August 11, 2010, received August 13, 2010, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Suprenza (phentermine hydrochloride) orally dissolving tablets (ODT), 15 mg, 30 mg, and 37.5 mg.

We acknowledge receipt of your amendments dated September 28 and October 25, 2011, and January 11 and 19, February 10, and March 2, 2012.

The September 28, 2011, submission constituted a complete response to our June 13, 2011, action letter.

NDA 202088 provides for the use of Suprenza orally dissolving tablets for the following indications which, for administrative purposes, we have designated as follows:

- NDA 202088/Original 1:

  15 mg and **30** mg ODT as a short-term (a few weeks) adjunct in a regimen of weight reduction based on exercise, behavioral modification, and caloric restriction in the management of exogenous obesity for patients with an initial body mass index ≥ 30 kg/m^2, or ≥ 27 kg/m^2 in the presence of other risk factors (e.g., controlled hypertension, diabetes, hyperlipidemia)

- NDA 202088/Original 2:

  37.5 mg ODT as a short-term (a few weeks) adjunct in a regimen of weight reduction based on exercise, behavioral modification, and caloric restriction in the management of exogenous obesity for patients with an initial body mass index ≥ 30 kg/m^2, or ≥ 27 kg/m^2 in the presence of other risk factors (e.g., controlled hypertension, diabetes, hyperlipidemia)

The subject of this action letter is NDA 202088/Original #2. A separate action letter was issued for NDA 202088/Original #1.

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

Sufficient stability data were submitted in the NDA to support a 24 month expiration dating period for the product packaged in [redacted] (b) (4) bottles.

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). 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/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

IMMEDIATE CONTAINER LABELS

Submit final printed container labels that are identical to the enclosed immediate container labels as soon as they are available, but no more than 30 days after they are printed. 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 "**Final Printed Container Labels for approved NDA 202088/Original #2**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

REQUIRED PEDIATRIC ASSESSMENTS

We are waiving the pediatric study requirement for this application because there is evidence strongly suggesting that the drug product would be ineffective and unsafe in all pediatric age

groups. Phentermine is an old drug that was approved for short-term use in adults prior to the currently accepted approach to obesity management. Obesity is not an acute condition, but a chronic condition that requires a lifetime of treatment. Adequate long-term data in adults are not available to support safely studying phentermine in children for chronic use.

POSTMARKETING REQUIREMENTS UNDER 505(o)

We remind you of your requirements as stated in the approval letter for NDA 202088/Original #1 for Suprenza (phentermine hydrochloride) orally dissolving tablets 15 mg and 30 mg, dated June 13, 2011:

PMR 1785-1: Nationally representative (or nationally projected) study of annual use of phentermine hydrochloride orally dissolving tablets for three years after product launch. This study must provide information on the distribution of age, sex, and BMI of patients treated with phentermine ODT, as well as the average duration of use, average size of prescriptions, average cumulative dose per patient, concomitant drug use and concomitant disease diagnoses.

Final Protocol Submission:	09/30/2011
Interim Report Submission:	12/03/2012
	12/03/2013
Final Report Submission:	12/03/2014

PMR 1785-2: A clinical trial to assess the effect of mild, moderate and severe renal impairment and end stage renal disease (ESRD) on the pharmacokinetics of phentermine.

Final Protocol Submission: 07/13/2012
Trial Completion: 01/31/2014
Final Report Submission: 06/30/2014

PROMOTIONAL MATERIALS

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

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

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see 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).

All 15-day alert reports, periodic (including quarterly) adverse drug experience reports, field alerts, annual reports, supplements, and other submissions should be addressed to **NDA 202088 / Original #1** for this drug product, not to this NDA. In the future, do not make submissions to this NDA except for the final printed labeling requested above.

If you have any questions, call Patricia Madara, Regulatory Project Manager, at (301) 796-1249.

Sincerely,

{See appended electronic signature page}

Eric Colman, M.D.
Deputy Director
Division of Metabolism and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURES:
Content of Labeling
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/

ERIC C COLMAN
03/27/2012