DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 202088/Original #1/S-002

SUPPLEMENT 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 Supplemental New Drug Application (sNDA) dated March 5, 2012, received March 6, 2012, 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 and 30 mg.

This "Prior Approval" supplemental new drug application, submitted in response to our "supplement request" letter issued on February 16, 2012, provides for revision of the immediate container labels to relocate the net quantity statement further away from the product strength.

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

IMMEDIATE CONTAINER LABELING

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.

The final printed labeling should be submitted 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 Labeling for approved NDA 202088/Original #1/S-002**." Approval of this submission by FDA is not required before the labeling is used.

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 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:
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