



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 202088/S-006

SUPPLEMENT APPROVAL

Citius Pharmaceuticals LLC
Attention: Steven Kates, PhD, Vice President
63 Great Road
Maynard, MA 01754

Dear Dr. Kates:

Please refer to your Supplemental New Drug Application (sNDA) dated January 11, 2013, received January 14, 2013, submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Suprenza™ (phentermine hydrochloride) Oral disintegrating Tablet.

This “Prior Approval” supplemental new drug application provides for the improvement in packaging of Suprenza™ (phentermine hydrochloride) Oral Disintegrating Tablet, 15, 30, and 37.5mg.

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

Submit final printed carton and container labels that are identical to the enclosed carton labels submitted on January 11, 2013, 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 “Product Correspondence – Final Printed Carton and Container Labels for approved NDA 202088/S-006.” Approval of this submission by FDA is not required before the labeling is used.

If you have any questions, call Priyanka Kumar, Regulatory Project Manager, at (240) 402-3722.

Sincerely,

{See appended electronic signature page}

Ramesh Raghavachari, Ph.D.
Acting Branch Chief, Branch IX
Division of New Drug Quality Assessment III
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

ENCLOSURE(S):
Carton Labeling

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

/s/

RAMESH RAGHAVACHARI
07/11/2013