DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-070/SCM-012 & SLR-013

First Horizon Pharmaceutical Corporation
Attention: Mark Pilato
6195 Shiloh Road
Alpharetta, GA 30005

Dear Mr. Pilato:

Please refer to your supplemental new drug applications SCM-012 dated December 31, 2002 and SLR-013 dated April 23, 2003, submitted under section 505(b)/pursuant to section 505 (b)(2) of the Federal Food, Drug, and Cosmetic Act for Cognex ® Capsules.

These supplemental new drug applications provide for the following:

1. SCM-012: Several SUPAC changes; a site change, a change in batch size, and a change in bottle design and resin of the container closure system. Also included are changes to the carton and container labels and editorial changes to the package insert.

2. SLR-013: Revised language to the "Warnings, Cardiovascular Condition" section of labeling to read as follows:

   Because of its pharmacological action, Cognex may have vagotonic effects on the sinoatrial and atrioventricular nodes possibly leading to bradycardia and/or heart block. These effects may be particularly harmful to patients with conduction abnormalities, bradyarrythmias, or a sick sinus syndrome, but may also occur in patients without known preexisting cardiac disease.

We completed our review of these supplemental new drug applications and they are approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on April 23, 2003.

Additionally, we request that the container labels be revised at the next printing with the following changes:

1. Decrease the prominence of the proprietary name and increase the prominence of the established name to reflect the ratio of 20:10.

2. Decrease the prominence of the company name/logo.

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

If you have any questions, call Melina Griffis, Senior Regulatory Project Manager, at (301) 594-5526.

Sincerely,

{See appended electronic signature page}

Russell Katz, M.D.
Director
Division of Neuropharmacological Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

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

/s/

Russell Katz
6/19/03 08:24:07 AM