DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

NDA 020866/S-002

SUPPLEMENT APPROVAL

VeroScience, LLC
Attention: Anthony H. Cincotta, Ph.D.
President and CSO
1334 Main Road
Tiverton, RI 02879

Dear Dr. Cincotta:

Please refer to your Supplemental New Drug Application (sNDA) dated September 24, 2010, received September 27, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Cycloset (bromocriptine maleate) Tablets, 0.8 mg.

This "Changes Being Effected" supplemental new drug application provided minor labeling revisions to the package insert, patient package insert, and immediate container labels.

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

We note that your September 24, 2010, submission includes final printed labeling (FPL) for the package insert and patient package insert, and they are acceptable.

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 (package insert and patient package insert), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

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/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes, and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number and annual report date(s).

IMMEDIATE CONTAINER LABELS

We acknowledge your September 24, 2010, submission containing final printed container labels.

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, please call Ms. Jena Weber, Regulatory Project Manager, at 301-796-1306.

Sincerely,

{See appended electronic signature page}

Mary H. Parks, M.D.
Director
Division of Metabolism and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURES:
Package Insert
Patient Package Insert
Trade Container (bottle) Labels (200- and 600-count)
Sample Container (bottle) Label (21-count)

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

/s/

MARY H PARKS
03/24/2011