DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21314/ S- 005

**APPROVAL LETTER**

Exalenz Bioscience, Inc.
Attention: Raffi Werner, CEO
US Agent for Exalenz Bioscience, Ltd. in Israel
2414 Morris Ave., Suite 201
Union, NJ 07083

Dear Mr. Werner:

Please refer to your Supplemental New Drug Application (sNDA) dated December 29, 2015, received January 4, 2016, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for IDkit:Hp™ containing $^{13}$C-Urea ($^{13}$C-urea tablet for oral solution) 75 mg.

This "Changes Being Effected in 30 Days" supplemental new drug application provides for the following change:

- (b) (4)

We have completed our review of this supplemental new drug application. This supplement is approved.

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 LCDR Luz Rivera, Senior Regulatory Business Process Manager, at (301) 796-4013.

Sincerely,

Hasmukh Patel, Ph.D.
Division Director (Acting)
Division of Post Marketing Activities I
Office of Lifecycle Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Hasmukh Patel

Digitally signed by Hasmukh Patel
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