



NDA 021876/S-006

SUPPLEMENT APPROVAL

Duchesnay Inc.
c/o OptumInsight Life Sciences Inc.
Attention: John J.K. Killackey, Ph.D.
Director, U.S. Regulatory Affairs
131 Morristown Road
Basking Ridge, NJ 07920

Dear Dr. Killackey:

Please refer to your Supplemental New Drug Application (sNDA) dated and received July 16, 2014, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Diclegis (doxylamine succinate and pyridoxine hydrochloride) delayed-release tablets.

This supplemental new drug application proposes to update the physician sample outer carton label and the physician sample and marketed product immediate container label to include symbols indicating both the kosher certification and the halal certification of Diclegis.

APPROVAL & LABELING

We have completed our review of this supplemental application. It is approved, effective on the date of this letter.

FDA has determined that the kosher and halal symbols on your updated labeling do not interfere with the required content of the labeling. FDA has not made an independent determination that your product is kosher or halal.

CARTON AND IMMEDIATE CONTAINER LABELS

We acknowledge your July 16, 2014, submission containing final printed carton and 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, call George Lyght, Pharm.D., Sr. Regulatory Health Project Manager, at (301) 796-0948.

Sincerely,

{See appended electronic signature page}

Audrey Gassman, M.D.
Deputy Director
Division of Bone, Reproductive, and Urologic Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

ENCLOSURE:
Carton and 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/

AUDREY L GASSMAN
12/16/2014