DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 209661

NDA APPROVAL

Duchesnay Inc.
c/o Mapi USA, Inc.
Attention: John J.F. Killackey, Ph.D.
Director, Regulatory Affairs
2343 Alexandria Drive, Suite 100
Lexington, KY 40504

Dear Dr. Killackey:

Please refer to your New Drug Application (NDA) dated and received October 7, 2015, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for BONJESTA (doxylamine succinate and pyridoxine hydrochloride) extended-release tablets.

We acknowledge receipt of your major amendment dated June 13, 2016, which extended the goal date by three months.

This new drug application provides for the use of BONJESTA for the treatment of nausea and vomiting of pregnancy in women who do not respond to conservative management.

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

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. Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*, available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and immediate container labels that are identical to the enclosed immediate container labels, 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 *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 "**Final Printed Carton and Container Labels for approved NDA 209661**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product with final printed labeling that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric study requirement for females aged birth through eleven years of age and males because necessary studies are impossible or highly impracticable. This is because pregnancy cannot occur in premenarchal females who are in this age range (birth through 11 years of age), the number of females at the upper ages in this range (9-11 years of age) who are able to become pregnant (postmenarchal) is too few, and pregnancy cannot occur in males.

We are deferring submission of your pediatric study for pregnant females ages 12 to 17 years for this application because this product is ready for approval for use in adult pregnant women and a pediatric study has not been completed.

The original approved application for Diclegis (doxylamine succinate and pyridoxine hydrochloride) delayed-release tablet includes a PREA requirement to conduct a single well-controlled trial in pregnant females 12 to 17 years of age.

Your ongoing pediatric study required by section 505B(a) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Diclegis is a required postmarketing study. The status of this postmarketing study must be reported annually according to 21 CFR 314.81 and section 505B(a)(3)(B) of the FDCA.

This required study is identified below:

PED-301 An adequately powered safety and efficacy study in pregnant adolescent girls, 12 to 17 years of age, with nausea and vomiting of pregnancy who are appropriate

candidates for pharmacologic therapy.

This required pediatric study for Diclegis is also intended to fulfill the PREA requirements for BONJESTA. Whether an additional study or trial in this population is needed for BONJESTA will be determined following review of your final study report for PED-301.

The final study report for your PED-301 required pediatric postmarketing study must be submitted to both the Diclegis NDA and the Bonjesta NDA. When submitting the reports, clearly mark your submission "**SUBMISSION OF REQUIRED PEDIATRICASSESSMENT"** in large font, bolded type at the beginning of the cover letter of the submission.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert, Medication Guide, and patient PI (as applicable) to:

OPDP Regulatory Project Manager
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
5901-B Ammendale Road
Beltsville, MD 20705-1266

Alternatively, you may submit a request for advisory comments electronically in eCTD format. For more information about submitting promotional materials in eCTD format, see the draft Guidance for Industry (available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM443702.pdf).

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. Form FDA 2253 is available at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf. Information and Instructions for completing the form can be found at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

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 A. Lyght, Pharm.D., Sr. Regulatory Health Project Manager, at (301) 796-0948.

Sincerely,

{See appended electronic signature page}

Hylton V. Joffe, M.D., M.M.Sc.
Director
Division of Bone, Reproductive, and Urologic Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosures:
Content of Labeling
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/

HYLTON V JOFFE
11/07/2016