NDA 209661/S-008

SUPPLEMENT APPROVAL

Duchesnay, Inc.
c/o ICON Clinical Research LLC
Attention: Jordan Samaniego
Consultant, US Regulatory Affairs
4130 Parklake Avenue, Suite 400
Raleigh, NC 27612

Dear Mr. Samaniego:

Please refer to your supplemental new drug application (sNDA) dated and received on March 30, 2022 submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Bonjesta extended-release tablets (doxylamine succinate and pyridoxine hydrochloride).

This Prior Approval sNDA provides for the removal of the descriptive term "asthma" from the labeling. Additional labeling revisions were made to sections Warnings and Precautions, Concomitant Medical Conditions, and Patient Information. An editorial correction of "principle" to "principal" was made under section 12.3 Pharmacokinetics.

APPROVAL & LABELING

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

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 FDA.gov.[1] Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information and Patient Information) 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 *SPL Standard for Content of Labeling Technical Qs and As*.[2]

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm
[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

The SPL will be accessible from publicly available labeling repositories.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), 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 in pediatric patients unless this requirement is waived, deferred, or inapplicable.

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 Sydney Tran, Regulatory Project Manager, at 301-796-1587.

Sincerely,

{See appended electronic signature page}

Catherine Sewell, MD, MPH (she/her)
Deputy Director for Safety
Division of Urology, Obstetrics and Gynecology
ORPURM/OND/CDER/FDA

ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information
  - Patient Information

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

CATHERINE A SEWELL
10/31/2022 11:36:15 AM