NDA 017962/ S-080 and S-089

**SUPPLEMENT APPROVAL**

Esjay Pharma LLC
Attention: Muthusamy Shanmugam
Founder and President
50 Millstone Road, Building 300, Suite 140
East Windsor, NJ 08520

Dear Muthusamy Shanmugam:

Please refer to your supplemental new drug applications (sNDAs) dated and received April 26, 2018, and May 26, 2026, respectively, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Parlodel (bromocriptine mesylate) tablets and capsules.

S-080 and S-089 Prior Approval sNDAs provide for changes to remove the pregnancy category in accordance with the final Pregnancy and Lactation Labeling Rule and content and format changes in accordance with the Physician Labeling Rule (PLR), respectively.

## APPROVAL & LABELING

We have completed our review of these applications, as amended. They are 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), with the addition of any annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*.[2]

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[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm
[2] We update guidance documents periodically. For the most recent version of a guidance document, 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.

Because none of these criteria apply to your supplemental applications, you are exempt from this requirement.

## 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, contact Kidist Berhanu, Senior Regulatory Project Manager, at (301) 837-7665 or Kidist.Berhanu@fda.hhs.gov.

Sincerely,

*{See appended electronic signature page}*

Audrey Gassman, M.D.
Deputy Director
Division of Urology, Obstetrics, and Gynecology
Office of Rare Diseases, Pediatrics, Urologic, and Reproductive Medicine
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURE: Content of Labeling - Prescribing Information

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**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.**

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/s/

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AUDREY L GASSMAN
06/30/2026 08:18:15 AM