NDA 020992/S-043

SUPPLEMENT APPROVAL

Aspen Pharma USA Inc.
c/o Lachman Consultant Services, Inc.
Attention: Jennifer Leaming
Principal Consultant
1600 Stewart Avenue, Suite 604
Westbury, NY 11590

Dear Jennifer Leaming:

Please refer to your supplemental new drug application (sNDA) dated and received November 20, 2025, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Cenestin (synthetic conjugated estrogens, A) tablets.

This Prior Approval sNDA provides for revisions to the Prescribing Information and Patient Information labeling in response to the Agency's November 9, 2025, Prior Approval Supplement Request correspondence.

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 Package Insert), 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 guidance douments 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.

Because none of these criteria apply to your supplemental application, 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 Samantha Bell, Regulatory Project Manager, at (301) 796-9687 or samantha.bell@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Christina Chang, MD, MPH
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

ENCLOSURES:
Content of Labeling
- Prescribing Information
- Patient Package Insert

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/

CHRISTINA Y CHANG
02/12/2026 08:51:15 AM