CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

212535Orig1s000

Trade Name:	NOURESS™ USP, 50 mg/mL.
Generic or Proper Name:	cysteine hydrochloride injection
Sponsor:	Avadel Legacy Pharmaceuticals, LLC
Approval Date:	December 13, 2019
Indication:	Provides for the use of NOURESS™ (cysteine hydrochloride injection) as an additive to amino acid solutions to meet nutritional requirements of neonates (preterm and term infants less than one month of age) requiring total parenteral nutrition (TPN).

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212535Orig1s000

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APPLICATION NUMBER:

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APPROVAL LETTER

NDA 212535

NDA APPROVAL

Avadel Legacy Pharmaceuticals, LLC
c/o The Weinberg Group LLC
Attention: Marla Scarola (US Authorized Agent)
Vice President, Regulatory Program Management
1129 Twentieth Street NW, Suite 600
Washington, DC 20036

Dear Ms. Scarola,

Please refer to your new drug application (NDA) dated and received on March 15, 2019, submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for NOURESS™ (cysteine hydrochloride injection) USP, 50 mg/mL.

We acknowledge receipt of your major amendment dated July 15, 2019, which extended the goal date by three months.

This new drug application provides for the use of NOURESS™ (cysteine hydrochloride injection) as an additive to amino acid solutions to meet nutritional requirements of neonates (preterm and term infants less than one month of age) requiring total parenteral nutrition (TPN).

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 text.

We note that your December 10, 2019, submission includes final printed labeling (FPL) for your Prescribing Information. We have not reviewed this FPL. You are responsible for assuring that the wording in this printed labeling is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

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 Prescribing Information as well as annual reportable changes not included in the enclosed labeling.

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

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]

The SPL will be accessible via publicly available labeling repositories.

CARTON AND CONTAINER LABELING

Submit final printed carton and container labeling that are identical to the enclosed carton and container labeling and carton and container labeling submitted on December 10, 2019, as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling electronically according to the guidance for industry Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications. For administrative purposes, designate this submission "Final Printed Carton and Container Labeling for approved **NDA 212535**." Approval of this submission by FDA is not required before the labeling is used.

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 application, you are exempt from this requirement.

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 Prescribing Information, Medication Guide, and Patient Package Insert (as applicable) to:

[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.

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