

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

212535Orig1s000

MULTI-DISCIPLINE REVIEW

Summary Review

Office Director

Cross Discipline Team Leader Review

Clinical Review

Non-Clinical Review

Statistical Review

Clinical Pharmacology Review

NDA/BLA Multi-disciplinary Review and Evaluation for **NDA 212535** Nouress (cysteine hydrochloride)

NDA/BLA Multi-Disciplinary Review and Evaluation

Application Type	NDA
Application Number(s)	212535
Priority or Standard	Priority
Submit Date(s)	3/15/2019
Received Date(s)	3/15/2019
Filing and Priority Review	5/13/2019
Extension Letter	7/31/2019
PDUFA Goal Date	9/15/2019 (original); 12/15/2019 (new date after extension)
Division/Office	Division of Gastroenterology and Inborn Errors Products (DGIEP)
Review Completion Date	12/13/2019
Established/Proper Name	Cysteine Hydrochloride
(Proposed) Trade Name	Nouress
Pharmacologic Class	Sulfur-containing amino acid
Applicant	Avadel Legacy Pharmaceuticals LLC
Dosage form	Injection
Applicant proposed Dosing Regimen	50 mg/mL
Applicant Proposed Indication(s)/Population(s)	Use as an additive to amino acid (AA) solutions to meet the nutritional requirements of neonates requiring total parental nutrition (TPN)
Recommendation on Regulatory Action	Approval
Recommended Indication(s)/Population(s) (if applicable)	Use as an additive to AA solutions to meet nutritional requirements of neonates (preterm and term infants less than one month of age) requiring total parenteral nutrition
Recommended Dosing Regimen	50 mg/mL

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