

Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

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Product Details for NDA 210660

ELCYS (CYSTEINE HYDROCHLORIDE)_
500MG/10ML (50MG/ML)_
 Marketing Status: Prescription

Active Ingredient: CYSTEINE HYDROCHLORIDE
Proprietary Name: ELCYS
Dosage Form; Route of Administration: SOLUTION; INTRAVENOUS
Strength: 500MG/10ML (50MG/ML)
Reference Listed Drug: Yes
Reference Standard: Yes
TE Code:
Application Number: N210660
Product Number: 001
Approval Date: Apr 16, 2019
Applicant Holder Full Name: EXELA PHARMA SCIENCES LLC
Marketing Status: Prescription
Patent and Exclusivity Information (patent_info.cfm?
Product No=001&Appl No=210660&Appl type=N)

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Additional Information about Patents

- Patent information is published on or after the submission date as defined in 21 CFR 314.53(d)(5).
- Patent listings published prior to August 18, 2003, only identify method-of-use claims. The listed patents may include drug substance and/or drug product claims that are not indicated in the listing.
- As of December 5, 2016, an NDA holder submitting information on a patent that claims both the drug substance and the drug product (and is eligible for listing on either basis) is required only to specify that it claims either the drug substance or the drug product. Orange Book users should not rely on an Orange Book patent listing, regardless of when first published, to determine the range of patent claims that may be asserted by an NDA holder or patent owner.

Patent and Exclusivity for: N210660

Product 001
CYSTEINE HYDROCHLORIDE (ELCYS) SOLUTION 500MG/10ML (50MG/ML)

Patent Data

Product No	Patent No	Patent Expiration	Drug Substance	Drug Product	Patent Use Code	Delist Requested	Submission Date
001	10478453	01/15/2039		DP	U-2752		11/19/2019
001	10583155	01/15/2039		DP	U-2752		03/10/2020

Product No	Patent No	Patent Expiration	Drug Substance	Drug Product	Patent Use Code	Delist Requested	Submission Date
001	10653719	01/15/2039		DP			07/02/2020

Exclusivity Data

Product No	Exclusivity Code	Exclusivity Expiration
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