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Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

Patent and Exclusivity Search Results from query on Appl No 020622 Product 003 in the OB_Rx list.

Patent Data

| Appl No | Prod No | Patent No | Patent Expiration | Drug Substance Claim | Drug Product Claim | Patent Use Code | Delist Requested |
|-------------------------|---------|-----------|-------------------|----------------------|--------------------|-------------------------|------------------|
| N020622 | 003 | 8232250 | Aug 19, 2030 | | | U - 441 | |
| N020622 | 003 | 8399413 | Aug 19, 2030 | | | U - 441 | |

Exclusivity Data

| Appl No | Prod No | Exclusivity Code | Exclusivity Expiration |
|-------------------------|---------|--------------------|------------------------|
| N020622 | 003 | NP | Jan 28, 2017 |

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| | |
|---|-------------------------|
| Active Ingredient: | GLATIRAMER ACETATE |
| Dosage Form;Route: | INJECTABLE;SUBCUTANEOUS |
| Proprietary Name: | COPAXONE |
| Applicant: | TEVA PHARMS USA |
| Strength: | 20MG/ML |
| Application Number: | N020622 |
| Product Number: | 002 |
| Approval Date: | Feb 12, 2002 |
| Reference Listed Drug | Yes |
| RX/OTC/DISCN: | RX |
| TE Code: | |
| Patent and Exclusivity Info for this product: | View |

| | |
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| Active Ingredient: | GLATIRAMER ACETATE |
| Dosage Form;Route: | INJECTABLE;SUBCUTANEOUS |
| Proprietary Name: | COPAXONE |
| Applicant: | TEVA PHARMS USA |
| Strength: | 40MG/ML |
| Application Number: | N020622 |
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