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Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

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Patent and Exclusivity for: N202107

Product 001
MIFEPRISTONE (KORLYM) TABLET 300MG

Patent Data

| Product No | Patent No | Patent Expiration | Drug Substance | Drug Product | Patent Use Code | Patent Status |
|------------|-----------|-------------------|----------------|--------------|-----------------|---------------|
| 001 | 10006924 | 08/12/2036 | | | U-1643 | |
| 001 | 10151763 | 01/18/2037 | | | U-1643 | |
| 001 | 10166242 | 04/20/2036 | | | U-1643 | |

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|-----|----------|------------|------------------------|
| 001 | 10166243 | 04/20/2036 | U-1643 |
| 001 | 10195214 | 06/19/2037 | U-1643 |
| 001 | 10231983 | 08/22/2038 | U-1643 |
| 001 | 10314850 | 08/22/2038 | U-1643 |
| 001 | 8921348 | 08/27/2028 | U-1643 |
| 001 | 9829495 | 08/15/2036 | U-1643 |
| 001 | 9943526 | 04/20/2036 | U-1643 |

Exclusivity Data

| Product No | Exclusivity Code | Exclusivity Expiration |
|------------|------------------------|------------------------|
| 001 | ODE-22 | 02/17/2019 |

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Product Details for NDA 202107

KORLYM (MIFEPRISTONE)
300MG

Marketing Status: Prescription

Active Ingredient: MIFEPRISTONE

Proprietary Name: KORLYM

Dosage Form; Route of Administration: TABLET; ORAL

Strength: 300MG

Reference Listed Drug: Yes

Reference Standard: Yes

TE Code:

Application Number: N202107

Product Number: 001

Approval Date: Feb 17, 2012

Applicant Holder Full Name: CORCEPT THERAPEUTICS INC

Marketing Status: Prescription

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