U.S. Food and Drug Administration
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Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

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Product Details for NDA 203971

XOFIGO (RADIUM RA-223 DICHLORIDE)
162mCi/6ML (27mCi/ML) Marketing Status: Prescription

Active Ingredient: RADIUM RA-223 DICHLORIDE
Proprietary Name: XOFIGO
Dosage Form; Route of Administration: SOLUTION; INTRAVENOUS
Strength: 162mCi/6ML (27mCi/ML)
Reference Listed Drug: Yes
TE Code:
Application Number: N203971
Product Number: 001
Approval Date: May 15, 2013
Applicant Holder Full Name: BAYER HEALTHCARE PHARMACEUTICALS INC
Marketing Status: Prescription
Patent and Exclusivity Information (patent_info.cfm?Product_No=001&Appl_No=203971&Appl_type=N)