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New Drug Application (NDA): 020262

Company: HQ SPCLT PHARMA

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Products on NDA 020262

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| Drug Name | Active Ingredients | Strength | Dosage Form/Route | Marketing Status | TE Code | RLD | RS |
|-----------|--------------------|----------|----------------------|------------------|---------|-----|----|
| TAXOL | PACLITAXEL | 6MG/ML | INJECTABLE;INJECTION | Prescription | AP | Yes | No |

Showing 1 to 1 of 1 entries

Approval Date(s) and History, Letters, Labels, Reviews for NDA 020262

Original Approvals or Tentative Approvals

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| Action Date | Submission | Action Type | Submission Classification | Review Priority; Orphan Status | Letters, Reviews, Labels, Patient Package Insert | Notes |
|-------------|------------|-------------|-------------------------------|--------------------------------|--|--------------------------------------|
| 12/29/1992 | ORIG-1 | Approval | Type 1 - New Molecular Entity | PRIORITY; Orphan | | Label is not available on this site. |

Showing 1 to 1 of 1 entries

| Action Date | Submission | Supplement Categories or Approval Type | Letters, Reviews, Labels, Patient Package Insert |
|--------------------|-------------------|---|---|
| 03/03/2015 | SUPPL-51 | Labeling- Package Insert, Labeling- Container/Carton Labels | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/020262s051lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/020262Orig1s051) |
| 06/27/2014 | SUPPL-50 | Manufacturing (CMC) | |
| 05/02/2011 | SUPPL-49 | Labeling, Labeling- Package Insert | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/020262s049lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2011/020262s049ltr.pdf) |
| 08/13/2010 | SUPPL-48 | Labeling | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/020262s048lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2010/020262s048ltr.pdf) Review (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/020262Orig1s048.pdf) |
| 03/05/2003 | SUPPL-41 | Labeling | Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2003/20262sr041ltr.pdf) |
| 12/12/2002 | SUPPL-42 | Manufacturing (CMC)- Packaging | |
| 08/29/2002 | SUPPL-35 | Labeling | Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2002/20262sr035ltr.pdf) |
| 03/04/2002 | SUPPL-38 | Labeling | Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2002/20262s36s37s38ltr.pdf) Review (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2002/020262s036,037,038_T) |
| 03/04/2002 | SUPPL-37 | Labeling | Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2002/20262s36s37s38ltr.pdf) Review (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2002/020262s036,037,038_T) |
| 05/23/2001 | SUPPL-40 | Manufacturing (CMC)-Control | |

| Action Date | Submission | Supplement Categories or Approval Type | Letters, Reviews, Labels, Patient Package Insert |
|--------------------|-------------------|---|---|
| 04/10/2001 | SUPPL-39 | Manufacturing (CMC) | |
| 06/20/2000 | SUPPL-36 | Efficacy-New Dosing Regimen | Label (PDF) https://www.accessdata.fda.gov/drugsatfda_docs/label/2000/20262S36LBL.PDF Letter (PDF) https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2000/20262S36LTR.PD Review (PDF) https://www.accessdata.fda.gov/drugsatfda_docs/nda/2000/020262s036,037,038_T |
| 12/10/1999 | SUPPL-32 | Labeling | |
| 10/25/1999 | SUPPL-33 | Efficacy-New Indication | Label (PDF) https://www.accessdata.fda.gov/drugsatfda_docs/label/1999/20262S33LBL.PDF Letter (PDF) https://www.accessdata.fda.gov/drugsatfda_docs/appletter/1999/20262S33LTR.PD |
| 03/19/1999 | SUPPL-30 | Manufacturing (CMC)-Control | |
| 01/08/1999 | SUPPL-31 | Labeling | Review (PDF) https://www.accessdata.fda.gov/drugsatfda_docs/nda/99/20262S031_Taxol.pdf |
| 01/08/1999 | SUPPL-21 | Labeling | Review (PDF) https://www.accessdata.fda.gov/drugsatfda_docs/nda/99/20262S031_Taxol.pdf |
| 01/08/1999 | SUPPL-16 | Labeling | Review (PDF) https://www.accessdata.fda.gov/drugsatfda_docs/nda/99/20262S031_Taxol.pdf |
| 01/08/1999 | SUPPL-14 | Labeling | Review (PDF) https://www.accessdata.fda.gov/drugsatfda_docs/nda/99/20262S031_Taxol.pdf |
| 11/05/1998 | SUPPL-29 | Manufacturing (CMC) | |

| Action Date | Submission | Supplement Categories or Approval Type | Letters, Reviews, Labels, Patient Package Insert |
|-------------|------------|--|---|
| 06/30/1998 | SUPPL-24 | Efficacy-New Indication | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/1998/20262s24) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/1998/20262s24ltr.pdf) Review (https://www.accessdata.fda.gov/drugsatfda_docs/nda/98/20262s024.cfm) |
| 04/09/1998 | SUPPL-28 | Labeling | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/1998/20262slb) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/1998/20262sltr.pdf) Review (https://www.accessdata.fda.gov/drugsatfda_docs/nda/98/020262s026s027s028.cfm) |
| 04/09/1998 | SUPPL-27 | Labeling | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/1998/20262slb) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/1998/20262sltr.pdf) Review (https://www.accessdata.fda.gov/drugsatfda_docs/nda/98/020262s026s027s028.cfm) |
| 04/09/1998 | SUPPL-26 | Efficacy-New Indication | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/1998/20262slb) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/1998/20262sltr.pdf) Review (https://www.accessdata.fda.gov/drugsatfda_docs/nda/98/020262s026s027s028.cfm) |
| 04/01/1998 | SUPPL-23 | Manufacturing (CMC)-Control | |
| 12/19/1997 | SUPPL-25 | Manufacturing (CMC)-Control | |
| 09/18/1997 | SUPPL-18 | Manufacturing (CMC) | |
| 08/04/1997 | SUPPL-22 | Efficacy-New Indication | |
| 04/25/1997 | SUPPL-19 | Manufacturing (CMC) | |
| 03/05/1997 | SUPPL-17 | Manufacturing (CMC) | |

| Action Date | Submission | Supplement Categories or Approval Type | Letters, Reviews, Labels, Patient Package Insert |
|-------------|------------|--|--|
| 12/13/1996 | SUPPL-15 | Manufacturing (CMC)-Packaging | |
| 04/03/1996 | SUPPL-13 | Manufacturing (CMC)-Control | |
| 04/01/1996 | SUPPL-12 | Labeling | |
| 05/05/1995 | SUPPL-11 | Manufacturing (CMC)-Formulation | |
| 02/15/1995 | SUPPL-10 | Manufacturing (CMC)-Control | |
| 10/19/1994 | SUPPL-8 | Manufacturing (CMC) | |
| 07/22/1994 | SUPPL-9 | Manufacturing (CMC) | |
| 06/22/1994 | SUPPL-3 | Efficacy-New Dosing Regimen | |
| 04/21/1994 | SUPPL-7 | Manufacturing (CMC)-Control | |
| 04/13/1994 | SUPPL-4 | Efficacy-New Indication | |

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