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New Drug Application (NDA): 021303

Company: SHIRE

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- [Medication Guide](#)
(http://www.accessdata.fda.gov/drugsatfda_docs/label/2017/021303s032lbl.pdf#page=15)
- [Other Important Information from FDA](#)
(<http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm11441.htm>)

Products on NDA 021303 ▼

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Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	F

ADDERALL XR 5	AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE; DEXTROAMPHETAMINE SULFATE	1.25MG;1.25MG;1.25MG;1.25MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	AB	Yes	N
ADDERALL XR 30	AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE; DEXTROAMPHETAMINE SULFATE	7.5MG;7.5MG;7.5MG;7.5MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	AB	Yes	Y
ADDERALL XR 25	AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE; DEXTROAMPHETAMINE SULFATE	6.25MG;6.25MG;6.25MG;6.25MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	AB	Yes	N
ADDERALL XR 20	AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE; DEXTROAMPHETAMINE SULFATE	5MG;5MG;5MG;5MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	AB	Yes	N
ADDERALL XR 15	AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE; DEXTROAMPHETAMINE SULFATE	3.75MG;3.75MG;3.75MG;3.75MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	AB	Yes	N
ADDERALL XR 10	AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE; DEXTROAMPHETAMINE SULFATE	2.5MG;2.5MG;2.5MG;2.5MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	AB	Yes	N

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Approval Date(s) and History, Letters, Labels, Reviews for NDA 021303



Original Approvals or Tentative Approvals**CSVExcelPrint**

Action Date	Submission	Action Type	Submission Classification	Review Priority; Orphan Status	Letters, Reviews, Labels, Patient Package Insert
10/11/2001	ORIG-1	Approval	Type 3 - New Dosage Form	STANDARD	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2001/01112001.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appl/2001/01112001.pdf) Review (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2001/01112001.pdf)

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Supplements**CSVExcelPrint**

Action Date	Submission	Submission Classification	Letters, Reviews, Labels, Patient Package Insert
01/06/2017	SUPPL-32	Labeling- Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/01062017.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appl/2017/01062017.pdf)
04/17/2015	SUPPL-31	Labeling- Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/04172015.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appl/2015/04172015.pdf)
03/03/2015	SUPPL-28	Manufacturing (CMC)	
07/24/2014	SUPPL-27	Labeling- Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/07242014.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appl/2014/07242014.pdf)
12/03/2013	SUPPL-26	Labeling- Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/12032013.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appl/2013/12032013.pdf)
06/14/2013	SUPPL-24	Labeling- Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/06142013.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appl/2013/06142013.pdf)
03/08/2013	SUPPL-25	Labeling- Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/03082013.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appl/2013/03082013.pdf)
02/07/2012	SUPPL-23	Labeling- Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/02072012.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appl/2012/02072012.pdf)

Action Date	Submission	Submission Classification	Letters, Reviews, Labels, Patient Package Insert
11/12/2010	SUPPL-22	Labeling- Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/011522s01.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2010/011522s01.pdf)
11/12/2010	SUPPL-20	Labeling	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/011522s01.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2010/011522s01.pdf)
11/12/2008	SUPPL-19	Labeling	Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2008/021303s013LTR.pdf)
05/22/2007	SUPPL-15	Labeling	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2007/011522s01.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2007/011522s01.pdf)
07/26/2006	SUPPL-13	Labeling	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2006/011522s01.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2006/011522s01.pdf)
06/16/2006	SUPPL-10	Labeling	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2006/011522s01.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2006/011522s01.pdf)
07/21/2005	SUPPL-9	Efficacy-New Patient Population	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2005/011522s01.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2005/011522s01.pdf) Review (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2005/011522s01.pdf)
08/11/2004	SUPPL-5	Efficacy-New Patient Population	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2004/011522s01.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2004/011522s01.pdf) Review (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2004/011522s01.pdf)
09/13/2002	SUPPL-3	Manufacturing (CMC)-Control	
05/22/2002	SUPPL-1	Manufacturing (CMC)	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2002/021303s013LTR.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2002/021303s013LTR.pdf) Review (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2002/021303s013LTR.pdf)

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Labels for NDA 021303 **Therapeutic Equivalents for NDA 021303** 