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New Drug Application (NDA): 022332

Company: ELI LILLY CO

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Products on NDA 022332

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Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	RLD	TE Code
ADCIRCA	TADALAFIL	20MG	TABLET;ORAL	Prescription	Yes	None

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Approval Date(s) and History, Letters, Labels, Reviews for NDA 022332

Original Approvals or Tentative Approvals

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Action Date	Submission	Action Type	Submission Classification	Review Priority; Orphan Status	Letters, Reviews, Lab
05/22/2009	ORIG-1	Approval	Type 6 - New Indication (no longer used)	STANDARD	Label (PDF) (https://www.accessdata.fda.gov/) Letter (PDF) (https://www.accessdata.fda.gov/) Review (https://www.accessdata.fda.gov/drug/)

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Supplements**CSVExcelPrint**

Action Date	Submission	Submission Classification	Letters, Reviews, Labels, Patient Package Insert
05/05/2017	SUPPL-9	Labeling- Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/022332s0) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2017/022332s0)
04/02/2015	SUPPL-7	Labeling- Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/022332s0) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2015/022332s0)
04/29/2014	SUPPL-6	Labeling- Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/022332s0) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2014/022332s0)
11/20/2013	SUPPL-5	Labeling- Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/022332s0) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2013/022332s0)
02/08/2011	SUPPL-3	Labeling- Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/022332s0) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2011/022332s0)

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Labels for NDA 022332

