

Drugs@FDA: FDA Approved Drug Products

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t [TWEET \(HTTPS://TWITTER.COM/INTENT/TWEET/?TEXT=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=BASICSEARCH.PROCESS\)](https://twitter.com/intent/tweet?text=drugs@fda: fda approved drug products&url=https://www.accessdata.fda.gov/scripts/cder/daif/index.cfm?event=basicsearch.process)



e [EMAIL \(MAILTO:?SUBJECT=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&BODY=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=BASICSEARCH.PROCESS\)](mailto:?subject=drugs@fda: fda approved drug products&body=https://www.accessdata.fda.gov/scripts/cder/daif/index.cfm?event=basicsearch.process)

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Biologic License Application (BLA): 125104

Company: BIOGEN IDEC

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- [Medication Guide \(https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/125104s966lbl.pdf#page=30\)](https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/125104s966lbl.pdf#page=30)
- [Summary Review \(http://www.accessdata.fda.gov/drugsatfda_docs/label/2006/125104Orig1s015SumR.pdf\)](http://www.accessdata.fda.gov/drugsatfda_docs/label/2006/125104Orig1s015SumR.pdf)
- [REMS \(http://www.accessdata.fda.gov/scripts/cder/remis/index.cfm?event=IndvRemsDetails.page&REMS=63\)](http://www.accessdata.fda.gov/scripts/cder/remis/index.cfm?event=IndvRemsDetails.page&REMS=63)

Products on BLA 125104 ▼

CSV Excel Print

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	RS
TYSABRI	NATALIZUMAB	300MG	VIAL; SINGLE-USE	Prescription	None	No	No

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Approval Date(s) and History, Letters, Labels, Reviews for BLA 125104**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
11/23/2004	ORIG-1	Approval		N/A	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2004/008221Orig1s01.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/letter/2004/008221Orig1s01.pdf) Review (https://www.accessdata.fda.gov/drugsatfda_docs/review/2004/008221Orig1s01.pdf)

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Supplements

CSV	Excel	Print
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Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert
08/05/2019	SUPPL-966	Supplement	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/008221Orig1s02.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2019/008221Orig1s02.pdf)
01/04/2019	SUPPL-965	Supplement	
04/18/2018	SUPPL-963	Supplement	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/008221Orig1s01.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2018/008221Orig1s01.pdf)
04/18/2018	SUPPL-960	Supplement	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/008221Orig1s01.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2018/008221Orig1s01.pdf)

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert
08/16/2017	SUPPL-959	Supplement	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/08162017.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/08162017.pdf)
09/22/2016	SUPPL-958	Supplement	Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2016/09222016.pdf)
05/18/2016	SUPPL-955	Supplement	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/05182016.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2016/05182016.pdf)
05/18/2016	SUPPL-953	Supplement	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/05182016.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2016/05182016.pdf)
05/12/2015	SUPPL-950	Supplement	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/05122015.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/05122015.pdf)
12/15/2013	SUPPL-889	Supplement	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/12152013.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2013/12152013.pdf)
12/15/2013	SUPPL-847	Supplement	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/12152013.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2013/12152013.pdf)
12/15/2013	SUPPL-840	Supplement	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/12152013.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2013/12152013.pdf)
05/24/2013	SUPPL-813	Supplement	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/05242013.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2013/05242013.pdf)
01/20/2012	SUPPL-576	Supplement	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/01202012.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2012/01202012.pdf)

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert
10/07/2011	SUPPL-570	Supplement	Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/ap
09/16/2011	SUPPL-658	Supplement	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label
04/01/2011	SUPPL-475	Supplement	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label
04/01/2011	SUPPL-438	Supplement	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label
01/21/2010	SUPPL-283	Supplement	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label
01/21/2010	SUPPL-48	Supplement	
10/03/2008	SUPPL-98	Supplement	
10/03/2008	SUPPL-67	Supplement	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/ap
08/25/2008	SUPPL-106	Supplement	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/ap
08/12/2008	SUPPL-89	Supplement	
01/14/2008	SUPPL-33	Supplement	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/ap) Review (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label
06/05/2006	SUPPL-15	Supplement	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/ap) Summary Review (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2006/125

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Labels for BLA 125104

