

# Drugs@FDA: FDA-Approved Drugs

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Biologic License Application (BLA): 125431  
Company: GLAXOSMITHKLINE LLC

[EMAIL \(MAILTO: ?SUBJECT=DRUGS@FDA:FDA APPROVED DRUG PRODUCTS&BODY=HTTP://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=OVERVIEW.PROCESS%26VARAPPLNO=125431\)](mailto:?SUBJECT=DRUGS@FDA:FDA APPROVED DRUG PRODUCTS&BODY=HTTP://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=OVERVIEW.PROCESS%26VARAPPLNO=125431)

- [Medication Guide \(https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2017/125431s019lbl.pdf#page=36\)](https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/125431s019lbl.pdf#page=36)
- [REMS \(http://www.accessdata.fda.gov/scripts/cder/remis/index.cfm?event=IndvRemsDetails.page&REMS=316\)](http://www.accessdata.fda.gov/scripts/cder/remis/index.cfm?event=IndvRemsDetails.page&REMS=316)
- [Summary Review \(http://www.accessdata.fda.gov/drugsatfda\\_docs/nda/2014/125431Orig1s000SumR.pdf\)](http://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/125431Orig1s000SumR.pdf)

## Products on BLA 125431

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	RS
TANZEUM	ALBIGLUTIDE	30MG	INJECTABLE;INJECTION	Discontinued	None	No	No

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## Approval Date(s) and History, Letters, Labels, Reviews for BLA 125431

### Original Approvals or Tentative Approvals

Action Date	Submission	Action Type	Submission Classification	Review Priority; Orphan Status	Letters, Reviews, Labels, Patient Package Insert	Notes
04/15/2014	ORIG-1	Approval		N/A	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/125431s000lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/125431s000lbl.pdf)</a> <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2014/125431Orig1s000ltr.pdf">Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2014/125431Orig1s000ltr.pdf)</a> <a href="https://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/125431Orig1s000TOC.cfm">Review (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/125431Orig1s000TOC.cfm)</a> <a href="https://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/125431Orig1s000SumR.pdf">Summary Review (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/125431Orig1s000SumR.pdf)</a>	

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### Supplements

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
12/20/2017	SUPPL-20	Supplement	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/125431s020lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/125431s020lbl.pdf)</a> <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2017/125431Orig1s020ltr.pdf">Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2017/125431Orig1s020ltr.pdf)</a>	
12/12/2017	SUPPL-21	Supplement	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2017/125431Orig1s021ltr.pdf">Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2017/125431Orig1s021ltr.pdf)</a>	Label is not available on this site.
08/01/2017	SUPPL-19	Supplement	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/125431s019lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/125431s019lbl.pdf)</a> <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2017/125431Orig1s019ltr.pdf">Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2017/125431Orig1s019ltr.pdf)</a>	
09/13/2016	SUPPL-18	Supplement	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/125431s018lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/125431s018lbl.pdf)</a> <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2016/125431Orig1s018ltr.pdf">Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2016/125431Orig1s018ltr.pdf)</a>	
07/27/2015	SUPPL-14	Supplement	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2015/125431Orig1s014ltr.pdf">Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2015/125431Orig1s014ltr.pdf)</a>	Label is not available on this site.
05/07/2015	SUPPL-9	Supplement	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/125431s009lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/125431s009lbl.pdf)</a> <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2015/125431Orig1s009ltr.pdf">Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2015/125431Orig1s009ltr.pdf)</a>	

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
03/09/2015	SUPPL-8	Supplement	Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2015/125431Orig1s008ltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2015/125431Orig1s008ltr.pdf</a> )	Label is not available on this site.

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[Labels for BLA 125431](#)



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- [REMS \(http://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=316\)](http://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=316)
- [Summary Review \(http://www.accessdata.fda.gov/drugsatfda\\_docs/nda/2014/125431Orig1s000SumR.pdf\)](http://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/125431Orig1s000SumR.pdf)

Products on BLA 125431

Approval Date(s) and History, Letters, Labels, Reviews for BLA 125431

Labels for BLA 125431

CSV Excel Print

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
12/20/2017	SUPPL-20	Labeling-Package Insert	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/125431s020lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/125431s020lbl.pdf)</a>	
12/20/2017	SUPPL-20	Labeling-Medication Guide	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/125431s020lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/125431s020lbl.pdf)</a>	
08/01/2017	SUPPL-19	Labeling-Medication Guide	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/125431s019lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/125431s019lbl.pdf)</a>	
08/01/2017	SUPPL-19	Labeling-Package Insert	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/125431s019lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/125431s019lbl.pdf)</a>	
09/13/2016	SUPPL-18	Labeling-Package Insert	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/125431s018lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/125431s018lbl.pdf)</a>	
05/07/2015	SUPPL-9	Labeling-Package Insert	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/125431s009lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/125431s009lbl.pdf)</a>	
04/15/2014	ORIG-1	Approval	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/125431s000lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/125431s000lbl.pdf)</a>	

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