

Drugs@FDA: FDA-Approved Drugs

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Biologic License Application (BLA): 125469
 Company: ELI LILLY AND CO

EMAIL (MAILTO:?SUBJECT=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&BODY=HTTP://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=OVERVIEW.PROCESS%26VARAPLNO=125469)

- [Medication Guide \(https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/125469s051lbl.pdf#page=16\)](https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/125469s051lbl.pdf#page=16)
- [Summary Review \(http://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/125469Orig1s000SumR.pdf\)](http://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/125469Orig1s000SumR.pdf)

Products on BLA 125469

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| Drug Name | Active Ingredients | Strength | Dosage Form/Route | Marketing Status | TE Code | RLD | RS |
|-----------|--------------------|--------------|----------------------|------------------|---------|-----|----|
| TRULICITY | DULAGLUTIDE | 0.75MG/0.5ML | INJECTABLE;INJECTION | Prescription | None | No | No |
| TRULICITY | DULAGLUTIDE | 1.5MG/0.5ML | INJECTABLE;INJECTION | Prescription | None | TBD | No |

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Approval Date(s) and History, Letters, Labels, Reviews for BLA 125469

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 |
|-------------|------------|-------------|---------------------------|--------------------------------|---|-------|
| 09/18/2014 | ORIG-1 | Approval | | N/A | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/125469Orig1s000Lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2014/125469Orig1s000ltr.pdf) Review (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/125469Orig1s000TOC.cfm) Summary Review (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/125469Orig1s000SumR.pdf) | |

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Supplements

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| Action Date | Submission | Supplement Categories or Approval Type | Letters, Reviews, Labels, Patient Package Insert | Note |
|-------------|------------|--|---|------|
| 11/17/2022 | SUPPL-51 | Supplement | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/125469s051lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2022/125469Orig1s051ltr.pdf) | |
| 06/10/2022 | SUPPL-52 | Supplement | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/125469s046s052lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2022/125469Orig1s046_s052ltr.pdf) | |
| 06/10/2022 | SUPPL-46 | Supplement | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/125469s046s052lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2022/125469Orig1s046_s052ltr.pdf) | |
| 09/30/2021 | SUPPL-44 | Supplement | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/125469s044lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2021/125469Orig1s044ltr.pdf) | |
| 09/03/2020 | SUPPL-36 | Supplement | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/125469s036lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2020/125469Orig1s036ltr.pdf) | |
| 02/21/2020 | SUPPL-33 | Supplement | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/125469s033lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2020/125469Orig1s033ltr.pdf) | |
| 01/15/2019 | SUPPL-23 | Supplement | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/125469s023lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2019/125469Orig1s023ltr.pdf) | |

| Action Date | Submission | Supplement Categories or Approval Type | Letters, Reviews, Labels, Patient Package Insert | Note |
|-------------|------------|--|---|--------------------------------------|
| 09/21/2018 | SUPPL-24 | Supplement | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/125469s024lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2018/125469Orig1s024ltr.pdf) | |
| 06/29/2018 | SUPPL-17 | Supplement | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/125469s017lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2018/125469Orig1s017ltr.pdf) | |
| 12/12/2017 | SUPPL-21 | Supplement | Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2017/125469Orig1s021ltr.pdf) | Label is not available on this site. |
| 08/01/2017 | SUPPL-13 | Supplement | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/125469s011s013lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2017/125469Orig1s011_125469Orig1s013ltr.pdf) | |
| 08/01/2017 | SUPPL-11 | Supplement | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/125469s011s013lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2017/125469Orig1s011_125469Orig1s013ltr.pdf) | |
| 01/27/2017 | SUPPL-8 | Supplement | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/125469s007s008lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2017/125469Orig1s007_s008ltr.pdf) | |
| 01/27/2017 | SUPPL-7 | Supplement | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/125469s007s008lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2017/125469Orig1s007_s008ltr.pdf) | |
| 07/27/2015 | SUPPL-4 | Supplement | Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2015/125469Orig1s004ltr.pdf) | Label is not available on this site. |
| 03/09/2015 | SUPPL-1 | Supplement | Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2015/125469Orig1s001ltr.pdf) | Label is not available on this site. |
| 12/19/2014 | SUPPL-2 | Supplement | Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2014/125469Orig1s002ltr.pdf) | Label is not available on this site. |

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Labels for BLA 125469



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Products on BLA 125469 ▼

Approval Date(s) and History, Letters, Labels, Reviews for BLA 125469 ▼

Labels for BLA 125469 ▲

| <div style="display: flex; justify-content: space-between; align-items: center;"> CSV Excel Print </div> | | | | |
|---|------------|--|---|------|
| Action Date | Submission | Supplement Categories or Approval Type | Letters, Reviews, Labels, Patient Package Insert | Note |
| 11/17/2022 | SUPPL-51 | Efficacy-New Patient Population | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/125469s051lbl.pdf) | |
| 06/10/2022 | SUPPL-52 | Labeling-Package Insert | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/125469s046s052lbl.pdf) | |
| 06/10/2022 | SUPPL-52 | Labeling-Medication Guide | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/125469s046s052lbl.pdf) | |
| 06/10/2022 | SUPPL-46 | Labeling-Package Insert | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/125469s046s052lbl.pdf) | |
| 09/30/2021 | SUPPL-44 | Labeling-Package Insert | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/125469s044lbl.pdf) | |
| 09/03/2020 | SUPPL-36 | Efficacy-New Dosing Regimen | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/125469s036lbl.pdf) | |
| 02/21/2020 | SUPPL-33 | Efficacy-New Indication | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/125469s033lbl.pdf) | |
| 01/15/2019 | SUPPL-23 | Efficacy-Labeling Change With Clinical Data | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/125469s023lbl.pdf) | |
| 09/21/2018 | SUPPL-24 | Labeling-Package Insert | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/125469s024lbl.pdf) | |
| 06/29/2018 | SUPPL-17 | Efficacy-Accelerated Approval Confirmatory Study | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/125469s017lbl.pdf) | |
| 08/01/2017 | SUPPL-13 | Labeling-Medication Guide | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/125469s011s013lbl.pdf) | |
| 08/01/2017 | SUPPL-11 | Labeling-Package Insert | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/125469s011s013lbl.pdf) | |
| 01/27/2017 | SUPPL-8 | Efficacy-Labeling Change With Clinical Data | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/125469s007s008lbl.pdf) | |
| 01/27/2017 | SUPPL-7 | Efficacy-New Indication | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/125469s007s008lbl.pdf) | |
| 09/18/2014 | ORIG-1 | Approval | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/125469Orig1s000Lbl.pdf) | |

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