

Drugs@FDA: FDA-Approved Drugs

[Home \(index.cfm\)](#) | [Previous Page](#)

New Drug Application (NDA): 021773
Company: ASTRAZENECA AB

EMAIL (MAILTO:?SUBJECT=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&BODY=HTTP://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=OVERVIEW.PROCESS%26VARAPPLNO=021773)

- [Medication Guide \(https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/021773s048lbl.pdf#page=33\)](https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/021773s048lbl.pdf#page=33)
- [Other Important Information from FDA \(http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm113705.htm\)](http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm113705.htm)

Products on NDA 021773

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| Drug Name | Active Ingredients | Strength | Dosage Form/Route | Marketing Status | TE Code | RLD | RS |
|-----------|---------------------|--------------------------|-------------------------|------------------|---------|-----|-----|
| BYETTA | EXENATIDE SYNTHETIC | 300MCG/1.2ML (250MCG/ML) | INJECTABLE;SUBCUTANEOUS | Prescription | None | Yes | Yes |
| BYETTA | EXENATIDE SYNTHETIC | 600MCG/2.4ML (250MCG/ML) | INJECTABLE;SUBCUTANEOUS | Prescription | None | Yes | Yes |

Showing 1 to 2 of 2 entries

Approval Date(s) and History, Letters, Labels, Reviews for NDA 021773

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 |
|-------------|------------|-------------|-------------------------------|--------------------------------|---|-------|
| 04/28/2005 | ORIG-1 | Approval | Type 1 - New Molecular Entity | STANDARD | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2005/021773lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2005/021773ltr.pdf) Review (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2005/021773_ByettaTOC.cfm) | |

Showing 1 to 1 of 1 entries

Supplements

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| Action Date | Submission | Supplement Categories or Approval Type | Letters, Reviews, Labels, Patient Package Insert | Note |
|-------------|------------|---|---|------|
| 12/21/2022 | SUPPL-48 | Labeling-Package Insert | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/021773s048lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2022/021773orig1s048ltr.pdf) | |
| 06/10/2022 | SUPPL-47 | Labeling-Package Insert | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/021773orig1s046s047lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2022/021773orig1s046_s047ltr.pdf) | |
| 06/10/2022 | SUPPL-46 | Labeling-Container/Carton Labels | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/021773orig1s046s047lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2022/021773orig1s046_s047ltr.pdf) | |
| 11/04/2021 | SUPPL-45 | Efficacy-Labeling Change With Clinical Data | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/021773s045lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2021/021773orig1s045ltr.pdf) | |
| 06/17/2021 | SUPPL-44 | Labeling-Package Insert | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/021773s044lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2021/021773orig1s044ltr.pdf) | |
| 02/28/2020 | SUPPL-43 | Labeling-Package Insert | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/021773s043lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2020/021773orig1s043ltr.pdf) | |

| Action Date | Submission | Supplement Categories or Approval Type | Letters, Reviews, Labels, Patient Package Insert | Note |
|-------------|------------|---|---|--------------------------------------|
| 12/20/2018 | SUPPL-41 | Labeling-Package Insert | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/021773s041lbl.pdf) | |
| 02/25/2015 | SUPPL-40 | Labeling-Container/Carton Labels, Labeling-Package Insert | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/021773s040lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2015/021773Orig1s040ltr.pdf) | |
| 11/24/2014 | SUPPL-36 | Efficacy-Labeling Change With Clinical Data | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/021773s036lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2014/021773Orig1s036ltr.pdf) | |
| 08/12/2014 | SUPPL-39 | Manufacturing (CMC) | | Label is not available on this site. |
| 06/04/2014 | SUPPL-38 | Manufacturing (CMC) | | Label is not available on this site. |
| 06/04/2014 | SUPPL-37 | Manufacturing (CMC) | | Label is not available on this site. |
| 04/23/2014 | SUPPL-35 | Manufacturing (CMC) | | Label is not available on this site. |
| 01/30/2014 | SUPPL-34 | Manufacturing (CMC) | | Label is not available on this site. |
| 10/19/2011 | SUPPL-30 | Efficacy-Labeling Change With Clinical Data | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/021773s029s030lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2011/021773s029_s030ltr.pdf) | |
| 10/19/2011 | SUPPL-29 | Efficacy-Labeling Change With Clinical Data | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/021773s029s030lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2011/021773s029_s030ltr.pdf) | |
| 08/05/2011 | SUPPL-31 | REMS-Assessment | Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2011/021773s031ltr.pdf) | Label is not available on this site. |
| 11/12/2010 | SUPPL-28 | Labeling | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/021773s028lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2010/021773s028ltr.pdf) | |
| 08/13/2010 | SUPPL-26 | Labeling-Container/Carton Labels | Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2010/021773s026ltr.pdf) | Label is not available on this site. |
| 10/30/2009 | SUPPL-25 | REMS-Proposal | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/021773s9s11s18s22s25lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2009/021773s009s011s017s018s022s025021919ltr.pdf) | |
| 10/30/2009 | SUPPL-22 | Labeling | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/021773s9s11s18s22s25lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2009/021773s009s011s017s018s022s025021919ltr.pdf) | |
| 10/30/2009 | SUPPL-18 | Labeling | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/021773s9s11s18s22s25lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2009/021773s009s011s017s018s022s025021919ltr.pdf) | |
| 10/30/2009 | SUPPL-17 | Labeling | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/021773s9s11s18s22s25lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2009/021773s009s011s017s018s022s025021919ltr.pdf) | |

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|-------------|------------|---|---|------|
| 10/30/2009 | SUPPL-11 | Labeling | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/021773s9s11s18s22s25lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2009/021773s009s011s017s018s022s025021919ltr.pdf) | |
| 10/30/2009 | SUPPL-9 | Labeling | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/021773s9s11s18s22s25lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2009/021773s009s011s017s018s022s025021919ltr.pdf) | |
| 06/17/2008 | SUPPL-10 | Labeling | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/021773s010lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2008/021773s010ltr.pdf) | |
| 01/11/2008 | SUPPL-12 | Labeling | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/021773s012lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2008/021773s012ltr.pdf) | |
| 02/10/2007 | SUPPL-7 | Labeling-Package Insert, Labeling-Container/Carton Labels | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2007/021773s007lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2007/021773s007ltr.pdf) | |
| 12/22/2006 | SUPPL-6 | Labeling | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2006/021773s022s006lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2006/021773s002, s006ltr.pdf) | |
| 12/22/2006 | SUPPL-2 | Efficacy-New Indication | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2006/021773s022s006lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2006/021773s002, s006ltr.pdf) | |
| 11/01/2006 | SUPPL-5 | Labeling | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2006/021773s005lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2006/021773s005ltr.pdf) | |
| 10/12/2006 | SUPPL-4 | Labeling | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2006/021773s004lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2006/021773s004LTR.pdf) | |

Showing 1 to 32 of 32 entries

[Labels for NDA 021773](#)



Drugs@FDA: FDA-Approved Drugs

[Home \(index.cfm\)](#) | [Previous Page](#)

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- [Medication Guide \(https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/021773s048lbl.pdf#page=33\)](https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/021773s048lbl.pdf#page=33)
- [Other Important Information from FDA \(http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm113705.htm\)](http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm113705.htm)

Products on NDA 021773 ▼

Approval Date(s) and History, Letters, Labels, Reviews for NDA 021773 ▼

Labels for NDA 021773 ▲

| CSV | Excel | Print | | | |
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| 12/21/2022 | SUPPL-48 | Labeling-Package Insert | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/021773s048lbl.pdf) | | |
| 06/10/2022 | SUPPL-47 | Labeling-Package Insert | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/021773orig1s046s047lbl.pdf) | | |
| 06/10/2022 | SUPPL-46 | Labeling-Container/Carton Labels | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/021773orig1s046s047lbl.pdf) | | |
| 11/04/2021 | SUPPL-45 | Efficacy-Labeling Change With Clinical Data | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/021773s045lbl.pdf) | | |
| 06/17/2021 | SUPPL-44 | Labeling-Package Insert | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/021773s044lbl.pdf) | | |
| 02/28/2020 | SUPPL-43 | Labeling-Package Insert | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/021773s043lbl.pdf) | | |
| 12/20/2018 | SUPPL-41 | Labeling-Package Insert | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/021773s041lbl.pdf) | | |
| 02/25/2015 | SUPPL-40 | Labeling-Container/Carton Labels | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/021773s040lbl.pdf) | | |
| 02/25/2015 | SUPPL-40 | Labeling-Package Insert | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/021773s040lbl.pdf) | | |
| 11/24/2014 | SUPPL-36 | Efficacy-Labeling Change With Clinical Data | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/021773s036lbl.pdf) | | |
| 10/19/2011 | SUPPL-30 | Efficacy-Labeling Change With Clinical Data | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/021773s029s030lbl.pdf) | | |
| 10/19/2011 | SUPPL-29 | Efficacy-Labeling Change With Clinical Data | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/021773s029s030lbl.pdf) | | |
| 11/12/2010 | SUPPL-28 | Labeling | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/021773s028lbl.pdf) | | |
| 10/30/2009 | SUPPL-25 | REMS-Proposal | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/021773s9s11s18s22s25lbl.pdf) | | |
| 10/30/2009 | SUPPL-22 | Labeling | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/021773s9s11s18s22s25lbl.pdf) | | |

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| 10/30/2009 | SUPPL-18 | Labeling | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/021773s9s11s18s22s25lbl.pdf) | |
| 10/30/2009 | SUPPL-17 | Labeling | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/021773s9s11s18s22s25lbl.pdf) | |
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| 10/30/2009 | SUPPL-9 | Labeling | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/021773s9s11s18s22s25lbl.pdf) | |
| 06/17/2008 | SUPPL-10 | Labeling | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/021773s010lbl.pdf) | |
| 01/11/2008 | SUPPL-12 | Labeling | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/021773s012lbl.pdf) | |
| 02/10/2007 | SUPPL-7 | Labeling-Package Insert | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2007/021773s007lbl.pdf) | |
| 02/10/2007 | SUPPL-7 | Labeling-Container/Carton Labels | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2007/021773s007lbl.pdf) | |
| 12/22/2006 | SUPPL-6 | Labeling | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2006/021773s022s006lbl.pdf) | |
| 12/22/2006 | SUPPL-2 | Efficacy-New Indication | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2006/021773s022s006lbl.pdf) | |
| 11/01/2006 | SUPPL-5 | Labeling | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2006/021773s005lbl.pdf) | |
| 10/12/2006 | SUPPL-4 | Labeling | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2006/021773s004lbl.pdf) | |
| 04/28/2005 | ORIG-1 | Approval | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2005/021773lbl.pdf) | |

Showing 1 to 28 of 28 entries