

Appendix 2. Drug-Specific Citations

Databases

Drugs@FDA: US Food and Drug Administration. Drugs@FDA: FDA-Approved Drugs. FDA. Accessed January 7, 2021. <https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm>

PMC: FDA/Center for Drug Evaluation and Research, Office of New Drugs. Postmarket Requirements and Commitments. FDA. Updated October 29, 2020. Accessed January 7, 2021.

<https://www.accessdata.fda.gov/scripts/cder/pmc/index.cfm>

Bezlotoxumab (Zinplava)

Label: Zinplava. Prescribing information. Merck Sharp & Dohme Corp.; 2016. Accessed January 7, 2021.

https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/761046s000lbl.pdf

Summary Review: US Food and Drug Administration, Center for Drug Evaluation and Research. Division Director Summary Review; BLA 761046, Bezloxtumab for injection. CDER; 2016. Accessed January 7, 2021. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/761046Orig1s000SumR.pdf

Risk Assessment and Risk Mitigation Review(s): US Food and Drug Administration, Center for Drug Evaluation and Research. Vision of Risk Management Review, Evaluation to determine if a REMS is necessary. CDER; 2016. Accessed January 7, 2021.

https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/761046Orig1s000RiskR.pdf

Medical Review: US Food and Drug Administration, Center for Drug Evaluation and Research. Clinical Review; BLA 761046, Bezlotoxumab. CDER; 2016. Accessed January 7, 2021.

https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/761046Orig1s000MedR.pdf

AdisInsight: Bezlotoxumab – Merck & Co. AdisInsight Drugs. Updated July 12, 2020. Accessed January 7, 2021. <https://adisinsight.springer.com/drugs/800044552>

Delafloxacin (Baxdela)

Label: Baxdela. Prescribing information. Melinta Therapeutics, Inc.; 2017. Accessed January 7, 2021.

https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/208610s000,208611s000lbl.pdf

Summary Review: US Food and Drug Administration, Center for Drug Evaluation and Research. Division Director Summary Review; NDAs 208610 and 208611, Baxdela (delafloxacin). CDER; 2017. Accessed January 7, 2021.

https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/208610Orig1s000,208611Orig1s000SumR.pdf

Clinical Review: US Food and Drug Administration, Center for Drug Evaluation and Research. Clinical Review; NDA 208610 and NDA 208611, BAXDELA (delafloxacin meglumine). CDER; 2016. Accessed January 7, 2021.

https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/208610Orig1s000,208611Orig1s000MedR.pdf

AdisInsight: Delafloxacin – Melinta Therapeutics/Wakunaga Pharmaceutical. AdisInsight Drugs. Updated November 20, 2020. Accessed January 7, 2021. <https://adisinsight.springer.com/drugs/800009417>

Meropenem-vaborbactam (Vabomere)

Label: Vabomere. Prescribing information. The Medicines Company; 2017. Accessed January 7, 2021.

https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/209776lbl.pdf

Summary Review. US Food and Drug Administration, Center for Drug Evaluation and Research. Combined Cross-Discipline Team Leader, Division Director, and Office Director Summary Review; NDA 209776 Vabomere (meropenem-vaborbactam). CDER; 2017. Accessed January 7, 2021.

https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/209776Orig1s000SumR.pdf

Clinical Review: US Food and Drug Administration, Center for Drug Evaluation and Research. Clinical Review; NDA 209776 (Meropenem-vaborbactam). CDER; 2017. Accessed January 7, 2017.

https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/209776Orig1s000MedR.pdf

AdisInsight: Meropenem/vaborbactam – Melinta Therapeutics. AdisInsight Drugs. Updated July 8, 2020. Accessed January 7, 2021. <https://adisinsight.springer.com/drugs/800039513>

Secnidazole (Solosec)

Label: Solosec. Prescribing information. Symbiomix Therapeutics LLC; 2017. Accessed January 7, 2021.

https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/209363s000lbl.pdf

Summary Review: US Food and Drug Administration, Center for Drug Evaluation and Research. NDA 209363I; Combined Cross-Discipline Team Leader, Division Director, and Deputy Office Director Summary Review. CDER; 2017. Accessed January 7, 2021.

https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/209363Orig1s000SumR.pdf

Clinical Review: US Food and Drug Administration, Center for Drug Evaluation and Research. Clinical Review; NDA 209363, SYM 1219 (secnidazole). CDER; 2017. Accessed January 7, 2021.

https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/209363Orig1s000MedR.pdf

AdisInsight: Secnidazole – Lupin. AdisInsight Drugs. Updated November 19, 2020. Accessed January 7, 2021. <https://adisinsight.springer.com/drugs/800040719>

Ozenoxacin (Xepi)

Label: Xepi. Prescribing information. Medimetriks Pharmaceuticals, Inc.; 2017. Accessed January 7, 2021.

https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/208945lbl.pdf

Summary Review: US Food and Drug Administration, Center for Drug Evaluation and Research. NDA 208945: Cross-Discipline Team Leader, Division Director and Deputy Office Director Summary Review for Regulatory Action. CDER; 2017. Accessed January 7, 2021.

https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/208945Orig1s000SumR.pdf

Risk Assessment and Risk Mitigation Review(s): US Food and Drug Administration, Center for Drug Evaluation and Research. Division of Risk Management Review, Addendum to DRISK Review to determine if a REMS is necessary, dated February 23, 2017. CDER; 2017. Accessed January 7, 2021.

https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/208945Orig1s000RiskR.pdf

Clinical Review: US Food and Drug Administration, Center for Drug Evaluation and Research. Clinical Review; NDA 208945, Ozenoxacin cream 1%. CDER; 2017. Accessed January 7, 2021.

AdisInsight: Ozenoxacin – Ferrer/Maruho. AdisInsight Drugs. Updated April 16, 2019. Accessed January 7, 2021. <https://adisinsight.springer.com/drugs/800016781>

Plazomicin (Zemdri)

Label: Zemdri. Prescribing information. Achaogen, Inc.; 2018. Accessed January 7, 2021.

https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/210303Orig1s000lbl.pdf

Summary Review: US Food and Drug Administration, Center for Drug Evaluation and Research. NDA 210303, Plazomicin for injection; Cross-Discipline Team Leader, Division Director and Office Director Summary Review for Regulatory Action. CDER; 2018.

Risk Assessment and Risk Mitigation Review(s): US Food and Drug Administration, Center for Drug Evaluation and Research. Division of Risk Management Review, Evaluation of Need for a REMS. CDER; 2018. Accessed January 7, 2021.

https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/210303Orig1s000RiskR.pdf

AdisInsight: Plazomicin – Cipla. AdisInsight Drugs. Updated July 7, 2020. Accessed January 7, 2021.

<https://adisinsight.springer.com/drugs/800029572>

Eravacycline (Xerava)

Label: Xerava. Prescribing information. Tetrphase Pharmaceuticals, Inc.; 2018. Accessed January 7, 2021.

https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/211109lbl.pdf

Multi-Disciplinary Review: US Food and Drug Administration, Center for Drug Evaluation and Research. NDA Multi-Disciplinary Review and Evaluation – NDA 211109: XERAVA (eravacycline) for injection. CDER; 2018. Accessed January 7, 2021.

https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/211109Orig1s000MultidisciplineR.pdf

AdisInsight: Eravacycline – Tetrphase Pharmaceuticals. AdisInsight Drugs. Updated August 31, 2020.

Accessed January 7, 2021. <https://adisinsight.springer.com/drugs/800032231>

Amikacin sulfate (Arikayce)

Label: Arikayce. Prescribing information. Insmmed Incorporated; 2018. Accessed January 7, 2021.

https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/207356s000lbl.pdf

Multi-Disciplinary Review: US Food and Drug Administration, Center for Drug Evaluation and Research. NDA Multi-Disciplinary Review and Evaluation – NDA 207356. CDER; 2018. Accessed January 7, 2021.

https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/207356Orig1s000MultidisciplineR.pdf

AdisInsight: Amikacin liposomal inhaled – Insmmed. AdisInsight Drugs. Updated January 5, 2021. Accessed January 7, 2021. <https://adisinsight.springer.com/drugs/800021086>

Omadacycline (Nuzyra)

Label: Nuzyra. Prescribing information. Paratek Pharmaceuticals, Inc.; 2018. Accessed January 7, 2021.

https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/209816_209817lbl.pdf

Multi-Disciplinary Review: US Food and Drug Administration, Center for Drug Evaluation and Research. NDA Multi-Disciplinary Review and Evaluation – NDAs 209816 and 209817. CDER; 2018. Accessed January 7, 2021.

https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/209816Orig1s000,209817Orig1s000MultidisciplineR.pdf

AdisInsight: Omadacycline – Paratek Pharmaceuticals. AdisInsight Drugs. Updated December 11, 2020. Accessed January 7, 2021. <https://adisinsight.springer.com/drugs/800017923>

Rifamycin (Aemcolo)

Label: Aemcolo. Prescribing information. Cosmo Technologies, Ltd.; 2018. Accessed January 7, 2021.

https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/210910s000lbl.pdf

Multi-Disciplinary Review: US Food and Drug Administration, Center for Drug Evaluation and Research. NDA Multi-disciplinary Review and Evaluation – NDA 210910. CDER; 2018. Accessed January 7, 2021. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/210910Orig1s000MultidisciplineR.pdf
AdisInsight: Rifamycin controlled-release – Cosmo/Dr Falk Pharma/Salix. AdisInsight Drugs. Updated December 12, 2020. Accessed January 7, 2021. <https://adisinsight.springer.com/drugs/800026559>

Imipenem-cilastatin-relebactam (Recarbrio)

Label: Recarbrio. Prescribing information. Merck Sharp and Dohme Corp.; 2019. Accessed January 7, 2021. https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/212819s000lbl.pdf
Multi-Disciplinary Review: US Food and Drug Administration, Center for Drug Evaluation and Research. NDA Multi-disciplinary Review and Evaluation (NDA 212819): RECARBRIO (imipenem/cilastatin/relebactam for injection). CDER; 2018. Accessed January 7, 2021. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2019/212819Orig1s000MultidisciplineR.pdf
AdisInsight: Cilastatin/imipenem/relebactam – Merck Sharp and Dohme. AdisInsight Drugs. Updated December 14, 2020. Accessed January 7, 2021. <https://adisinsight.springer.com/drugs/800042881>

Pretomanid (Pretomanid)

Label: Pretomanid. Prescribing information. Mylan Laboratories, Ltd.; 2019. Accessed January 7, 2021. https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/212862s000lbl.pdf
Multi-Disciplinary Review: US Food and Drug Administration, Center for Drug Evaluation and Research. NDA Multi-disciplinary Review and Evaluation – NDA 212862. CDER; 2016. Accessed January 7, 2021. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2019/212862Orig1s000MultidisciplineR.pdf
AdisInsight: Pretomanid – Global Alliance for TB Drug Development/Novartis. AdisInsight Drugs. Updated December 17, 2020. Accessed January 7, 2021. <https://adisinsight.springer.com/drugs/800007841>

Lefamulin (Xenleta)

Label: Xenleta. Prescribing information. Nabriva Therapeutics, Inc.; 2019. Accessed January 7, 2021. https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/211672s000,211673s000lbl.pdf
Multi-Disciplinary Review: US Food and Drug Administration, Center for Drug Evaluation and Research. NDA/BLA Multi-disciplinary Review and Evaluation NDA 211672 and NDA 21167: XENLETA (Lefamulin injection and tablets). CDER; 2018. Accessed January 7, 2021. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2019/211672Orig1s000,%20211673Orig1s000MultidisciplineR.pdf
AdisInsight: Lefamulin – Nabriva Therapeutics. AdisInsight Drugs. Updated September 2, 2020. Accessed January 7, 2021. <https://adisinsight.springer.com/drugs/800031605>

Omeprazole magnesium-amoxicillin-rifabutin (Talcia)

Label: Talcia. Prescribing information. RedHill Biopharma Inc; 2019. Accessed January 7, 2021. https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/213004lbl.pdf
Multi-Disciplinary Review: US Food and Drug Administration, Center for Drug Evaluation and Research. Multi-Disciplinary Review and Evaluation NDA 213004: TALICIA (rifabutin, amoxicillin, omeprazole). CDER; 2019. Accessed January 7, 2021. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2019/213004Orig1s000MultidisciplineR.pdf

AdisInsight: Amoxicillin/omeprazole/rifabutin - RedHill Biopharma. *AdisInsight* Drugs. Updated August 1, 2020. Accessed January 7, 2021. <https://adisinsight.springer.com/drugs/800026964>

Cefiderocol (Fetroja)

Label: Fetroja. Prescribing information. Shionogi Inc.; 2019. Accessed January 7, 2021.

https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/209445s000lbl.pdf

Multi-Disciplinary Review: US Food and Drug Administration, Center for Drug Evaluation and Research.

Multi-Disciplinary Review and Evaluation NDA 209445: FETROJA (cefiderocol) for Injection. CDER; 2019.

Accessed January 7, 2021.

https://www.accessdata.fda.gov/drugsatfda_docs/nda/2019/209445Orig1s000MultidisciplineR.pdf

AdisInsight: Cefiderocol – Shinogi. *AdisInsight* Drugs. Updated January 6, 2021. Accessed January 7, 2021.

<https://adisinsight.springer.com/drugs/800036159>