Withdrawn CDER Product-Specific Guidances

Updated August 28, 2026

Active Ingredient	Route and Dosage Form	RLD	Date PSG Posted	Date PSG Withdrawn	Reason for PSG Withdrawal
Infigratinib phosphate	Oral Capsule	214622	February 2023	August 2026	NDA approval withdrawn under 21 CFR 314.150(d)
Mesalamine	Oral Tablets, Delayed-Release	019651	October 2016	August 2026	NDA approval withdrawn under 21 CFR 314.150(d)
Obeticholic acid	Oral Tablet	207999	October 2024	August 2026	NDA approval withdrawn under 21 CFR 314.150(d)
Olaparib	Oral Capsule	206162	October 2017	August 2026	NDA approval withdrawn under 21 CFR 314.150(d)
Panobinostat	Oral Capsule	205353	October 2024	August 2026	NDA approval withdrawn under 21 CFR 314.150(d)
Sodium phenylbutyrate; Taurursodiol	Oral Suspension	216660	October 2024	August 2026	NDA approval withdrawn under 21 CFR 314.150(d)
Tazemetostat hydrobromide	Oral Tablet	211723	August 2021	August 2026	NDA approval withdrawn under 21 CFR 314.150(d)
Mobocertinib succinate	Oral Capsule	215310	August 2023	August 2024	NDA approval withdrawn under 21 CFR 314.150(d)
Oxymorphone hydrochloride	Oral Tablet, Extended-Release	201655	October 2016	July 2024	NDA approval withdrawn under 21 CFR 314.150(d)
Melphalan flufenamide hydrochloride	Intravenous Powder	214383	November 2022	April 2024	NDA approval withdrawn under section 506(c)(3) of the Food, Drug, and Cosmetic Act (21 U.S.C. 365(c)(3))
Hydroxyprogesterone caproate	Subcutaneous Solution	021945	September 2019	April 2023	NDA approval withdrawn under section 506(c)(3) of the Food, Drug, and Cosmetic Act (21 U.S.C. 356(c)(3)) and 21 CFR 314.530(a)

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Niacin; Lovastatin	Oral Tablet, Extended-Release	021249	July 2009	May 2021	NDA approval withdrawn and determined to be withdrawn from sale for reasons of safety or effectiveness under 21 CFR 314.161
Niacin; Simvastatin	Oral Tablet, Extended-Release	022078	October 2011	May 2021	NDA approval withdrawn and determined to be withdrawn from sale for reasons of safety or effectiveness under 21 CFR 314.161
Lorcaserin hydrochloride	Oral Tablet, Extended-Release	022529	March 2015	March 2021	NDA approval withdrawn under 21 CFR 314.150(d) and determined to be withdrawn from sale for reasons of safety or effectiveness under 21 CFR 314.161.
Lorcaserin hydrochloride	Oral Tablet, Extended-Release	208524	May 2017	March 2021	NDA approval withdrawn under 21 CFR 314.150(d) and determined to be withdrawn from sale for reasons of safety or effectiveness under 21 CFR 314.161.
Butenafine hydrochloride	Topical Cream	021408	March 2012	February 2015	Contained studies that are no longer recommended (NDA never marketed)