



February 20, 2026

Notice Regarding 340B Ceiling Price Restatement and Offer of Refunds to 340B Covered Entities

Idorsia Pharmaceuticals US, Inc. (“Idorsia”) recently restated the Best Price (BP) for the third quarter of 2025 (Q3-2025). This restatement resulted in 340B Ceiling Prices for QUVIVIQ® (daridorexant) that were higher than the correct statutory ceiling prices for sales during the period of January 1, 2026 through January 29, 2026 (“Affected Period”). As a result of the restatement, Idorsia has determined that (pursuant to 42 U.S.C. § 256b(d)(1)(B)(ii) and 42 C.F.R. § 10.11(b)(4)), a refund is due to any 340B Covered Entity that purchased the below NDCs during the Affected Period.

Corrective Action Taken: Idorsia reported the corrected Q3-2025 pricing data to the Centers for Medicare & Medicaid Services (CMS) via the Medicaid Drug Portal (MDP). The 340B Ceiling Prices were updated in Idorsia’s systems on January 30, 2026, to reflect the accurate corrected pricing. The table below identifies the NDCs that are subject to a refund.

Affected Period	Product Description	NDC-11
01/01/2026 – 01/29/2026	QUVIVIQ (daridorexant) 25mg Tablets (30ct)	80491-7825-03
01/01/2026 – 01/29/2026	QUVIVIQ (daridorexant) 50mg Tablets (30ct)	80491-7850-03

Refund Process: Idorsia has partnered with its third-party logistics provider, Prasco, to identify and resolve overcharged amounts. Prasco has used wholesaler chargeback records to calculate refunds and has completed a credit rebill process for all affected 340B purchases made during the Affected Period. Credits have been issued through each Covered Entity’s wholesaler.

Idorsia has asked the Health Resources and Services Administration (HRSA) to post this Notice on the HRSA public website <https://www.hrsa.gov/opa/manufacturing-notices> to ensure transparency to all 340B Covered Entities regarding the Ceiling Price restatement and the status of repayments to Covered Entity that purchased the above NDCs during the Affected Period. Covered Entities that believe they may be entitled to a refund but have not received a credit, or who have questions about the above-referenced restatement, are invited to contact Idorsia via email at trade-distribution.us@idorsia.com, with a reference to the applicable NDC and time period.

Idorsia is committed to 340B Program integrity and has conducted a thorough internal review of its reporting procedures. Enhanced validation controls have been implemented to prevent a recurrence of this error.