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August 10, 2023

## **Notice Regarding Offer of Refunds to 340B Covered Entities**

Meitheal Pharmaceuticals, Inc. ("Meitheal") has recently recalculated 340B Ceiling Prices for the NDCs referenced below for the period of **January 1, 2018 (1Q2018) through December 31, 2022 (4Q2022)** (the "Refund Period"). As a result of the recalculated 340B Ceiling Prices, Meitheal 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 or may be owed to 340B Covered Entities that purchased any of the products, set out by NDC below, during the Refund Period.

The table below identifies the NDCs that are subject to a refund for the Refund Period. The recalculated Ceiling Prices are the result of the revised pricing data that were submitted to the Centers for Medicare & Medicaid Services.

Time Period	Product	Unit of Sale
(Refund Period Unless		NDC Number
Otherwise Noted)		
1/1/2020 - 3/31/2020	Ampicillin and Sulbactam for Injection, USP	71288-0005-20
10/1/2021 - 12/31/2021	1.5g 20mL Vial	
10/1/2022 - 12/31/2022		
10/1/2019 - 12/31/2019	Ampicillin and Sulbactam for Injection, USP	71288-0006-30
4/1/2021 - 12/31/2021	3g 30mL Vial	
1/1/2021 - 3/31/2021	Atracurium Besylate Injection, USP 100mg	71288-0702-10
10/1/2021 - 12/31/2021	10mL (10mg/mL) MDV	
4/1/2022 - 12/31/2022		
1/1/2022 - 3/31/2022	Atracurium Besylate Injection, USP 50mg	71288-0701-05
	5mL (10mg/mL) SDV	
1/1/2021 - 3/31/2021	Bleomycin for Injection, USP 15 Units 10mL	71288-0106-10
= /1 /2010	SDV	<b>-12</b> 00 0000 <b>2</b> 0
7/1/2019 – 9/30/2019	Cefepime for Injection, USP 2g 20mL SDV	71288-0009-20
4/1/2022 – 9/30/2022		
4/1/2022 - 9/30/2022	Cisatracurium Besylate Injection, USP 10mg	71288-0712-06
	5mL (2mg/mL) SDV Pres Free	
1/1/2021 - 12/31/2021	Daptomycin for Injection 500mg 10mL SDV	71288-0018-10
7/1/2021 – 9/30/2021	Fosaprepitant for Injection 150mg 10mL SDV	71288-0418-10
7/1/2019 – 12/31/2021	Gemcitabine for Injection, USP 1g 50mL	71288-0114-50
4/1/2022 - 6/30/2022	SDV	
7/1/2019 – 9/30/2020	Gemcitabine for Injection, USP 200mg 10mL SDV	71288-0113-10

Based on the recalculation of the product(s) noted above, Meitheal intends to refund any amount equal to or in excess of \$100 (aggregate overpayments for all applicable NDCs) for the periods

listed directly to the 340B Covered Entity of Record. Separate correspondence regarding details of the payment will be sent to the 340B Covered Entity on Meitheal's behalf by a third party.

For 340B Covered Entities that may be entitled to an aggregated refund across applicable NDCs for less than \$100 will not be contacted directly by, or on behalf of, Meitheal. Instead, Meitheal is offering a refund to these 340B Covered Entities through this Notice. If a 340B Covered Entity does not receive a communication from, or on behalf of, Meitheal, and that 340B Covered Entity believes it is entitled to a refund on the applicable NDCs, then the 340B Covered Entity should contact Meitheal at <a href="mailto:340BRefunds@meithealpharma.com">340BRefunds@meithealpharma.com</a> to request the refund. Meitheal will then work with the 340B Covered Entity to validate and process any refund that is due to the 340B Covered Entity for the applicable NDCs.

Meitheal has asked the Health Resources and Services Administration (HRSA) to post this Notice on the HSRA public website to ensure transparency to all 340B Covered Entities regarding the Ceiling Price recalculations for all NDCs listed above and to offer to refund any of the 340B Covered Entities that may have purchased the above NDCs during the relative time periods. Please direct any questions or other requests for additional information to Meitheal at 340BRefunds@meithealpharma.com.