Rajesh Gurjar
Senior Manager, Regulatory Affairs
Baxter Healthcare Corporation
1 Baxter Parkway
Deerfield, IL 60015

February 17, 2023

Re: Docket No. FDA-2022-P-2842

Dear Rajesh Gurjar:

This letter responds to your citizen petition received on November 11, 2022, requesting that the Food and Drug Administration (FDA) determine whether D.H.E. 45 (dihydroergotamine mesylate) injection USP, 1 milligram (mg)/milliliter (mL), approved under New Drug Application (NDA) 005929, held by Bausch Health US LLC, has been voluntarily withdrawn for reasons of safety or effectiveness.

FDA has reviewed its records and determined that D.H.E. 45 (dihydroergotamine mesylate) injection USP, 1 mg/mL, was not withdrawn from sale for reasons of safety or effectiveness. Thus, FDA will maintain D.H.E. 45 (dihydroergotamine mesylate) injection USP, 1 mg/mL, in the "Discontinued Drug Product List" section of *Approved Drug Products With Therapeutic Equivalence Evaluations* (the Orange Book).

Enclosed is a copy of the *Federal Register* notice that announces the FDA determination. If you require any further information, please feel free to call me at (301) 796-3600.

Sincerely,

Donna C. Tran -S

Digitally signed by Donna C. Tran -S
Date: 2023.02.17 09:53:38 -05'00'

Donna Tran
Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure

U.S. Food & Drug Administration
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