U.S. FOOD & DRUG ADMINISTRATION

Dr. Milind Narvekar
Vice President Regulatory Affairs
Encube Ethicals Private Limited
Unit No. 24, Steelmade Industrial Estate, Andheri (East)
Mumbai, Maharashtra, 400059, India

August 20, 2024

Re: Docket No. FDA-2024-P-2220

Dear Dr. Narvekar:

This letter responds to your citizen petition received on May 6, 2024, requesting that the Food and Drug Administration (FDA) determine whether Pennsaid (diclofenac sodium) topical solution, 2%, new drug application 204623, held by Horizon Therapeutics Ireland DAC, has been voluntarily withdrawn for reasons of safety or effectiveness.

FDA has reviewed its records and determined that Pennsaid (diclofenac sodium) topical solution, 2%, was not withdrawn from sale for reasons of safety or effectiveness. Thus, FDA will maintain Pennsaid (diclofenac sodium) topical solution, 2%, 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) 796-0110.

Sincerely,

Awo Archampong-gray -S

Digitally signed by Awo Archampong-gray -S
Date: 2024.08.20 10:06:22 -04'00'

Awo Archampong-Gray
Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure

U.S. Food & Drug Administration
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