

Date – May 06, 2024

**VIA ELECTRONIC SUBMISSION**

Division of Dockets Management  
Food and Drug Administration  
Department of Health and Human Services  
5630 Fishers Lane,  
Room 1061 (HFA-305)  
Rockville, MD 20852

**Citizen Petition**

Dear Sir/ Madam,

The undersigned, for Encube Ethicals Private Limited (Encube), respectfully submits this petition pursuant to the Federal Food, Drug and Cosmetic Act (“FDC Act”) and in accordance with regulations at 21 C.F.R. §10.25(a), § 10.30, and 21 C.F.R. § 314.161 and 314.122, requesting the Commissioner of Food and Drug Administration to provide a determination on whether a listed drug has been withdrawn for reasons of safety or effectiveness as outlined below.

**A. Action Requested**

The Petitioner requests that the Commissioner of the Food and Drug Administration determine whether the Reference Listed Drug (RLD), ‘PENNSAID’ (diclofenac sodium) topical solution 2% w/w (NDA# N204623) held by Horizon Therapeutics Ireland DAC, has been voluntarily withdrawn from the commercial market or withdrawn from sale for safety or effectiveness reasons.

**B. Statement of Grounds**

The Food and Drug Administration maintains a list of drug products in the Orange Book. The list, Approved Drug Products with Therapeutic Equivalence Evaluations, referred to as the “Orange Book”, lists all FDA approved drug products. These drug products are eligible for submission under Section 505(j) of the FD&C Act as ANDAs. ‘PENNSAID’ (diclofenac sodium) topical solution 2% w/w, New Drug Application (NDA) Number N204623, held by Horizon Therapeutics Ireland DAC, was Approved on January 16, 2014. The product was then considered to be a “Reference Listed Drug Product” in the Orange Book.

‘PENNSAID’ (diclofenac sodium) topical solution 2% w/w now appears in the “Discontinued Section” of the Orange Book (refer [Attachment-I](#)), indicating that it is currently not available for sale. Currently, the orange book displays Diclofenac Solution 2% (A208021) of LUPIN PHARMACEUTICALS INC as RS. Several other generic players are also approved and commercially available as mentioned in the below [Attachment-I](#).

If an RLD appears in the discontinued section of the Orange Book and the FDA has not determined whether the drug was withdrawn from sale for reasons of safety or effectiveness, a person wishing to submit an ANDA for the drug must submit a citizen petition under 21 C.F.R. § 10.25(a) and § 10.30 before or at the same time of the ANDA submission, seeking a determination on whether the listed drug

has been withdrawn from sale for safety or effectiveness reasons. Such a petition must contain all evidence available to the petitioner concerning the reason that the drug product was withdrawn from sale under 21 C.F.R. § 314.122(a).

The regulations provide that the Agency must make a determination as to whether a listed drug is withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (21 C.F.R. § 314.161 (a)(1)).

If the FDA determines that the listed drug was withdrawn from sale for reasons of safety and effectiveness (or if FDA withdraws or suspends NDA approval for reasons of safety or effectiveness), then the drug listing is removed from the Orange Book. See *id.* See 21 C.F.R. § 314.122, § 314.161, and § 314.162. If FDA determines that the listed drug was not withdrawn from sale for reasons of safety and effectiveness, then the drug listing remains in the Orange Book and may be cited in an ANDA as a RLD.

Petitioner is further unaware of any reason why 'PENNSAID' (diclofenac sodium) topical solution 2% w/w may have been removed from sale and believes the discontinuation of 'PENNSAID' (diclofenac sodium) topical solution 2% w/w was due to only commercial considerations. Petitioner requests that FDA determine whether the NDA holder for 'PENNSAID' (diclofenac sodium) topical solution 2% w/w (NDA Number N204623) has withdrawn the product for reason of safety or effectiveness.

#### **C. Environmental Impact**

In Accordance with the requirements set forth in 21 C.F.R. § 25.31 (a), the petitioner hereby requests a Categorical Exclusion from the requirements to prepare an Environmental Impact Assessment

#### **D. Economic Impact**

In accordance with 21 C.F.R. § 10.30(b), economic impact information is to be submitted only when requested by the Commissioner following review of the petition. The Petitioner hereby commits to promptly provide this information, if so requested.

#### **E. Certification**

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which is unfavorable to the petition.

Sincerely,

Dr.  
Milind  
Narvekar  
Digitally signed  
by Dr. Milind  
Narvekar  
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**Dr. Milind Narvekar**

Vice President Regulatory Affairs

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