



Jayant Muley  
General Manager, Regulatory Affairs  
Encube Ethicals Private Limited  
Unit 24, Steelmade Industrial Estate  
Marol village, Andheri (E)  
Mumbai, Maharashtra  
India 400059

Re: Docket No. FDA-2019-P-2074

**NOV 06 2019**

Dear Mr. Muley:

I am writing to inform you that the Food and Drug Administration (FDA or the Agency) has not yet resolved the issues raised in your citizen petition received on April 30, 2019. Your petition requests that the Agency designate an alternate reference standard for Efudex (Fluorouracil 5% Solution) topical, in the active section of the Orange Book.

FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Carol J. Bennett  
Deputy Director  
Office of Regulatory Policy  
Center for Drug Evaluation and Research