U.S. FOOD & DRUG ADMINISTRATION

Meenal Kheterpal, MD
40 Duke Medicine Circle
Durham, NC 27710

February 26, 2021

Re: Docket No. FDA-2020-P-1831

Dear Dr. Kheterpal:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on August 31, 2020. Your petition requests that the Agency require vismodegib and any future hedgehog pathway inhibitor products have labeling that warns patients about musculoskeletal reactions and includes requirements for creatine kinase monitoring as an indicator of muscle damage.

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. 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 possible given the numerous demands on the Agency's resources.

Sincerely,

Carol Bennett -S

Digitally signed by Carol Bennett -S
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Carol J. Bennett
Deputy Director
Office of Regulatory Policy
Center for Drug Evaluation and Research

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