



Eric Gruff, PhD, MBA  
President, E4 Consulting  
15696 Oakstand Road  
Poway, CA 92064-2264

December 18, 2020

Re: Docket No. FDA-2020-P-1617

Dear Dr. Gruff:

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 June 24, 2020, and submitted on behalf of your client. Your petition requests that the Agency determine if BACTROBAN (mupirocin) nasal ointment, 2%, was withdrawn from sale for reasons of safety or effectiveness.

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 Bennett -S

Digitally signed by Carol Bennett -S  
DN: c=US, o=U.S. Government, ou=HHS,  
ou=FDA, ou=People, cn=Carol Bennett -S,  
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Carol J. Bennett  
Deputy Director  
Office of Regulatory Policy  
Center for Drug Evaluation and Research