



James Grote
147 Lashmett Lane
Pittsfield, IL 62363

Re: Docket No. FDA-2019-P-5266

Dear Mr. Grote:

May 6, 2020

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 November 7, 2019. Your petition requests that the Agency determine whether acetic acid 2% in aqueous aluminum acetate (acetic acid, glacial; aluminum acetate) (ANDA 040063, ANDA 088606 and ANDA 084476) has been withdrawn for safety or effectiveness reasons.

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 possible given the numerous demands on the Agency's resources.

Sincerely,

Carol Bennett - 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