



Sarah A. Norring, Ph.D.

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Sent via email to: [sarahanorring@gmail.com](mailto:sarahanorring@gmail.com)

December 16, 2024

Re: Docket No. FDA-2024-P-2952

Dear Dr. Norring:

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 20, 2024. Your petition requests that the Agency determine whether the listed drug Lunelle, which has been voluntarily withdrawn from sale, was withdrawn for safety or effectiveness reasons.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 we have reached a decision on your request.

Sincerely,

**Carol Bennett -**

**S**

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

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Bennett -S  
Date: 2024.12.16 12:22:19  
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