



Michelle Ryder
Lachman Consulting Services, Inc.
1600 Stewart Ave., Suite 604
Westbury, NY 11590

May 3, 2021

Re: Docket No. FDA-2020-P-2174

Dear Ms. Ryder:

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 5, 2020. Your petition requests that the Agency determine whether Atrovent (ipratropium bromide) nasal spray, 0.021 micrograms (mcg)/spray, approved under New Drug Application (NDA) Number 020393, and Atrovent (ipratropium bromide) nasal spray, 0.042 mcg/spray, approved under NDA Number 020394, held by Boehringer Ingelheim Pharmaceuticals, Inc., have been voluntarily withdrawn for reasons of safety or effectiveness.

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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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