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

June 7, 2021

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

Dear Ms. Ryder:

This letter responds to your citizen petition received on November 5, 2020, requesting that the Food and Drug Administration (FDA) determine whether Atrovent (ipratropium bromide), metered spray, 0.021 micrograms (mcg)/spray (new drug application (NDA) 020393) and 0.042 mcg/spray (NDA 020394), held by Boehringer Ingelheim Pharmaceuticals, Inc., was withdrawn from sale for reasons of safety or effectiveness.

FDA has reviewed its records and determined that Atrovent (ipratropium bromide), metered spray, 0.021 mcg/spray and 0.042 mcg/spray, was not withdrawn from sale for reasons of safety or effectiveness. Thus, FDA will maintain Atrovent (ipratropium bromide), metered spray, 0.021 mcg/spray and 0.042 mcg/spray, in the "Discontinued Drug Product List" section of Approved Drug Products With Therapeutic Equivalence Evaluations (the Orange Book).

Enclosed is a copy of the Federal Register notice that announces the FDA determination. If you require any further information, please feel free to call me at (301) 796-8363.

Sincerely,

Stacy Kane -S

Digitally signed by Stacy Kane -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Stacy Kane -S, 0.9.2342.19200300.100.1.1=0011381014
Date: 2021.06.07 09:53:08 -04'00'

Stacy Kane
Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure

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