



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring MD 20993

November 5, 2020

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

Sent via email to: m.ryder@lachmanconsultants.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting the FDA determine whether Atrovent (ipratropium bromide) Nasal Spray, 0.021MG/SPRAY approved under New Drug Application ("NDA") Number N020393 and Atrovent (ipratropium bromide) Nasal Spray, 0.042MG/SPRAY approved under New Drug Application ("NDA") Number N020394, held by BOEHRINGER INGELHEIM PHARMACEUTICALS INC, has been voluntarily withdrawn for reasons of safety or effectiveness was received by this office on 11/05/2020 and it was assigned docket number FDA-2020-P-2174.

Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Dynna Bigby
Supervisory Administrative Proceedings Officer
Division of Dockets Management
FDA/Office of Operations (OO)