

UNITED STATES OF AMERICA  
FEDERAL TRADE COMMISSION  
WASHINGTON, D.C. 20580

Office of the Director  
Bureau of Competition

November 7, 2023

**By Federal Express**

Boehringer Ingelheim  
Pharmaceuticals, Inc.  
Attn: General Counsel  
c/o: The Corporation Trust Co.  
Corporation Trust Center  
1208 Orange St.  
Wilmington, New Castle, DE,  
19801

Re: Improper Orange Book-Listed Patents for Atrovent HFA, Combivent Respimat,  
Spiriva, and Spiriva Respimat

To whom it may concern:

On September 14, 2023, the Federal Trade Commission (“FTC”) issued a Statement Concerning Brand Drug Manufacturers’ Improper Listing of Patents in the Orange Book.

<b>NDA</b>	<b>Product Number</b>	<b>Product</b>	<b>Patent Number</b>	<b>Listing Type</b>
21527	1	Atrovent HFA	8474447	DP
21747	1	Combivent Respimat	7284474	DP
			7396341	DP
			7837235	DP
			7896264	DP
			8733341	DP
			9027967	DP
21395	1	Spiriva	7694676*PED	DP
			7694676	DP
			9010323	DP

21936

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For decades, the FTC has sought to reduce the anticompetitive effects that result from improperly listing patents in the Orange Book, through enforcement and through amicus briefs articulating that improper listings may violate the antitrust laws.<sup>7</sup> The FTC's Policy Statement serves to reinforce the FTC's concerns about the anticompetitive consequences of improper Orange Book listings and provide notice that the "FTC will continue to use all its tools to halt unlawful business practices that contribute to high drug prices."<sup>8</sup>

As detailed in the Policy Statement, the FTC has several tools at its disposal to address improper Orange Book listings. One of those tools is using the FDA's process to dispute "the accuracy or relevance of patent information submitted" to the FDA for publication in the Orange Book.<sup>9</sup>

We have opted to use the FDA's regulatory dispute process to address the improper listings, but we retain the right to take any further action the public interest may require, which may include investigating this conduct as an unfair method of competition under Section 5 of the FTC Act, 15 U.S.C. § 45, and as described in the Policy Statement.

Sincerely,

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Rahul Rao  
Deputy Director  
Bureau of Competition

cc: Kathleen Collins  
kathleen.collins@boehringer-ingenelheim.com

Enclosure: FTC Policy Statement Concerning Brand Drug Manufacturers Improper Listing of Patents in the Orange Book

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<sup>7</sup> Policy Statement at 3; Decision and Order, 2002); Federal Trade Commission's Brief as

., FTC Dkt. No. C-4060 (F.T.C. Oct. 2,