

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

Office of the Director  
Bureau of Competition

November 7, 2023

By Federal Express

|                               |                                  |
|-------------------------------|----------------------------------|
| Glaxo Group Limited           | Robert MacRae                    |
| Attn: General Counsel         | General Counsel, U.S. Commercial |
| Gsk Medicines Research Centre | GSK                              |
| Gunnels Wood Road             | 2929 Walnut St                   |
| Stevenage, Great Britain      | Philadelphia, PA 19104           |
| SG1 2NY                       | Rob.R.Macrae@gsk.com             |
| United Kingdom                |                                  |

James FID 35t4Ba6 17m6

Re: Improper Orange Book listed Patents for Avair HFA and Flovent HFA

Dear Messrs. Ford and MacRae:

On September 14, 2023, the Federal Trade Commission (“FTC”) issued a Statement Concerning Brand Drug Manufacturers’ Improper Listing of Patents in the Orange Book. The Policy Statement, a copy of which is appended to this letter, highlights the negative impact improper Orange Book patent listings may have on drug competition and notifies market participants that the FTC intends to scrutinize [such] improper listings as unfair methods of competition in violation of Section 5 of the Federal Trade Commission<sup>2</sup> Act.”

This letter is to inform you that we believe certain patents have been improperly or inaccurately listed in the Orange Book with regard to Glaxo Group Limited’s products and that

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<sup>1</sup> Federal Trade Commission, Statement Concerning Brand Drug Manufacturers’ Improper Listing of Patents in the Orange Book (Sept. 14, 2023), [FTC Policy Statement Concerning Brand Drug Manufacturers’ Improper Listing of Patents in Orange Book](#) (hereinafter “Policy Statement”).

we have availed

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

Enclosure: FTC Policy Statement Concerning Brand Drug Manufacturer Proper Listing of Patents in the Orange Book