



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

Office of the Director
Bureau of Competition

November 7, 2023

By Federal Express

Kaleo Inc.
Attn: Ned Ruffin, Chief Legal &
Compliance Officer
c/o United States Corporation
Agents, Inc.
300 Delaware Ave.
Ste. 210-A
Wilmington, New Castle, DE
19801

Ned Ruffin
Chief Legal & Compliance Officer
Kaleo Inc.
111 Virginia Street
Richmond, VA 23225
ned.ruffin@kaleo.com

Re: Improper Orange Book-Listed Patents for AUVI-Q

Dear Mr. Ruffin:

On September 14, 2023, the Federal Trade Commission (“FTC”) issued a Statement Concerning Brand Drug Manufacturers’ Improper Listing of Patents in the Orange Book.¹ The Policy Statement, a copy of which is appended to this letter, highlights the negative impacts that 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 Act.”²

This letter is to inform you that we believe certain patents have been improperly or inaccurately listed in the Orange Book with regard to Kaleo Inc.’s AUVI-Q product and that we have availed ourselves of the FDA’s regulatory process and submitted patent listing dispute communications to the FDA regarding the patents listed below:³

¹ 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”).

² Policy Statement at 1.

³ The Orange Book listings identified as improper in this chart should not be read as an exhaustive list of every patent that your company may have improperly submitted. Indeed, your firm bears the burden of listing patents in the Orange Book accurately and in accordance with all relevant statutory and regulatory requirements.

NDA	Product Number	Product	Patent Number	Listing Type
201739	2	AUVI-Q	7731686	DP
			7731690	DP
			7749194	DP
			8016788	DP
			8920377	DP
			8926594	DP
			9238108	DP
			10960155	DP

As the Policy Statement explains, patents improperly listed in the Orange Book may delay lower-cost generic drug competition. By listing their patents in the Orange Book, brand drug companies may benefit from an automatic, 30-month stay of FDA approval of competing generic drug applications.⁴ In addition to delays resulting from such a stay of approval, the costs associated with litigating improperly listed patents may disincentivize investments in developing generic drugs, which risks delaying or thwarting competitive entry. The Supreme Court recognizes that improper Orange Book listings have prevented or delayed generic drug entry since at least the 1990s.⁵ Even brief delays in generic competition can reduce patient access to more affordable alternatives and increase costs across the entire health care system.⁶

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.⁷ 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.”⁸

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.⁹

⁴ Policy Statement at 3 (citing 21 U.S.C. § 355(j)(5)(B)(iii)).

⁵ Policy Statement at 3 (citing *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 408 (2012)).

⁶ Policy Statement at 4.

⁷ Policy Statement at 3; *see also* Decision and Order, *In re Biovail Corp.*, FTC Dkt. No. C-4060 (F.T.C. Oct. 2, 2002); Federal Trade Commission’s Brief as *Amicus Curiae*, *Jazz Pharms., Inc. v. Avadel CNS Pharms.* No. 1:21-cv-00691 (D. Del. Nov. 10, 2022) (Doc. No. 22-3),

https://www.ftc.gov/system/files/ftc_gov/pdf/P163500JazzPharmaAmicusBrief.pdf; *see also* Mem. of Law of *Amicus Curiae* the Federal Trade Commission In Opposition to Defendant’s Motion to Dismiss, *In re: Buspirone Patent Litig.*, MDL Docket No. 1410 (S.D.N.Y. Jan. 8, 2002),

https://www.ftc.gov/sites/default/files/documents/amicus_briefs/re-buspirone-antitrust-litigation/buspirone.pdf.

⁸ Policy Statement at 6.

⁹ Policy Statement at 6 (citing 21 C.F.R. § 314.53(f)(1)).

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,

Rahul Rao
Deputy Director
Bureau of Competition

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