

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

April 30, 2024

By Federal Express and Email

Brian Matlock
General Counsel
Amphastar Pharmaceuticals Inc.
11570 6th Street
Rancho Cucamonga, CA 91730
brianm@amphastar.com

Re: Improper Orange Book Patent Listings for Baqsimi

Dear Mr. Matlock,

On September 14, 2023, the Federal Trade Commission (“FTC”) issued a Statement Concerning Brand Drug Manufacturers’ Improper Listing of Patents in the Orange Book. Policy Statement, a copy of which is appended to this letter, highlights the negative impact that improper Orange Book patent listings may have on drug competition and notifies market participants “that the FTC intends to scrutinize improper listings as unfair methods of competition in violation of Section 5 of the Federal Trade Commission 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 Amphastar Pharmaceuticals Baqsimi and that we have availed ourselves of the FDA’s regulatory process and submitted patent listing dispute communications to the FDA regarding the listing identified below.³

¹ idi

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(s)	Proprietary Name	Patent Number	Listing Type
210134	1	Baqsimi	10894133	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 has recognized that improper Orange Book listings prevent or delay generic drug entry.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 .21(6F) 0.96 379.4 (12)2 (ao/-TjE)-1 Tw409.

Deputy Director
Bureau of Competition

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