



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

Office of the Director
Bureau of Competition

November 7, 2023

By Federal Express

Impax Laboratories LLC	Jason B. Daly
Attn: General Counsel	Chief Legal Officer
c/o Corporation Service Company	Amneal Pharmaceuticals, Inc.
251 Little Falls Drive	400 Crossing Blvd
Wilmington, New Castle, DE	Bridgewater, NJ 08807
19808	

Re: Improper Orange Book listed Patents for Adrenaclick

Dear Mr. Daly

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 Commission² 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 Impax Laboratories LLC’s Adrenaclick patent listing dispute communications to the FDA regarding the patents listed below:

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, 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

Sincerely,

Rahul Rao
Deputy Director
Bureau of Competition

cc: Robert Loewenstein
rloewenstein@amneal.com

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