



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

Bureau of Competition

June 2, 2025

Hanok George
Chief Legal and Compliance Officer
Azurity Pharmaceuticals, Inc.
8 Cabot Road, Suite 2000
Woburn, MA 01801

Re: Orange Book Patent Listings for Tudorza and Duaklir Pressair

Dear Mr. George,

I write to follow up on my May 21, 2025 letter regarding Covis Pharma GMBH's ("Covis") listings of patents in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") for Tudorza Pressair and Duaklir Pressair. I understand that your company, Azurity Pharmaceuticals, has acquired Covis.

As you know, my May 21 letter followed a similar letter from the FTC Bureau of Competition on April 30, 2024. In that letter, the FTC called Covis's attention to two improper Orange Book listings for U.S. patent number 8051851. The Federal Circuit later confirmed the FTC's position when it declared similar listings improper in a December 20, 2024 decision in *Teva v. Amneal*.

I am pleased to learn that, in light of these developments, Covis sent a request to the FDA to withdraw the improper listings. I understand that the request was issued shortly before my May 21 letter. Accordingly, the FTC has withdrawn the patent listing dispute previously submitted to the FDA.

Sincerely,

/s/ Kelse Moen

Kelse Moen
Deputy Director
Bureau of Competition