

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

Office of the Director  
Bureau of Competition

November 7, 2023

By Federal Express

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er Orange Book listed Patents for AUVQ

r 14, 2023, the Federal Trade Commission ("FTC") issued a Statement  
Manufacturers' Improper Listing of Patents in the Orange Book.

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.<sup>1</sup>

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 AUVQ product and that we  
have availed ourselves of the FDA's regulatory process and subsequent patent listing dispute  
communications to the FDA regarding the patents listed below.<sup>3</sup>

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NDA	Product Number	Product	Patent Number	Listing Type
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