

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

Office of the Director Bureau of Competition

April 30, 2024

NDA	Product(s)	Proprietary Name	Patent Number	Listing Type
			7762994	DP
			8684969	DP
			8920383	DP
			9108002	DP
			9132239	DP
			9457154	DP
			9616180	DP
209637	1, 2, 3, & 4	Ozempic	9687611	DP
207037			9775953	DP
			9861757	DP
			10220155	DP
			10357616	DP
			10376652	DP
			11097063	DP
			11311679	DP
			11446443	DP
			RE46363	DP
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			9687611	DP
			9775953	DP
			9861757	DP
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			11311679	DP
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NDA	Product(s)	Proprietary Name	Patent Number	Listing Type
NDA 22341	Product(s)		Patent Number 7762994	Listing Type 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. In addition to delays resulting from ng f, i tht(, 4 (t.s)-4 (1)(1)-2 (r)3 (e)4 (s)-9i)(thtere is the orange Book may delay the orange Book may delay the orange Book may delay to the orange Book may delay the orange Book may delay to the orange Book may delay lower-cost generic drug approval of competing generic drug applications.

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/s/ Rahul Rao

Deputy Director

Bureau of Competition

Enclosure: FTC Policy Statement Concerning Brand Drug Manufacturers Improper Listing

of Patents in the Orange Book