



Press Release

Primer: FTC Scrutinizes Orange Book Listings

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In September 2023, the Federal Trade Commission (FTC) issued a policy statement warning pharmaceutical companies of potential legal action if patents listed in the Food and Drug Administration's (FDA) Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book, are found to be improper or inaccurate. In a new primer, Director of Competition Policy Fred Ashton walks through the FTC's statement and its aftermath so far.

Key points:

- The FTC asserted that improper Orange Book listings may harm competition from generic alternatives.
- The FTC sent notice letters – the first tranche in November 2023 and the second in April 2024 – to drug manufacturers challenging more than 400 patents and filed patent listing dispute notifications with the FDA.
- The FTC asserted that improper or inaccurate listings block or delay competition from generic alternatives and that such activity could be considered an unfair method of competition in violation of Section 5 of the FTC Act.

[Read the analysis](#)