

# Publications

July 14, 2025 • Updates

## Device Patents in the Orange Book: May 21, 2025, FTC Warning Letters Appear to have Minimal Impact

### Key Takeaways

- The Federal Trade Commission (FTC) has continued its scrutiny of Orange Book listings for device patents, signaling bipartisan concern over potential anti-competitive practices.
- Actions taken by the FTC have not significantly changed the behavior of brand drugmakers.

On May 23, 2025, we reported on the new FTC leadership issuing new Warning Letters to seven companies that were similar to the ones sent under prior leadership in 2023 and 2024, questioning the legitimacy of certain Orange Book patent listings for multiple products. Like the previous Warning Letters, FTC took action by instituting patent dispute procedures at the U.S. Food and Drug Administration (FDA).

On July 11, 2025, the FDA updated the “Patent Listing Disputes” page on its website. While the actual submissions made by the NDA holders are submitted confidentially, the impact of the renewed FTC initiative appears to be minimal. The most recent FDA update provides information on ten different NDAs that were the subject of six of the seven May 21, 2025, Warning Letters. Of those ten NDAs, in one instance, the Orange Book patent listing was updated. However, for nine of the NDAs, no changes were made to the Orange Book.

This most recent update largely mirrors the one from July 2024, when similar results were seen in response to Warning Letters issued by FTC on April 30, 2024 (i.e., the Orange Book listings remained unchanged).

Utilizing the Patent Listing Dispute procedure has not proven effective to cause brand companies to remove questionable patents from the Orange Book. It will be interesting to see if FTC tries different approaches as it continues to scrutinize Orange Book patent listings.

If your business needs strategic legal advice or anticipates potential impacts resulting from these announcements, contact the authors or your Polsinelli contact.

### Related People

- Chad A. Landmon
- Andrew M. Solomon

### Related Capabilities

- Hatch-Waxman & Biologics
- Food, Drug & Device
- Life Sciences
- Intellectual Property
- Intellectual Property Litigation
- Biotechnology & Life Sciences Patent Prosecution

