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Orange Book Transparency Act Creates Some New Obligations

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The Orange Book Transparency Act of 2020, signed into law on January 5, amends section 505(j) of the Federal Food, Drug and Cosmetic Act, codifying and clarifying some patent listing requirements of existing FDA regulations. It also requires that the FDA provide a list of exclusivities and a report related to certain types of device-related patents.

The act does not significantly impact the form or function of the Orange Book, but several aspects are worth noting.

- While the FDA is currently considering comments regarding the scope of listable patents, the act provides essentially the same identification of listable patents as the existing related regulations – i.e., “drug substance (active ingredient),” “drug product (formulation or composition)” and “method of using such drug for which approval is sought or has been granted.”
- The act broadens the list of exclusivity information available in the Orange Book to include 180-day generic exclusivity determinations (§505(j)(5)(B)(iv)-(v)).
- NDA holders must now notify the FDA within 14 days after invalidation by a court, USPTO, or the Patent Trial and Appeal Board of a listed patent, and “request that such patent or patent information, as applicable, be amended or withdrawn in accordance with the decision issued by the Patent Trial and Appeal Board or a court.”
- The act requires, no later than one year after enactment of the act, solicitation of public comment regarding the types of patent information that should be included on, or removed from, the Orange Book (§505(j)(7)).
- The act does not resolve longstanding issues regarding listing certain device-related patents, but it does require a report from the comptroller general, no later than two years of enactment of the act, with recommendations regarding the kinds of device-related patents that should be submitted for listing.

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