FDA introduces patent submission date updates to the Orange Book

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On November 21, 2017, the U.S. Food and Drug Administration (FDA) introduced an important data update to **Approved Drug Products with Therapeutic Equivalence Evaluations (/Drugs/InformationOnDrugs/ucm129662.htm)** – known as the "Orange Book." Search results and drug listings now show patent submission dates where available. The FDA is publishing this data to improve transparency and provide additional information to regulated industry and the public. This information may help generic drug manufacturers determine the earliest date when they may be able to market new generic medicines. Increased competition in the market can help lower drug prices, and earlier availability may help prices decrease more quickly.

Why is the Orange Book publishing patent submission dates now?

The FDA is publishing patent submission dates to fulfill a commitment in the October 2016 final rule "**Abbreviated New Drug Applications and 505(b)(2) Applications (https://www.gpo.gov/fdsys/pkg/FR-2016-10-06/pdf/2016-22690.pdf)**," which implemented portions of Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). The final rule states, "FDA intends to list the date of submission of patents and patent information in the Orange Book on a prospective basis beginning as soon as is practicable after the effective date of this rule."

How can I view patent submission date information?

To view patent submission date information, on the Product Details page for a given drug product, choose "Patent and Exclusivity Information" near the end of the product data. If patent submission date information is available, it will appear in the far right column on the Patent and Exclusivity page for that product.

Why doesn't the Orange Book include patent submission dates for most records?

The FDA began patent submission date data collection in 2013. There are now about 4,000 patent records for which submission dates are available, and these are now published in the Orange Book. The final October 2016 final rule "**Abbreviated New Drug Applications and 505(b)(2) Applications (https://www.gpo.gov/fdsys/pkg/FR-2016-10-06/pdf/2016-22690.pdf)**" states, "FDA intends to list the date of submission of patents and patent information in the Orange Book on a prospective basis beginning as soon as is practicable after the effective date of this rule." The Orange Book will now publish patent submission dates for all new records going forward.

How can an NDA holder request a patent submission date error correction?

NDA holders should email error correction requests, including justification for the request to **orangebook@fda.hhs.gov (mailto:orangebook@fda.hhs.gov)**. Requests will be considered on a case by case basis and, if accurate, will be updated in the Orange Book as soon as is practicable.

What is a patent submission date?

A patent submission date is the date on which the FDA receives patent information from the new drug application (NDA) holder. See 21 C.F.R. 314.53(d)(ii)(5). Additional information can be found in the **Patent and Exclusivity FAQs web page (/Drugs/DevelopmentApprovalProcess/ucm079031.htm)**.

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