

See 21 CFR 314.107 Date of approval of a 505(b)(2) application or ANDA  
 See 21 CFR 314.108 New drug product exclusivity  
 See 21 CFR 316.31 Scope of orphan-drug exclusive approval  
 See 21 CFR 316.34 FDA recognition of exclusive approval  
 Code of Federal Regulations on the Government Publishing Office website.

7. How is an NDA holder notified if their application has received a period of exclusivity?

No letters are sent to the application holder to indicate that a period of exclusivity has attached to his or her application. The posting of exclusivity information in the Orange Book is the official vehicle for dissemination of this information.

8. When should an NDA holder submit patent information?

Patent information is required to be submitted with all NDAs and certain supplemental applications (sNDAs) on Form FDA 3542a at the time of submission of the NDA or sNDA. Patent information for listing in the Orange Book must be submitted on Form FDA 3542 within 30 days following the approval of an NDA or supplemental application. For patents issued after the approval of the NDA or supplement, the NDA holder must submit the required patent information within 30 days of the issuance of the patent for it to be considered timely filed. If the NDA holder timely submits the required patent information, but the FDA notifies the NDA holder that its Form FDA 3542 is incomplete or shows that the patent is not eligible for listing, the NDA holder must submit an acceptable Form FDA 3542 within 15 days of the FDA's notification to be considered timely filed as of the date of the original submission of patent information. New patent information may still be submitted after 30 days of the issuance of the patent, but such information is not considered timely filed.

9. What is a patent submission date?

A patent submission date is the date on which the FDA receives patent information from the NDA holder. See 21 CFR 314.53(d)(ii)(5).

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

The FDA began patent submission date data collection in 2013. The October 2016 final rule "Abbreviated New Drug Applications and 505(b)(2) Applications" 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.

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

The 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.

12. How should an NDA holder correct or request the removal of patent information?