U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Frequently Asked Questions on Patents and Exclusivity

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Orange Book Frequently Asked Questions (/Drugs/InformationOnDrugs/ucm114166.htm)

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1. What is the difference between patents and exclusivity?

Patents and exclusivity work in a similar fashion but are distinctly different from one another. Patents are granted by the patent and trademark office anywhere along the development lifeline of a drug and can encompass a wide range of claims. Exclusivity is exclusive marketing rights granted by the FDA upon approval of a drug and can run concurrently with a patent or not. Exclusivity is a statutory provision and is granted to an NDA applicant if statutory requirements are met. See **21 C.F.R. 314.108 (http://frwebgate.access.gpo.gov/cgi-bin/get-cfr.cgi?TITLE=21&PART=314&SECTION=108&YEAR=1999&TYPE=TEXT)**. Exclusivity was designed to promote a balance between new drug innovation and generic drug competition.

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2. How long is a patent granted for?

Patents expire 20 years from the date of filing. Many other factors can affect the duration of a patent.

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3. How long is exclusivity granted for?

It depends on what type of exclusivity is granted.
Orphan Drug (ODE) - 7 years
New Chemical (NCE)- 5 years
"Other" Exclusivity - 3 years for a "change" if criteria are met
Pediatric Exclusivity (PED) - 6 months added to existing Patents/Exclusivity
Patent Challenge – (PC) – 180 days (this exclusivity is for ANDAs only)

See **21 C.F.R. 314.108 (http://frwebgate.access.gpo.gov/cgi-bin/get-cfr.cgi?TITLE=21&PART=314&SECTION=108&YEAR=1999&TYPE=TEXT)**
New Drug Product Exclusivity.

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4. Why does the exclusivity expire before the patent?
Patent before exclusivity?
Why does a particular drug product only have patents?
Only have exclusivity?
Have neither?

Patents can be expired before drug approval, issued after drug approval, and anywhere in between. Exclusivity is granted upon approval of a drug product if the statutory requirements are met. Some drugs have both patent and exclusivity protection while others have just one or none. Patents and exclusivity may or may not run concurrently and may or may not encompass the same claims. Exclusivity is not added to the patent life. Expired patents and exclusivity are not included in the published list.

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5. Why don't I see some antibiotic drugs products listed in the Patent and Exclusivity section of the Orange Book?

Title I of the 1984 Amendments did not apply to drug products submitted or approved under the former Section 507 of the Federal Food, Drug, and Cosmetic Act (antibiotic products). Therefore,
(1) holders of approved applications for antibiotic products did not need to submit the patent information required of other NDA application holders,
(2) these antibiotic products were not eligible for exclusivity protection, and
(3) applicants submitting abbreviated applications for these antibiotic products were not required to provide the patent certification statement that was included in ANDAs.

Antibiotics submitted after the effective date of the Food and Drug Administration Modernization Act (FDAMA) are covered or subject to the provisions of Title I. See Guidance for Industry and Reviewers **Repeal of Section 507 of the Federal Food, Drug and Cosmetic Act (/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM080566.pdf)**for more information.

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6. What are the PED designations on patents and exclusivity as listed in the Orange Book?

When pediatric exclusivity is granted to a drug product, a period of 6 months exclusivity is added to all existing patents and exclusivity on all applications held by the sponsor for that active moiety. Pediatric exclusivity does not stand alone. PED is annotated in the exclusivity column and is linked to exclusivity formerly granted. In the patent column, the patent is shown twice-once with the original patent expiration date and a second time reflecting the six month period of EXCLUSIVITY that links to that particular patent. Related information can be found on the **Pediatric Medicine Page (/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm049867.htm)** and **Pediatric FAQ page (/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm077915.htm)**.

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7. Where can I find patent and exclusivity regulations in the C.F.R.?

See 21 C.F.R. **314.52 (http://frwebgate.access.gpo.gov/cgi-bin/get-cfr.cgi?TITLE=21&PART=314&SECTION=52&YEAR=1999&TYPE=TEXT)**	Notice of certification of invalidity or noninfringement of a patent.
See 21 C.F.R. **314.53 (http://frwebgate.access.gpo.gov/cgi-bin/get-cfr.cgi?TITLE=21&PART=314&SECTION=53&YEAR=1999&TYPE=TEXT)**	Submission of patent information.

See 21 C.F.R. **314.95 (http://frwebgate.access.gpo.gov/cgi-bin/get-cfr.cgi?TITLE=21&PART=314&SECTION=95&YEAR=1999&TYPE=TEXT)**	Notice of certification of invalidity or noninfringement of a patent.
See 21 C .F.R. **314.107 (http://frwebgate.access.gpo.gov/cgi-bin/get-cfr.cgi?TITLE=21&PART=314&SECTION=107&YEAR=1999&TYPE=TEXT)**	Effective date of approval of a 505(b)(2) application or abbreviated new drug application under section 505(j) of the act.
See 21 C.F.R. **314.108 (http://frwebgate.access.gpo.gov/cgi-bin/get-cfr.cgi?TITLE=21&PART=314&SECTION=108&YEAR=1999&TYPE=TEXT)**	New drug product exclusivity.
See 21 C.F.R. **316.31 (http://frwebgate.access.gpo.gov/cgi-bin/get-cfr.cgi?TITLE=21&PART=316&SECTION=31&YEAR=1999&TYPE=TEXT)**	Scope of orphan-drug exclusive approval.
See 21 C.F.R. **316.34 (http://frwebgate.access.gpo.gov/cgi-bin/get-cfr.cgi?TITLE=21&PART=316&SECTION=34&YEAR=1999&TYPE=TEXT)**	FDA recognition of exclusive approval.

C.F.R (Code of Federal Regulation) (http://www.access.gpo.gov/cgi-bin/cfrassemble.cgi?title=199921). An external link to the ***Code of Federal Regulations*** on the Government Printing Office web site.

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8. How long does an applicant holder have to submit patent information?

Patent information is required to be submitted with all new drug applications at the time of submission of the NDA. Patent information is published after approval upon receipt of post approval submitted FDA form 3542. For patents issued after approval of the NDA, the applicant holder has 30 days in which to file the patent to have it considered as a timely filed patent. Patents may still be submitted beyond the 30 day timeframe but the patent is not considered a timely filed patent. ANDA holders are not required to make a certification to an untimely filed patent if the generic application is submitted before the patent.

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9. Is there a specific format in which patent information needs to be submitted to the agency?

As of August 18, 2003, patent information is required to be submitted on **FDA form 3542a (/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048352.pdf)** or **FDA form 3542 (/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048345.pdf)** depending on the approval status of the application. Form FDA 3542 is the only form that will be used for Orange Book publication

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10. How is an NDA holder notified if their application is granted exclusivity by the FDA?

No letters are sent to the sponsor indicating the grant of exclusivity. The **Orange Book (http://www.fda.gov/cder/ob/default.htm)** is the official vehicle for dissemination of this information.

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