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 and exclusivity apply to drugs in different ways. Patents can be issued or expire at any time, regardless of the drug's approval status. Exclusivity attaches upon the 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 neither. Patents and exclusivity may or may not run concurrently and may or may not cover the same aspects of the drug product. Patents and exclusivities that have expired are removed from the Orange Book.

5. What information related to pediatric exclusivity is listed in the Orange Book?

   When pediatric exclusivity is obtained, a 6-month period of 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 but attaches to existing exclusivity. When pediatric exclusivity attaches, in the patent column of the Orange Book, the patent is shown twice—once with the original patent expiration date and a second time reflecting the 6-month period of pediatric exclusivity linked to that particular patent. Related information can be found on the web page Qualifying for Pediatric Exclusivity Under Section 505A of the Federal Food, Drug, and Cosmetic Act: Frequently Asked Questions on Pediatric Exclusivity (505A), The Pediatric "Rule," and their Interaction.

6. Where can I find patent and exclusivity regulations in the Code of Federal Regulations (CFR)?

   See 21 CFR 314.50 Content and format of an NDA

   See 21 CFR 314.52 Notice of certification of invalidity, unenforceability, or noninfringement of a patent

   See 21 CFR 314.53 Submission of patent information

   See 21 CFR 314.54 Procedure for submission of a 505(b)(2) application requiring investigations for approval of a new indication for, or other change from, a listed drug

   See 21 CFR 314.60 Amendments to an unapproved NDA, supplement, or resubmission

   See 21 CFR 314.70 Supplements and other changes to an approved NDA

   See 21 CFR 314.94 Content and format of an ANDA

   See 21 CFR 314.95 Notice of certification of invalidity, unenforceability, or noninfringement of a patent

   See 21 CFR 314.96 Amendments to an unapproved ANDA

   See 21 CFR 314.97 Supplements and other changes to an ANDA

   See 21 CFR 314.101 Filing an NDA and receiving an ANDA