For patents that are granted after the drug application is filed, the brand name drug maker has 30 days to list the patent(s) from the grant date.

To seek approval for a generic drug, the generic drug maker must certify to the FDA that (i) there are no Orange Book-listed patents for the brand name drug or (ii) the patent(s) has (have) either expired or (iii) will expire by the time approval is sought or (iv) the listed patent(s) is (are) invalid or will not be infringed. If the latter, the notice of the certification is given to the patent owner and to the brand name drug maker, with an explanation as to why the patent(s) is (are) invalid or not infringed. If the patent owner does not bring a patent infringement suit against the generic drug maker within 45 days, the FDA may approve the generic version. Otherwise, the approval process is stayed for the shorter of 30 months or till the date when a court concludes the patent(s) is (are) either invalid or not infringed.

It requires generic manufacturers to demonstrate to the FDA that their generic drug is therapeutically equivalent to an approved brand name drug; that is, it is equivalence in terms of safety, strength, quality, purity, performance, intended use, and other characteristics. It reviews drug applications for generics more quickly. The FDA is hiring 40 generic drug experts to expedite the approval process and to institute targeted research to expand the range of generic drugs available to consumers.

It has improved the review process for generic drugs by instituting internal reforms. The reforms include making early communications with generic drug manufacturers who submit applications and guiding generic manufacturers in preparing and submitting quality, complete applications.

The recent decision in the U.S. patent infringement case Madey versus Duke is very important to academic researchers and the industry. Duke University had challenged the general assumption that academic research using a patented device or method cannot constitute infringement. The subject matter was a laser device, which had originally been developed and patented by Duke University. When the inventor left the university to pursue commercial applications for the laser, Duke University continued to use their model for research purposes. Duke claimed that it was entitled to continue using the laser for noncommercial purposes under the experimental use exception in the U.S. patent law. However, the court held that Duke University's use of the laser "unmistakably" furthered its commercial goals, including facilitating the education of students. The court further held that research using the laser had helped the university to obtain research grants. The equivalent provision in English law is section 60(5)(b) of the Patents Act 1977, which states that an act relating to the subject matter of a patent that is done for "experimental purposes" will not constitute infringement. The provision does not set out whether the exemption is available to those whose experimental purposes have a commercial element. There is no U.K. equivalent, however, of the U.S. exemption, which permits the unauthorized use of a patented device or method by a person seeking the FDA's approval to market a new product. The exemption applies only while the application is pending but extends to the use of patented devices or drugs in clinical trials, their sale for use in trials, demonstrations at trade shows, and the reporting of clinical data to potential investors.

The United States Patent and Trademark Office prescribes specific regulations regarding patent term adjustment (PTA):

- Application filed prior to June 8, 1995: 17 years from the date of issuance, regardless of the length of prosecution.