

proper location within the corporation in a timely manner.” In addition, the individual listed as the “agent for service” could change, resulting in confusion and delay in providing notice.

(Comment 16) Another comment suggested we require ANDA and 505(b)(2) applicants to file a new complete application for every drug product listed separately in the Orange Book rather than allow applicants to file supplements to approved applications. This comment would require new applications for each drug strength listed in the Orange Book as a separate product.

(Response) We decline to adopt the comment’s suggestions. Our current policies regarding supplements to ANDA and 505(b)(2) applications allow for significant administrative efficiencies and reduced application review times. Requiring separate ANDA or 505(b)(2) applications would substantially increase costs for applicants, as well as the agency, to accommodate the burden of creating, submitting, processing, and reviewing multiple, complete applications. Our policy regarding supplemental ANDAs for multiple strengths of a drug has been a major factor in reducing ANDA review times. Before 1991 (when applicants had to submit separate ANDAs for different strengths of a drug), the median approval time for an ANDA was 33 months. Today it is approximately 18 months. A key purpose of this final rule is to help expedite the approval of generic products so that they can more quickly be introduced to the marketplace. If we adopted the suggestion, the probable effect would be to delay the introduction of generic drugs into the market because the review times would increase. Requiring multiple applications would not provide any additional value to our review of ANDA applications. Consequently, we decline to require separate applications as suggested by the comment.

*c. Should the Single 30-Month Stay Be Further Limited?*

(Comment 17) Many comments agreed with our determination that the delay in approval of ANDA or 505(b)(2) applications could be limited to one 30-month stay per application. Other comments agreed with the limitation but stated that the single 30-month limitation was or should be:

- Per drug;
- Per ANDA, for all patents submitted before any ANDA filing; or
- Limited only to patents submitted within 30 days of NDA approval.

(Response) We decline to adopt the additional limitations as suggested by the comments. The act requires a certification for each listed patent for each application filed under sections 505(b)(2) or 505(j) of the act. We construe section 505(c)(2) of the act to require submission of patent information after NDA approval, without regard to when an ANDA or 505(b)(2) application has been filed. We decline to limit the 30-month stay resulting from a paragraph IV certification to only those patents submitted before any ANDA or 505(b)(2) filing, or those filed only within 30 days of NDA approval, or per listed drug instead of per application.

*d. Will the Application of Only One 30-Month Stay Affect Declaratory Judgment Actions Under the Act?*

(Comment 18) Several comments supported the single 30-month stay but expressed concern that limiting the notice requirement and 30-month stays to the first paragraph IV certification could affect the ability of ANDA and 505(b)(2) applicants to file a declaratory judgment action to resolve patent infringement issues. Some comments believed that in the absence of both notice to the NDA holder and patent owner and the ensuing 45-day period within which a patent infringement suit could be initiated, a declaratory judgment action could not be brought. Other comments opposed the single 30-month stay and also expressed concern about the ability to pursue a declaratory judgment action under the proposal. Some comments questioned whether a declaratory judgment action could be filed under other statutory provisions; the comments explained that the Hatch-Waxman Amendments created the act of patent infringement and, if litigation were brought “outside” the act, there would be no “case or controversy” required by those provisions. One comment cited *Cordis Corp. v. Medtronic, Inc.*, 835 F.2d 859, 862 (Fed. Cir. 1987), noting that “when the generic cannot meet the subjective standard of proving a reasonable apprehension of a suit by the brand company,” the case may be dismissed because there was no “case or controversy.” Another comment cited *Teva Pharmaceuticals, USA, Inc. v. FDA*, 182 F.3d 1003 (D.C. Cir. 1999), to claim that if no notification were received, arguably no declaratory action could be brought. Other comments suggested that limiting NDA holders to a single 30-month stay per ANDA or 505(b)(2) application would encourage the delay of litigation designed to resolve patent issues and thus would

reduce “certainty” for ANDA applicants.

(Response) We appreciate the desire to resolve patent issues quickly, but believe the concerns expressed about the ability to pursue declaratory judgment actions are unwarranted. Section 505(j)(5)(B)(iii) of the act provides: “Until the expiration of forty-five days from the date the notice made under paragraph (2)(B)(i) is received, no action may be brought under section 2201 of title 28, United States Code, for a declaratory judgment with respect to the patent.” We interpret this particular section as creating an exception to the general right of a party to bring a declaratory judgment action at any time that jurisdictional requirements are satisfied under title 28, United States Code. The general rule allowing declaratory judgments under 28 U.S.C. 2201 would be applicable as long as a party can satisfy the “case or controversy” requirement that is necessary to file a declaratory judgment action. The exception created in section 505(j) of the act restricts the timing when a declaratory judgment action may be filed under certain limited circumstances. Under the act, if notice of a paragraph IV certification is required, no declaratory judgment action can be filed until 45 days after that notice is given to the NDA holder and patent owner. However, if no notice is required to be provided to the NDA holder and patent owner, the exception created in section 505(j) of the act no longer applies, and the general rule permitting declaratory judgments to be filed at any time under 28 U.S.C. 2201 would apply.

We also disagree with the conclusions drawn from the cases cited in the comments that, in the absence of the notice of subsequent paragraph IV certifications, there would be no case or controversy on which to base a declaratory judgment action. A case or controversy can exist where first, there is reasonable fear of a lawsuit and, second, the plaintiff has actually produced the product in question or is prepared to produce the product. (See *Cordis Corp. v. Medtronic, Inc.*, 835 F.2d 859 (Fed. Cir. 1987)). In *Vanguard Research, Inc. v. PEAT, Inc.*, 304 F.3d 1249, 1255 (Fed. Cir. 2002), the court found that fear of a lawsuit existed when the competitor was engaged in activity subject to a patent infringement charge, and the patent holder already had sued the competitor to protect its technology. The court noted that: “[f]iling a lawsuit for patent infringement would be just another logical step in its quest to protect its technology.” This is similar to the