

and to obtain a 30-month stay on ANDA or 505(b)(2) approval. The phrase "one full opportunity for a 30-month stay" used throughout this preamble means a notice of a paragraph IV certification followed by either the full 45 day period, or notice followed by the initiation of patent litigation before the 45 days expire.

Only where both the 45 days have not run and the ANDA or 505(b)(2) applicant has not been sued for patent infringement will this exception apply. If the NDA holder brings suit before the 45 days, and the ANDA or 505(b)(2) applicant then changes its application to omit any paragraph IV certifications, the court where suit is pending can determine how to proceed.

For effective enforcement of this provision of the regulations, notice of the first paragraph IV certification(s) must be given by the ANDA or 505(b)(2) applicant either: (1) When the applicant receives from us an acknowledgement that the ANDA or 505(b)(2) application is sufficiently complete to permit substantive review, or (2) at the same time that the amendment to the ANDA or 505(b)(2) application is submitted to us. These requirements are already contained in our regulations at § 314.95(b) and (d) and § 314.52(b) and (d). (These also apply to a second notice of a paragraph IV certification when the first notice did not result in a full opportunity for a 30-month stay.) The importance of ANDA and 505(b)(2) applicants providing this notice was recently reaffirmed in *TorPharm, Inc. v. Thompson*, Civ. No. 03-0254 (D.D.C. April 25, 2003) (appeal pending). ANDA and 505(b)(2) applicants shall submit proper documentation of notice to us as required by §§ 314.95(e) and 314.52(e).

Second, an applicant who filed a paragraph IV certification with its original ANDA or 505(b)(2) application could change its paragraph IV certification (generally to a paragraph III certification) after a patent infringement suit is filed and after the 30-month stay has commenced. Such a change could occur, for example, as a result of a court order after a finding of infringement in the patent litigation. In this circumstance, an application that previously contained a paragraph IV certification would no longer do so. If such an application is subsequently amended to add a new paragraph IV certification, the notice obligation will not be triggered for the new certification. The notice requirement and one full opportunity for 30-month stay will have been exhausted when the first patent lawsuit was filed and a 30-month stay was imposed.

The third situation could occur when an applicant withdraws an ANDA or 505(b)(2) application that contained a paragraph IV certification after it has provided notification to the NDA holder and patent owner. If an ANDA or 505(b)(2) applicant were to reactivate its withdrawn application, it might contend that the notice that it provided prior to withdrawal of the ANDA or 505(b)(2) application was the only notice that could trigger a 30-month stay, regardless of whether the 45 day period had run, whether patent infringement litigation was initiated, or whether that litigation was terminated because of withdrawal of the application.

Our pre-existing regulations prevent an applicant from using withdrawal to defeat the opportunity for one 30-month stay. Under §§ 314.52(b) and 314.95(b), the applicant is not to give notice until it receives an acknowledgement letter from us stating that its application is sufficiently complete to permit review. Any notice sent prior to receipt of such letter will not constitute the notice that creates the full opportunity for the single 30-month stay.

Once the review period begins, an application may not be withdrawn and then "reactivated." If the ANDA or 505(b)(2) application is withdrawn during the review period, we "will treat the resubmission as a new application or abbreviated application" under § 314.100(b). If the applicant wishes to have the withdrawn ANDA or 505(b)(2) application reviewed, it must submit it as a new ANDA or 505(b)(2) application. The "decision to withdraw the application is without prejudice to refiling" as noted in § 314.65. However, we will treat the new ANDA or 505(b)(2) application in the same manner as any other original application. The applicant will be required to provide notice for paragraph IV certifications contained in the new ANDA or 505(b)(2) application, with the possibility of a single 30-month stay. If the new ANDA or 505(b)(2) application contains no paragraph IV certification, notice must be provided if it is later amended to include such a certification. In short, withdrawal of an ANDA or 505(b)(2) application will not defeat the opportunity for a 30-month stay of approval for the resubmitted ANDA or 505(b)(2) application.

We do not agree that § 314.94(a)(12)(viii) supports a "relation back" theory. The provision does provide that when an ANDA or 505(b)(2) applicant changes a certification in its application, "the application will no longer be considered to contain the prior certification," but it cannot be read to suggest that the

application will be considered to have contained only the changed certification retroactively to the date that the original certification was filed. If interpreted in that manner, an ANDA or 505(b)(2) applicant could amend certifications to other patents and make them paragraph IV certifications. Among other difficulties, an applicant could then argue that, by virtue of relating back, such a paragraph IV certification was the "first" application with a paragraph IV certification, potentially entitling the applicant to exclusivity under section 505(j)(5)(B)(iv) of the act. This theory would lead to absurd results in the application of 180-day exclusivity.

Furthermore, we note that ANDA applicants have substantial incentives to avoid manipulation of the patent certification process. The 180-day marketing exclusivity provided in section 505(j)(5)(B)(iv) of the act is a significant incentive for ANDA applicants to file legitimate paragraph IV certifications. Exclusivity as to each listed patent is available only to the first ANDA applicant filing a paragraph IV certification. Frequently, there is a race to submit the first paragraph IV certification. Consequently, given this incentive, we do not anticipate that ANDA applicants will manipulate their patent certification filings, because they could jeopardize their chances of obtaining the valuable 180-day exclusivity.

We encourage ANDA and 505(b)(2) applicants to resolve their concerns about commencing litigation quickly by providing voluntary notice to the NDA holder and patent owner as they wish. There is nothing in the final rule to prevent ANDA or 505(b)(2) applicants from providing notice on their own initiative, nothing to prevent NDA holders or patent owners from responding with patent litigation, and nothing to prevent ANDA or 505(b)(2) applicants from not marketing during the litigation. To the extent that ANDA or 505(b)(2) applicants seek resolution of outstanding patent issues before entering the market, we note that the applicant can file a declaratory judgment action (as discussed below) and enter into a stipulated preliminary injunction pursuant to which the ANDA or 505(b)(2) applicant will not enter the market during the course of the litigation. Such a stipulation, of course, must be consistent with FTC precedent and established antitrust requirements. Information on pertinent FTC consent orders may be obtained from the FTC or its Internet Web site.

The interpretation we are adopting in the final rule allows only one 30-month stay per ANDA or 505(b)(2) application;