

it does not permit multiple 30-month stays. Revising the rule to impose additional 30-month stays would be contrary to our interpretation of the act and the reasons for the rulemaking. Furthermore, requiring notice and imposing a second full opportunity for an additional 30-month stay under the circumstances described would be inconsistent with our legal basis for a single 30-month stay since we permit notice and one full opportunity for a 30-month stay per ANDA or 505(b) application. Multiple 30-month stays increase the delay in approval of generic drugs and result in increased costs to consumers because the cost of individual drugs is reduced when generic drugs enter the marketplace and compete with the NDA drug.

b. *Should All Paragraph IV Certifications Be Made Public and Should the Notice Requirements Be Modified?* The proposed rule would limit when a notice of a paragraph IV certification is provided to NDA holders and patent owners but did not address the content or format of the notice. The proposed rule did not address whether or not paragraph IV certifications were subject to public disclosure. We invited comment on whether our regulations regarding the notice by ANDA and 505(b)(2) applicants to the NDA holder and patent owner could and should be amended (67 FR 65454).

(Comment 14) Several comments suggested that we should post all paragraph IV certifications on our Web site because, these comments argued, there is no basis to exempt the paragraph IV certifications from public disclosure. The comments also suggested that we disclose all paragraph IV certifications.

(Response) We decline to amend the proposed rule to make public all paragraph IV certifications or otherwise provide notice of paragraph IV certifications to NDA holders and patent owners. Under current practice, paragraph IV certifications are subject to public disclosure under the Freedom of Information Act (FOIA) and FDA's public disclosure regulations once the notice of the paragraph IV certification has been provided to the NDA holder and patent owner. Because the notice to the NDA holder or patent owner of the paragraph IV certification is considered a public disclosure after notice has been given, the certification is available under FOIA. The final rule requires notice only for the first paragraph IV certification of an ANDA or 505(b)(2) application if that notice results in a full opportunity for a 30-month stay. Notice for a subsequent paragraph IV certification will be required only if the

full opportunity did not result. Only the paragraph IV certifications for which notice is required will be routinely subject to public disclosure prior to approval. All other certifications in an application would be considered confidential, commercial information. Unless the ANDA or 505(b)(2) applicant makes the subsequent certification public on its own accord, we are prohibited from any disclosure that would reveal the applicant's identity, contents of the application, or the timing of the application (see §§ 20.61(b) and 314.430). We do not believe that amending our FOIA regulations to permit the release of information typically considered confidential, commercial information, i.e. information that could cause competitive harm is appropriate, without deciding at this time that we could even do so.

Although parties are free to make paragraph IV certifications public themselves, we will continue to adhere to our pre-existing FOIA and public disclosure requirements as applicable to paragraph IV certifications. We also intend to publish on our Internet Web site, for each drug, the number of paragraph IV certifications filed to patents submitted after the effective date of this final rule, if it can be done in a manner that is consistent with FOIA. To avoid any inappropriate public identification, we will not publish the number of subsequent paragraph IV certifications if there is only one ANDA or 505(b)(2) application containing a paragraph IV certification because such publication would be tantamount to a public disclosure of that applicant's confidential, commercial information.

The NDA holder and patent owner also have other means to determine whether subsequent paragraph IV certifications have been filed. If a lawsuit is filed after notice of the paragraph IV certification, the NDA holder or patent owner can use the litigation process to discover the ANDA or 505(b)(2) applicant's certifications to subsequent patents. Furthermore, additional public information is available if we issue a tentative approval letter to the ANDA or 505(b)(2) applicant with a paragraph IV certification. These letters are publicly available before the ANDA or 505(b)(2) applicant receives an approval and note the applicable patents, patent certifications, and exclusivities affecting the timing of the approval of the ANDA or 505(b)(2) application.

We note that comments concerning public disclosure of paragraph IV certifications and the need for quick resolution of patent issues were

submitted both by brand name or innovator firms and their trade associations and by generic drug firms or related interests. We believe such mutual interests will encourage the voluntary disclosure of paragraph IV certifications.

(Comment 15) Several comments responded to our request for comments on whether our regulations concerning the certifications filed by ANDA and 505(b)(2) applicants and the notice to NDA holders and patent owners could or should be modified. Most comments agreed that we had the authority to modify both the certifications and the notice. One comment suggested that we "clarify the elements of a proper paragraph IV notification" to "ensure that paragraph IV notifications communicate meaningful information regarding the basis for an assertion that a listed patent is invalid or not infringed" and that "adequate" information is provided. Another comment suggested that the notice provided to the NDA holder and patent owner of a paragraph IV certification should include an explanation of the relationship between the patent claims as construed by the ANDA or 505(b)(2) applicant and the drug product. Another comment said we should require the NDA holder and patent owner to identify an "agent for service" and require service by registered mail to ensure that the notice will reach its "proper location within the corporation in a timely manner."

(Response) In reviewing the current notification requirements at § 314.95(c), we do not believe that the suggested solutions for clarification or more detailed explanations would improve upon the current regulation. The current regulation requires specific information in a notice that explains in full, and in detail, the nature of the claim that the listed patent is invalid or, unenforceable or will not be infringed. Our regulations, at §§ 314.52(a) and 314.95(a), require notification by registered or certified mail, return receipt requested. Our regulations also require documentation of a receipt establishing that the notice was received by the listed NDA holder and patent owner (see § 314.52(e) and § 314.95(e)). A receipt other than a return receipt or a letter from the recipient acknowledging receipt can be provided only with advance FDA agreement.

We do not believe it would be appropriate to further limit delivery of the notice, nor do we believe it is appropriate to require "agents for service." We are not persuaded that such agents would solve the comment's problem that "notice is not reaching its