

NDA holder and patent owner (see sections 505(b)(3) and 505(j)(2)(B) of the act (21 U.S.C. 355(b)(3) and 355(j)(2)(B)). The notice states that an ANDA or 505(b)(2) application containing a paragraph IV certification to a listed patent has been submitted for the NDA holder's approved drug product (known as the "listed drug"). The notice also includes a "detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed" (*id.*). If the NDA holder or patent owner brings an action for patent infringement within 45 days after notice of the paragraph IV certification has been received, then we may not make the approval of an ANDA or 505(b)(2) application effective for 30 months, or such shorter or longer period as a court may order, or until the date of a court decision (see sections 505(c)(3)(C) and 505(j)(5)(B)(iii) of the act (21 U.S.C. 355(c)(3)(C) and 355(j)(5)(B)(iii)). (We will refer to the date the approval of an ANDA or 505(b)(2) application is made effective as the "approval date" throughout the remainder of this preamble.)

B. What Did the Proposed Rule Say?

In the **Federal Register** of October 24, 2002 (67 FR 65448), we published a proposed rule (proposed rule) that would address:

- The types of patents that must and must not be submitted by NDA applicants and NDA holders or patent owners (for purposes of this preamble, an NDA applicant is someone who is seeking FDA approval of a specific new drug application or supplement, whereas an NDA holder is someone whose NDA we have approved);
- The types of patents that we will list in the Orange Book;
- The patent declaration that NDA applicants must submit as part of an NDA, an amendment, a supplement, or when submitting information on a newly issued patent; and
- The 30-month stay of the effective date of approval for an ANDA or 505(b)(2) application.

The preamble to the proposed rule noted that, on occasion, we have seen NDA holders submit new patents for listing shortly before other listed patents for the same drug were to expire (see 67 FR 65448 at 65449). We explained that, in some disputes over recently listed patents, the parties had questioned whether particular patents met the regulatory requirements for submission and listing in the Orange Book. These disputes sometimes resulted in judicial decisions that are inconsistent with our regulatory policies or our interpretation of our own regulations (*id.*). We

proposed to clarify our regulatory policies regarding patent submission, listing, certification, and notice. We also issued the proposal to respond, in part, to concerns raised by the Bureau of Competition and the Policy Planning Staff of the Federal Trade Commission (FTC). On May 16, 2001, the FTC submitted a citizen petition to FDA (FDA docket number 01P-0248) ("FTC Citizen Petition") asking for guidance concerning the criteria that a patent must meet before it is listed in the Orange Book. The FTC Citizen Petition asked us to clarify several patent listing issues and indicated that the FTC was conducting an extensive study of generic drug competition.

In July 2002, the FTC published the results of the study in a report entitled "Generic Drug Entry Prior to Patent Expiration: An FTC Study" ("FTC Report"). The FTC Report focused on the procedures used to facilitate a generic drug's entry into the market before the expiration of a patent or patents that claim the brand-name drug product. The FTC also recommended changing Federal law to "permit only one automatic 30-month stay per drug product per ANDA to resolve infringement disputes over patents listed in the Orange Book prior to the filing date of the generic applicant's ANDA" (see FTC Report at page ii). The FTC Report explained "To permit only one 30-month stay per drug product per ANDA should eliminate most of the potential for improper Orange Book listings to generate unwarranted 30-month stays" (*id.* at page v (footnote omitted)). In an appendix to its report, the FTC asked us to issue a regulation or guidance clarifying whether an NDA holder could submit various types of patents for listing in the Orange Book. The types of patents for which the FTC sought clarification were patents that claimed metabolites, polymorphs, intermediates, product-by-process patents, and double patents (see FTC Report at pages A-39-A-45).

C. What Does This Final Rule Do?

The comments received expressed both support for, and opposition to, various provisions of the proposed rule. After careful review of these comments, we are making final most of the provisions of the proposed rule with certain modifications. The final rule:

- Allows a full opportunity for only one 30-month stay per ANDA or 505(b)(2) application;
- Prohibits the submission of patents claiming packaging, intermediates, or metabolites;
- Requires the submission of certain patents claiming a different

polymorphic form of the active ingredient described in the NDA;

- Adds a requirement that for submission of polymorph patents the NDA holder must have test data demonstrating that a drug product containing the polymorph will perform the same as the drug product described in the NDA;

- Makes changes to the patent information required to be submitted and provides declaration forms for submitting that information to FDA, both with the NDA and after NDA approval; and

- Does not require claim-by-claim listing on the declaration form except for method-of-use patents claiming approved methods of use.

II. Comments on the Proposed Rule

We received over 35 comments on the proposed rule. The comments represented a diverse range of interests such as: Health insurance programs, brand name pharmaceutical companies, generic pharmaceutical companies, law firms, consumer organizations, pharmacy associations, the FTC, the New York Department of Health, large corporations, and individuals. In general, most comments supported the rule, either in whole or in part, and believed that the rule would help reduce prescription drug costs by making generic drugs available more quickly. However, other comments opposed the rule because they felt we had misinterpreted the act or because they felt that new legislation, rather than a regulation, was necessary. We describe the comments, and our responses to the comments, in this section. To make it easier to identify the comments and our responses, the word "Comment" in parentheses, will appear before the description of the comment, and the word "Response" in parentheses, will appear before our response. We also have numbered each comment to make it easier to identify a particular comment. The number assigned to each comment is only for organizational purposes. It does not signify the comment's value, importance, or the order in which we received it.

A. Comments on Specific Aspects of the Proposed Rule

1. What Patents Must and Must Not Be Submitted? (Section 314.53(b))

Proposed § 314.53(b) would require NDA applicants and holders or patent owners to submit information on the following types of patents for listing in the Orange Book. In brief, the proposed