

number. The comment also would require additional information on patents in the declaration form to identify that the product in the product-by-process patent was a novel product.

(Response) We agree, in part, with the comments that the information that would be required in the declaration should be modified. Also, we have created standardized declaration forms which will encompass the required patent declaration information.

The final rule changes the general requirements in pre-existing § 314.53(c)(1) by requiring that the patent information which must be submitted must be provided on the declaration forms in full. In final § 314.53(c)(2), we substitute declaration forms which must be used in place of the checklist described in the proposed rule. Each declaration form is a standard form that must be used by all NDA applicants or holders or patent owners for submission of patent information at the time of initial NDA or supplement filing, and upon and after NDA or supplement approval.

For several years our Internet Web site has included a sample format which can be used in submitting patent information required under pre-existing regulations. Although use of the sample format is purely voluntary, it is used extensively to submit patent information to us. Based on this experience, and given the additional information required in the final rule, we concluded that mandatory declaration forms are appropriate to obtain the patent information. We, thus, require use of forms in the final rule. Since we determined that forms are appropriate, we have consolidated information currently required by pre-existing regulations with the new required information. For example, we require a response on whether there are relevant patents related to the drug product, information currently required under pre-existing § 314.53(c)(3). This was not contained in the proposal but, for administrative efficiency, and to lessen the burden on NDA applicants or holders or patent owners, we have included in the declaration forms all of the required information relating to the patent submission.

The NDA applicant must provide a declaration form when an NDA, amendment, or supplement to an NDA is filed. The NDA holder must also submit another declaration form after NDA or supplement approval to provide information on all patents relevant to the approved NDA or supplement, whether or not information on any such patent was previously submitted. The declaration forms filed with us must be

attested to as to the accuracy of the patent information being submitted. Examples of the two declaration forms, FDA Form 3542 and 3542a, are provided in the Appendix found at the end of this document. The declaration forms will be available on the Internet at <http://www.fda.gov> by searching for the word "forms".

The final rule also revises pre-existing § 314.53(c)(2)(ii) and (c)(3) to conform to the changes we made to the patent information required on the declaration forms. The final rule requires a declaration form to be filed with us within 30 days after NDA approval; this is consistent with the pre-existing requirement. This form must also be used to file patent information on any patents submitted or issued after NDA approval. This declaration form requires the NDA holder or patent owner to provide the patent information applicable to the approved NDA. It is similar to the declaration form filed upon the filing of an NDA, supplement, or amendment. However, the declaration form filed upon or after NDA approval requires information on the approved product and a description of the approved methods of use for the use code listing in the Orange Book. This description will be limited to 240 characters as discussed in the response to comment 7.

The final rule describes other information required for the declaration forms not identified in the proposed rule. Some of the additional information will allow us to more easily determine the eligibility of the patent for listing, while other information will provide more complete information related to the responsibilities of the NDA holders or ANDA applicants. For example, we require the issue date of the patent in order to determine whether the patent has been submitted to us within the required 30 days. We require information on whether the patent being submitted has been submitted previously for the NDA or supplement referenced in the declaration. For example, an earlier listed patent may have included several method-of-use claims but only one method of use previously approved and submitted. A second method of use may be approved in a supplement and must be submitted for listing. Such information will assist the Orange Book staff with its administrative listing responsibilities. The address and contact information of the patent owner required in the declaration forms will assist in the required notification to the patent owner of a paragraph IV certification. We have elaborated on the requirement for asserting that the polymorph is the

"same" as the active ingredient approved in the NDA. We require information on whether the patents submitted claim metabolites or intermediates to help ensure that the patents prohibited from submission under final § 314.53(b) are not submitted. Similarly, we require information on patents claiming the drug product to prevent the submission of patents claiming packaging.

The final rule also requires information on product-by-process patents as discussed in the response to comment 2 of section II.A of this document. We have added a requirement that the NDA applicant or holder or patent owner state whether the patent being submitted is a product-by-process patent in which the product claimed is novel. This is to help ensure that process patents are not submitted for listing.

We agree that the attestation in the declaration form should be revised in the final rule. In the proposal, we stated that we had revised the declaration so that applicants would "make careful and well-considered representations" and "stand behind the accuracy of that information" (see 67 FR 65448 at 65453). In the final rule, we revise the statement to be more specific about the need to ensure the information is accurate. We adopt the attestation statement contained in 28 U.S.C. 1746 for unsworn declarations and include attestations in the declaration forms. The attestation statements in the declaration forms read as follows:

(Declaration Form 3542a submitted with NDA, amendment or supplement.)

The undersigned declares that this is an accurate and complete submission of patent information for the NDA, amendment, or supplement pending under section 505 of the Federal Food, Drug, and Cosmetic Act. This time-sensitive patent information is submitted pursuant to 21 CFR 314.53. I attest that I am familiar with 21 CFR 314.53 and this submission complies with the requirements of the regulation. I verify under penalty of perjury that the foregoing is true and correct.

(Declaration Form 3542 submitted upon or after NDA approval.)

The undersigned declares that this is an accurate and complete submission of patent information for the NDA or supplement approved under section 505 of the Federal Food, Drug, and Cosmetic Act. This time-sensitive patent information is submitted pursuant to 21 CFR 314.53. I attest that I am familiar with 21 CFR 314.53 and this submission complies with the requirements of the regulation. I verify under penalty of perjury that the foregoing is true and correct. We also include a warning statement in the declaration forms to alert the submitter that a willfully and knowingly false statement is a criminal offense under 18 U.S.C. 1001.