

We decline to revise the proposed rule to list every excluded type of patent as requested by some comments. Based on our experience, we believe that if we attempted to include questions on all types of patents, such as "business method" or "registry" patents, or specifically list all exclusions in the final rule, there would be disagreements over whether the examples are all-inclusive or whether other types of patents were excluded as well. We believe the patent information requested is sufficient to ensure only eligible patents are submitted for listing.

We also decline to revise the declaration to require identification of an NDA applicant or NDA holder's patent applications that are under review by the PTO. The act does not contain any references to pending patents. In contrast, sections 505(b) and 505(c)(2) of the act contain requirements for patent information to be submitted after the patent is issued. Section 505(b) of the act requires that the information submitted on any patent claiming the drug include the patent number and expiration date of the patent. We publish that information when we list the patent in the Orange Book. A patent number and expiration date are available only when the PTO issues a patent and are not available for pending patent applications. Accordingly, we will not require submission of information regarding pending patent applications.

Although we do not require submission of information concerning pending patent applications, we understand that pending patent applications are generally publicly disclosable by the PTO if pending for more than 18 months at the PTO or foreign patent offices. In addition, information concerning pending patents would not provide any useful information if the PTO never issued the patent.

We note that we will not evaluate a patent to assess whether the declaration is accurate or whether the patent has been appropriately submitted for listing (see our response to comment 8). We will, however, review the declaration for completeness and to determine that the information given by the NDA applicant or holder or patent owner indicates that the patent is eligible for listing.

Although section 505(b)(1) of the act requires submission of patent information upon the filing of an NDA, we will rely only on the declaration form filed upon or after NDA approval under § 314.53(c)(2)(ii) to list patent information in the Orange Book. Patent information for newly approved NDAs,

NDA supplements, or newly issued patents will not be published in the Orange Book unless and until we receive a complete declaration submitted post-NDA approval indicating the patent is eligible for listing.

We interpret the statute to permit listing of only those patents claiming the approved drug product and its approved uses. Even though the NDA applicant must submit patent information prior to NDA approval, it is not until the NDA or supplement has been approved that the scope of that approval is known. For example, we might approve only one of two indications proposed in an NDA and, thus, patents on an unapproved indication or use, although submitted with the original NDA, could not be listed. Therefore, as a way of confirming or amending the original patent information, a declaration form must be submitted after approval. If the declaration form submitted after NDA approval is incomplete or indicates a patent is not eligible for listing, we will notify the NDA holder and indicate the reason. The NDA holder must resubmit the declaration form with complete information indicating that the patent is eligible for listing. If the declaration form is incomplete or indicates the patent is not eligible for listing, we will refuse to list the patent until an appropriate declaration form has been submitted.

For patents newly issued by the PTO after the NDA is approved, section 505(c)(2) of the act requires that the NDA holder submit the patent information to us within 30 days to be considered timely filed. All such patent information must be contained in a complete declaration submitted post-NDA approval indicating that the patent is eligible for listing. A patent is considered listed in the Orange Book as of the date it is received in the Central Document Room as required in § 314.53(d)(4) and (d)(5), if it is accompanied by a declaration form that is both complete and contains information indicating that the patent is eligible for listing. If we must notify an NDA holder that a declaration form is incomplete or the patent is not eligible for listing, and the NDA holder then submits an acceptable declaration within 15 calendar days, we will consider the patent timely filed. So, for example, suppose an NDA holder submits information on a new patent to us 20 days after the patent is issued by PTO, and we notify the NDA holder 5 days later that the declaration is incomplete. If the NDA holder submits an adequate declaration within 15

calendar days of the notification, we will consider the patent information to have been submitted as of the date we originally received it, that is, within the 30 day period allowed by the statute. If the NDA holder submits the adequate declaration more than 15 calendar days after notification, we will consider the patent information to have been submitted on the day the revised declaration form is received, which may be more than 30 days after the date of patent issuance. Such patents will be subject to patent certification only as described in § 314.94(a)(12)(vi). If the NDA holder does not submit an adequate declaration for the newly issued patent, we will not list the patent in the Orange Book. This approach is appropriate because it gives the NDA holder who promptly submits information on a newly-issued patent a reasonable period of time to correct a mistake in a patent declaration, while at the same time ensuring that there are adequate declarations and minimal delays for listed patents. We will accept certifications to any patent only from the date an acceptable declaration is submitted.

The process established in § 314.53(f) for patent listing challenges is not altered by our requirements for patent information and declaration forms. Interested parties may still rely on that process if they believe a patent has been submitted and listed in error.

We are aware of NDA holders that have submitted patents for listing that have been listed in the Orange Book and then, at a later time, been removed from the Orange Book at the NDA holder's request. If, after the patent has been removed from the Orange Book, the NDA holder again seeks to submit the patent for listing, we will require resubmission of the patent information and the filing of an accompanying patent declaration before the patent will be relisted. Such resubmission will be governed under the final rule. If the resubmission of a previously listed patent takes place after the effective date of this rule, the final rule applies as described in section IV of this document.

The final rule does not require us to review or evaluate patents, but will simplify and clarify the submission process for NDA applicants and holders and patent owners, and will promote administrative efficiency. The additional information required by the declaration form will help ensure that only appropriate patents are submitted for listing.