

and validity of patents to the PTO and the courts.

iii. *What Should the Patent Declaration Say?* (Proposed § 314.53(c)).

Proposed § 314.53(c) would require a patent declaration for NDA applicants and holders and patent owners to complete as part of the NDA, an amendment, a supplement, or for information on a later-issued patent. The proposed revised declaration in the proposal was a "checklist" that focused on individual patent claims. The proposed declaration required information on each claim to help ensure that applicants submit only appropriate patent information, and that they stand behind the accuracy of the information. The proposed requirement to identify claims was intended to help all parties focus on the same claim and help prevent arguments as to whether a particular claim claimed the approved drug product.

(1) *Should the Declaration Identify Individual Patent Claims?*

(Comment 11) Several comments objected to identifying patent claims as part of the declaration. The comments stated that a claim-by-claim listing:

- Would be "unnecessarily onerous" because patents may contain many claims;
- Could threaten the patent holder's legitimate rights if the NDA applicant failed to list a patent claim because the failure to list that claim could be used as an admission against the NDA holder's or patent owner's interests in litigation;
- Could expose the NDA holder to criminal and civil liability if the claim cited in the declaration is later found not to claim the drug; or,
- Is irrelevant to patent listing because the patent, and not the patent claims, is what we must list in the Orange Book.

Other comments supported the claim-by-claim listing. Some comments requested that we impose a 30-month stay only if the specific claims submitted in the patent declaration were the subject of the patent litigation filed within the 45-day time period.

(Response) We have re-examined our rationale for proposing a claim-by-claim listing and have concluded that submission of a claim-by-claim declaration for all patents is not warranted. Such detailed information is not explicitly required by the act and is not necessary for a patent to be listed in the Orange Book. Section 505(b)(1) of the act requires that the patent be one that "claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably

be asserted \* \* \*." The number of claims contained within a particular patent does not affect the ability of the patent to be listed as long as there is at least one claim that meets the two required elements.

Individual patent claims are relevant for purposes of the Orange Book only in the context of method-of-use patents. The specific method-of-use claims are essential to our review because sections 505(j)(2)(A)(viii) and 505(b)(2)(B) of the act allow ANDA and 505(b)(2) applicants to file statements which assert that the method-of-use patent does not claim a use for which the applicant is seeking approval. The ANDA or 505(b)(2) applicant does not have to seek approval for all uses approved for the reference listed drug. Thus, the claim-by-claim listing of method-of-use patents will permit ANDA and 505(b)(2) applicants to assess whether they are seeking approval for a use claimed in the listed patent, and thus determine whether to submit a patent certification or a section viii statement. Additionally, we can verify that the certification or statement is correct, and that only the appropriate methods of use are included in the proposed labeling for the ANDA or 505(b)(2) drug product.

We decline to adopt the recommendation made in some comments to require all claims to be listed and then provide a 30-month stay only for litigation involving a claim listed in the Orange Book. This suggestion would require us to significantly exceed our ministerial responsibility in listing patents because we would be obliged to evaluate patent lawsuits and their relation to individual patent claims. We discuss our ministerial role in the response to comment 8. Removing the proposed requirement of a claim-by-claim listing in the final rule should not be detrimental to ANDA or 505(b)(2) applicants. In fact, several generic companies, the FTC and the Generic Pharmaceutical Association (GPhA), stated in their comments that no "prudent generic company" would rely solely on Orange Book listings to evaluate patent information for litigation exposure, particularly when all patents cannot be listed in the Orange Book. Thus, we believe that identification of the relevant patent(s), as opposed to the individual patent claims (other than for method-of-use patents), satisfies the act's explicit requirements, provides sufficient information to potential applicants to determine if a more thorough patent search or analysis is warranted, and will

help to ensure appropriate patent submissions.

(2) *Should the Declaration Be Expanded or Modified?* The proposed rule would revise § 314.53(c)(2) and would replace the existing, general declaration with a more detailed declaration. The proposed declaration would be a "checklist" that required information on the approved drug product including trade name, active ingredient(s), strength(s), dosage form(s), and approval date. For each patent submitted, each claim of a patent which applied to the drug substance (active ingredient), drug product (formulation or composition), and method of use would need identification. A "yes" or "no" check-off would be required as to each individual applicable patent claim. The proposed § 314.53 would require the NDA applicant or holder or patent owner to state in the declaration that the information was provided for an NDA submitted under section 505 of the act.

(Comment 12) Several comments supported our proposed changes to the declaration but also suggested additions to the declaration. These comments would add the following information to the declaration:

- Specific exclusions of patents for forms of the active ingredient not marketed, such as acids, freebases, salts, and isomers;
- Exclusion of patents claiming labeling matters such as business methods, registries, titration/dosing schedules, or ornamental designs;
- Exclusion of a patent claiming a drug substance claimed in conjunction with another active ingredient or method of using the combination which is not the claimed drug substance;
- Various forms of statements indicating or certifying the submitter has filed accurate information;
- Identification of the NDA applicant's pending patent applications; and
- Additional information for product-by-process patents.

The comments suggested that it was necessary to identify each of the excluded patents in the declaration form and the codified text. Several comments suggested requiring a sworn statement and an acknowledgement that a false statement was subject to criminal penalties. For example, one comment suggested that the declaration include the statement: "The undersigned declares that all of the above information has been provided in accordance with Title 28, section 1746, entitled 'Unsworn declarations under penalty of perjury,'" followed by the signature, date, title, and telephone