

rule is invalid, we wish to emphasize our intent that the remaining provisions of the final rule be permitted to take effect.

4. Implementation and Effective Date

The preamble to the proposed rule described how a final rule would be applied to pending applications (see 67 FR 65448 at 65457) as follows:

- For patents filed for an NDA that has not been approved by the effective date of a final rule, the rule would apply on the effective date. For example, if the final rule were to become effective 60 days after the date of publication in the **Federal Register**, and an NDA was pending on the 60th day after the final rule's publication date, the NDA applicant would have to comply with the final rule's patent listing and patent declaration requirements. ANDA and 505(b)(2) application applicants would be subject to the revised notice requirement. Each ANDA or 505(b)(2) application referencing that NDA would be subject to the possibility of only one 30-month stay per ANDA or 505(b)(2) application.

- If we have approved the NDA as of the final rule's effective date, and no ANDA has been filed before that date, then any patent listed before that date would be subject to the pre-existing regulation. For example, if the final rule were to become effective 60 days after the date of publication in the **Federal Register**, and we approved the NDA on the 59th day after the date of publication, the NDA applicant would not have to amend its patent listing and patent declaration to comply with the final rule. ANDA and 505(b)(2) applications submitted after the effective date would be subject to the revised notice requirement. Each ANDA or 505(b)(2) application referencing that NDA would be subject to the possibility of only one 30-month stay per ANDA or 505(b)(2) application.

- If we have approved the NDA as of the final rule's effective date, and an ANDA or 505(b)(2) application has been filed before that date, then any patent listed before that date would be subject to the pre-existing regulations, as described in the example immediately above. The ANDA or 505(b)(2) application applicant would have to provide notice to the patent owner and NDA holder if the ANDA or 505(b)(2) application contained a paragraph IV certification. Multiple 30-month stays in the approval date would be possible.

- If the NDA holder or NDA applicant files patent information after the final rule's effective date, then the NDA holder or applicant is subject to the final rule's patent listing and patent

declaration requirements, and ANDA or 505(b)(2) application applicants would not have to provide notice if their applications previously contained a paragraph IV certification. Only one 30-month stay per each ANDA's or 505(b)(2) application's approval date would be possible. We invited comment on how a final rule should be implemented.

(Comment 24) Several comments suggested alternative effective dates including the following:

- Apply the final rule to all ANDAs filed before the effective date of the final rule and cancel any existing multiple 30-month stays;

- Apply the final rule retroactively to all current NDA holders by requiring all NDA holders to be subject to only one 30-month stay and apply the declaration provisions to require all current NDA holders or patent owners to file a new declaration and certification for already listed patents using the declaration statement in the proposal;

- Apply the new declaration requirements retroactively to require the new information on patents currently listed in the Orange Book; if the propriety of a patent listed in Orange Book for a current NDA holder or patent owner is questioned, the NDA holder or patent owner must file a new declaration or FDA should delist the patent.

In contrast, other comments supported the implementation plan as proposed.

(Response) We will implement the final rule on a prospective basis, as we stated in the proposed rule. The fact that we made our intent public in a proposed rule and the time lag between when the rule was proposed and when this final rule is effective provides sufficient time for most parties to adjust their practices and expectations, or to take other steps to suit their business practices.

We do delay the implementation date for submission of information concerning a patent claiming a polymorph that is the active ingredient of the drug product described in the approved NDA. We provide a longer period of implementation to accommodate the tests required to establish that the drug product containing the polymorph will perform the same as the drug product described in the NDA. This test data must exist when a polymorph patent is submitted to us. We recognize that the testing necessary to obtain the data for submission of polymorph patents claiming the active ingredient of the product described in the NDA may take at least 6 months to complete. There will be NDA applicants and holders and

patent owners who have not already conducted testing. The 6 months will provide time for NDA applicants and holders and patent owners with patents pending at the PTO to conduct the tests needed to produce the data required for the declaration statement in time to submit any newly issued patent within 30 days of issuance.

We also decline to apply the final rule retroactively. If we canceled all multiple 30-month stays currently applicable to ANDAs and 505(b)(2) applications or applied the declaration requirements to already submitted patents for existing NDAs, we would be applying the provisions retroactively. As we noted in the proposal (67 FR 65448 at 65457): "If we were to adopt an alternative implementation plan, we would risk upsetting legitimate expectations held by those who had relied on our earlier interpretation of the act." As a general matter, a statutory grant of legislative rulemaking does not encompass the power to implement such regulations on a retroactive basis in the absence of express language granting such power (see *Bowen v. Georgetown University Hospital*, 488 U.S. 204, 208–09 (1988)). There is no question that this rule "changes the legal landscape" (see *National Mining Ass'n v. Department of Labor*, 292 F.3d 849, 858 (D.C. Cir. 2002)). Applying this rule retroactively would subject us to potential legal challenge. Thus, adopting these suggestions would lead to even greater uncertainty as to the applicability of the provisions.

After further consideration, however, we believe that the proposed rule's implementation plan will not fully effect our intent to implement the provisions only prospectively. Accordingly, as described in section IV of this document, we have clarified our implementation plan to ensure prospective application of the final rule. Nevertheless, patent owners may voluntarily complete, and NDA holders may voluntarily complete and submit, new patent declarations, using FDA Forms 3542 and 3542a, for patents not subject to the final rule and currently listed in the Orange Book. This course is particularly advisable for method-of-use patents, in light of the *Purepac* decision and concerns about implementation of section 505(j)(2)(A)(viii) of the act. Such voluntary submission of new patent declarations will not bring patents within the scope of the final rule with respect to notice and 30-month stays.