

- Give us clear legal authority to act or be less vulnerable to judicial review; or,

- Result in timely and predictable access to generic drugs.

One comment noted that Congress had considered several bills to address 30-month stays. The comment declared that such proposed legislative action indicated both that we lacked authority to issue the rule and that new legislation was needed. Another comment suggested that we support legislation to allow only one 30-month stay and only for patents that are listed within 30 days of an NDA's initial approval.

(Response) We believe that, under our existing regulations, there have been delays in generic drugs reaching the market, as well as confusion over certain patent listing requirements. This rule is intended to help ensure that lower cost, safe and effective generic drugs become available to Americans without any inappropriate delays, while still preserving incentives to innovate. These changes can be achieved through rulemaking, using our existing legal authority. We cannot predict whether, if at all, legislation addressing these issues will be enacted. The possibility that there could be legislation to address problems associated with 30-month stays and generic drug approvals cannot, and should not, preclude us from using our existing authority to address these problems. We also note that those comments favoring legislative solutions over regulatory ones apparently assume that legislative changes would necessarily lead to less litigation than a rule. Based on our past experience in defending statutory interpretations, we question whether such a presumption is appropriate here. We recognize that a regulation may not always be a perfect solution due to limits on our statutory authority, but that recognition does not mean that we cannot use our existing legal authority to engage in rulemaking to improve our regulatory approach.

Additionally, we disagree with the comments that claimed we lack authority to issue the rule. The preamble to the proposed rule discussed our legal authority (see 67 FR 65448 at 65457). We will not repeat that discussion here. The fact that Congress has considered, or is currently considering, bills on the 30-month stay issue does not preclude us from exercising our existing authority, nor demonstrate that we presently lack that authority. As the Supreme Court has explained:

We have stated * * * that failed legislative proposals are a particularly dangerous ground on which to rest an

interpretation of a prior statute.

Congressional inaction lacks persuasive significance because several equally tenable inferences may be drawn from such inaction, including the inference that existing legislation already incorporated the offered change.

(See *Central Bank of Denver v. First Interstate Bank of Denver*, 511 U.S. 164, 187 (1994).)

(Citations and internal quotation marks omitted.)

Although it would be both inappropriate and premature for us to take a position on any legislative concept without seeing the details of any specific proposed or draft legislation, we are always willing to work with Congress. Until then, we will not take a position on legislation to allow only one 30-month stay for patents filed within 30 days after NDA approval.

2. Will the Different Interpretation Affect Existing Exclusivities?

We stated in the preamble to the proposed rule that the implementation of the final rule would not affect an ANDA's eligibility for 180-day exclusivity under 505(j)(5)(B)(iv) of the act (see 67 FR 65448 at 65457).

(Comment 22) Several comments addressed different aspects of the 180-day and 3 year exclusivity provisions of the Hatch-Waxman Amendments. The comments offered suggestions on changing the exclusivity trigger, requiring the forfeit of the exclusivity if parties agree to delay marketing and expressed concerns about the potential increase in the availability of 180-day exclusivity if we allow additional patents to be filed.

(Response) We appreciate the complexities of the various exclusivities provided by the act. As we noted in the proposed rule, eligibility for 180-day exclusivity will follow the same general principles as before implementation of this final rule. The first ANDA applicant to file a substantially complete ANDA, or supplement, containing a paragraph IV certification to a listed patent will be eligible for exclusivity as to that patent under section 505(j)(5)(B)(iv) of the act. For a paragraph IV certification to be effective for exclusivity purposes, when notice is required, notice must be given as described in the response to comment 13 of section II.A of this document. However, when notice is not required, a paragraph IV certification will be effective for exclusivity purposes without notice. We understand that each patent listed in the Orange Book may form the basis for a claim to 180-day exclusivity. Thus an increase or decrease in listed patents as a result of

this final rule could affect the number of exclusivity periods. Other suggestions made in the comments are beyond the scope of the final rule. We are not altering our interpretation of exclusivity in the final rule.

3. Should the Provisions of the Final Rule Be Severable?

The proposed rule did not address whether each provision should be considered independent of other provisions and, thus, severable if any provision were determined to be invalid.

(Comment 23) Although there were no comments that directly addressed severability, one comment suggested that the limitation on multiple 30-month stays was unnecessary because the revised patent listing provisions would prevent improper patents from being submitted for listing in the Orange Book.

(Response) Although we agree that the changes to the patent submission and listing provisions and the information required on the declaration forms will help ensure that improper patents are not submitted for listing, we also believe that eliminating multiple 30-month stays will help maintain the balance intended by the Hatch-Waxman Amendments and is equally important to the final rule. Each of the final rule provisions reinforces interrelated goals. Clarifying that certain patents may not be submitted for listing should lead to the submission of fewer improper patents. Requiring additional patent declaration information from NDA applicants or holders or patent owners also should help ensure that only eligible patents are submitted. Eliminating the opportunity for multiple 30-month stays also should reduce incentives to submit improper patents.

Based on our past experience we acknowledge that the provisions of this final rule will neither completely resolve all issues governing patent submission, nor will they eliminate attempts to manipulate the final rule for market advantage. We also believe that each provision will reduce the opportunities for manipulation and, thus, is independently justified and worthwhile. However, we believe each provision stands on its own as a legal and practical matter.

From the comments we have received to the proposed rule, we believe there is a possibility that we will be challenged on various portions of the final rule. We expect we will prevail in any such challenge, as the final rule and each of its provisions is legally sound. If, however, a court should conclude that any one or more provisions of the final