

application prior to the amendment of the application, section 505(j)(2)(B)(iii) of the act applies. But when an ANDA or 505(b)(2) application contained a paragraph IV certification prior to the amendment and one full opportunity arose for a 30-month stay, no notice obligation is triggered for subsequent paragraph IV certifications.

We do not agree with the comment that the legislative history indicates that Congress changed the 18-month stay to a 30-month stay because it intended that patent litigation be resolved before a generic application could be approved. The House Judiciary Committee rejected an "amendment [that] would have required that either the patent expire before approval, or that there be a final decision by a Federal District Court that the patent in question was not valid" (see H. Rept. 98-857, Part 2, 98th Cong. 2d Sess., 9 (1984)). It appears that the amendment was rejected because the effect "would have been to substantially delay generics from getting onto the market when they seek to challenge the validity of a patent" (*id.* at 10). Congress explicitly rejected amendments to prohibit generic entry before judicial resolution of the patent issues prior to approval, but accepted a 30-month stay period, whether or not litigation was finally resolved, because, as a practical matter, it was believed the time period would not affect when generic manufacturers would begin to market their drugs (see 130 Congressional Record H9118 (September 6, 1984) (remarks of Rep. Waxman)).

We also believe that the legislative history quoted in the comments is ambiguous at most and can be interpreted in a way that does not undercut our changed interpretation. The report states: "In the case where the patent certification is amended in an ANDA to allege invalidity or non-infringement of a patent, the FDA may not make the approval effective within the 45 day period that an action for patent infringement may be brought." Although this language does not distinguish explicitly between situations when an application already contained a paragraph IV certification and those when it did not, it would not be unreasonable to interpret it to apply only when invalidity or non-infringement of a patent is alleged for the first time. Language describing when an ANDA is "amended * * * to allege invalidity or non-infringement of a patent" can be read in another way as "amended to include" a paragraph IV certification. When an ANDA or 505(b)(2) application is amended to include an allegation of invalidity or non-infringement of a listed patent for

the first time, we cannot approve the application for 45 days, and notification of the paragraph IV certification will be required. For additional paragraph IV certifications, when a patent has already resulted in a paragraph IV certification and a full opportunity for a 30-month stay, no notice is required and we do not need to wait for 45 days to approve an ANDA or 505(b)(2) application if it is otherwise ready for approval.

f. *Is There a Sufficient Basis to Adopt the Change in Legal Interpretation?* In the preamble to the proposed rule, we detailed the factual basis for our decision to reevaluate our legal interpretation of the maximum number of 30-month stays per ANDA or 505(b)(2) application (see 67 FR 65448 at 65455). We noted that our impression that multiple 30-month stays were increasing was confirmed by the FTC Report. In addition, the FTC Report found that there was an increase in submission of later-issued patents, many of which "do not appear to claim the approved drug product or an approved use of the drug" (*id.*).

(Comment 20) Several comments questioned the factual basis for what they called our "dramatic change in position" and argued that the information used in the FTC Report was already known to us. Since there was no "new information," the comments maintained that the facts did not provide an "adequate" basis for our adoption of a single 30-month stay per ANDA or 505(b)(2) application.

(Response) We disagree with the contention that our factual basis underlying our rule was inadequate. At the outset, we note that the comments proceed from a false premise to a flawed conclusion. The "newness" of the underlying data is not the appropriate legal standard for evaluating the reasonableness of our different interpretation. An agency must consider "the wisdom of its policy on a continuing basis" "with or without a change in circumstances" (see *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 863, 104 S. Ct. 2778, 2792 (1984); *Motor Vehicle Manufacturers Ass'n v. State Farm Mut. Automobile Ins. Co.*, 463 U.S. 29, 57, 103 S. Ct. 2856, 2873 (1983)). Our pre-existing regulations permitting multiple 30-month stays have led to protracted delays in generic drug approvals and, therefore, need to be changed.

If "newness" of the underlying data were the test, the data here would satisfy it. Over the last several years, there has been an increasing number of multiple 30-month stays for a single drug product. These stays have caused

significant delays in the approval of generic versions of frequently prescribed drugs. We anticipate that if we do not address the current situation, these multiple 30-month stays and resulting delays in generic drug approvals would continue to increase. There will be an increasing number of patents expiring in the next few years covering innovator drugs currently on the market. According to our records, over 500 drug patents will expire between 2003 and 2009. We have identified 26 top-selling drugs subject to patents with expiration dates between 2003 and 2005. These 26 drugs had combined 2001 retail sales exceeding \$38 billion (over 25 percent of all 2001 prescription drug expenditures) and include 7 of the top 10 best selling drugs. The pressure on NDA holders and innovator companies to protect their market share and delay generic competition into the market will continue to increase. We would expect to see an increase in the conduct documented in FTC Report if our regulations remained the same.

The FTC's comprehensive and discerning analyses of the data it collected substantiated the seriousness of the problem. The FTC analyzed the relationship between patent listings and multiple 30-month stays, conducted an extensive review of various lawsuits involving multiple 30-month stays (including lawsuits in which we were not a party) and analyzed the outcome of the litigation. Although we provided some raw data to the FTC to assist its investigations (and thus that information was not "new" to us), we did not have all of the data that the FTC collected nor had we analyzed the data in the manner done by the FTC.

We have concluded that our regulations permitting multiple 30-month stays have led to considerable delays in the approval of generic drugs. This consequence was not intended either by Congress or by FDA. Thus, we have changed our regulations to address this problem.

B. Miscellaneous Comments

1. Do We Need Legislation to Accomplish Our Goals?

The preamble to the proposed rule did not discuss any legislative efforts to enhance the availability of generic drugs.

(Comment 21) Several comments said that legislation would be better than rulemaking or that we should support legislation. In general, the comments felt that legislation would:

- Better resolve intellectual property issues than our rule;