

NDA holders submit two or more patents for a single NDA. While this may continue to occur, we believe that this final rule may reduce the number of patents submitted for listing because we have clarified the type of patents that must be submitted. The number of patents submitted could increase because we allow polymorph patents to be submitted or it could decrease if no test data exist to demonstrate that a drug product containing the polymorph will perform the same as the drug product described in the NDA. We, thus, estimate the number of annual certifications at 1.5×74 (the number of original certifications). Thus, the information collection burden for §§ 314.50(i)(1)(i) and 314.94(a)(12) (certifications) would be 444 hours (74 respondents \times 1.5 response per respondent \times 4 hours per response = 444 hours). The information burden for §§ 314.52(a)(3) and 314.95(a)(3) (notices) would be 897 hours (74 respondents \times 1.01 response per respondent \times 12 hours per response).

To estimate the number of enhanced patent declarations that will be submitted annually, we referred to historical data on patent submissions. For the years 1998 to 2002, the numbers of patents submitted to us were 159, 205, 321, 280, and 268 respectively, for an annual average of 246.6 ((159 patents + 205 patents + 321 patents + 280 patents + 268 patents) / 5 years = 247 patents / year). Because many of these individual patents are included in multiple NDA submissions, there could be multiple declarations for a single patent. From our review of submissions, we believe the number of duplicate patent listings to be 20 percent of the number of unique patents. Therefore, we estimate 49.2 (246.6 patents \times 20 percent) patent declarations will be multiple listings, and there will be 296 (247 declarations + 49 declarations) total annual patent declarations. As we received 115 and 99 NDAs in 2000 and 2001, respectively, we assume there will be 107 ((115 applications + 99 applications) / 2 years = 80 applications / year) instances where an NDA holder would be affected by the patent declaration requirements and that each of these holders would, on average, submit 2.8 (296 declarations / 107 instances = 2.8 declarations per instance) on FDA Forms 3542 or 3542a.

However, § 314.53(b) and (c) have different impacts on the hours per response. On the one hand, § 314.53(b) might decrease the reporting burden because it would specify certain patents that must not be submitted, and thus NDA applicants and holders and patent owners will not submit information on

those patents. On the other hand, § 314.53(b) will require NDA applicants and holders or patent owners to submit patent information on different forms of the active ingredient described in the NDA, and this could result in more patent information being submitted or less patent information if test data do not exist to demonstrate that a drug product containing the polymorph will perform the same as the drug product described in the NDA. We cannot determine whether the potential net effect will increase, decrease, or not change the overall burden associated with submitting patent information, so we have not assigned any change in the total reporting burden for the change in patent information alone.

In contrast, § 314.53(c) makes the patent declaration more detailed. The change in the declaration will increase the burden hours per response under § 314.50(h) (the provision under which we covered patent declarations described in § 314.53(c)) because respondents will be required to be more precise in their declarations. Based on other rules that require respondents to compile and submit information in their possession, we estimate that the information required to be submitted on the patent declaration forms, FDA Forms 3542 or 3542a, will result in an additional information collection burden of 18 hours. However, the previous burden hour estimate of 1,666 hours for § 314.50 covered paragraphs (a) through (f), in addition to paragraphs (h) and (k) (see 66 FR 29143 at 29146, May 29, 2001). We are unable to determine how many of the 1,666 hours were devoted to patent declarations, so, in this table, we simply add 18 hours to the 1,666 hour estimate for § 314.50(a) through (f), (h), and (k), resulting in a burden hour estimate of 1,684 hours (1,666 hours + 18 hours) to account for a respondent's need for more time to make and verify the patent declaration. Thus, the information collection burden for § 314.50(a) through (f), (h), and (k) (citing § 314.53) will increase from the estimate we made in the proposed rule of 209,560 hours to 498,464 hours (296 annual responses \times 1,684 hours per response = 498,464 hours).

The information collection provisions of this final rule have been submitted to OMB for review. Prior to the effective date of this final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it

displays a currently valid OMB control number.

IX. Analysis of Economic Effects

We have examined the impacts of the rule under Executive Order 12866, and the Regulatory Flexibility Act (5 U.S.C. 601–612), and under the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages, distributive impacts, and equity). Unless the agency certifies that the rule is not expected to have a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act, as amended by the Small Business Regulatory Flexibility Act (SBREFA), requires agencies to analyze regulatory options that would minimize any significant economic impact of a rule on small entities. Section 202 of UMRA requires that agencies prepare a written statement of anticipated costs and benefits before proposing any rule that may result in expenditures by State, local, and tribal governments in the aggregate, or by the private sector, of \$100 million in any one year (adjusted annually for inflation). We have conducted analyses of the rule, and have determined that the rule is consistent with the principles set forth in the Executive Order and in these statutes.

The final rule is a significant regulatory action as defined by the Executive Order. With respect to the Regulatory Flexibility Act, we certify that this final rule is not expected to have a significant impact on a substantial number of small entities. This regulatory action is also a major rule under the Congressional Review Act. The discussion of costs and benefits is consistent with the requirements of the UMRA.

A. Summary

The economic impacts arise from a variety of effects of this rule. The primary effect is the elimination of multiple 30-month stays, which (as explained earlier) will result in earlier market entry by generic drug manufacturers without appreciable effects on pharmaceutical innovation. Earlier generic competition will result in gains for two groups. It will reduce pharmaceutical prices to consumers and increase net revenues of generic drug manufacturers. Earlier competition also