

erosion of market share is \$3.160 billion and the reduction in support costs would reduce this loss by \$142 million. We estimate the 1-year cost of providing the patent declaration information by completing the patent declaration forms is \$293,000 and the cost associated with polymorph patents is \$3.3 million. Thus, we estimate the 1-year cost to innovator firms is \$3.022 billion.

We recognize that in projecting the future impact of this final rule, we must account for changes in the market for pharmaceuticals. The Office of the Actuary at CMS, projects that expenditures on prescription pharmaceuticals will increase dramatically in the near future. As in the proposed rule, we account for the projected growth in pharmaceutical expenditures by escalating our 1-year estimate by the annual CMS projected growth in prescription drug expenditures. We estimate the 10-year costs for the final rule are \$51.584 billion. We annualized over the 10-year period at a 7 percent discount rate yields to obtain a cost of \$4.871 billion.

#### D. Summary of Costs and Benefits

We estimate the 10-year cost of this final rule to be \$51.584 billion and the annualized cost to be \$4.871 billion. The 10-year benefit of this final rule is estimated to be \$53.940 billion and the annualized benefit is \$5.093 billion. These benefit and cost figures include the estimated impacts of an economic transfer. Thus, the 10-year net benefit is \$2.356 billion and the annualized net benefit is \$222 million. The quantified benefits exceed the quantified costs.

Moreover, there are benefits that are difficult to quantify. These benefits include reduced costs of litigation and more predictability in the business environment. The benefits to consumers also involve favorable secondary benefits, such as improved access to less expensive drugs. It also preserves the balance struck in the Hatch-Waxman Amendments.

#### E. Regulatory Alternatives

In creating this final rule, we considered several regulatory alternatives, including not enacting this rule. We rejected the alternative of not enacting this final rule because under the current situation, NDA holders and patent owners are able to use multiple 30-month stays to delay generic entry and frustrate the intent of the Hatch-Waxman Amendments. We considered allowing the submission of polymorph patents for listing in the Orange Book without the required test data demonstrating "sameness." We rejected this alternative as we decided that a

patent claiming different polymorphs of the active ingredient described in the NDA needed to have test data demonstrating that a drug product containing the polymorph will perform the same as the drug product described in the NDA. This requirement is similar to the requirement of establishing bioequivalence.

We also considered using the current system of patent declarations. This alternative was also rejected because the pre-existing declaration information may be insufficient to prevent NDA applicants and holders and patent owners from submitting patents to us that should not be submitted and listed under the act. The choices to require tests demonstrating "sameness" for polymorph patents and the required patent information provided in the patent declarations are particularly important in light of the fact that we lack the authority, expertise and resources to evaluate patents submitted to determine whether they should be listed in the Orange Book.

#### F. Small Business Impact

Unless the agency certifies that the rule is not expected to have a significant impact on a substantial number of small entities, the Regulatory Flexibility Act, as amended by SBREFA, requires agencies to analyze regulatory options that would minimize any significant economic impact of a rule on small entities. In the proposed rule, we certified that we believed the rule is not expected to have a significant impact on a substantial number of small entities, as we did not know of any small innovator companies that use or would use multiple 30-month stays to block entry from generic competitors. We did not receive comment on this certification and we continue to believe that this final rule will not have a significant impact on a substantial number of small entities.

#### List of Subjects in 21 CFR Part 314

Administrative practice and procedure, Confidential business information, Drugs, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 314 is amended as follows:

#### PART 314—APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG

■ 1. The authority citation for 21 CFR part 314 continues to read as follows:

**Authority:** 21 U.S.C. 321, 331, 351, 352, 353, 355, 355a, 356, 356a, 356b, 356c, 371, 374, 379e.

■ 2. Section 314.52 is amended by redesignating paragraph (a)(3) as paragraph (a)(4) and by adding new paragraph (a)(3) to read as follows:

#### § 314.52 Notice of certification of invalidity or noninfringement of a patent.

(a) \* \* \*

(3) This paragraph does not apply if the applicant amends its application to add a certification under § 314.50(i)(1)(i)(A)(4) when the application already contained a certification under § 314.50(i)(1)(i)(A)(4) to a patent unless:

(i) The notice of the previous certification under § 314.50(i)(1)(i)(A)(4) was withdrawn or changed to a certification other than a certification under § 314.50(i)(1)(i)(A)(4); and

(ii) The 45-day period under section 505(c)(3) of the act had not expired; and

(iii) No person receiving notice under paragraphs (a)(1) and (a)(2) of this section had brought an action against the applicant for infringement of the patent that was the subject of the withdrawn or changed certification under § 314.50(i)(1)(i)(A)(4).

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■ 3. Section 314.53 is amended by revising paragraph (b) and paragraphs (c)(1) through (c)(3) to read as follows:

#### § 314.53 Submission of patent information.

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(b) *Patents for which information must be submitted and patents for which information must not be submitted*—(1) *General requirements.* An applicant described in paragraph (a) of this section shall submit the required information on the declaration form set forth in paragraph (c) of this section for each patent that claims the drug or a method of using the drug that is the subject of the new drug application or amendment or supplement to it and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product. For purposes of this part, such patents consist of drug substance (active ingredient) patents, drug product (formulation and composition) patents, and method-of-use patents. For patents that claim the drug substance, the applicant shall submit information only on those patents that claim the drug substance that is the subject of the pending or approved application or that claim a drug substance that is the same as the active ingredient that is the subject of the approved or pending