repeat here some parts of our analysis that were described in detail in the proposal (see 67 FR 65448 at 65459 to 65464).

B. Benefits of the Regulation

We have identified two sources of benefits from the elimination of 30-month stays. Generic drug manufacturers gain the market share lost by innovators. Generic revenues, therefore, would be expected to increase. Also, to the extent that these generic drugs are less expensive than innovator drugs, consumers will save money from earlier access. Our model, as described in the proposed rule (see 67 FR 65448 at 65460 to 65462), estimates costs and benefits to consumers and innovators and generic drug firms for the first year the rule would be in effect. The projected changes in market shares and prices in the model are based on studies published in the economic literature and by FDA. We then escalate the 1-year estimates by the CMS—projected annual percentage increases in prescription drug expenditures to obtain estimates for 10 years. This 10-year stream is then annualized at a 7-percent discount rate to obtain the annualized estimate.

1. Gains to Consumers

Generic drugs are cheaper than their innovator counterparts. As a generic drug gains market share and its price falls, consumers save more money. The elimination of multiple 30-month stays per ANDA and 505(b)(2) applications and earlier market entry by generic drugs will reduce consumer expenditures on pharmaceuticals. We estimate that the 1-year savings to consumers are projected to be $2.040 billion. We use the CMS pharmaceutical expenditure projections to escalate the base year figure results in a 10-year consumer savings estimate of $34.822 billion for the final rule. Our annualized benefit

using a 7-percent discount rate is $3.288 billion, the same as the proposed rule.

2. Gains to the Generic Drug Industry

Innovator market share erosion is accompanied by a gain in generic market share. We estimate the 1-year increase in revenues to be $1.120 billion. Escalating this impact by the annual increases in pharmaceutical expenditures yields a 10-year revenue gain of $19.117 billion. Our annualized impact using a 7-percent discount rate is $1.805 billion. These estimates are the same as in the proposed rule.

3. Benefits Not Quantified

Many important benefits associated with this final rule are difficult to quantify. We believe that by eliminating multiple 30-month stays, we are improving consumer access to lower-priced versions of safe and effective medications. This benefit is consistent with the objective of improving access to affordable quality healthcare. Consumers with better access to affordable safe and effective therapies are healthier and enjoy a higher quality of life.

The costs of allocating legal resources to defend patent protections are substantial. We do not know the extent to which this final rule will reduce such costs, but by eliminating multiple 30-month stays per ANDA and 505(b)(2) application, we are reducing the number of instances where innovator and generic drug firms would engage in such litigation. Moreover, we believe that this rule will reduce litigation because it clarifies which patents must and must not be submitted and reduces incentives for submitting patents that may ultimately be found invalid. It logically follows that the reduction in resources devoted to litigation would result in savings to both innovator and generic drug firms.

This final rule reduces the level of uncertainty associated with drug marketing decisions. For example, the final rule diminishes incentives associated with submitting later-issued patents late in the patent life or exclusivity period of the product described in the NDA. Increasing the predictability of the generic drug entry process reduces product introduction costs faced by generic drug firms. In the final rule, we are also addressing a source of confusion over the submission of polymorph patents for listing in the Orange Book. We believe that a more predictable business environment benefits both innovator and generic drug firms.

Another important benefit of the final rule involves the balance between rewarding innovation and the availability of less expensive drugs. In striking this balance, we do not believe that the Hatch-Waxman Amendments intended to create the potential for NDA holders to obtain multiple 30-month stays to delay generic competitors. We believe this balance to be important, yet find the value difficult to quantify. Nevertheless, in addressing the issue of multiple 30-month stays, we believe this action has the very valuable benefit of preserving the balance struck in the Hatch-Waxman Amendments.

4. Total Benefits of the Regulation

The total quantified benefits of this final rule include the gains in generic drug manufacturer revenues and consumer savings from earlier access to less expensive pharmaceuticals. The 1-year benefits to generic drug manufacturers and consumers are $1.119 billion and $2.040 billion, respectively. Escalating these base year costs over 10 years yields generic drug manufacturer revenue gains of $19.117 billion and consumer savings of $34.822 billion, for a total of $53.940 billion. The 10-year annualized benefits, using a 7-percent discount

rate, are $1.805 billion for generic drug manufacturers and $3.288 billion for consumers, for a total of $5.093 billion.

C. Costs of the Regulation

In the proposed rule, we identified two sources of costs. Innovators lose revenues from earlier generic competition and innovators must complete patent declarations. We summarize the revenue loss and we assess the costs associated with the declaration requirement. In addition, we estimate the burden to industry from the requirement that, for submission of patents claiming different polymorphs of the active ingredient described in the NDA, there must be test data demonstrating that a drug product containing the polymorph will perform the same as the drug product described in the NDA.

In the proposed rule, we addressed potential concerns about the effect this action may have on innovation. After considering potential impacts, we concluded that any negative effect would be minimal. As discussed in the proposed rule, while the initial 30-month stay is part of the balance struck in the Hatch-Waxman amendments to reward innovation, the subsequent stays are not part of this balance. According to the FTC report, most of the court rulings examined by the FTC, which involved a subsequent 30-month stay, found the underlying patent to be either invalid or not infringed. Extending market exclusivity through multiple stays is a strategy that has become popular in the last few years and is not a longstanding source of research funding. Subsequent stays could actually hinder innovation through the replacement effect, in that they provide a disincentive for an NDA holder to improve upon its own product. Moreover, to the extent that subsequent 30-month stays might be associated with increases in spending on research, these increases do not necessarily improve social welfare (see 67 FR 65460). We received no comment

on our assessment of the impact on innovation and continue to believe it to be reasonable.

1. Innovator Revenue Loss

As discussed in the analysis of impacts in the proposed rule, the elimination of multiple 30-month stays per ANDA or 505(b)(2) application allows generic drugs to enter the market earlier. Upon entry, generic versions of an innovator drug gradually lower their prices and take market share from the innovator. With the loss of market share, innovator revenues are lower than they would be had the innovator been allowed to use multiple 30-month stays to delay generic entry. In the analysis in the proposed rule, we used data from instances where generics had been blocked with multiple 30-month stays and calculated the impact of a typical drug being blocked for a typical period of time. We estimated the 1-year loss in innovator revenues to be $3.160 billion. As discussed in the proposed rule, we believe that the negative impact on innovators from earlier generic competition will be mitigated somewhat by a reduction in required innovators' costs. With earlier generic competition, innovators will reduce marketing expenses. In the proposed rule, we estimated the 1-year reduction in support costs to be approximately $142 million. For the final rule, we estimate that the 1-year loss in revenues, after adjusting for the reduction in support costs, is $3.017 billion, the same as in the proposed rule.

2. Declaration Costs

In the proposed rule, we used earlier information collection data to estimate there will be 124 annual patent declarations by innovator firms. We now believe that the number of patents submitted to us each year would better estimate the annual number of patent declarations. 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. We understand that many of these individual patents are included in multiple NDA submissions, so there could be multiple declarations for a single patent and this method could underestimate the number of declarations. 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 x 20 percent) patent declarations will be multiple listings, and there will be 295.8 (246.6 + 49.2) annual patent declarations. We have created patent declaration forms to make the submission of patent information less burdensome. The two forms, for filing with an NDA submission and upon or after NDA approval, will contain more information, but we have simplified the format to make these easier to complete. In simplifying the forms, we believe our initial estimate of 24 additional hours per declaration to complete these forms likely overstates the actual burden. To account for the simplification of the declaration process, we have lowered the expected time required to complete a patent declaration to 18 hours.

A regulatory affairs specialist could perform the tasks associated with this process. Based on the total average hourly compensation of $55.14[3] the estimated cost would be $992 ($55.14 per hour x 18 hours) per event. The burden on individual firms would depend on the number of declarations they submit. We estimate that the 1-year burden for submitting patent declaration forms is $293,000 ($992 per event x 295.8 events).

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[3] The figure of $55.14 represents the hourly rate for "lawyer" from the Bureau of Labor Statistics 2003 National Compensation Survey of $38.77, and then adjusted for inflation at 1.58 percent (unadjusted CPI–U) and increased 40 percent to account for benefits.

3. Cost of Submitting Polymorph Patents

We are requiring the submission of patent information for patents that claim different polymorphs of the active ingredient described in the NDA. NDA holders will now be able to submit these polymorph patents for listing in the Orange Book, as long as they have test data demonstrating that a drug product containing the polymorph will perform the same as the drug product described in the NDA.

We cannot make a precise estimate of the impact of these requirements, as costs can vary substantially depending on the substance being tested, the number of subjects required, the cost of raw materials, and other factors. As part of an unrelated study in 1998, we commissioned a contractor, Eastern Research Group (ERG) to estimate the cost of bioequivalence testing. We believe the burden of demonstrating that a drug product containing the polymorph will perform the same as the drug product described in the NDA to be similar to that of demonstrating bioequivalence. Our estimates include both the cost of manufacturing the batch and the cost of conducting the bioequivalence testing. ERG found the cost of performing such testing to be between $70,000 and $750,000.[4] We believe the cost of showing "sameness" to be at the higher end of this range, and estimate the burden to be between $500,000 and $750,000. The midpoint of this estimate is $625,000.

We believe a firm's decision to submit a polymorph patent for listing will depend on whether the expected benefits to the firm from listing exceed the costs of showing "sameness." We recognize that potential benefits from listing polymorph patents may be reduced by the elimination in the final rule of multiple 30-month stays in approval of ANDA or 505(b)(2) applications. Thus,

[4] Pharmaceutical Industry Cost Savings Through Use of the Scale-up and Post-Approval Change Guidance for Immediate Release Solid Oral Dosage Forms (SUPAC–IR), prepared for FDA, 1998, p. 63.

the cost of demonstrating "sameness" would deter submitting patents for listing with expected values less than approximately $625,000. We believe the typical value of a deterred polymorph patent to be substantially less than the cost of submission of the patent for listing, as many of the patents have little value without the ability to delay generic entry through multiple 30-month stays. For this analysis, we assume such low value patents to be worth approximately 20 percent of the cost of showing "sameness," or $125,000.

We believe the annual number of polymorph patents that will be submitted for listing to be small, but we do not know with certainty. We reviewed a publicly available listing of NDAs in which an outside party had identified patents it judged to be polymorph patents. Of the 105 NDAs in the sample, there were 13 polymorph patents. Applying that same ratio to the 107 expected NDAs per year, we estimate 13.2 (107 x 13 / 105) potential polymorph patents to be submitted for listing per year. We assume that a polymorph patent will have a high potential value (greater than $625,000) and be submitted, or will have a low potential value ($125,000) and not be submitted. With the elimination of multiple 30-month stays per ANDA or 505(b)(2) application, we believe the number of high-value polymorph patents to be a subset of the number of total polymorph patents, and assume three-fourths of the potential patents will not be submitted for listing. Thus, we assume 3.3 (13.2 potential patents x 0.25 likelihood of being high value) patents will be submitted for listing at a 1-year cost of $2.06 million (3.3 patents x $625,000 cost per patent). Likewise, we assume 9.9 (13.2 potential patents x 0.75 likelihood of being low value) patents will not be submitted each year. We estimate the 1-year cost from the inability to submit these patents for listing to be $1.24 million (9.9 patents x $125,000 value of low-value patent) and the 1-year burden associated

with the test data demonstrating "sameness" for polymorph patents to be submitted for listing is estimated to be $3.3 million ($2.06 million + $1.24 million).

4. Total Costs of the Regulation

The total costs of the final rule include the lost revenues to innovator firms from the erosion of market share, mitigated by the decrease in support costs, the cost of completing a more detailed patent declaration, and the costs associated with the requirement that test data exist demonstrating "sameness" in order to submit a polymorph patent for listing. The estimated 1-year loss in revenues from 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. 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 remains 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 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*).

* * * * *

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.

* * * * *

(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 application. For patents that claim a polymorph that is the same as the active ingredient described in the approved or pending application, the applicant shall certify in the declaration forms that the applicant has test data, as set forth in paragraph (b)(2) of this section, demonstrating that a drug product containing the polymorph will perform the same as the drug product described in the new drug application. For patents that claim a drug product, the applicant shall submit information only on those patents that claim a drug product, as is defined in § 314.3, that is described in the pending or approved application. For patents that claim a method of use, the applicant shall submit information only on those patents that claim indications or other conditions of use that are described in the pending or approved application. The applicant shall

separately identify each pending or approved method of use and related patent claim. For approved applications, the applicant submitting the method-of-use patent shall identify with specificity the section of the approved labeling that corresponds to the method of use claimed by the patent submitted. Process patents, patents claiming packaging, patents claiming metabolites, and patents claiming intermediates are not covered by this section, and information on these patents must not be submitted to FDA.

(2) *Test Data for Submission of Patent Information for Patents That Claim a Polymorph.* The test data, referenced in paragraph (b)(1) of this section, must include the following:

(i) A full description of the polymorphic form of the drug substance, including its physical and chemical characteristics and stability; the method of synthesis (or isolation) and purification of the drug substance; the process controls used during manufacture and packaging; and such specifications and analytical methods as are necessary to assure the identity, strength, quality, and purity of the polymorphic form of the drug substance;

(ii) The executed batch record for a drug product containing the polymorphic form of the drug substance and documentation that the batch was manufactured under current good manufacturing practice requirements;

(iii) Demonstration of bioequivalence between the executed batch of the drug product that contains the polymorphic form of the drug substance and the drug product as described in the NDA;

(iv) A list of all components used in the manufacture of the drug product containing the polymorphic form and a statement of the composition of the drug product; a statement of the specifications and analytical methods for each component; a description of the manufacturing and packaging procedures and

in-process controls for the drug product; such specifications and analytical methods as are necessary to assure the identity, strength, quality, purity, and bioavailability of the drug product, including release and stability data complying with the approved product specifications to demonstrate pharmaceutical equivalence and comparable product stability; and

(v) Comparative in vitro dissolution testing on 12 dosage units each of the executed test batch and the new drug application product.

(c) *Reporting requirements*—(1) *General requirements.* An applicant described in paragraph (a) of this section shall submit the required patent information described in paragraph (c)(2) of this section for each patent that meets the requirements described in paragraph (b) of this section. We will not accept the patent information unless it is complete and submitted on the appropriate forms, FDA Forms 3542 or 3542a. These forms may be obtained on the Internet at http://www.fda.gov by searching for "forms".

(2) *Drug substance (active ingredient), drug product (formulation or composition), and method-of-use patents*—(i) *Original Declaration.* For each patent that claims a drug substance (active ingredient), drug product (formulation and composition), or method of use, the applicant shall submit FDA Form 3542a. The following information and verification is required:

(A) New drug application number;

(B) Name of new drug application sponsor;

(C) Trade name (or proposed trade name) of new drug;

(D) Active ingredient(s) of new drug;

(E) Strength(s) of new drug;

(F) Dosage form of new drug;

(G) United States patent number, issue date, and expiration date of patent submitted;

(H) The patent owner's name, full address, phone number and, if available, fax number and e-mail address;

(I) The name, full address, phone number and, if available, fax number and e-mail address of an agent or representative who resides or maintains a place of business within the United States authorized to receive notice of patent certification under sections 505(b)(3) and 505(j)(2)(B) of the act and §§ 314.52 and 314.95 (if patent owner or new drug application applicant or holder does not reside or have a place of business within the United States);

(J) Information on whether the patent has been submitted previously for the new drug application;

(K) Information on whether the expiration date is a new expiration date if the patent had been submitted previously for listing;

(L) Information on whether the patent is a product-by-process patent in which the product claimed is novel;

(M) Information on the drug substance (active ingredient) patent including the following:

(*1*) Whether the patent claims the drug substance that is the active ingredient in the drug product described in the new drug application or supplement;

(*2*) Whether the patent claims a polymorph that is the same active ingredient that is described in the pending application or supplement;

(*3*) Whether the applicant has test data, described in paragraph (b)(2) of this section, demonstrating that a drug product containing the polymorph will perform the same as the drug product described in the new drug application or supplement, and a description of the polymorphic form(s) claimed by the patent for which such test data exist;

(*4*) Whether the patent claims only a metabolite of the active ingredient; and

(*5*) Whether the patent claims only an intermediate;

(N) Information on the drug product (composition/formulation) patent including the following:

(*1*) Whether the patent claims the drug product for which approval is being sought, as defined in § 314.3; and

(*2*) Whether the patent claims only an intermediate;

(O) Information on each method-of-use patent including the following:

(*1*) Whether the patent claims one or more methods of using the drug product for which use approval is being sought and a description of each pending method of use or related indication and related patent claim of the patent being submitted; and

(*2*) Identification of the specific section of the proposed labeling for the drug product that corresponds to the method of use claimed by the patent submitted;

(P) Whether there are no relevant patents that claim the drug substance (active ingredient), drug product (formulation or composition) or method(s) of use, for which the applicant is seeking approval 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;

(Q) A signed verification which states:

"The undersigned declares that this is an accurate and complete submission of patent information for the NDA, amendment or supplement pending under section 505 of the Federal Food, Drug, and Cosmetic Act. This time-sensitive patent information is submitted pursuant to 21 CFR 314.53. I attest that I am familiar with

21 CFR 314.53 and this submission complies with the requirements of the regulation. I verify under penalty of perjury that the foregoing is true and correct."; and

(R) Information on whether the applicant, patent owner or attorney, agent, representative or other authorized official signed the form; the name of the person; and the full address, phone number and, if available, the fax number and e-mail address.

(ii) *Submission of patent information upon and after approval.* Within 30 days after the date of approval of its application or supplement, the applicant shall submit FDA Form 3542 for each patent that claims the drug substance (active ingredient), drug product (formulation and composition), or approved method of use. FDA will rely only on the information submitted on this form and will not list or publish patent information if the patent declaration is incomplete or indicates the patent is not eligible for listing. Patent information must also be submitted for patents issued after the date of approval of the new drug application as required in paragraph (c)(2)(ii) of this section. As described in paragraph (d)(4) of this section, patent information must be submitted to FDA within 30 days of the date of issuance of the patent. If the applicant submits the required patent information within the 30 days, but we notify an applicant that a declaration form is incomplete or shows that the patent is not eligible for listing, the applicant must submit an acceptable declaration form within 15 days of FDA notification to be considered timely filed. The following information and verification statement is required:

(A) New drug application number;

(B) Name of new drug application sponsor;

(C) Trade name of new drug;

(D) Active ingredient(s) of new drug;

(E) Strength(s) of new drug;

(F) Dosage form of new drug;

(G) Approval date of new drug application or supplement;

(H) United States patent number, issue date, and expiration date of patent submitted;

(I) The patent owner's name, full address, phone number and, if available, fax number and e-mail address;

(J) The name, full address, phone number and, if available, fax number and e-mail address of an agent or representative who resides or maintains a place of business within the United States authorized to receive notice of patent certification under sections 505(b)(3) and 505(j)(2)(B) of the act and §§ 314.52 and 314.95 (if patent owner or new drug application applicant or holder does not reside or have a place of business within the United States);

(K) Information on whether the patent has been submitted previously for the new drug application;

(L) Information on whether the expiration date is a new expiration date if the patent had been submitted previously for listing;

(M) Information on whether the patent is a product-by-process patent in which the product claimed is novel;

(N) Information on the drug substance (active ingredient) patent including the following:

(*1*) Whether the patent claims the drug substance that is the active ingredient in the drug product described in the approved application;

(*2*) Whether the patent claims a polymorph that is the same as the active ingredient that is described in the approved application;

(*3*) Whether the applicant has test data, described at paragraph (b)(2) of this section, demonstrating that a drug product containing the polymorph will perform the same as the drug product described in the approved application

and a description of the polymorphic form(s) claimed by the patent for which such test data exist;

(*4*) Whether the patent claims only a metabolite of the active ingredient; and

(*5*) Whether the patent claims only an intermediate;

(O) Information on the drug product (composition/formulation) patent including the following:

(*1*) Whether the patent claims the approved drug product as defined in § 314.3; and

(*2*) Whether the patent claims only an intermediate;

(P) Information on each method-of-use patent including the following:

(*1*) Whether the patent claims one or more approved methods of using the approved drug product and a description of each approved method of use or indication and related patent claim of the patent being submitted;

(*2*) Identification of the specific section of the approved labeling for the drug product that corresponds to the method of use claimed by the patent submitted; and

(*3*) The description of the patented method of use as required for publication;

(Q) Whether there are no relevant patents that claim the approved drug substance (active ingredient), the approved drug product (formulation or composition) or approved method(s) of use 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;

(R) A signed verification which states: "The undersigned declares that this is an accurate and complete submission of patent information for the NDA,

amendment or supplement approved under section 505 of the Federal Food, Drug, and Cosmetic Act. This time-sensitive patent information is submitted pursuant to 21 CFR 314.53. I attest that I am familiar with 21 CFR 314.53 and this submission complies with the requirements of the regulation. I verify under penalty of perjury that the foregoing is true and correct."; and

(S) Information on whether the applicant, patent owner or attorney, agent, representative or other authorized official signed the form; the name of the person; and the full address, phone number and, if available, the fax number and e-mail address.

(3) *No relevant patents.* If the applicant believes that there are no relevant patents that claim the drug substance (active ingredient), drug product (formulation or composition), or the method(s) of use for which the applicant has received approval, 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, the applicant will verify this information in the appropriate forms, FDA Forms 3542 or 3542a.

* * * * *

4. Section 314.95 is amended by redesignating paragraph (a)(3) as paragraph (a)(4) and by adding new paragraph (a)(3) to read as follows:

§ 314.95 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 § 314.94(a)(12)(i)(A)(*4*) when the application already contained a certification under § 314.94(a)(12)(i)(A)(*4*) to a patent unless:

(i) The notice of the previous certification under § 314.94(a)(12)(i)(A)(*4*) was withdrawn or changed to a certification other than a certification under § 314.94(a)(12)(i)(A)(*4*);

(ii) The 45-day period under 505(j)(5)(B)(iii) 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 § 314.94(a)(12)(i)(A)(*4*).

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[This appendix will not appear in the Code of Federal Regulations.]

[FR Doc. 03–????? Filed ??–??–03; 8:45 am]

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