

(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.

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■ 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);