DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# PATENT INFORMATION SUBMITTED WITH AN NDA, AMENDMENT, OR SUPPLEMENT

***For Each Patent That Claims a Drug Substance (Active Ingredient), Drug Product (Formulation and Composition) and/or Method of Use***

Form Approved: OMB No. 0910-0001
Expiration Date: 03/31/2024
See OMB Statement on last page.

NDA Number

Name of NDA Applicant

***Refer to instruction sheet (FORM FDA 3542a SUPPLEMENT) for more information.***

*The following is provided in accordance with Section 505(b) and (c) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).*

Active Ingredient(s)

Trade Name (or proposed Trade Name)

Strength(s) *(Include applicable Product Number, if available - See instructions)*

Dosage Form(s)

Route(s) of Administration

Type of Use

☐ Prescription ☐ Over-the-Counter

This patent declaration form is required to be submitted to the Food and Drug Administration (FDA) with an NDA, amendment, or supplement as required by 21 CFR 314.53 at the address provided in 21 CFR 314.53(d)(4). Within thirty (30) days after the date of approval of an NDA or supplement, or within thirty (30) days of issuance of a new patent, a new patent declaration must be submitted on Form FDA 3542 pursuant to 21 CFR 314.53(c)(2)(ii) with all of the required information based on the approved NDA or supplement. FDA will not list or publish patent information in the Orange Book if it is not submitted in the declaration form submitted upon or after approval.

***FDA will not list patent information if the patent declaration does not contain the information required by 21 CFR § 314.53(c)(2) or the patent declaration indicates the patent is not eligible for listing.***

***For each patent submitted for the pending NDA, amendment, or supplement referenced above, you must submit the information described below. If you are not submitting any patents for this pending NDA, amendment, or supplement, complete the section above and sections 5 and 6.***

**1. GENERAL** *(Please note: If 1.a is NOT entered, then section 5 later in form must be marked as "Yes" in its check box.)*

a. United States Patent Number

b. Issue Date of Patent

c. Expiration Date of Patent

d. Name of Patent Owner

Address *(of Patent Owner)*

City

State/Province/Region

Country

ZIP or Postal Code

FAX Number *(if available)*

Telephone Number

E-Mail Address *(if available)*

*Click for additional set of 1.d. entries (includes all address and related contact items above). May be repeated.* Add Section 1.d.



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e. Name of NDA Applicant

| Address *(of NDA Applicant)* | City | |
|---|---|---|
| State/Province/Region | Country | ZIP or Postal Code |
| FAX Number *(if available)* | Telephone Number | E-Mail Address *(if available)* |

f. Name of U.S. agent or representative who resides or maintains a place of business within the United States authorized to receive notice of patent certification under section 505(b)(3) and (j)(2)(B) of the FD&C Act and 21 CFR 314.52 and 314.95. Using the checkboxes provided, indicate whether the person represents the patent owner, NDA applicant, or both.

Name:

Represents *(Select the appropriate checkbox)*:

☐ Patent Owner ☐ NDA Applicant ☐ Both

| Address *(of agent or representative named in 1.f.)* | |
|---|---|
| City/State | |
| ZIP Code | FAX Number *(if available)* |
| Telephone Number | E-Mail Address *(if available)* |

*Click for additional set of 1.f. entries (includes all address and related contact items above). May be repeated.* Add Section 1.e.

g. Has the patent referenced above been submitted previously for listing for this drug product? ☐ Yes ☐ No

h. If the answer to question 1.g. is "Yes," identify all change(s) from the previously submitted Form 3542a and specify whether each change is related to the patent or related to an FDA action or procedure.

***For the patent referenced above, provide the following information on whether the patent claims the drug substance, drug product, and/or method of use that is the subject of the pending NDA, amendment, or supplement.***

- ***If the patent is eligible for listing as claiming the drug substance and section 2 is completed, it is not necessary to complete section 3 even if the patent also is eligible for listing as claiming the drug product.***
- ***If the patent is eligible for listing as claiming the drug product and section 3 is completed, it is not necessary to complete section 2 even if the patent also is eligible for listing as claiming the drug substance.***

## 2. DRUG SUBSTANCE (ACTIVE INGREDIENT)

**2.1** Does the patent claim the drug substance that is the active ingredient in the drug product described in the pending NDA, amendment, or supplement? If yes, skip to Question 2.5. ☐ Yes ☐ No

**2.2** Does the patent claim only a drug substance that is a different polymorph of the active ingredient described in the pending NDA, amendment, or supplement? ☐ Yes ☐ No

**2.3** If the answer to question **2.2** is "Yes," do you certify that, as of the date of this declaration, you have test data demonstrating that a drug product containing the polymorph will perform the same as the drug product described in the NDA? The type of test data required is described at 21 CFR 314.53(b). ☐ Yes ☐ No

**2.4** Specify the polymorphic form(s) claimed by the patent for which you have the test results described in **2.3**.

**2.5** Does the patent claim only a metabolite of the active ingredient pending in the NDA or supplement? *(Complete the information in section 4 below if the patent claims a pending method of using the pending drug product to administer the metabolite.)* ☐ Yes ☐ No

**2.6** Does the patent claim only an intermediate? ☐ Yes ☐ No

**2.7** If the patent referenced in **2.1** is a product-by-process patent, is the product claimed in the patent novel? ☐ Not Applicable ☐ Yes ☐ No

## 3. DRUG PRODUCT (COMPOSITION/FORMULATION)

**3.1** Does the patent claim the drug product, as defined in 21 CFR 314.3, in the pending NDA, amendment, or supplement? ☐ Yes ☐ No

**3.2** Does the patent claim only an intermediate? ☐ Yes ☐ No

**3.3** If the patent referenced in **3.1** is a product-by-process patent, is the product claimed in the patent novel? ☐ Not Applicable ☐ Yes ☐ No

## 4. METHOD OF USE

***NDA applicants must submit the information in section 4 for each method of using the proposed drug product for which approval is being sought and that is claimed by the patent. An NDA applicant may list together multiple patent claims for each pending method of use; however, each pending method of use claimed by the patent must be separately identified within this section. Continuation pages may be used to separately list method of use information within this section. For each pending method of use claimed by the patent, provide the following information:***

**4.1** Does the patent claim one or more methods of use for which approval is being sought in the pending NDA, amendment, or supplement? ☐ Yes (only one pending method of use) ☐ Yes (more than one pending method of use) ☐ No

**4.2** Patent Claim Number(s) *(as listed in the patent) (Please separate numbers with commas.)*

Does (Do) the patent claim(s) referenced in **4.2** claim a pending method of use for which approval is being sought in the pending NDA, amendment, or supplement? ☐ Yes ☐ No

**4.2a** If the answer to **4.2** is "Yes," for each pending method of use, separately identify the specific section(s) and subsection(s) of the proposed labeling for the drug product that describe the method of use claimed by the patent. If there is no applicable subsection, insert "subsection N/A". If there is more than one pending method of use, please use the "Add Section 4.2" button for additional entries as needed.

Use *(In your answer below, please list each section on a separate line. Within each line, separate each subsection with a comma.)*

*If more than one pending method of use, click to add a new set of Section 4.2 entries. May be repeated.* Add Section 4.2

## 5. NO RELEVANT PATENTS

For this pending NDA, amendment, or supplement, 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. ☐ Yes

## 6. DECLARATION CERTIFICATION

**6.1** ***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.***

***Warning: A willfully and knowingly false statement is a criminal offense under 18 U.S.C. 1001.***

| | |
|---|---|
| **6.2** Authorized Signature of NDA Applicant or Patent Owner *(Attorney, Agent, Representative or other Authorized Official) (Provide Information below)* Sign | Date Signed |
| **6.3** Countersignature of Authorized U.S. Agent Countersign | Date Signed |

**NOTE: Only an NDA applicant may submit this declaration directly to the FDA. A patent owner who is not the NDA applicant is authorized to sign the declaration but may not submit it directly to FDA. 21 CFR 314.53(c)(4) and (d)(4).**

**Check applicable box and provide information below.**

| | |
|---|---|
| ☐ NDA Applicant | ☐ NDA Applicant's Attorney, Agent (Representative) or Other Authorized Official |
| ☐ Patent Owner | ☐ Patent Owner's Attorney, Agent (Representative) or Other Authorized Official |

| | | |
|---|---|---|
| Name | | |
| Address | | City |
| State/Province/Region | Country | ZIP or Postal Code |
| FAX Number *(if available)* | Telephone Number | E-Mail Address *(if available)* |

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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