DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

PATENT INFORMATION SUBMITTED UPON AND AFTER APPROVAL OF AN NDA OR SUPPLEMENT

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

Form Approved: OMB No. 0910-0513
Expiration Date: xx/xx/xxxx
See OMB Statement on last page.

NDA Number

Name of NDA Holder

Refer to instruction sheet (Form FDA 3542 Supplement) for more information.

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

Trade Name	Active Ingredient(s)
Dosage Form(s)	Strength(s)
Route(s) of Administration	Type of Use ☐ Prescription ☐ Over-the-Counter

Approval Date of NDA or Supplement to which patent information relates *(Enter date, and select either NDA or Supplement.)*

☐ NDA ☐ Supplement

This patent declaration form is required to be submitted to the Food and Drug Administration (FDA) within thirty (30) days after the date of approval of an NDA or supplement or within thirty (30) days of issuance of a patent as required by 21 CFR 314.53(c)(2)(ii) at the address provided in 21 CFR 314.53(d)(4). Except as provided in 21 CFR 314.53(f)(1), a patent declaration form containing an amendment to the description of the approved method(s) of use claimed by the patent is required to be submitted to FDA within thirty (30) days of patent issuance, within thirty (30) days of approval of a corresponding change to product labeling, or within thirty (30) days of a decision described in 21 CFR 314.50(i)(4)(i)(C) or 314.94(a)(12)(vi)(A)(*3*).

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 approved NDA or supplement referenced above, you must submit the information described below. If you are not submitting any patents for this NDA 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.

e. Name of 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 Federal Food, Drug, and Cosmetic Act and 21 CFR 314.52 and 314.95 (if patent owner or NDA holder does not reside or have a place of business within the United States) Name:	Address *(of agent or representative named in 1.e.)*	
	City/State	
	ZIP Code	FAX Number *(if available)*
	Telephone Number	E-Mail Address *(if available)*

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

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

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 3542 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, or method of use that is the subject of the approved NDA or supplement. 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.

- ***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.***

FDA will consider incomplete a patent declaration that does not include a response to all required questions contained within each section below applicable to the patent referenced above.

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 approved NDA 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 NDA? ☐ 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 approved active ingredient? *(Complete the information in section 4 below if the patent claims an approved method of using the approved 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

FDA will not list the patent in the Orange Book as claiming the drug substance if:

- **the answers to 2.1 and 2.2 are "No," or,**
- **the answer to 2.2 is "Yes" and the answer to 2.3 is "No," or,**
- **the answer to 2.3 is "Yes" and there is no response to 2.4, or,**
- **the answer to 2.5 or 2.6 is "Yes."**
- **the answer to 2.7 is "No."**

3. DRUG PRODUCT (COMPOSITION/FORMULATION)

3.1 Does the patent claim the approved drug product as defined in 21 CFR 314.3? ☐ 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

FDA will not list the patent in the Orange Book as claiming the drug product if:

- **the answer to question 3.1 is "No," or,**
- **the answer to question 3.2 is "Yes," or,**
- **the answer to 3.3 is "No."**

4. METHOD OF USE

NDA holders must submit the information in section 4 for each approved method of using the approved drug product claimed by the patent. An NDA holder may list together multiple patent claims for each approved method of use; however, each approved 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 approved method of use claimed by the patent, provide the following information:

4.1 Does the patent claim one or more approved methods of using the approved drug product? *(Select one)*

☐ Yes (only one approved method of use) ☐ No

☐ Yes (more than one approved method of use)

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 an approved method of use of the approved drug product?

☐ Yes ☐ No

4.2a If the answer to **4.2** is "Yes," for each approved method of use, separately identify the specific section(s) and subsection(s) of the approved labeling for the drug product that describe the approved method of use claimed by the patent. If there is more than one approved 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.)*

4.2b If the answer to 4.2 is "Yes," also provide the information on the approved method of use claimed by the patent for the Orange Book "Use Code" description.	Use *(Submit the description of the specific approved method of use claimed by the patent that FDA should include as the "Use Code" in the Orange Book, using no more than 250 total characters including spaces.)*

FDA will not list the patent in the Orange Book as claiming the method of use if:

- **the answer to question 4.1 or 4.2 is "No," or**
- **the answer to 4.2 is "Yes" and the information requested in 4.2a and 4.2b is not provided in full.**

If more than one approved 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 NDA or supplement, there are no relevant patents that claim the approved drug substance (active ingredient) or the approved drug product (formulation or composition) or approved method(s) of use 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 or supplement approved under section 505 of the Federal Food, Drug, and Cosmetic Act. This time-sensitive patent information or response to a request under 21 CFR 314.53(f)(1) 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 Holder or Patent Owner *(Attorney, Agent, Representative or other Authorized Official) (Provide Information below)*	Date Signed
6.3 Countersignature of Authorized U.S. Agent	Date Signed

NOTE: Only an NDA holder may submit this declaration directly to the FDA. A patent owner who is not the NDA holder 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 Holder	☐ NDA Holder'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.

The burden time for this collection of information is estimated to average 10 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Operations
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"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 number."