**INSTRUCTIONS FOR FILLING OUT FORM FDA 3542a**
**PATENT INFORMATION SUBMITTED WITH AN NDA, AMENDMENT, OR SUPPLEMENT**

*(The field numbers below correspond to the numbered and lettered boxes on the Form FDA 3542a.)*

**NOTE: Please submit a new Form FDA 3542a for each patent that claims a drug substance (active ingredient), drug product (formulation or composition), and/or method of using the proposed drug product. Complete a separate form for each patent. Complete the pages of the form sequentially and use the "add section" option as applicable.**

## GENERAL INSTRUCTIONS

- The New Drug Application (NDA) applicant must submit patent information to its NDA using the appropriate form (see 21 CFR 314.53(d)). Use this Form FDA 3542a only if the NDA applicant is submitting information on a patent that claims a proposed drug or a proposed method of using the drug that is the subject of the pending NDA, an amendment, or a supplement. If the NDA applicant is submitting patent information on a patent that claims an approved drug or an approved method of using the drug, you must use Form FDA 3542.
- Please do *not* submit this form directly to the Orange Book Staff in the Office of Generic Drugs. The form must be submitted to the NDA.
- Please do *not* submit a copy of the patent to FDA.
- If you are a patent owner and are completing the form for the NDA applicant to submit to its NDA (see 21 CFR 314.53(c)(2)(i)(R) and (c)(4)), please note that you may need to obtain information from the NDA applicant in order to complete the form. If required information is not provided on the form, you will not be able to electronically sign the form and FDA will not consider the form to be complete.

## INFORMATION ON THE PROPOSED DRUG PRODUCT(S) FOR WHICH PATENT INFORMATION IS BEING SUBMITTED

**NDA Number**: Provide the six-digit application number and, if applicable, the supplement number (e.g., S-001). For application numbers less than six digits, the application number should be preceded by one or more zeros (e.g., for NDA 12345 enter 012345). Provide only one NDA number. If you are submitting patent information on proposed drug products submitted in different NDAs, you must submit a separate form for each NDA.

**Name of NDA Applicant**: Provide the name of the person or legal entity that submitted the NDA for the proposed drug product(s) for which patent information is being submitted.

**Trade Name**: Provide the proprietary name or proposed proprietary name of the proposed drug product(s), if any. If there is no trade name or proposed trade name for the proposed drug product(s), leave this field blank.

**Active Ingredient(s)**: List the active ingredient(s) in the proposed drug product(s) for which the patent information is being submitted.

**Dosage Form(s)**: List the dosage form(s) of the proposed drug product(s) claimed by the patent for which the patent information is being submitted.

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**Strength(s)**: List the strength(s) of the proposed drug product(s) claimed by the patent for which the patent information is being submitted. For products already approved and listed in the Orange Book publication, specify the assigned product number(s), if applicable. For parenteral products, if no product number is specified, include the total volume (e.g., 500 mg/20 mL).

**Route(s) of Administration**: List the route(s) of administration of the proposed drug product(s) claimed by the patent for which the patent information is being submitted.

**Type of Use**: Indicate whether the proposed drug product(s) for which the patent information is being submitted is/are proposed for prescription or over-the-counter use.

## SECTION 1 — GENERAL

**NOTE: If there are no relevant patents for this pending NDA, amendment, or supplement, leave Sections 1, 2, 3, and 4 blank and proceed to Section 5 "NO RELEVANT PATENTS."**

**Field 1.a**: Provide the United States patent number (using no more than 10 characters, including commas). Provide only one patent number. If you are submitting information on more than one patent with the submission of the NDA, an amendment, or a supplement, you must submit a separate form for each patent.

**Field 1.b**: Provide the date on which the patent was issued by the U.S. Patent and Trademark Office (PTO). You may manually enter the date in MM/DD/YYYY format or you may use the calendar.

**Field 1.c**: Provide the patent expiration date, including any patent term extension that already has been granted under 35 U.S.C. 156(e). You may manually enter the date in MM/DD/YYYY format or you may use the calendar. Do not include any applicable pediatric exclusivity. FDA will publish any applicable pediatric exclusivity in FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations" (the Orange Book).

**Field 1.d**: Provide the name, street address, city, state/province/region, country, zip or postal code, telephone number and, if available, the fax number and e-mail address of each owner of the patent. Complete each required section, including country, and provide the area code or country code, as applicable, for the telephone or fax number. If there is more than one owner of the patent, click the "Add section 1.d" button for an additional set of 1.d entries.

**Field 1.e**: Provide the name, street address, city, state/province/region, country, zip or postal code, telephone number and, if available, the fax number and e-mail address of the NDA applicant. Complete each required section, including country, and provide the area code or country code, as applicable, for the telephone or fax number.

**Field 1.f**: If applicable, provide the name, street address, city, state, zip code, telephone number, and fax number, and e-mail address of the agent or representative who resides or maintains a place of business in the United States. Complete each required section and provide the area code for the telephone or fax number. Use the checkboxes provided to indicate whether the person represents the patent owner, NDA applicant, or both (select the appropriate checkbox). If there is more than one agent or representative (i.e., because the NDA applicant and one or more owners of the patent do not reside or maintain a place of business in the United States), click the "Add section 1.f" button for an additional set of 1.f entries. If the NDA applicant and each patent owner reside or maintain a place of business in the United States, leave this field blank.

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**Field 1.g**: Indicate whether the patent has been submitted previously for listing in the Orange Book for this drug product.

**Field 1.h**: If the answer to question 1.g is "yes," identify all change(s) from the previously submitted Form FDA 3542a and specify whether each change is related to the patent (e.g., a patent term extension or patent-specific decision by the PTO or a Federal court) or related to an FDA action or procedure (e.g., submission of a supplement that proposes to change the conditions of use of the drug).

## SECTION 2 – DRUG SUBSTANCE (ACTIVE INGREDIENT)

**If the patent is eligible for listing as claiming the drug substance AND section 2 is completed, you do not need to complete section 3 even if the patent also is eligible for listing as claiming the drug product.**

If the patent claims a drug substance that is the subject of the pending NDA, amendment, or supplement AND you are submitting the patent on this basis, complete all required fields within this section.

**Field 2.1**: If you answer "yes" to question 2.1, you can skip to question 2.5.

**Field 2.2**: Answer this question only if you answer "no" to question 2.1.

**Field 2.3**: Answer this question only if you answer "yes" to question 2.2.

**Field 2.4**: Answer this question only if you answer "yes" to question 2.3.

**Field 2.5**: A patent that claims only a metabolite of the proposed active ingredient will not be listed. If the patent claims a proposed method of using the proposed drug product to administer the metabolite, complete the information in section 4.

**Field 2.6**: Answer this question, as appropriate.

**Field 2.7**: Answer this question, as appropriate.

## SECTION 3— DRUG PRODUCT (COMPOSITION/FORMULATION)

**If the patent is eligible for listing as claiming the drug product AND section 3 is completed, you do not need to complete section 2 even if the patent also is eligible for listing as claiming the drug substance.**

If the patent claims the drug product that is the subject of the pending NDA, amendment, or supplement AND you are submitting the patent on this basis, complete all required fields within this section.

**Field 3.2**: Answer this question, as appropriate.

**Field 3.3**: Answer this question, as appropriate.

## SECTION 4 —METHOD OF USE

Complete all required fields in this section if the patent claims one or more proposed method(s) of using the proposed drug product. If you answer yes to question 4.1, you also are required to state whether the patent also claims the drug substance or drug product. Accordingly, make sure you have completed section 2 or section 3, if appropriate.

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**Field 4.1**: Indicate whether the patent claims one or more proposed method(s) of using the proposed drug product. If the patent claims more than one proposed method of use, separately identify and complete Fields 4.2, 4.2a, and 4.2b for each proposed method of use claimed by the patent. Click the "Add section 4.2" button to add a new set of section 4.2 entries for each proposed method of use claimed by the patent.

**Field 4.2**: For each proposed method of use claimed by the patent, identify by number the claim(s) listed in the patent that claim that specific proposed method of use. You may list together multiple patent claim numbers (as listed in the patent) for each proposed method of use (e.g., list "claims 1, 2, 3" for the first proposed method of use); however, each proposed method of use must be separately identified with a new set of section 4.2 entries. (After completing section 4.2 for the first proposed method of use, click the "Add section 4.2" button to add a new set of section 4.2 entries if needed. For example, list "claims 4, 5, 6" for the second proposed method of use claimed by the patent). Use a comma to separate each patent claim number provided for the proposed method of use. Confirm whether the patent claim(s) listed in section 4.2 claim a proposed method of using the proposed drug product by checking the appropriate box. If there is more than one patent claim number listed in section 4.2, each of the patent claim(s) listed in section 4.2 must claim a pending method of use for which approval is being sought in the pending NDA, amendment, or supplement to check the "yes" box.

**Field 4.2a**: For each proposed method of use, list the specific section(s) and subsection(s) of the proposed product labeling that contain information describing the specific proposed method of use claimed by the patent. List each section of proposed labeling on a separate line using the format described below. Within each line, separate each subsection with a comma.

- Prescription drug products with labeling in the "physician labeling rule" (PLR) format: the section(s) and subsection(s) of the proposed labeling should be identified by the section and subsection number (see 21 CFR 201.56(d) and 201.57). For example, "section 1, subsection 1" refers to the first indication listed in proposed product labeling (see 21 CFR 201.57(c)(2)). If there is no applicable subsection, insert "subsection N/A."

- Prescription drug products with labeling not in PLR format: the section(s) and subsection(s) of the proposed labeling should be identified by the section and subsection title (see 21 CFR 201.56(b) and (e) and 201.80). For example, "section 'Indications and Usage,' subsection 'Hypertension.'" If there is no applicable subsection, insert "subsection 'N/A.'"

- Nonprescription drug products: the section(s) and subsection(s) of the proposed labeling should be identified by the section and subsection title (see 21 CFR 201.66). For example, "section 'Uses,' subsection 'temporarily relieves minor aches and pains due to headache.'" If there is no applicable subsection, insert "subsection 'N/A.'"

**SECTION 5 – NO RELEVANT PATENTS**

Complete this section only if there are no relevant patents for this pending NDA, amendment, or supplement, AND section 1.a is blank.

**SECTION 6 – DECLARATION CERTIFICATION**

Fields 6.1 through 6.3: Read the required declaration, then date and sign the form in Field 6.2. If the person signing the form in field 6.2 does not reside or have a place of business in the United States, the form must also be dated and countersigned in Field 6.3 by an attorney, agent, or other authorized official who resides or maintains a place of business within the United States. Check the applicable

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box that describes the authorized signature provided in Field 6.2, and provide the name, street address, city, state/province/region, country, zip or postal code, telephone number and, if available, the fax number and e-mail address of the person signing the form in Field 6.2. Complete each required section, including country, and provide the area code or country code, as applicable, for the telephone or fax number.