INSTRUCTIONS FOR FILLING OUT FORM FDA 3542 – PATENT INFORMATION SUBMITTED UPON AND AFTER APPROVAL OF AN NDA OR SUPPLEMENT

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

NOTE: Please submit a new Form FDA 3542 for each patent that claims a drug substance (active ingredient), drug product (formulation or composition), and/or method of using the approved 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) holder must submit patent information to its NDA using the appropriate form (see 21 CFR 314.53(d)). Use this Form FDA 3542 only if the NDA holder is submitting information on a patent that claims an approved drug or an approved method of using the drug. If the NDA holder is submitting patent information with an original NDA, an amendment, or a supplement prior to approval, you must use Form FDA 3542a.

- Form FDA 3542 must be submitted to the NDA within 30 days after the date of approval of the NDA or supplement or within 30 days of issuance of a patent as required by 21 CFR 314.53(c)(2)(ii). Except as provided in 21 CFR 314.53(f)(1), an amendment to the description of the approved method(s) of use claimed by the patent is required to be submitted on Form FDA 3542 within 30 days of patent issuance, within 30 days of approval of a corresponding change to product labeling, or within 30 days of a decision by the U.S. Patent and Trademark Office or by a Federal district court, the Court of Appeals for the Federal Circuit, or the U.S. Supreme Court that is specific to the patent and alters the construction of a method-of-use claim (s) of the patent, and the amendment contains a copy of the decision (see 21 CFR 314.50(i)(4)(i)(C) and 314.94(a)(12)(vi)(A)(3)).

- Provide all patent information required by 21 CFR 314.53(c)(2). FDA will not list patent information if Form FDA 3542 does not contain the required information or if the submission indicates that the patent is not eligible for listing. Patent information on a listed drug that has been discontinued from marketing is eligible for listing, provided that the general requirements for patent listing are met.

- If the NDA holder timely submits the required patent information on Form FDA 3542, but FDA notifies the NDA holder that its Form FDA 3542 is incomplete or shows that the patent is not eligible for listing, the NDA holder must submit an acceptable Form FDA 3542 within 15 days of FDA's notification to be considered timely filed as of the date of the original submission of patent information (see 21 CFR 314.53(c)(2)(ii)). An NDA holder must correct all deficiencies within 15 days in order to maintain its original submission date. If an acceptable Form FDA 3542 (i.e., a Form free from deficiencies) is not submitted within 15 days of FDA's original notification, the Form FDA 3542 will be considered filed as of the date an acceptable Form FDA 3542 is submitted.

- 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 holder to submit to its NDA (see 21 CFR 314.53(c)(2)(ii)(S) and (c)(4)), please note that you may need to obtain information from the NDA holder in order to complete the form. If required information is not provided on

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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 APPROVED 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 drug products approved in different NDAs, you must submit a separate form for each NDA.

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

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

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

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

Strength(s): List the strength(s) of the approved 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 approved drug product(s) claimed by the patent for which the patent information is being submitted.

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

Approval Date of NDA or Supplement To Which Patent Information Relates: Indicate whether the patent information relates to the drug product(s) approved in the original NDA or the drug product(s) as changed by an approved supplement to the NDA, and enter the corresponding “date of approval” as defined in 21 CFR 314.3(b). You may manually enter the date in MM/DD/YYYY format or you may use the calendar.

SECTION 1 – GENERAL

NOTE: If there are no relevant patents for this NDA 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 for the NDA or supplement, you must submit a separate form for each patent.

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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 holder. 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, 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 holder, or both (select the appropriate checkbox). If there is more than one agent or representative (i.e., because the NDA holder 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 holder and each patent owner reside or maintain a place of business in the United States, leave this field blank.

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 3542 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 (e.g., FDA approval of a supplement that changes the approved conditions of use of the drug) or an FDA procedure (e.g., an NDA holder's response to a patent listing dispute). For changes related to the method(s) of use listed for the patent (for example, an FDA approval of a supplement that changes the approved conditions of use of the drug), specify whether you intend to add a new "use code" in the Orange Book, or remove or modify an existing use code(s) for this patent. If the latter, identify the use code(s) in 1h that you intend to delist. The Agency considers either removal or modification to an existing use code to be a delist of patent information.

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.

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If the patent claims a drug substance that is the subject of the approved NDA or supplement AND you are submitting the patent for listing on this basis, complete all required fields within this section. FDA will consider incomplete a patent declaration that does not include a response to all required questions contained within each applicable 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 approved active ingredient will not be listed. If the patent claims an approved method of using the approved drug product to administer the metabolite, the patent may be listed as a method-of-use patent depending on the responses in section 4.

Field 2.6: A patent that claims only an intermediate of the drug substance that is the active ingredient in the approved drug product will not be listed.

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 approved NDA or supplement AND you are submitting the patent for listing on this basis, complete all required fields within this section. FDA will consider incomplete a patent declaration that does not include a response to all required questions contained within each applicable section.

Field 3.2: A patent that claims only an intermediate of the approved drug product will not be listed.

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 approved method(s) of using the approved 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.

Field 4.1: Indicate whether the patent claims one or more approved method(s) of using the approved drug product. If the patent claims more than one approved method of use, separately identify and complete Fields 4.2, 4.2a, and 4.2b for each approved 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 approved method of use claimed by the patent.

Field 4.2: For each approved method of use claimed by the patent, identify by number the claim(s) listed in the patent that claim that specific approved method of use. You may list together multiple

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patent claim numbers (as listed in the patent) for each approved method of use (e.g., list "claims 1, 2, 3" for the first approved method of use); however, each approved method of use must be separately identified with a new set of section 4.2 entries. (After completing section 4.2 for the first approved 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 approved method of use claimed by the patent). Use a comma to separate each patent claim number provided for the approved method of use. Confirm whether the patent claim(s) listed in section 4.2 claim an approved method of using the approved 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 an approved method of using the approved drug product to check the "yes" box.

Field 4.2a: For each approved method of use, list the specific section(s) and subsection(s) of the approved product labeling that contain information describing the specific approved method of use claimed by the patent. List each section of 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 approved 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 approved 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 approved labeling should be identified by the section and subsection titles (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 approved labeling should be identified by the section and subsection titles (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.'"

Field 4.2b: For each approved method of use, provide 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. Each use code must describe only an approved method of use claimed by the patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the patent owner engaged in the manufacture, use, or sale of the drug product. In other words, the scope of the use code must not extend beyond the scope of the patent claim(s) and, within the boundary established by the patent claim(s), the use code must only describe a patented method of use that has been approved by FDA as reflected in approved product labeling. The use code must contain adequate information to assist 505(b)(2) application and abbreviated new drug application (ANDA) applicants in determining whether a listed method-of-use patent claims a use for which the 505(b)(2) application or ANDA applicant is not seeking approval (see 21 CFR 314.53(c)(2)(ii)(P)(3)). If you intend to use an existing use code that satisfies the current requirements of the statute and regulations, submit the existing use code for listing in the Orange Book. Use a maximum of 250 characters for each use code, and follow the general principles described below.

- Patented method of use is broader than an indication or other approved condition of use in the labeling: The use code must only describe a patented method of use that is described

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in FDA-approved product labeling. If the method of use claimed by the patent uses different terminology than the approved labeling and/or is broader than an indication or other approved condition of use, then the use code would need to be phrased more narrowly than the patent claim to only describe the specific patented method of use that is described in FDA-approved product labeling.

- Patented method of use is co-extensive with an indication or other approved condition of use in the labeling: The use code must describe only the specific approved method of use claimed by the patent.
- Patented method of use is narrower than an indication or other approved condition of use in the labeling: If the method of use claimed by the patent does not cover an indication or other approved condition of use in its entirety, then the NDA holder must describe only the specific approved method of use claimed by the patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the patent owner engaged in the manufacture, use, or sale of the drug product—not the broader indication or other approved condition of use that may include, but is broader than, the use claimed by the patent.

SECTION 5 – NO RELEVANT PATENTS

Field 5: Complete this section only if there are no relevant patents for this NDA 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 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.