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| Department of Health and Human Services Food and Drug Administration PATENT INFORMATION SUBMITTED WITH THE FILING OF AN NDA, AMENDMENT, OR SUPPLEMENT <i>For Each Patent That Claims a Drug Substance (Active Ingredient), Drug Product (Formulation and Composition) and/or Method of Use</i> | | Form Approved: OMB No. 0910-XXXX Expiration Date: XX-XX-XX See OMB Statement on Page 3. | |
| | | NDA NUMBER | |
| | | NAME OF APPLICANT / NDA HOLDER | |
| <i>The following is provided in accordance with Section 505(b) and (c) of the Federal Food, Drug, and Cosmetic Act.</i> | | | |
| TRADE NAME (OR PROPOSED TRADE NAME) | | | |
| ACTIVE INGREDIENT(S) | | STRENGTH(S) | |
|  | | | |
| DOSAGE FORM | | | |
| <p>This patent declaration form is required to be submitted to the Food and Drug Administration (FDA) with an NDA application, amendment, or supplement as required by 21 CFR 314.53 at the address provided in 21 CFR 314.53(d)(4).</p> <p>Within thirty (30) days after approval of an NDA or supplement, or within thirty (30) days of issuance of a new patent, a new patent declaration must be submitted pursuant to 21 CFR 314.53(c)(2)(ii) with all of the required information based on the approved NDA or supplement. The information submitted in the declaration form submitted upon or after approval will be the <i>only</i> information relied upon by FDA for listing a patent in the Orange Book.</p> | | | |
| <p>For hand-written or typewriter versions (only) of this report: If additional space is required for any narrative answer (i.e., one that does not require a "Yes" or "No" response), please attach an additional page referencing the question number.</p> | | | |
| <p>FDA will not list patent information if you submit an incomplete patent declaration or the patent declaration indicates the patent is not eligible for listing.</p> | | | |
| <p>For each patent submitted for the pending NDA, amendment, or supplement referenced above, you must submit all the information described below. If you are not submitting any patents for this pending NDA, amendment, or supplement, complete above section and sections 5 and 6.</p> | | | |
| 1. GENERAL | | | |
| 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 | |
| | | ZIP Code | FAX Number (if available) |
| | | Telephone Number | E-Mail Address (if available) |
| 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 applicant/holder does not reside or have a place of business within the United States) | | Address (of agent or representative named in 1.e.) | |
| | | City/State | |
| | | ZIP Code | FAX Number (if available) |
| | | Telephone Number | E-Mail Address (if available) |
| f. Is the patent referenced above a patent that has been submitted previously for the approved NDA or supplement referenced above? <input type="checkbox"/> Yes <input type="checkbox"/> No | | | |
| g. If the patent referenced above has been submitted previously for listing, is the expiration date a new expiration date? <input type="checkbox"/> Yes <input type="checkbox"/> No | | | |