

Patent Submission Sample Format**DRAFT**

This is a format for submission of patent information for NDAs submitted under section 505 of the Federal Food Drug and Cosmetic Act. For more detailed information please refer to 21 CFR 314.53 for NDA # _____

Time sensitive patent information pursuant to 21 CFR 314.53 for NDA# _____

The following is provided in accordance with the Drug Price Competition and Patent Term Restoration Act of 1984:

Trade Name: _____

Active Ingredient(s): _____

Strengths: _____

Dosage Form: _____

Approval Date: _____

A. This information should be provided for each individual Patent submitted.

1. US patent number: _____
2. Identify each claim which covers the drug substance or the drug product for which the applicant submitted the application or which covers a method of using such drug substance or product and can reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use or sale of the drug _____
3. Expiration date _____
4. Name of the Patent Owner: _____
5. US Agent (if patent owner or applicant does not reside or have place of business in the US) _____

B. For each claim identified in A2, please provide the following information:

1. The type of claim:
2. Drug Substance (Active Ingredient) _____ Yes _____ No
3. Drug Product (Composition/Formulation): _____ Yes _____ No
4. Method of Use: _____ Yes _____ No

C. For each Drug Substance claim identified, please provide the following information:

1. Does the claim cover the drug substance that is the subject of this application for which approval is sought in the same physical form as the drug substance for which approval is being sought? _____ YES _____ NO

[If the answer is "NO," stop here; the patent may not be listed in the Orange Book.]

2. If YES, is the claim a product by process claim? YES NO

[If the answer is "NO," please proceed to question 4.].

3. If YES, has the product of the claim by the process for making it been known per se, independently, of that process and/or has the product, per se, been claimed in any other patent? YES NO

[If the answer is "YES," stop here; the patent may not be listed in the Orange Book.].

4. Statement of the basis for concluding why this claim meets 21 CFR 314.53

D. For each Drug Product claim identified, please provide the following information:

1. Does the claim cover the approved formulation or composition and/or the formulation or composition for which approval is being sought?

YES NO

[If the answer is "NO," stop here; the patent may not be listed in the Orange Book.].

2. If YES, is the claim a product by process claim? YES NO

[If the answer is "NO," please proceed to question 4.].

3. If YES, has the product of the claim by the process for making it been known per se, independently, of that process and/or has the product, per se, been claimed in any other patent? YES NO

[If the answer is "YES," stop here; the patent may not be listed in the Orange Book.].

4. Statement of the basis for concluding why this claim meets 21 CFR 314.53

E. For each Method of Use claim identified, please provide the following information:

1. Does the claim cover (a) an approved method of use of the approved drug product, or (b) a method of use of the approved drug product for which use approval is being sought, or (c) a method of use of the drug product for which use approval is being sought? YES NO

[If the answer is "NO," stop here; the patent may not be listed in the Orange Book.].

2. Statement of the basis for concluding why this claim meets 21 CFR 314.53

The undersigned declares that all the above information have been provided in accordance with Title 28, Section 1746 entitled "Unsworn declarations under penalty of perjury".

Signed: _____

Date: _____

Title _____

Telephone Number _____