INSTRUCTIONS FOR COMPLETION OF FORM FDA 2252 – TRANSMITTAL OF ANNUAL REPORTS FOR DRUGS AND BIOLOGICS FOR HUMAN USE

(The field numbers below correspond to the numbered areas on Form FDA 2252)

NOTE: Form FDA 2252 should accompany all annual report submissions for NDAs, ANDAs, and BLAs. (21 CFR 314.81(b)(2), 601.70(b), and 601.12(d)) and may accompany other reports.

Field 1: Identify the appropriate application type, New Drug Application (NDA), Abbreviated New Drug Application (ANDA), or Biologics License Application (BLA), to which the annual report submission applies.

Field 2: Enter the application number.

Fields 3 and 4:

When U.S. applicants are submitting the report on their own behalf: Enter the name and phone number of the applicant in these fields.

When authorized U.S. agents are submitting the report on behalf of an applicant: Enter the name and phone number of the U.S. agent in **Field 3** and **Field 4**. Note that an authorized U.S. agent is required if the applicant does not reside or have a place of business within the United States (21 CFR 314.50(a)(5)). For biologic products, the name of applicant in **Field 3** is the name of the person or legal entity to whom the license has been issued.

Field 5: Enter the type of report being submitted.

Field 6: Enter the proprietary and established names for the product.

Field 7: Enter additional NDA, ANDA, or BLA number(s) if any part of the report applies to more than one application number. Use the continuation page as needed.

Field 8: Enter the beginning and end dates that encompass the reporting period covered by the report.

Field 9: NDA/ANDA REPORT INFORMATION REQUIRED

Under the *IDENTIFICATION* column, enter the type of information included in the report, the electronic file name or volume number(s) if a paper submission, and the pages of the report the designated information can be found on. If you have nothing to report for the type of information listed in the table, enter 'none' under *IDENTIFICATION*. See 21 CFR 314.81(b)(2) for the full details of each type of information.

a. **Summary of Significant New Information:** A brief summary of significant new information, relative to the previous year's report, that might affect the safety, effectiveness, or labeling of the drug product.

b. **Distribution Data:** Information about the quantity of the drug product distributed under the approved application, including that distributed to distributors. Under *TYPE OF INFORMATION*, indicate if distribution data for an authorized generic drug product is included. Also include in the body of the report information about the authorized generic described under 21 CFR 314.81(b)(2)(ii)(b).

c. **Labeling:** Provide the currently used professional labeling, patient brochures or package inserts, and a representative sample of the package (e.g., carton, container) labels.

d. **Chemistry, Manufacturing, and Controls Changes:** Reports of studies or tests involving the physical or chemical properties of the drug as described under 21 CFR 314.81(b)(2)(iv) and a full description of the manufacturing and controls changes that do not require a supplemental application under 21 CFR 314.70 (b) and (c).

e. **Nonclinical Laboratory Studies:** Copies of unpublished reports and summaries of published reports of new toxicological finding in animal studies and in vitro studies concerning the ingredients of the drug product (21 CFR 314.81(b)(2)(v)).

f. **Clinical Data:** Published clinical trials of the drug concerning safety and effectiveness: (e.g., studies of new uses, biopharmaceutic, pharmacokinetic, and clinical pharmacology studies, epidemiologic) (21 CFR 314.81(b)(2)(vi)(a)); summaries of completed unpublished clinical trials (21 CFR 314.81(b)(2)(vi)(b)); analysis of available safety and efficacy data in the pediatric population (21 CFR 314.81(b)(2)(vi)(c)).

g. **Status Reports of Postmarketing Study Commitments:** A status report of each postmarketing study of the drug concerning clinical safety, clinical efficacy, clinical pharmacology, and nonclinical toxicology that is required by FDA (e.g., accelerated approval clinical benefit studies, pediatric) or that the applicant committed to conduct (21 CFR 314.81(b)(2)(vii)).

h. **Status of Other Postmarketing Studies:** A status report of any postmarketing study not included under 21 CFR 314.81(b)(2)(vii), including chemistry, manufacturing, and controls studies that the applicant has agreed to conduct and for all product stability studies (21 CFR 314.81(b)(2)(viii)).

i. **Log of Outstanding Regulatory Business (optional):** A list of any open regulatory business with FDA concerning the drug product (e.g., a list of the applicant's unanswered correspondence with the agency, a list of the agency's unanswered correspondence with the applicant) (21 CFR 314.81(b)(2)(ix)).

Field 10: BLA REPORT INFORMATION REQUIRED

Status Reports of Postmarketing Studies: A status report of each postmarketing study of the drug concerning clinical safety, clinical efficacy, clinical pharmacology, and nonclinical toxicology that is required by FDA (e.g., accelerated approval clinical benefit studies, pediatric studies) or that the applicant committed to conduct (21 CFR 601.70). Check the box under *CONTENTS* if the submission is the *STATUS REPORTS OF POSTMARKETING STUDY COMMITMENTS*.

Fields 11-13: In **Fields 11 and 12** of the form, enter the name, title, and street address of the applicant's Responsible Official or Authorized U.S. Agent to which any correspondence regarding the annual report should be sent. This person is responsible for certifying compliance with applicable laws and regulations regarding annual reporting requirements. The authorized U.S. agent named in **Field 3** of the form may also act as the applicant's Responsible Official. The form must be signed in **Field 13** by the applicant, or the applicant's attorney, agent, or other authorized official. 21 CFR 601.2(a). If the person named in **Field 3** does not reside or have a place of business within the United States, the form must be signed in **Field 13** by an attorney, agent, or other authorized official who resides or maintains a place of business within the United States. 21 CFR 314.50(a)(5).