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|---|--|------------------------------|--|---|--|------|-------|--|--|--|
| <b>TRANSMITTAL OF ANNUAL REPORTS FOR DRUGS<br/>AND BIOLOGICS FOR HUMAN USE<br/>(21 CFR 314.81)</b>  |  |                              | DATE SUBMITTED   |   | Form Approved: OMB No. 0910-0001<br>Expiration Date: September 30, 2014<br>See OMB Statement on Reverse Side.  |      |       |  |  |  |
| <p><b>NOTE:</b> This report is required by law (21 USC 355; 21 CFR 314.81). <i>Failure to report can result in withdrawal of approval of the New Drug or Biologics License Application.</i></p> <p style="text-align:center;"><b>INSTRUCTIONS</b></p> <p>Complete a transmittal for each application for which an annual report is being submitted. If submitting electronically, submit one copy of the form and annual report to FDA. If submitting in paper, submit two copies of the transmittal form along with two copies of the annual report to FDA.</p> <p>If any part of the annual report applies to more than one application, list in item 7 all other applications to which such parts apply.</p> |  |                              |  |   | 1. Application Type  |      |       |  |  |  |
|   |  |                              |  |   | 2. Application Number  |      |       |  |  |  |
|   |  |                              |  |   | <b>Report No. (For FDA Use Only)</b> <table border="1" style="display:inline-table; border-collapse: collapse;"> <tr> <td style="width:30px; height:20px;"></td> <td style="width:30px; height:20px;"></td> <td style="width:30px; height:20px;"></td> <td style="width:30px; height:20px;"></td> </tr> </table> |      |       |  |  |  |
|   |  |                              |  |   |  |      |       |  |  |  |
| <b>APPLICANT NOTE</b><br>Reference NDA and Y, or BLA numbers (entered on Acknowledgement Copy) in any subsequent correspondence regarding report.   |  |                              |  |   |  |      |       |  |  |  |
| 3. APPLICANT/AUTHORIZED U.S. AGENT  |  | 4. PHONE NUMBER<br>(       ) |  | 5. TYPE OF REPORT (Check one)<br><input type="checkbox"/> ANNUAL <input type="checkbox"/> OTHER |  |      |       |  |  |  |
| 6. DRUG/BIOLOGIC NAME   |  |                              |  |   |  |      |       |  |  |  |
| 7. OTHER NDA OR BLA NUMBERS (List all numbers if any part of report applies to more than one number.)   |  |                              |  | 8. PERIOD COVERED BY REPORT   |  |      |       |  |  |  |
|   |  |                              |  | FROM  |  | TO   |       |  |  |  |
|   |  |                              |  | YEAR  | MONTH  | YEAR | MONTH |  |  |  |
| <b>NDA REPORT INFORMATION REQUIRED (See § 314.81 for description)</b>   |  |                              |  |   |  |      |       |  |  |  |
| 9. (Enter type of information attached under "Identification." If you have nothing to report, enter None.)<br>(INFORMATION IN "9b" AND "9c" IS ALWAYS REQUIRED.)  |  |                              |  |   |  |      |       |  |  |  |
| TYPE OF INFORMATION   |  |                              | IDENTIFICATION (Electronic file name or eCTD location or Volume No.(s) / Tab(s) / Page(s) of Report) |   |  |      |       |  |  |  |
| a. SUMMARY OF SIGNIFICANT NEW INFORMATION   |  |                              |  |   |  |      |       |  |  |  |
| b. DISTRIBUTION DATA  |  |                              |  |   |  |      |       |  |  |  |
| c. LABELING (Whether or not previously submitted)   |  |                              |  |   |  |      |       |  |  |  |
| d. CHEMISTRY MANUFACTURING AND CONTROLS CHANGES <input type="checkbox"/> SUPAC  |  |                              |  |   |  |      |       |  |  |  |
| e. NONCLINICAL LABORATORY STUDIES   |  |                              |  |   |  |      |       |  |  |  |
| f. CLINICAL DATA  |  |                              |  |   |  |      |       |  |  |  |
| g. STATUS REPORTS OF POSTMARKETING STUDY COMMITMENTS  |  |                              |  |   |  |      |       |  |  |  |
| h. STATUS OF OTHER POSTMARKETING STUDIES (e.g., voluntary studies, CMC commitment studies, and product stability studies)   |  |                              |  |   |  |      |       |  |  |  |
| i. LOG OF OUTSTANDING REGULATORY BUSINESS (Optional)  |  |                              |  |   |  |      |       |  |  |  |
| <b>BLA REPORT INFORMATION REQUIRED (See § 601.70 for description)</b>   |  |                              |  |   |  |      |       |  |  |  |
| TYPE OF INFORMATION   |  |                              | CONTENTS (Check box)   |   |  |      |       |  |  |  |
| a. ANNUAL PROGRESS REPORTS OF POSTMARKETING STUDIES   |  |                              | <input type="checkbox"/>   |   |  |      |       |  |  |  |
| 11. TYPED NAME AND TITLE OF RESPONSIBLE OFFICIAL OR AGENT   |  |                              |  | 13. SIGNATURE   |  |      |       |  |  |  |
| 12. APPLICANT'S RETURN ADDRESS  |  |                              |  | <b>FDA USE ONLY</b>   |  |      |       |  |  |  |
| Name of Sponsor / Applicant / Submitter   |  |                              |  | NDA OR ANDA NUMBER  |  |      |       |  |  |  |
| Address 1   |  |                              |  | DATE OF RECEIPT   |  |      |       |  |  |  |
| Address 2   |  |                              |  |   |  |      |       |  |  |  |
| City  |  | State                        | ZIP or Postal Code   |   |  |      |       |  |  |  |

This section applies only to requirements of the Paperwork Reduction Act of 1995.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

The burden time for this collection of information is estimated to average 5 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
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Office of Chief Information Officer  
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*PRAStaff@fda.hhs.gov*

*“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”*