

<b>TRANSMITTAL OF ANNUAL REPORTS FOR DRUGS AND BIOLOGICS FOR HUMAN USE (21 CFR 314.81)</b>			DATE SUBMITTED	Form Approved: OMB No. 0910-0001 Expiration Date: September 30, 2014 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> </tr> </table>					
<b>APPLICANT NOTE</b> 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 (        )		5. TYPE OF REPORT (Check one) <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>9. NDA REPORT INFORMATION REQUIRED (See § 314.81 for description)</b> (Enter type of information attached under "Identification." If you have nothing to report, enter None.) (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>10. 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						

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