

TRANSMITTAL OF ANNUAL REPORTS FOR DRUGS AND BIOLOGICS FOR HUMAN USE (21 CFR 314.81)				DATE SUBMITTED		Form Approved: OMB No. 0910-0001 Expiration Date: March 31, 2021 See OMB Statement on Reverse Side.									
NOTE: 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> INSTRUCTIONS 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. 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.						1. Application Type									
						2. Application Number									
						Report No. (For FDA Use Only)									
						APPLICANT NOTE Reference NDA and Y, or BLA numbers (entered on Acknowledgement Copy) in any subsequent correspondence regarding report.									
3. APPLICANT			4. PHONE NUMBER ()			5. TYPE OF REPORT (Check one) ☐ ANNUAL ☐ 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						
9. NDA REPORT INFORMATION REQUIRED (See § 314.81 for description) (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 Authorized Generic info															
c. LABELING (Whether or not previously submitted)															
d. CHEMISTRY MANUFACTURING AND CONTROLS CHANGES ☐ 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)															
10. BLA REPORT INFORMATION REQUIRED (See § 601.70 for description)															
TYPE OF INFORMATION				CONTENTS (Check box)											
a. ANNUAL PROGRESS REPORTS OF POSTMARKETING STUDIES				☐											
11. TYPED NAME AND TITLE OF RESPONSIBLE OFFICIAL OR AGENT					13. SIGNATURE										
12. APPLICANT'S RETURN ADDRESS Name of Sponsor / Applicant / Submitter Address 1 Address 2 City State ZIP or Postal Code					FDA USE ONLY										
					NDA OR ANDA NUMBER										
					<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 15%; height: 20px;"></td> <td style="width: 15%; height: 20px;"></td> <td style="width: 15%; height: 20px;"></td> <td style="width: 15%; height: 20px;"></td> <td style="width: 15%; height: 20px;"></td> <td style="width: 15%; height: 20px;"></td> </tr> </table>										
DATE OF RECEIPT															

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