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: December 31, 2017
See OMB Statement on Reverse Side.

NOTE: This report is required by law (21 USC 355; 21 CFR 314.81). *Failure to report can result in withdrawal of approval of the New Drug or Biologics License Application.*

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

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9. **NDA REPORT INFORMATION REQUIRED** ***(See §314.81 for description)***
(Enter type of information attached under "Identifi cation." If you have nothing to report, enter None.)
(INFORMATION IN "9b" AND "9c" IS ALWAYS REQUIRED.)

TYPE OF INFORMATION	IDENTIFICATION *(Electronic fi le name or eCTD location or Volume No.(s) / Tab(s) / Page(s)of Report)*
INFORMATION	
b. DISTRIBUTION DATA Authorized Generic info	
c. LABELING *(Whether or not previously submitted)*	
d. CHEMISTRY MANUFACTURING AND CONTROLS CHANGES SUPAC ☐	
f. CLINICAL DATA	
STUDY COMMITMENTS	
STUDIES *(,voluntary studies,CMC commitment studies, and product stability studies)*	
BUSINESS *(Optional)*	

10. **BLA REPORT INFORMATION REQUIRED** *(See § 601.70 for description)*

TYPE OF INFORMATION CONTENTS *(Check box)*	
	☐

11. TYPED NAME AND TITLE OF RESPONSIBLE OFFICIAL OR AGENT

13. SIGNATURE Sign

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

DATE OF RECEIPT