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: September 30, 2014
See OMB Statement on Reverse Side.

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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/AUTHORIZED U.S. AGENT	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.)*

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8. PERIOD COVERED BY REPORT

FROM		TO	
YEAR	MONTH	YEAR	MONTH

NDA REPORT INFORMATION REQUIRED *(See § 314.81 for description)*

9. ***(Enter type of information attached under "Identification." If you have nothing to report, enter None.)***
(INFORMATION IN "9b" AND "9c" IS ALWAYS REQUIRED.)

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b. DISTRIBUTION DATA	
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

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