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: May 31, 2008
See OMB Statement on Reverse.

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 form for each application for which an annual report is being submitted. Retain the carbon copy labeled "applicant." Submit the remaining 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. NDA, ANDA, OR BLA NUMBER
N

2. Report No. *(FDA Complete)*
Y-

APPLICANT NOTE
Reference NDA and Y, or BLA numbers *(entered on Acknowledgement Copy)* in any subsequent correspondence regarding report.

3. APPLICANT

PHONE NUMBER
( )

5. TYPE OF REPORT *(Check one)*
☐ ANNUAL ☐ OTHER

4. DRUG/BIOLOGIC NAME

6. OTHER NDA OR BLA NUMBERS *(List all numbers if any part of report applies to more than one number.)*

7. PERIOD COVERED BY REPORT

FROM		TO	
YEAR	MONTH	YEAR	MONTH

Fold Line

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

8. ***(Enter type of information attached under "Identification." If you have nothing to report, enter None.)***
(INFORMATION IN "8b" AND "8c" IS ALWAYS REQUIRED.)

TYPE OF INFORMATION	IDENTIFICATION *(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 ☐ SUPAC	
e. NONCLINICAL LABORATORY STUDIES	
f. CLINICAL DATA	
g. STATUS REPORTS OF POST-MARKETING STUDY COMMENTMENTS	
h. STATUS OF OTHER POSTMARKETING STUDIES *(e.g., voluntary studies, CMC commitment studies, and product stability studies)*	
i. LOG OF OUTSTANDING REGULATORY BUSINESS *(Optional)*	

Fold Line

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

TYPE OF INFORMATION	CONTENTS *(Check box)*
a. ANNUAL PROGRESS REPORTS OF POSTMARKETING STUDIES	☐

TYPED NAME AND TITLE OF RESPONSIBLE OFFICIAL OR AGENT

SIGNATURE

APPLICANTS RETURN ADDRESS *(Type within the window envelope tic marks)*

FDA USE ONLY

10. NDA OR ANDA NUMBER
N

11. DATE OF RECEIPT

FORM FDA 2252 (6/05) PREVIOUS EDITION IS OBSOLETE. PSC Media Arts (301) 443-1090 EF

Public reporting burden for this collection of information is estimated to average 5 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
CDER, HFD-336
7520 Standish Place
Rockville, MD 20855-2737

Food and Drug Administration
CBER, HFM-99
1401 Rockville Pike, Suite 200N
Rockville, MD 20852-1448

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 control number.