**TRANSMITTAL OF ANNUAL REPORTS FOR DRUGS FOR HUMAN USE**
***(21 CFR 314.81)***

DATE SUBMITTED

*Form Approved: OMB No. 0910-0001*
*Expiration Date: March 31, 2005*
*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 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 OR ANDA NUMBER
N

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

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

4. APPLICANT

PHONE NUMBER
( )

3. CFR SECTION NUMBER *(Antibiotic only)*

5. DRUG NAME

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

7. OTHER NDA / ANTIBIOTIC APPLICATION 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 |
| | | | |

Fold Line

**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.)***

| 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 REPORT POST-MARKETING STUDIES | |
| h. STATUS OF OPEN REGULATORY BUSINESS *(Optional)* | |

Fold Line

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

**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 Adminstration
CDER, HFD-336
7520 Standish Place
Rockville, MD 20855-2737

*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.*