INSTRUCTIONS FOR COMPLETING PRESCRIPTION DRUG USER FEE COVER SHEET FORM FDA 3397

Form FDA 3397 is to be completed for and submitted with each new drug or biologic product original application or supplemental application submitted to the Agency on or after April 30, 2001, unless specifically exempted below. Form FDA 3397 should be placed in the first volume of the application with the application (FORM FDA 356(h)) form. Form FDA 3397 is to be completed on-line at www.fda.gov/oc/pdufa/coversheet.html. If you need assistance in completing the form call 301-827-9539 or email: userfees@fda.gov.

NOTE: Form FDA 3397 need not be submitted for:

CDER

505(j) applications
Supplements to 505(j) applications

CBER

Any supplement that does not require clinical data for approval.
Applications and supplements for:

- Products for further manufacturing use only
- Whole blood or blood components for transfusion
- Bovine blood product for topical application licensed before September 1, 1992
- A crude allergenic extract product
- An in vitro diagnostic biological product licensed under Section 351 of the PHS Act

ITEM NO.:	INSTRUCTIONS
1-2.	**Self-explanatory**
3.	**PRODUCT NAME –** Include generic name and trade name, as applicable.
4.	**BLA STN / NDA NUMBER – FOR AN ORIGINAL BIOLOGIC LICENSE APPLICATION (BLA) –** Indicate the 6-digit BLA number (Submission Tracking Number (STN)) if pre-assigned, otherwise leave blank. For A **SUPPLEMENT** enter the BLA STN. **FOR DRUG PRODUCTS –** Indicate the new drug application (NDA) number. NDA numbers can be obtained by completing the information at http://www.fda.gov/cder/regulatory/ersr/preassigned_application.htm.
5.	**CLINICAL DATA –** The definition of 'clinical data' for the assessment of user fees is found in FDA's Guidance for Industry: Submitting Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees. FDA's guidance on the definition of clinical data can be found on CDER's web site: http://www.fda.gov/cder/pdufa/default.htm.
6.	**USER FEE I.D. NUMBER –** Please include the ID number (generated when completing Form FDA 3397) on the application payment check.
7.	**PRIORITY REVIEW VOUCHER:** If you are redeeming a priority review voucher awarded to a sponsor of a tropical disease product application (see section 524 of the Federal Food, Drug, and Cosmetic Act (FD&C Act)), please include the priority review voucher number assigned when the voucher was initially granted. See FDA's Guidance for Industry: Tropical Disease Priority Review Vouchers for further information. FDA's guidance can be found on CDER's web site: http://www.fda.gov/cder/guidance.
8.	**EXCLUSIONS:** The application is for an orphan drug product. Under section 736(a) (1) (E) of the FD&C Act, a human drug application is not subject to an application fee if the proposed product is for a rare disease or condition designated under section 526 of the FD&C Act (orphan drug designation) AND the application does not include an indication that is not so designated. A supplement is not subject to an application fee if it proposes to include a new indication for a rare disease or condition, and the drug has been designated pursuant to section 526 for a rare disease or condition with regard to the indication proposed in the supplement. A copy of the FDA letter granting orphan designation should be included with the BLA/NDA submission.
9.	**WAIVER –** Complete this section only if a waiver of user fees, including the small business waiver, has been granted for this application. *A copy of the official FDA notification that the waiver has been granted must be provided with the BLA/NDA submission.*