

Form Approved: OMB No. 0910 - 0718 Expiration Date: August 31, 2015. See instructions for OMB Statement, below.

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

**BIOSIMILAR USER FEE COVER
SHEET**

APPLICANT'S NAME AND ADDRESS
FDA TEST COMPANY

WHAT SUBMISSION DOES THIS COVER SHEET
REFERENCE?

PRE-IND AND/OR IND NUMBER(S): 123456
 INITIAL BPD
 REACTIVATION

NAME, TELEPHONE NUMBER, AND E-MAIL OF
REPRESENTATIVE

SUBMISSION TRACKING NUMBER (STN):
 351(k) APPLICATION
 351(k) SUPPLEMENT

PRODUCT NAME(S)

REQUIRING CLINICAL DATA

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Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research
Office of Information Management (HFA-710)
8455 Colesville Road, COLE-14-14253
Silver Spring, MD 20993-0002

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PRINTED NAME AND SIGNATURE OF AUTHORIZED
REPRESENTATIVE

TITLE

DATE


USER FEE I.D. NUMBER

USER FEE PAYMENT AMOUNT FOR THIS SUBMISSION

INSTRUCTIONS FOR COMPLETING BIOSIMILAR USER FEE COVER SHEET FORM FDA 3792

Complete this form for:

- a biosimilar biological product development (BPD) meeting;
- an investigational new drug application (IND) intended to support a biologics license application submitted under section 351(k) of the Public Health Service Act ("351(k) application");
- a 351(k) application; or
- a 351(k) supplement.

See accompanying exceptions. Submit form FDA 3792 with the IND, application, and supplement, and place in the first volume with the cover page (FORM FDA 1571 and FDA 356(h)). If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. If you need assistance in completing the form call 301-796-7200  or email: userfees@fda.gov. Payment instructions and fee rates can be found on [FDA's Website](#).

Form FDA 3792 need not be submitted for a BPD meeting, an IND intended to support a 351(k) application, a 351(k) application, or a 351(k) supplement, if:

- The BPD meeting, IND, application, or supplement is for:
 - whole blood or blood component for transfusion;
 - an allergenic extract product;
 - an in vitro diagnostic biological product;
 - a biological product for further manufacturing use only;
- The BPD meeting, IND, application, or supplement cites as the reference product:
 - a bovine blood product for topical application that was approved before September 1, 1992;
 - a large volume parenteral drug product that was approved before September 1, 1992;
- You are a state or federal government entity being granted a BPD meeting, or submitting an IND, application, or supplement for a product that is not distributed commercially.

Submit Form 3792 and pay a fee for:	UNLESS specifically exempted above or
A BPD meeting ¹ for a product	You have already paid, in the current fiscal year: <ul style="list-style-type: none"> ● an initial BPD fee² for the product; ● an annual BPD fee³ for the product; ● a reactivation fee⁴ for the product OR You submitted a 351(k) application for the product that was accepted for filing
An IND that is intended to support a 351(k) application	You have already paid, in the current fiscal year: <ul style="list-style-type: none"> ● an initial BPD fee for the product; ● an annual BPD fee for the product; ● a reactivation fee for the product OR You submitted a 351(k) application for the product that was accepted for filing
A 351(k) application	You are resubmitting the application, for the same product for the same indications, after submitting a 351(k) application that was accepted for filing and was not approved or withdrawn
A 351(k) supplement	Your supplement does not require clinical data, other than comparative bioavailability studies, for approval; OR You are resubmitting the supplement, for the same product for the same indications, after submitting a 351(k) supplement that was accepted for filing and was not approved or withdrawn.

¹ The term "BPD meeting" means any meeting, other than a "biosimilar initial advisory meeting", regarding the content of a biosimilar development program, including a proposed design for, or data from, a study intended to support a biosimilar biological product application.

A "biosimilar initial advisory meeting" is a meeting that is limited to a general discussion regarding whether licensure under section 351(k) may be feasible for a particular product, and, if so, general advice on the expected content of the development program. It does not include any meeting that involves substantive review of summary data or full study reports. No fees are assessed for a biosimilar initial advisory meeting.

² The "initial BPD fee" is the fee a sponsor pays to join FDA's BPD Program for a product.

³ The "annual BPD fee" is the fee a sponsor pays to continue participating in FDA's BPD Program for a product. Specifically, once a sponsor has paid the initial BPD fee for a product, beginning in the next fiscal year, an annual BPD fee will be assessed for the product until the sponsor or applicant submits a marketing application for the biological product that is accepted for filing, or discontinues participation in the BPD Program for the product.

⁴ The "reactivation fee" is the fee a sponsor must pay to resume participation in the BPD Program for a product, if the sponsor previously discontinued participation for that product.

Form FDA 3792 (08/12) (BACK)

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