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
- 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: [insert link]

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; or
  - a large volume parenteral drug product that was approved before September 1, 1992; **OR**
- 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: • an initial BPD fee[2] for the product; • an annual BPD fee[3] for the product; or • a reactivation fee[4] 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: • an initial BPD fee for the product; • an annual BPD fee for the product; or • 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

[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 Ptogram 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.

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.

ITEM NO.	INSTRUCTIONS
1-2.	**Self-explanatory**
3.	**PRODUCT NAME(S):** Include proper name, trade or proprietary name, and code name, as applicable.
4.	**SUBMISSION –** Check the box to indicate the type of submission this cover sheet references. **PRE-IND NUMBER OR IND NUMBER -** indicate the Pre-IND or IND number. If not assigned, contact the document room for a pre-assigned number. **STN NUMBER - FOR A BIOLOGICS LICENSE APPLICATION SUBMITTED UNDER SECTION 351(K) OF THE PHS ACT(351(K) APPLICATION) -** Indicate the 6-digit submission tracking number (STN). If not assigned, contact the product division. For a **351(K)SUPPLEMENT REQUIRING CLINICAL DATA** enter the STN.
5.	**WAIVER:** Complete this section only if a small business waiver of the application fee has been granted for this application. *A copy of the official FDA notification that the waiver has been granted must be provided with the 351(k) application submission.*
6.	**PREVIOUSLY PAID INITIAL BPD FEES, ANNUAL BPD FEES, AND REACTIVATION FEES:** The application fee for a biosimilar biological product is equal to: • the amount of the fee for a human drug application described in section 736(a)(1)(A)(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for that fiscal year, minus • the cumulative amount (if any) of initial BPD fees, annual BPD fees, and reactivation fees paid for the product.
7.	**RESUMING PARTICIPATION IN BPD PROGRAM:** Following discontinuation of participation in the BPD program for a product, a person must pay a reactivation fee in order to resume participation in the BPD program for the product. The reactivation fee is equal to 20 percent of the amount of the fee for a human drug application described in section 736(a)(1)(A)(i) of the FD&C Act for that fiscal year.
8.	**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 FDA's web site: [insert link]
9.	**USER FEE I.D. NUMBER:** Please include the ID number (generated when completing this form) on the check, bank draft, or postal money order. Please reference the ID number with the wire transfer payment.

Form Approved: OMB No.[insert number] Expiration Date:[insert expiration date]. See instructions for OMB statement, below.

DEPARTMENT OF HEALTH AND HUMAN SERVICES **FOOD AND DRUG ADMINISTRATION**	BIOSIMILAR USER FEE COVER SHEET

1. APPLICANT'S NAME AND ADDRESS	4. WHAT SUBMISSION DOES THIS COVER SHEET REFERENCE? PRE-IND or IND NUMBER:_____ [ ] INITIAL BPD [ ] REACTIVATION SUBMISSION TRACKING NUMBER (STN):_____ [ ] 351(k) APPLICATION [ ] 351(k) SUPPLEMENT REQUIRING CLINICAL DATA
2. NAME, TELEPHONE NUMBER, AND E-MAIL OF REPRESENTATIVE	
3. PRODUCT NAME(S)	

Item 5 applies to 351(k) applications

5. HAS A SMALL BUSINESS WAIVER BEEN GRANTED FOR THIS APPLICATION?
[ ] YES [ ] NO
If a waiver has been granted, include a copy of the official FDA notification that the waiver has been granted, with your submission.

Item 6 applies to Pre-INDs, INDs, and 351(k) applications

6. HAVE YOU PREVIOUSLY PAID:

- AN INITIAL BPD FEE
- AN ANNUAL BPD FEE; OR
- A REACTIVATION FEE

FOR THE PRODUCT NAMED IN THIS COVER SHEET?
[ ] YES [ ] NO

IF YOUR RESPONSE IS “YES”, INDICATE THE PRE-IND OR IND NUMBER(S) OF THE PRODUCT NAMED IN THIS COVER SHEET.
PRE-IND OR IND NUMBER:

Item 7 applies to Pre-INDs and INDs

7. HAVE YOU PREVIOUSLY DISCONTINUED PARTICIPATION IN THE BPD PROGRAM FOR THE PRODUCT NAMED IN THIS USER FEE COVER SHEET?
[ ] YES [ ] NO

IF YOUR RESPONSE IS “YES”, HAVE YOU ALREADY PAID AN INITIAL OR ANNUAL BPD FEE OR REACTIVATION FEE FOR THE PRODUCT IN THE CURRENT FISCAL YEAR?
[ ] YES [ ] NO

Item 8 applies to 351(k) applications

8. DOES THIS APPLICATION REQUIRE CLINICAL DATA, OTHER THAN COMPARATIVE BIOAVAILABILITY STUDIES, FOR APPROVAL?
[ ] YES [ ] NO

Privacy Act Notice: This notice is provided pursuant to the Privacy Act of 1974, 5 U.S.C. 552a. The collection of this information is authorized by 21 U.S.C. 371, 379, 379e, 379h, 379h-1, 379j, 379j-12, 379j-21, 387s, and 393(d)(2); 42 U.S.C. 263b(r)(1); 5 U.S.C. 301 and 552; and 42 U.S.C. 3101. FDA will use the information to assess, collect and process user fee payments, and, facilitate debt collection under the Debt Collection Improvement Act. FDA may disclose information to courts and the Department of Justice in the context of litigation and requests for legal advice; to other Federal agencies in response to subpoenas issued by such agencies; to HHS and FDA employees and contractors to perform user fee services; to the National Archives and Records Administration and General Services Administration for records management inspections; to the Department of Homeland Security and other Federal agencies and contractors in order to respond to system breaches; to banks in order to process payment made by credit card; to Dun and Bradstreet to validate submitter contact information, and to other entities as permitted under the Debt Collection Improvement Act. Furnishing the requested information is mandatory. Failure to supply the information could prevent FDA from processing user fee payments. Additional detail regarding FDA’s use of information is available online: http://www.fda.gov/RegulatoryInformation/FOI/PrivacyAct/default.htm.

OMB Statement:
Public reporting burden for this collection of information is estimated to average 30 minutes 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:

Department of Health and Human Services Food and Drug Administration Center for Biologics Evaluation and Research Office of Information Management (HFA-710) 1350 Piccard Drive, 4th Floor Rockville, MD 20850	Department of Health and Human Services Food and Drug Administration Center for Drug Evaluation and Research Office of Information Management (HFA-710) 1350 Piccard Drive, 4th Floor Rockville, MD 20850	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.

PRINTED NAME AND SIGNATURE OF AUTHORIZED REPRESENTATIVE	TITLE	DATE

9. USER FEE I.D. NUMBER
10. USER FEE PAYMENT AMOUNT FOR THIS SUBMISSION $

Close Print Cover sheet