4.3 – APPENDIX C: ALLOWABLE AND EXCLUDED COSTS FOR THE BSUFA PROGRAM

Introduction

Section 744G of the FD&C Act, as amended, defines the term "process for the review of biosimilar biological product applications" and the costs that may be included in that process. Fees may only be spent for activities that are included in this definition, although fee-generating activities are only a small subset of the activities that are included in this definition. FDA identifies those activities that are applicable to the BsUFA program in this appendix. In Appendix D, FDA describes how the costs for the BsUFA program are developed, based on the allowable activities identified below.

BsUFA Program Costs

Included Activities

Section 744G(13) of the FD&C Act defines the term "process for the review of biosimilar biological product applications" to mean the following activities of FDA with respect to the review of submissions in connection with biosimilar biological product development, biosimilar biological product applications, and supplements:

A. The activities necessary for the review of submissions in connection with biosimilar biological product development, biosimilar biological product applications, and supplements.

B. Actions related to submissions in connection with biosimilar biological product development, the issuance of action letters which approve biosimilar biological product applications or which set forth in detail the specific deficiencies in such applications, and where appropriate, the actions necessary to place such applications in condition for approval.

C. The inspection of biosimilar biological product establishments and other facilities undertaken as part of FDA's review of pending biosimilar biological product applications and supplements.

D. Activities necessary for the release of lots of biosimilar biological products under section 351(k) of the Public Health Service Act.

E. Monitoring of research conducted in connection with the review of biosimilar biological product applications.

F. Postmarket safety activities with respect to biologics approved under biosimilar biological product applications or supplements, including the following activities:

    i. Collecting, developing, and reviewing safety information on biosimilar biological products, including adverse-event reports.

    ii. Developing and using improved adverse-event data-collection systems, including IT systems.

iii. Developing and using improved analytical tools to assess potential safety problems, including access to external databases.

iv. Implementing and enforcing section 505(o) of the FD&C Act (relating to post-approval studies and clinical trials and labeling changes) and section 505(p) of the FD&C Act (relating to risk evaluation and mitigation strategies).

v. Carrying out section 505(k)(5) of the FD&C Act (relating to adverse-event reports and postmarket safety activities).

All costs represented by the above activities are collectively referred to in this report as costs for "the process for the review of biosimilar biological product applications."

Section 744G(9) of the FD&C Act defines the term "costs of resources allocated for the process for the review of biosimilar biological product applications" as the expenses in connection with the BsUFA program for:

A. Officers and employees of the FDA, contractors of FDA, advisory committees, and the costs related to such officers, employees, and committees, and to contracts with such contractors;

B. Management of information and the acquisition, maintenance, and repair of computer resources;

C. Leasing, maintenance, renovation, and repair of facilities and acquisition, maintenance and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies; and

D. Collecting fees under section 744H and accounting for resources allocated for the review of submissions in connection with biosimilar biological product development, biosimilar biological product applications, and supplements.

Excluded Activities

The following types of products are not subject to BsUFA fees, and FDA excludes from the BsUFA program activities in connection with the following types of applications for licensure under section 351(k) of the Public Health Service Act:

- Applications that cite as the reference product a product approved before September 1, 1992, that is either a bovine blood product for topical application or a large-volume parenteral drug;

- Allergenic extract products;

- Whole blood or a blood component for transfusion;

- In vitro diagnostic biologic products; and

- A biological product for further manufacturing use only.

Excluded Process Activities

BsUFA fees may not be spent on the following types of activities:

- Enforcement policy development not related to sections 505(o) and (p) of the FD&C Act;
- Post-approval compliance activities not related to the enforcement of sections 505(o) and (p) of the FD&C Act;
- Advertising review activities once marketing of the product has begun;
- Inspections unrelated to the review of covered applications, unless undertaken for the enforcement of sections 505(o) and (p) of the FD&C Act; and
- Research unrelated to the BsUFA program.