## 4.3 – APPENDIX C: INCLUDED AND EXCLUDED COSTS FOR THE GDUFA PROGRAM

### Introduction

Section 744A of the FD&C Act, as amended by GDUFA, defines the term "human generic drug activities" and the costs that may be included in that process, collectively referred to as the GDUFA program in this document. Fees may be spent only for activities that are included in this definition. FDA identifies those activities and resources that are applicable to the GDUFA program in this appendix. In Appendix D, FDA describes how the costs for the GDUFA program are developed, based on the allowable activities identified below.

### GDUFA Program Costs

#### Included Activities

Section 744A(8) of the FD&C Act defines in general, the term "human generic drug activities" as the activities associated with generic drugs and inspection of facilities associated with generic drugs. In summary, costs related to the following have been attributed to human generic drug activities:

A. The activities necessary for the review of generic drug submissions, including review of DMFs referenced in such submissions.

B. The issuance of—

    i. approval letters which approve ANDAs or prior approval supplements to such applications.

    ii. complete response letters 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 issuance of letters related to Type II active pharmaceutical ingredient DMFs which:

    i. set forth in detail, the specific deficiencies in such submissions, and where appropriate, the actions necessary to resolve those deficiencies; or

    ii. document that no deficiencies need to be addressed.

D. Inspections related to generic drugs.

E. Monitoring of research conducted in connection with the review of generic drug submissions and DMFs.

F. Postmarket safety activities with respect to drugs approved under abbreviated new drug applications or supplements, including the following activities:

    i. Collecting, developing, and reviewing safety information on approved drugs including adverse event reports.

ii. Developing and using improved adverse-event data collection systems, including information technology 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) (relating to post-approval studies and clinical trials and labeling changes) and section 505(p) (relating to risk evaluation and mitigation strategies) insofar as those activities relate to abbreviated new drug applications.

v. Carrying out section 505(k)(5)(relating to adverse-event reports and postmarket safety activities).

G. Regulatory science activities related to generic drugs.

All user-fee-related costs represented by the above activities are collectively referred to in this report as human generic drug activities or the GDUFA program.

Section 744A(11) of the FD&C Act defines the term “resources allocated for human generic drug activities” as expenses for the following:

A. Officers and employees of the Food and Drug Administration, contractors of the Food and Drug Administration, advisory committees, and costs related to such officers, employees, 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 user fees under subsection (a) and accounting for resources allocated for the review of abbreviated new drug applications and supplements and inspections related to the generic drugs.

**Excluded Activities**

The GDUFA Program excludes from the term “human generic drug activities” costs related to the following:

A. All activities necessary for the review of new drug applications (NDAs), biologic license applications (BLAs), and investigational new drugs (INDs) for drugs that will not be approved under ANDAs.

B. The issuance of correspondence unrelated to abbreviated new drug submissions or prior approval supplements.

C. Inspections unrelated to human generic drugs.

D. Monitoring of research unrelated to human generic drug submissions and DMFs.

E. Post-market safety activities apart from those drugs approved under ANDAs or supplements.