

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

Introduction

The FD&C Act, as amended by AGDUFA II, defines the “process for the review of abbreviated applications for generic new animal drugs” and the costs that may be included in that process, collectively referred to as the AGDUFA program in this document. 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. Using the statutory definition and the methodologies described in Appendix D, the Agency identified those activities that were applicable to the AGDUFA program.

AGDUFA Program Costs

Included Activities

Section 741(k)(3) *The term ‘costs of resources allocated for the process for the review of abbreviated applications for generic new animal drugs’ means the expenses incurred in connection with the process for the review of abbreviated applications for generic new animal drugs for—*

Section 741(k)(3)(A) *officers and employees of the Food and Drug Administration, contractors of the Food and Drug Administration, advisory committees consulted with respect to the review of specific abbreviated applications, supplemental abbreviated applications, or investigational submissions, and costs related to such officers, employees, committees, and contractors, including costs for travel, education, and recruitment and other personnel activities;*

This includes costs for management and administrative services related to the AGDUFA program, as well as costs for personnel development and training such as:

- scientific, clinical, and statistical training;
- managerial and other administrative training;
- policy/regulatory training;
- professional development (coursework, attendance at professional meetings, library resources); and
- site visit program for premarket reviewers.

Section 741(k)(3)(B) *management of information, and the acquisition, maintenance, and repair of computer resources;*

Section 741(k)(3)(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*

Section 741(k)(3)(D) *collecting fees under this section and accounting for resources allocated for the review of abbreviated applications, supplemental abbreviated applications, and investigational submissions.*

Sections 741(k)(3)(B) through (D) include, but are not limited to, all forms of information management, facility rental, maintenance and repair, and infrastructure acquisitions in support of the AGDUFA program and in support of user fee collections and accounting.

Section 741(k)(10) *The term ‘process for the review of abbreviated applications for generic new animal drugs’ means the following activities of the Secretary with respect to the review of abbreviated applications, supplemental abbreviated applications, and investigational submissions:*

Section 741(k)(10)(A) *The activities necessary for the review of abbreviated applications, supplemental abbreviated applications, and investigational submissions.*

This encompasses, among other things, the review of the following types of information:

- with respect to ANADAs—original applications, pre- and post-market supplements, chemistry reports, reactivations, Veterinary Master Files, Public Master Files, and application-related correspondence; and
- with respect to Generic Investigational New Animal Drug Submissions (JINADs)—initial submissions, reauthorization requests, protocols with or without data, and studies with or without data.

Furthermore, the activities necessary for the review of ANADAs, supplemental ANADAs, and JINADs include:

- Agency-initiated action related to these applications and submissions;
- general ANADA and JINAD activities that do not directly relate to a pending submission, such as staff training and administrative support;
- administrative processing of these applications and submissions;
- maintenance and support of automated systems that track these applications and submissions; and
- quality assurance and quality control standards and policy development activities related to the review of these applications and submissions.

Section 741(k)(10)(B) *The issuance of action letters which approve abbreviated applications or supplemental abbreviated applications or which set forth in detail the specific deficiencies in abbreviated applications, supplemental abbreviated applications, or investigational submissions and, where appropriate, the actions necessary to place such applications, supplemental applications, or submissions in condition for approval.*

This includes activities such as the issuance of deficiency letters, meetings with applicants to discuss such letters, and review of the responses.

Section 741(k)(10)(C) *The inspection of generic new animal drug establishments and other facilities undertaken as part of the Secretary's review of pending abbreviated applications, supplemental abbreviated applications, and investigational submissions.*

Section 741(k)(10)(D) *Monitoring of research conducted in connection with the review of abbreviated applications, supplemental abbreviated applications, and investigational submissions.*

This includes monitoring of clinical and other research conducted in connection with the review of these applications and submissions.

Section 741(k)(10)(E) *The development of regulations and policy related to the review of abbreviated applications, supplemental abbreviated applications, and investigational submissions.*

This includes activities such as development of drug-specific, cross-cutting, and program-related guidance, and Standard Operating Procedures.

Section 741(k)(10)(F) *Development of standards for products subject to review.*

This includes FDA activities on national and international standards development for products subject to review.

Section 741(k)(10)(G) *Meetings between the Agency and the generic new animal drug sponsor.*

This includes activities such as:

- informal consultation in person and via phone, mail, e-mail, and facsimile;
- meetings between FDA and sponsors, such as pre-submission conferences;
- use of advisory committees and outside experts in the review of ANADAs; and
- FDA-sponsored conferences/workshops related to ANADAs.

Section 741(k)(10)(H) *Review of advertising and labeling prior to approval of an abbreviated application or supplemental abbreviated application, but not after such application has been approved.*

Excluded Activities

- Review of new animal drug applications and other pioneer submissions;
- Enforcement policy development;
- Post-approval surveillance and compliance activities;
- Post-approval activities relating to the review of advertising;
- Inspections unrelated to the AGDUFA program; and
- Research unrelated to the AGDUFA program.