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

Introduction

The FD&C Act, as amended, defines the "process for the review of animal drug applications" and the costs that may be included in that process; this is collectively referred to as the "ADUFA 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 ADUFA program.

ADUFA Program Costs

Included Activities

Section 739(8) *The term 'process for the review of animal drug applications' means the following activities of the Secretary with respect to the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions:*

Section 739(8)(A) *The activities necessary for the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.*

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

- with respect to New Animal Drug Applications (NADAs)—original applications, pre- and post-market supplements, chemistry reports, reactivations, Veterinary Master Files, Public Master Files, and application-related correspondence; and

- with respect to Investigational New Animal Drugs (INADs)—initial submissions, reauthorization requests, protocols with or without data, and studies with or without data.

Furthermore, the activities necessary for the review of NADAs, supplemental animal drug applications, and INADs include among other activities:

- Agency-initiated action related to these applications and submissions;

- general NADA and INAD 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 739(8)(B) *The issuance of action letters which approve animal drug applications or supplemental animal drug applications or which set forth in detail the specific deficiencies in animal drug applications, supplemental animal drug applications, or investigational animal drug*

submissions and, where appropriate, the actions necessary to place such applications, supplements 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 739(8)(C) *The inspection of animal drug establishments and other facilities undertaken as part of the Secretary's review of pending animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.*

Section 739(8)(D) *Monitoring of research conducted in connection with the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.*

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

Section 739(8)(E) *The development of regulations and policy related to the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.*

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

Section 739(8)(F) *Development of standards for products subject to review.*

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

Section 739(8)(G) *Meetings between the Agency and the 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 pre-market applications; and
- FDA sponsored conferences/workshops related to pre-market submissions.

Section 739(8)(H) *Review of advertising and labeling prior to approval of an animal drug application or supplemental animal drug application, but not after such application has been approved.*

Section 739(9) *The term 'costs of resources allocated for the process for the review of animal drug applications' means the expenses incurred in connection with the process for the review of animal drug applications for—*

Section 739(9)(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 animal drug applications, supplemental animal drug applications, or investigational animal drug 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 ADUFA 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
- a site visit program for premarket reviewers.

Section 739(9)(B) *management of information, and the acquisition, maintenance, and repair of computer resources,*

Section 739(9)(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 739(9)(D) *collecting fees under section 740 and accounting for resources allocated for the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.*

Sections 739(9)(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 ADUFA program and in support of user fee collections and accounting.

Excluded Activities

- Review of Abbreviated New Animal Drug Applications
- Enforcement policy development
- Post-approval surveillance and compliance activities
- Post-approval activities relating to the review of advertising
- Inspections unrelated to the ADUFA program
- Research unrelated to the ADUFA program