ADUFA IV: Summary of the Proposed Changes to the FD&C Act and Proposed Bill Language

This document provides a high level section by section summary of the changes being proposed to the Animal Drug User Fee Act (ADUFA IV).

I. Proposed User Fee-Related Changes to the FD&C Act

SEC. 739. DEFINITIONS.

The definition of the term “animal drug application” at subsection (1) is amended to also include an application for conditional approval submitted under section 571.

The definition of the term “process for the review of animal drug applications” at subsection (8) of this section is amended to also include certain activities related to implementation of the US-EU GMP Mutual Inspection Agreement with respect to animal drug products subject to review.

SEC. 740. AUTHORITY TO ASSESS AND USE ANIMAL DRUG FEES.

Subsection (a)(3)(C) of this section is amended to eliminate reference to the PDUFA establishment fee since this type of fee was eliminated when PDUFA was reauthorized (PDUFA VI) recently.

Subsection (b) of this section is modified to reflect the total fee revenue amounts for fiscal year 2019 and subsequent fiscal years through 2023.

Subsection (c) of this section modifies the workload adjustment provision, inserts a provision for reduction of workload adjustment increases by certain excess collections, and modifies final year adjustment dates.

Subsection (d) of this section is modified to add exemptions from fees for certain labeling supplements to add the number of the approved application to the labeling for approved animal drugs (see proposed new labeling requirement in SEC. 502 provided in the final section of this redline). This subsection also provides exemptions to annual product, sponsor, and establishment fees, for persons who otherwise would be subject to such fees for their work in connection with an animal drug application, supplemental animal drug application, or investigational animal drug submission involving the intentional genomic alteration of an animal that is intended to produce human medical products that will be separately regulated by other FDA Centers and subject to user

fees by those Centers. This will provide CVM with resources that can be used to review of the NADAwithout triggering annual fees for the sponsor from both the human and animal review programs.

Subsection (g) of this section updates the authorization of appropriations provision, inserts an excess collections provision, deletes the offset provision, and modifies the recovery of collection shortfalls provision to provide for reductions of shortfall-based fee increases by prior year excess collections.

SEC. 740A. REAUTHORIZATION; REPORTING REQUIREMENTS.

This section is modified for dates related to this reauthorization.

II. Proposed Bill Language

SEC. XXX. SHORT TITLE; FINDING.

This section includes proposed bill language referring to the reauthorization legislation as the “Animal Drug User Fee Amendments of 2018” and also includes proposed finding language stating that the fees authorized by the amendments will be dedicated toward enhancing the new animal drug development process and the review of new animal drug applications and submissions process as stated in the goals letter.

SEC. XXX. SAVINGS CLAUSE.

This section provides that animal drug applications and supplemental animal drug applications submitted and accepted for filing on or after October 1, 2013, but before October 1, 2018, and which are still pending as of ADUFA IV enactment, will continue to be subject to ADUFA III fees.

SEC. XXX. EFFECTIVE DATES.

Subsection (a) of this section provides that amendments made under the reauthorization bill will take effect on October 1, 2018, or the date of enactment, whichever is later. This section also provides that FDA will assess ADUFA IV fees for animal drug applications and supplemental animal drug applications received on or after October 1, 2018, regardless of the date of the enactment.

Subsection (b) of this section provides that the misbranding provisions for certain labeling requirements in section 502(w)(3) of the Federal Food, Drug, and Cosmetic Act will become effective on September 30, 2023.

SEC. XXX. SUNSET DATES.

This section extends the ADUFA sunset date for section 740 through October 1, 2023 and extends the sunset date for the ADUFA reporting requirements in section 740A through January 31, 2024. In addition, this section strikes the previous sunset provisions in ADUFA III.

III. Additional Proposed Changes to the FD&C Act

SEC. XXX. ELECTRONIC SUBMISSIONS

This section would require that beginning October 1, 2018, new animal drug applications and submissions must be submitted by electronic means in such electronic format as specified by the Secretary.

SEC. 572. INDEX OF LEGALLY MARKETED UNAPPROVED NEW ANIMAL DRUGS FOR MINOR SPECIES.

This section modifies the required labeling statement for indexed new animal drugs..

SEC. 502. MISBRANDED DRUGS AND DEVICES.

This section is amended by adding to subsection (w) a requirement to identify an approved animal drug product’s application number on its labeling, except that this provision will not apply to representative labeling required for Type A Medicated Articles. (Note: Section 740(d)(4) provides an exemption from user fees for those persons who previously have not been subject to user fees under ADUFA and are submitting a supplement merely to comply with this requirement).