AGDUFA III: 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 Generic Drug User Fee Act (AGDUFA III).

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

SEC.741. AUTHORITY TO ASSESS AND USE GENERIC NEW ANIMAL DRUG FEES.

Subsection (b) of this section modifies the fee revenue approach, and delineates the revenue distribution percentage for each fee type for AGDUFA III.

Subsection (c) of this section inserts an inflation adjustment provision, 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 an exemption 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).

Subsection (g) of this section modifies the authorization of appropriations provision, inserts an excess collections provision, and deletes the offset provision.

Subparagraph (I) is added to paragraph (k) (10) of this section, so that the term ‘process for the review of abbreviated applications for generic new animal drugs’ includes processing of Freedom of Information Act requests related to applications.

SEC.742. 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 Generic 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 generic new animal drug development process and the review of generic new animal drug applications and submissions process as stated in the goals letter.

SEC. XXX. SAVINGS CLAUSE.

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

SEC. XXX. EFFECTIVE DATES.

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. In addition, this section provides that FDA will assess AGDUFA III fees for generic new animal drug applications and abbreviated supplemental applications for generic new animal drugs received on or after October 1, 2018, regardless of the date of the enactment.

SEC. XXX. SUNSET DATES.

This section extends the AGDUFA sunset date for section 741 through October 1, 2023 and extends the sunset date for the AGDUFA reporting requirements in section 742 through January 31, 2024. In addition, this section strikes the previous sunset provisions in AGDUFA II.

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. 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 741(d) provides an exemption from user fees for those persons who previously have notbeen subject to user fees under AGDUFA and are submitting a supplement merely to comply with this requirement).