OFFICE OF NEW ANIMAL DRUG EVALUATION REVIEWER'S CHAPTER

COMPLETING THE GREEN BOOK AND ANIMAL DRUGS @ FDA (GBAAD) FORM

I. PURPOSE

This document explains how to complete a Green Book and Animal Drugs @ FDA (GBAAD) form when finalizing original and supplemental applications that result in an update to the Animal Drugs @ FDA (ADAFDA) database. It also explains the process for completing a GBAAD form when errors are found in ADAFDA.

II. BACKGROUND

A GBAAD form is required to be completed for all original and certain supplemental approvals (see P&Ps 1243.3800, 1243.6020, and 1243.6040). The information contained in the GBAAD form is used by the Business Informatics (BI) Team in the Office of New Animal Drug Evaluation (ONADE) to update the ADAFDA database. The BI Team updates ADAFDA on a monthly basis for applications approved the previous month. They also make corrections to the database periodically when errors are identified by either internal or external stakeholders.

III. COMPLETING SECTION 1 OF THE GBAAD FORM FOR ORIGINAL AND SUPPLEMENTAL APPROVALS

For original approvals, complete the top section and section 1 of the GBAAD form. The BI Team will get the remaining information needed to populate ADAFDA from the Freedom of Information (FOI) Summary for the approval. For each item below, if a particular item is not applicable to the approval, check "No Change or N/A". Complete section 1 as follows.

A. Withdrawal Period(s) and Residue Warnings

For food-producing animals, enter all information from the Residue Warnings section (typically between the compressed arrows) on the labeling.

B. Tolerance(s)

For food-producing animals, provide the tolerance information only for the species included in the approval. Copy the information from the drug listing in 21 CFR

556.XXX(b). For example, the tolerance information for erythromycin approved in cattle would appear as follows in the tolerance section of the GBAAD form:

§556.230 Erythromycin

(b) Tolerances. The tolerances for erythromycin are:

(1) Cattle. (i) Edible tissues (excluding milk): 0.1 ppm.

(ii) Milk: Zero.

C. Exclusivity(ies)

Enter the items that have been granted exclusivity as a result of the approval and the number of years of exclusivity granted. Do not enter the expiration date of the exclusivity. Note: we do not remove expired exclusivity language from the ADAFDA database.

For example: “Exclusivity granted for the control of colibacillosis in groups or pens of weaned pigs where colibacillosis associated with Escherichia coli has been diagnosed.” (3 years).

D. Patent Number(s)/Exp. Date(s)

Enter all patent numbers and expiration dates. Note: we do not remove expired patents from the ADAFDA database.

IV. COMPLETING SECTION 2 OF THE GBAAD FORM FOR SUPPLEMENTAL APPROVALS

For supplemental approvals, complete the top section of the GBAAD form, and sections 1 (see section III above) and 2. The BI Team will also use the FOI Summary, if applicable, to identify any new information resulting from the approval and enter it into the ADAFDA database. For each item below, check “Replace”, “Add”, or “Delete” as appropriate. If you select “Add” or “Delete”, enter the information to be added or deleted. If you select “Replace”, be sure to note the text being replaced in addition to the new text replacing it. In addition, if a particular item is not applicable, or no change is required, check “No Change or N/A”. Complete section 2 of the GBAAD form as follows.

A. Sponsor Name and Address

Enter the revised sponsor name and/or address as listed in 21 CFR 510.600(c), if applicable.

B. Proprietary Name(s)

This section applies to changes to proprietary name(s), including changes in the trademark. Format the proprietary name(s) utilizing the appropriate trademark symbols (® or ™) as it is written on the labeling. Do not include the dosage form unless it is part of the proprietary name. Do not write the name in all-caps unless that is how it is written on the labeling.

C. Drug Product Established Name

Enter the Drug Product Established Name as it appears on the labeling. For the purposes of the Green Book, ADAFDA and CFR, we use the chemical name/API rather than the Drug Product Established Name. Hence the BI Team will modify what is entered here when updating ADAFDA.

D. Dosage Form

Enter the dosage form as it appears in the FOI Summary and/or the Memorandum Recommending Approval (MRA).

E. Amount of Active Ingredient/Concentration

If applicable, enter the concentration of the drug (e.g., Each chewable tablet contains 5 mg of lotilaner).

F. Marketing Status

Utilize the drop-down and select either Over-the-Counter (OTC), Prescription (Rx), or Veterinary Feed Directive (VFD).

G. Conditions of Use

This section of the GBAAD form refers to the Species/Class, Indications for Use, and Dosage and Administration sections located under the Proprietary Name hyperlink in ADAFDA. Complete this section for each applicable product proprietary name under the abbreviated or new animal drug application (A)NADA, as the conditions of use can vary.

We are no longer including limitations text in the Dosage and Administration section of ADAFDA. Rather, all Withdrawal Periods and Residue Warnings will be listed under “Withdrawals”. For applications with previous approvals that describe limitations, it could be potentially misleading to the user to see newer approvals without limitations. To prevent the user from incorrectly inferring that the listed limitations apply only to some products but not others, the limitations associated with previous approvals should be deleted.

If more than one change is required (e.g., removing limitations from multiple previous approvals), you can check “Delete” and specify in the text field to delete all limitations for previous approvals. The same approach can be used if you are updating/replacing text for more than one previous approval. See Appendices 1 through 3 for examples.

V. COMPLETING THE GBAAD FORM WHEN ERRORS ARE IDENTIFIED IN ADAFDA

If an error is identified in ADAFDA, complete a GBAAD form and email it to Internal information redacted. . When completing the top section of the form, enter only the document type code and number (e.g., N-xxxxxx) in the Submission ID field, as there is no associated submission code or number. You can leave the other three fields blank, as they all refer to an approval, which is not pertinent in this situation. Complete sections 1 and/or 2 as appropriate. The BI Team will make the correction to ADAFDA the following month when the monthly update to ADAFDA is performed.

If an external stakeholder identifies an error in ADAFDA, they also may email Internal information redacted. . Because they don't have access to a GBAAD form, they will need to be clear and specific about what needs to be corrected in the database.

VI. REFERENCES

Code of Federal Regulations (Title 21)

21 CFR 510.600(c)

21 CFR 556

CVM Program Policies and Procedure Manual - ONADE Reviewer's Chapter

1243.3900 Maintaining the Animal Drugs @ FDA Website and the Green Book

1243.3800 Preparing and Processing an Approval Package

1243.6020 Review of NADA and ANADA Labeling Supplements NL Subclass

1243.6040 Review of A NADA 60-day NF Qualifying Labeling Supplements

VII. VERSION HISTORY

July 31, 2018 – Original version.

September 17, 2020 – Revised to add instructions regarding the OSC-initiated changes section of the form.

February 2, 2021 – Revised to delete the section regarding the Code of Federal Regulations

April 24, 2023 - Section IV G OSC Initiated Label Changes was deleted b/c this section was deleted OSC-initiated labeling supplements are no longer published on the Green Book Monthly Update webpage. These safety related labeling changes are now published on the Animal Drug Safety-Related Labeling Changes | FDA web page, which is managed by OSC. The font of this document was changed from Verdana 10-point font to Arial 11-point font. In order to bring all office quality system documentation into compliance with the FDA Visual Identity Program approved fonts, ONADE has adopted Arial 11-point font.

December 13, 2023 – Put the entire document into the current format and template. Added the example for formatting tolerances in section III. B. It had been deleted in error in the April 2023 version.

APPENDIX 1. DELETING LIMITATIONS THAT ARE CURRENTLY LISTED UNDER THE DOSAGE AND ADMINISTRATION SECTION

Conditions of Use:	☐	Do not slaughter cattle within 21 days of treatment. Because a withholding time for milk has not been established, do not use in female dairy cattle of breeding age. A withdrawal period has not been established for preruminating calves. Do not use in calves to be processed for veal.	Replace☐ Add ☐ Delete ☒

APPENDIX 2. REPLACING INFORMATION UNDER THE DOSAGE AND ADMINISTRATION SECTION

Conditions of Use:	☒	Replace the following: Dosage and Administration: One dose (implant) containing 200 mg trenbolone acetate and 20 mg estradiol is administered to each animal. The implant is placed under the skin on the posterior aspect of the ear by means of an implanting tool. With the following: Dosage and Administration: One dose (implant) containing 400 mg trenbolone acetate and 30 mg estradiol is administered to each animal. The implant is placed under the skin on the posterior aspect of the ear by means of an implanting tool.	Replace☒ Add ☐ Delete ☐

APPENDIX 3. DELETING AND REPLACING TEXT

Conditions of Use:	☒	Replace the following: Dosage and Administration: One dose (implant) containing 200 mg trenbolone acetate and 20 mg estradiol is administered to each animal. The implant is placed under the skin on the posterior aspect of the ear by means of an implanting tool. With the following: Dosage and Administration: One dose (implant) containing 400 mg trenbolone acetate and 30 mg estradiol is administered to each animal. The implant is placed under the skin on the posterior aspect of the ear by means of an implanting tool.	Replace☒ Add ☐ Delete ☐