OFFICE OF NEW ANIMAL DRUG EVALUATION REVIEWER'S CHAPTER

UPDATING THE ANIMAL DRUGS @ FDA WEBSITE AND GREEN BOOK

I. PURPOSE

This P&P documents the processes for submitting new or updated information to the Food and Drug Administration (FDA)/Center for Veterinary Medicine (CVM) Animal Drugs @ FDA (ADAFDA) internet website and the FDA/CVM Green Book.

II. BACKGROUND

On November 16, 1988, Congress enacted the Generic Animal Drug and Patent Term Restoration Act (GADPTRA), which amended Section 512 (n)(4) of the Federal Food Drug and Cosmetic Act (FD&C Act). This section of the FD&C Act "Requires the Secretary to publish and update a list of the official and proprietary name of each new animal drug which has been approved and continues to be approved for safety and effectiveness, including patent information as it comes in." The first bound book, FDA Approved Animal Drug Products was published and made available on January 15, 1989. Because the book had a green cover, it was referred to as the Green Book.

The Green Book consists of eight lists. The lists are: approved animal drugs (by trade name [proprietary name], application number, and sponsor), approved animal drugs (by active ingredients), patent information, exclusivity periods, products subject to Notice of Hearing, voluntary withdrawals, suitability petition actions, and monthly updates. The Green Book is made available to the public through the ADAFDA website. CVM's Business Informatics (BI) Team in the Office of New Animal Drug Evaluation (ONADE) maintains the Green Book.

As an adjunct to the Green Book, a searchable database, ADAFDA, was created that allows the public access to publicly available information on all approved pioneer and generic new animal drugs. The BI Team is responsible for the maintenance of the database, quality assurance/quality control checks of the data, and publishing the data on the website.

ADAFDA contains the following information: (abbreviated) new animal drug application ((A)NADA) number, proprietary name(s), sponsor name and address, ingredients, indications, tolerances and withdrawal times, applicable patent(s), applicable marketing exclusivities, (A)NADA products that have been voluntarily withdrawn, conditional, biotechnology approvals, approval related documents (Freedom of Information Summaries, Environmental Assessments, Findings of No Significant Impact, and some

labeling), approved medicated feed mill licenses, and a veterinary feed directive distributor notifications list.

III. PROVIDING INFORMATION FOR INCLUSION IN THE ADAFDA AND THE GREEN BOOK

A. Identifying Submissions Requiring a New Entry or Update to ADAFDA and the Green Book

The following types of submissions may contain information that will result in an update to ADAFDA and/or the Green Book. A Green Book and Animal Drugs (GBAAD) form should be filled out and included with the approval package for:

- Original approvals that publish in the FEDERAL REGISTER (FR),
- Supplemental approvals that publish in the FR,
- 180-day supplements with the NF subclass code, and
- Some CMC supplements that result in a labeling change.[1]

Labeling supplements with the NL subclass code and NF supplements with a 60-day review time typically do not require the GBAAD form, as they generally do not result in changes to ADAFDA or the Green Book. Rather, for these supplements, it should be noted in the Memorandum Recommending Approval (MRA) whether or not there are changes needed to ADAFDA or the Green Book. In addition, changes in sponsor information (name change, transfer of ownership, address change) withdrawals of approval, and changes in patent information will require an update to ADAFDA and the Green Book, but do not require a GBAAD form.

B. Error Corrections

If you find an error in the ADAFDA database or Green Book, fill out the GBAAD form for the applicable fields, identify the error and supply the correct information. Submit the GBAAD form to the Internal information redacted mailbox in Outlook.

IV. REFERENCES

Generic Animal Drug and Patent Term Restoration Act (GADPTRA) of 1988

FDA Approved Animal Drug Products 1989

CVM Program Policy and Procedures Manual – ONADE Reviewer's Chapter

1243.3801 – Completing the Green Book and Animal Drugs @ FDA (GBAAD) Form

[1] See P&P 1243.6030 Review of Labeling Changes in Manufacturing Supplements for additional information.

1243.6030 - Review of Labeling Changes in Manufacturing Supplements

V. VERSION HISTORY

January 16, 2008 – Original P&P version

March 6, 2008 – Minor corrections to formatting made.

April 6, 2009 – Major overhaul of process / Separation of Green Book and New AnimalDrugs@FDA.gov searchable database.

November 25, 2009 – Updated instructions to include the GBAAD form.

October 5, 2010 – Updated to provide more specific instructions for completing the GBAAD form. Added information on the Green Book.

August 24, 2012 – Major rewrite of P&P to include screen shots and more detailed instructions for users.

February 11, 2015 – Updated to provide revised instructions for when to use the GBAAD form. Revised and added screen shots based on an update to ADAFDA.

June 30, 2017 – Revised to remove internal instructions and screenshots for updating the ADAFDA database.

March 6, 2020 – Minor formatting revisions made. No substantive revisions.

September 17, 2020 – Revised to incorporate information related to completion of a GBAAD form for OSC-initiated labeling changes.

January 25, 2022 – Revised to add approved medicated feed mill licenses and a veterinary feed directive distributor notifications list to the list of information contained in ADAFDA.

April 24, 2023 - Because OSC-initiated labeling changes are no longer published on the ADAFDA website, Section III A was updated to remove the last bullet that stated for OSC- initiated labeling supplements need a GBAAD created for posting of that information to ADAFDA. They are now published on the Animal Drug Safety-related Labeling Changes webpage, Animal Drug Safety-Related Labeling Changes | FDA, 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.