
OFFICE OF NEW ANIMAL DRUG EVALUATION REVIEWER'S CHAPTER

**MAINTAINING THE GREEN BOOK
THE LIST OF FDA APPROVED ANIMAL DRUG PRODUCTS**

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I. PURPOSE

This document establishes the procedures to maintain the “Green Book.” The Green Book is a published list of all currently approved animal drugs.

II. BACKGROUND

On November 16, 1988, Congress passed into Law the Generic Animal Drug and Patent Term Restoration Act (GADPTRA) of 1988. GADPTRA “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.”¹ The law provides for a publicly available published list of all currently approved animal drugs within 60 days of the Act’s enactment (November 16, 1988). On January 15, 1989, the Center for Veterinary Medicine (CVM) published the first bound book of approved animal drugs. The Green Book got its name from its green cover. The current Green Book, a contracted project, contains eight sections of all approved animal drugs; trade names and sponsors, active ingredients, patent information, exclusivity periods, products subject to Notice of Hearing, voluntary withdrawals, suitability petitions and monthly updates made during the course of the year.

¹ U.S. Department of Health and Human Services, U.S. Food and Drug Administration internet web site. <http://www.fda.gov/opacom/laws/88SUM.html>

III. RESPONSIBILITIES FOR MAINTAINING THE GREEN BOOK

The responsibility for maintenance of the Green Book resides in CVM, Office of New Animal Drug Evaluation (ONADE). Designated ONADE personnel are responsible for the creation of the Green Book's monthly updates and interaction with CVM, Office of Management (OM) staff who is responsible for posting the Green Book and its monthly updates on the FDA, CVM Internet Web site. The designated ONADE personnel review, in its entirety, the Green Book listings for completeness and accuracy. The contractor is responsible for maintaining the Green Book's database and interactive Web portals.

IV. CONTENTS OF THE GREEN BOOK

The Green Book contains all applicable approvals (published in the FEDERAL REGISTER or FR), patent, exclusivity, and suitability petition information. FR Notices may be included but are not required.

Applicable supplemental approvals and some labeling regulatory supplements may include but are not limited to the following minor changes:²

- Change in indication, species, trade name change,
- Marketing exclusivities, speciation of bacteria, and limitations,
- Warning and Precaution statements

V. GREEN BOOK MONTHLY UPDATES PROCEDURE

The monthly updates consist of all applicable approved new animal drugs and their supplements. Applicable approvals are any approvals that change, add, or delete information contained in the Green Book. The following describes the creation process for the monthly update and the process to transmit the information to the contractor.

See Appendix 1 for Green Book Template.

² P&P 1243.6020 provides a checklist of minor supplements that impact the Green Book

A. Original Approvals: Check the FEDERAL REGISTER daily for any FDA CVM-related information or:

1. On the last day of the month, run a Submission Tracking and Reporting System (STARS) report to get all completed submission activity at the office level for that month. Run the STARS report again prior to sending the electronic copy to the contractor no later than five days from the last day of the month to assure all applicable submissions become part of the Green Book's monthly update.

In the STARS field, select "Report Excel." In the Excel spreadsheet, delete all submissions from consulting divisions.³

Delete all incomplete submissions, meeting minutes, slaughter authorizations, consulting reviews, etc., from the review divisions and teams.⁴ The remaining submissions should have the following final action codes: SUP SIG LD, SUP MIN LD, ORG APP LD, and ACK letters listed in the "Final Action" field. Delete all ACK codes that do not have sponsor name changes and patent information listed in the "Purpose of Submission" field.

2. Compare the month's list of approvals in your spreadsheet to 1) Paper copies received through QA, and 2) CVM-wide e-mail notices of approval. Check the ONADE Records Drive (R:drive), application jackets (located in the Document Control Unit (DCU)), and /or division for confirmation, documentation, and labeling of the approvals to reconcile any discrepancies.
3. Check FR publications that pertain to CVM from the first to the last day of the current month. This check includes CVM-related final rules (new original approvals, supplements to NADAs and ANADAs), technical amendments, and notices. The electronic daily posting of FR publications is located at the following Internet address: <http://www.gpoaccess.gov/fr/browse.html>.

Go to "Back Issues," select "Year" (i.e. 2007), select the individual date, and scroll down to the header "Food and Drug Administration". Under FDA is a

³ Includes; the Division of Manufacturing Technologies, the Division of Human Food Safety, and all teams under the Office of the Director with the exception of the Generic Animal Drugs Team.

⁴ Includes; the Generic Animal Drugs Team, the Division of Therapeutic Drugs for Non-Food Animals, the Division of Production Drugs, and the Division of Therapeutic Drugs for Food Animals.

list of rules, amendments, and notices for all Centers, choose only those that are applicable to CVM.

4. Create the new monthly update using the template provided by the contractor (See Appendix 1). Delete any template section(s) that are not applicable. Remember if the approval is for a new sponsor published in the Code of Federal Regulations (CFR) Part 21 Section 510.600; create a new category in the template called “New Sponsors.” List the new sponsor with their address and Drug Labeler Code in the monthly update.
5. Populate the monthly update template (See Appendix I for an example of the template) using current dates (header and footer) and information. Note that drugs used in food producing animals have two extra categories, which are Withdrawal times and Tolerances. Be sure to check the electronic version of the CFR (e-CFR)⁵ to assure all tolerances and withdrawal times are correct and listed. Be sure to list any patents and marketing exclusivity.
6. For contractor use, list all applicable CFR citations in red italics at the end of the drug approval information and if applicable, the FR publication volume and page number.

The Green Book does not publish trade names in all capital letters. Be sure to type the trade name with only the first letter capitalized and the rest in lower case. Place the appropriate trademark symbol after the trade name (i.e. ® or ™). Do not include dosage form in the name of the product (e.g. NEO-BIOTIC oral solution may appear in CVM internal documents for the Green Book it should appear as Neo-Biotic®).

7. All Approvals with Freedom of Information (FOI) Summaries: Retrieve the electronic FOI (e-FOI) Summary from the ONADE Records Drive. Do a cursory comparison of the paper and electronic copy of the FOI Summary. Save a copy of the FOI Summary (e-FOI Summary) to your computer. See below for file naming convention information. On the cover page of the e-FOI, enter the approval date as it appears on the cover page of the paper copy of the FOI Summary. Also on the e-FOI, delete the cc block, preparer line, signature page and/or anything below the listing of attachments.

⁵ ECFR website <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&tpl=/index.tpl>

Name this e-FOI Summary as the Green Book copy with the submission numberFOI.doc, no hyphens (e.g., N141260foi.doc) then save the document under S:\\HFV-104/pending/Green Book/FOI<year>/month of update as an archive file.

If the application does not have an FOI Summary, send the contractor a scanned image of the label.⁶

8. Examine labeling. The FOI Summary sent by QA will have labeling attached to it.

Check proprietary name, indications, effect of supplement, patents, exclusivity information, etc., against information in the Memorandum Recommending Approval (MRA) and FOI Summary.

9. Save the complete copy of the new monthly update template as the first draft of the monthly update under: S:\\HFV-104/pending/Green Book/<year>/month of update (i.e., Feb2007.doc).
10. Send the monthly Green Book update draft document, all Green Book copies of the e-FOI Summaries (in Word format), and scanned labels of any approval that does not have a e-FOI Summary for review to the contractor via e-mail. The contractor's name and e-mail address are:

Jeff R. Wilcke, DVM, MS, DACVCP, Director, Drug Information Laboratory at Virginia Tech/ Drug Information Laboratory e-mail at jwilcke@vt.edu.

Provide the draft to the contractor within the first five days of the start of the following month. For example, if the monthly update is for May you will send the draft to the contractor by June 5th. Communicate via e-mail, using track changes and comments, to reach agreement on the final version.

11. Receive the monthly update back from the contractor after review and editing (may be multiple times). The contractor provides CVM the final monthly update by the 15th of each month. Save the final version, you receive as a .pdf file and as an MS Word document (e.g. 2007_02.pdf, 2007_02.doc).

⁶ If an FOI Summary is not required, such as with minor regulatory supplements, e-mail the scanned copy to the designated ONADE personnel and their backup by the QA staff as a .pdf file.

12. Send the CVM Webmaster via e-mail the Green Book finalized monthly update and e-FOI Summary copies for posting on the FDA/CVM Internet Web site.
13. The contractor will mail hardcopy (currently 10 copies) of the final monthly update for distribution within the Center. Distribute hardcopy monthly updates to personnel.⁷

B. Applicable supplemental approvals and labeling supplements as described in Section III.

The same procedure is followed for supplemental approvals and labeling supplements. Follow the template (Appendix 1). The data for supplemental approvals and labeling supplements is not as detailed as that for the original approvals. Be sure to list any patents and marketing exclusivity.

VI. GREEN BOOK YEARLY UPDATE PROCEDURE

The contractor sends a draft “new year” version of the Green Book during the month of December. Review each section for accuracy. Assure that all information from the previous year’s monthly updates have been incorporated into this draft “new year” version of the Green Book.

Communicate via e-mail, using track changes and comments, to reach agreement on the final version. We receive the New Year’s Green Book by January 15th.

The contractor will send 10 copies of the New Year’s Green Book for distribution.

You will send the CVM Webmaster the finalized New Year’s Green Book for posting on the FDA/CVM Internet Web site via e-mail.

VII. REFERENCES

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

FDA Approved Animal Drug Products 1989

⁷ ONADE management will determine the distribution of hardcopies of the Green Book.

VIII. VERSION HISTORY

January 16, 2008 - Original P&P version

March 6, 2008 – Minor corrections to formatting made.

APPENDIX 1: GREEN BOOK MONTHLY UPDATE TEMPLATE

The following corrections or additions to the January *<insert date of current full Green Book>* list were published in the Federal Register in *<insert month and year of FEDERAL REGISTER checked>*.

New Approvals

ANADA Number: XXX-XXX

Pioneer Product: *<insert NADA number of pioneer product>*
Trade Name: *<insert trade name with trade mark symbol where applicable>*
Ingredients:
Sponsor: *<as listed on FOI Summary/label>*.
Approval Date: *<date from Approval letter date stamp>*
Status: OTC, Rx, VFD
Route:
Species: *<include species and if applicable class>*
Drug Form:
Concentration:
Indications: *<as on label>*
Tolerance: *<as listed in 21 CFR 556.>*
Withdrawal:

21 CFR number 72 FR page number(s)

NADA Number: XXX-XXX

Trade Name:
Ingredients:
Sponsor:
Approval Date:
Status:
Route:
Species:
Drug Form:
Concentration:
Indications:
Tolerance:

Withdrawal:
Exclusivity:
Patent(s):

21 CFR number 72 FR page number(s)

Supplemental Approvals

This section displays the change(s) to the original approval. To read the complete approval, please refer to 21CFR Parts 500 and the related Federal Register notices.

NADA Number: XXX-XXX

Trade Name:
Ingredients:
Sponsor:
Approval Date:
Exclusivity:

This application provides for *<insert effect of supplement from MRA or FOI>*

21CFR number 72 FR page number(s)

ANADA Number: XXX-XXX

Pioneer Product
Trade Name:
Ingredients:
Sponsor:
Approval Date:
Exclusivity:

This application provides for *<insert effect of supplement from MRA or FOI>*

21CFR number 72 FR page number(s)

Label Revisions

NADA Number: XXX-XXX

Trade Name:
Ingredients:
Sponsor:
Approval Date:

For example: This application provides for the trademark TM to be changed to Registered trademark [®].

21CFR page number 72 FR page number(s) Note: FOIs and FR Notices are rarely associated with these supplements

ANADA Number: XXX-XXX

Pioneer Product
Trade Name:
Ingredients:
Sponsor:
Approval Date:

This application provides for the trademark TM to be changed to Registered trademark [®].

21CFR

Green Book Errata

Patents

NADA Number: XXX-XXX

Patent Number :
Expiration Date:

New Sponsor(s)

NADA Number: XXX-XXX

Sponsor Name:
Mailing address as published in 21 CFR 510.600

Drug Labeler Code:

Notice(s)

<insert all notices pertaining to CVM - provide a summary only, contact information if provided>

For Example:

The Food and Drug Administration (FDA) is announcing a tentative schedule of forthcoming meetings of its public advisory committees for 2007.

CENTER FOR VETERINARY MEDICINE

<Insert a brief summary of description of notice and any deadlines, due dates or comment periods>

FOR FURTHER INFORMATION CONTACT: Theresa L. Green, Advisory Committee Oversight and Management Staff (HF-4), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1220.

71 FR 78443-78445, Insert date of FR notice publishing