MEMORANDUM RECOMMENDING APPROVAL (MRA) FOR ORIGINAL AND SUPPLEMENTAL NEW ANIMAL DRUG APPLICATIONS (NADA)

I. PURPOSE

This document provides instructions on how to use the office template to format and prepare a Memorandum Recommending Approval (MRA) for a New Animal Drug Application (NADA). An MRA should always be part of the approval package for an NADA.[1,2,3]

II. PURPOSE OF AN MRA

An MRA is always part of an approval package for an NADA and briefs the individual signing the approval (i.e., the center director, office director, or Director of the Division of Manufacturing Technologies) on the basis for our recommendation to approve an NADA. The MRA incorporates by reference the data, information, and reviews that support our recommendation.

III. WHO IS RESPONSIBLE FOR CREATING THE MRA USING THE OFFICE TEMPLATE

The preparer of the MRA is the reviewer, consumer safety officer (CSO), or other individual designated by the division to prepare the approval package for an application.

[1] See P&P 1243.3800.
[2] This P&P also applies to NADAs for Animal Drug Availability Act feed combinations.
[3] This P&P does not apply to minor labeling supplements or conditional approvals. See P&P 1243.6020 and 1243.6030 for information on minor labeling supplements.

You, throughout this document refers to the preparer of the approval package. When you are preparing the final approval package, you should refer to P&P 1243.3800.

Team leaders and division directors are responsible for ensuring that the correct version of the office template was used to create the NADA MRA and confirming the accuracy of the dates and submission codes referenced in the MRA. The Quality Assurance Team is no longer responsible for confirming the accuracy of this information.

IV. INSTRUCTIONS FOR USING THE OFFICE TEMPLATE TO CREATE THE MRA

Use the office template to create the NADA MRA. Instructions for finding and using templates are located on the ONADE Reviewer's Reference Page under Review Aids/Approved Products on the ONADE Templates page.

A. General instructions for using the MRA template

1. Words not in italics or brackets, (i.e., < >), in the MRA are boilerplate and should be included in your MRA verbatim.

2. Words in bracketed italics may provide instruction, describe the information you are to provide, or may give examples of the type of information that you are to include in a particular portion of the MRA.

3. Where you see brackets, provide information relating to your specific application.

4. Include all eighteen sections (#1-18) identified in the template in each MRA. For each section, include the boilerplate language or appropriate information described in the NADA MRA template.

5. When writing the proprietary name, do not use the trademark symbols (i.e., ® or TM). To identify the proprietary name refer to the proprietary name box on the most recently submitted Form 356V. We write the portion of the proprietary name to the left of the trademark symbol in ALL CAPITAL letters in our documents. If the proprietary name contains words to the right of the trademark symbol, capitalize the first letter of each word (e.g., Program® Injectable Solution would be PROGRAM Injectable Solution). For proprietary names that are not trademarked, capitalize the first letter of each word.

B. The "To" line of the MRA

1. Original NADA approvals

   Address the MRA to the Center Director, through the Director, Office of New Animal Drug Evaluation (ONADE).

2. Supplemental NADA approvals

   You will address most MRAs for supplemental approvals to the Director, ONADE, from the appropriate division director, except for:

   a. Supplements that would approve a new claim, new species, or change in Rx/OTC status will be addressed to the Center Director, through the Director, ONADE; and

   b. Manufacturing supplemental approvals will be addressed to the Director, Division of Manufacturing Technologies.

V. DISTRIBUTION COPIES

We no longer distribute paper copies of the MRA. Fill in the appropriate application number in the cc: block of the office template to ensure that the paper copy is filed to the appropriate administrative file.

VI. REFERENCES

CVM Program Policy and Procedures Manual

1240.2325 – CVM Guidance on Media Inquiries

1243.3030 – Completing Final Action Packages for STARS Submissions

1243.3800 – Approval Process and Approval Package

1243.5761 – Freedom of Information Summary for an NADA

1243.5780 – Exclusivity Wording for Use in the Following Documents: Memorandum Recommending Approval and Letter to Applicant

1243.6020 – Review of NADA and ANADA labeling supplements

1243.6030 – Review of labeling changes in manufacturing supplements

VII. VERSION HISTORY

November 16, 2001 - ONADE Reviewers Manual revised and incorporated into CVM's Program Policy and Procedures Manual; this is the original P&P version

September 7, 2006 - Revised to include changes agreed upon by ONADE Management and to include some instructions for the template. The P&P no longer includes the standardized language for the MRA because it is included in the office template.

December 10, 2007 – Revised to remove redundant information covered in P&P 1243.3800 and updated to be consistent with current policies and P&Ps.