FREEDOM OF INFORMATION (FOI) SUMMARY FOR ORIGINAL AND SUPPLEMENTAL NEW ANIMAL DRUG APPLICATIONS (NADA)

I. PURPOSE

This document provides instructions on how to use the office template to prepare a Freedom of Information (FOI) Summary for an original or supplemental New Animal Drug Application (NADA). This document also describes the information we include in the FOI Summary for original and supplemental NADAs other than minor labeling supplements.[1,2]

II. WHY DO WE NEED AN FOI SUMMARY?

An FOI Summary provides the public a summary of the safety and effectiveness data on which we based our decision to approve the new animal drug. After we publish an approval of an original or supplemental NADA in the FEDERAL REGISTER, we are required to make "immediately available for public disclosure", among other things, a summary of "the safety and effectiveness data and information submitted with or

[1] See P&P 1243.6020 and 1243.6030 for information on minor labeling supplements.
[2] This P&P does not apply to conditional approvals.

incorporated by reference in the NADA file". We must make this disclosure "unless extraordinary circumstances are shown".[3]

III. WHAT NADA APPLICATIONS NEED AN FOI SUMMARY?

ONADE prepares an FOI Summary for each approved original application.[4] In addition, it is our current practice to prepare an FOI Summary for a supplemental NADA that:

- changes the existing CFR,
- does not change the CFR but involves significant review of data, or
- does not change the CFR but has a significant impact on how the drug is used.

If you have questions, about which applications need FOI Summaries, consult your team leader.

IV. WHO PREPARES AN FOI SUMMARY?

We will prepare the final version of the FOI Summary.[5] Generally, a reviewer in the Target Animal Safety Division will be responsible for preparing the FOI Summary, but the preparer may be any other individual designated by office, division, or team procedures. If the reviewer has questions about who prepares the FOI Summary, they should consult with their team leader or division director.

V. GENERAL PRINCIPLES FOR FOI SUMMARIES

A. The FOI Summary should:

1. Be detailed

[3] Although the regulations do not use the specific term "FOI Summary," FDA uses this term to describe the summary we prepare pursuant to 21 CFR 514.11(e). We refer to this document as an FOI Summary because it contains the information that we would disclose in response to an information request under the Freedom of Information Act.
[4] See 21 CFR 514.11(e).
[5] FDA regulations allow either CVM or the sponsor (with CVM review and revision) to prepare the FOI Summary (21 CFR 514.11(e)(2)(ii)). Sponsors often submit a draft FOI Summary with each applicable technical section (under the INAD) or with a non-administrative original or supplemental NADA. It is ONADE policy that we prepare the FOI Summary.

The FOI Summary should summarize effectiveness and safety data and other information in sufficient detail to show the basis on which the agency approved the NADA. Be clear and accurate.

For supplemental NADAs, you (the preparer) should only include data relevant to the approval of the current supplemental NADA in the FOI Summary. The FOI Summary may include references to data reviewed and summarized in previous FOI Summaries.

2. Be consistent with all reviews conducted for the approval

   If there are differences between the FOI Summary and the related reviews of the data, explain these differences in the "Q" submission. In the rare instance that they are discovered during the preparation of the approval package, document them in the Memorandum Recommending Approval (MRA).

3. Be internally consistent

   For example, always reference the new animal drug in the same manner, and make sure that information you include in the text matches that in the tables and the tabular values are arithmetically valid.

4. Define acronyms the first time they appear in the document

5. Reference previous approvals when needed

   If the FOI Summary includes references to previous approvals, each reference should include the NADA number and the date of the FOI Summary that contains the information you reference (i.e., refer to the FOI Summary for NADA XXX-XXX dated DATE).[6] If the FOI Summary you are referencing does not have a date, use another reference (i.e., approval letter, or, if you cannot find a dated approval letter, a FEDERAL REGISTER notice). Clearly identify the document to which you refer and its date (i.e., NADA XXX-XXX, approved DATE or approval of NADA XXX-XXX, as published in the FEDERAL REGISTER (volume number FR page number) on DATE).

[6] ONADE uses the date of the FOI Summary because it is most closely associated with the information being referenced. Some older FOI Summaries contain approval dates or FR notice dates. In general, the date on the front page of the FOI Summary is the same as the date on the approval letter. In most cases, the FR notice date will not match the approval letter (or FOI Summary) date.

6. Use plain language

   The purpose of the FOI Summary is to explain the basis for the approval to the public. Write it using plain language [www.plainlanguage.gov].

B. Do not include trade secrets or confidential commercial information in the FOI Summary

The Freedom of Information Act exempts trade secrets and confidential commercial information from disclosure.[7] In addition, Federal law prohibits the disclosure of trade secrets submitted to FDA.[8] If you have questions regarding what information to include in the FOI Summary, discuss them with your team leader and the Center's FOI Officer.

VI. PREPARING THE FOI SUMMARY LANGUAGE FOR EACH TECHNICAL SECTION

Each technical section complete (TSC) letter under the INAD should include the relevant FOI Summary language for that section. The division issuing the technical section complete letter will determine who (within their division) will prepare the FOI Summary language.[9] If time permits, the reviewer of the technical section may

[7] 5 USC §552(b)(4). 21 CFR 20.61.

[8] See Section 301(j) of the Federal Food, Drug, and Cosmetic Act (21 USC §331(j)), 18 USC §1905, and 21 CFR §20.61.

[9] If you send a consult to the Biometrics Team during review of the Target Animal Safety and Effectiveness technical sections, they will return final consulting reviews on or before the STARS consulting due date and offer to provide a post-final review to ensure the accuracy and relevance of statistical comments in the sections of the FOI Summary pertaining to Target Animal Safety and Effectiveness. Biometrics will provide language for transmission to the sponsor regarding the experimental design, statistical analysis, results and conclusions in their final consulting review of Target Animal Safety and/or Effectiveness technical sections. The review will include one or more paragraphs describing the statistical analysis plan(s) for use in the FOI Summary. (If the sponsor has already included acceptable paragraphs, the statistician will indicate this.) There will be no further discussion with the Biometrics Team regarding the language unless the Target Animal Division elects to make a change to the FOI Summary.
With regard to the portions of the FOI summary written by the TAD reviewer, no consultation with Biometrics Team will occur if those portions do not address statistics. If portions of the FOI summary written by the TAD reviewer incorporate or reference the statistics review, then the TAD reviewer should work with the statistician to make sure that the review accurately reflects the statistics (including context). This interaction should take place during the drafting stage, prior to the final action package going to the TAD Team Leader and Division Director. The TAD Team Leader reviews the package for scientific accuracy and completeness and compliance with the regulations and Office procedures. In rare instances where a TAD Team Leader has concerns about any incorporation or reference to statistics, they will direct the TAD

communicate with the sponsor informally before issuance of a TSC letter to inform the sponsor about the language that they have prepared to incorporate into the FOI Summary for that technical section. If the sponsor disagrees with FOI Summary language that is included in a TSC letter and wants changes (after the letter is issued and any time before approval of the new animal drug), we may have to reopen the relevant technical section. Remember that the FOI Summary is a CVM document because its purpose is to describe our basis for recommending approval of a new animal drug. Thus, the reviewer needs to make the final decision regarding which information to include in the FOI Summary.

The primary reviewer should be aware that if the Human Food Safety technical section complete (including the Human Food Safety section of the FOI Summary) is the last "P" submission, it may impact the completion of the All Other Information and Labeling ("M") submissions, as well as the FOI Summary ("Q") submission.[10]

VII. PREPARING THE FOI SUMMARY DOCUMENT

A. Administrative NADAs

For applications that sponsors plan to submit as administrative NADAs, the division responsible for review of the Target Animal Safety and Effectiveness technical sections will:

1. Create a "Q" submission

   Create a "Q" submission under the INAD when the sponsor submits the last technical section (usually an "M" submission).[11] Request that the DCU assign the "Q" submission the same due date as the last "M" submission.

2. Assemble the FOI Summary document

   When you create the "Q" submission, assemble the FOI Summary from the FOI Summary language contained in each technical section complete letter and

reviewer to consult with the Biometrics Team and make changes, as appropriate. Keeping in mind, the first interaction between the TAD reviewer and the statistician should not be at the point a final action package is forwarded to the TAD Team Leader for review. The TAD Division Director focuses on making sure the package is consistent with Office policies.

[10] The Division of Human Food Safety will send an email to the target animal safety reviewer letting them know that the HFS FOI section will soon be available on the archive.

[11] See the STARS Forms page for the Agency Initiated Submission Request Form.

prepared for any pending submissions. Issues related to factual errors and editorial changes should have been resolved with each technical section. Focus on consistency and completeness at the "Q" stage.

If the FOI Summary is for an application for use in a food-producing species, request a consulting review from the Division of Human Food Safety so that they can review the Human Food Safety language in the FOI Summary. At this point, the Division of Human Food Safety will review and make any necessary edits to their portion of the FOI Summary and inform you whether the tolerance and withdrawal time information in the regulation will need to be changed when the application is received. Discuss any changes you make to the FOI Summary language provided by any consulting reviewer with that reviewer and document the discussion and the resultant changes in the administrative file.

If time permits, you may communicate with the sponsor informally before issuance of a "Q" letter to allow them to review the FOI Summary document.

3. Preparing the "Q" submission final action package

Final out the "Q" submission following current procedures.[12] If we issue a TSC letter for the last technical section (i.e., the last "M" submission), the appropriate final action for the "Q" submission is to issue an acknowledgement letter to the sponsor enclosing a copy of the FOI Summary document. The letter should inform the sponsor that they may request changes to correct typographical errors. If we cannot issue a TSC letter for the last technical section, your review should state that we could not complete the "Q" submission because we could not issue a TSC letter for the last technical section. In this case, the appropriate final action is FNR/memo. The "Q" submission final action package should include a copy of the draft FOI Summary document and your review. Your review should summarize the extent and substance of the preparation of the FOI Summary document up to the point that you stopped review of the last technical section. Type "Draft Incomplete – See Review" and the date in the date field of the FOI Summary title page.

[12] See P&P 1243.3030.

4. Requests for changes[13]

   If the sponsor contacts us to let us know there are errors, review the request and reopen the relevant technical section(s) if needed. There is no guarantee the proposed changes will be incorporated into the FOI Summary.

   If the sponsor proposes minor editorial changes that you determine will make the FOI Summary more accurate or identifies factual errors, then we will not reopen relevant technical sections. Incorporate those minor changes into the FOI Summary that you include in the approval package.

B. Non-administrative NADAs

For non-administrative NADAs, begin to prepare the FOI Summary document when you receive an application, and continue building the FOI Summary document as you and the consulting reviewers complete your reviews of each technical section.[14] If applicable, incorporate any FOI Summary language that was previously agreed upon in technical sections completed under the INAD. Time permitting, you may

[13] We will close out the "Q" submission if the sponsor requests changes that result in reopening a technical section while the "Q" submission is still open. The appropriate final action for the "Q" submission is FNR/memo.

[14] If you send a consult to the Biometrics Team during review of the non-administrative NADA, they will return final consulting reviews on or before the STARS consulting due date and offer to provide a post-final review to ensure the accuracy and relevance of statistical comments in the sections of the FOI Summary pertaining to Target Animal Safety and Effectiveness. Biometrics will provide one or more paragraphs describing the statistical analysis plan(s) for you to incorporate into the FOI Summary. (If the sponsor has already included acceptable paragraphs, the statistician will indicate this.) There will be no further discussion with the Biometrics Team regarding the language unless the Target Animal Division elects to make a change to the FOI Summary.
With regard to the portions of the FOI summary written by the TAD reviewer, no consultation with Biometrics Team will occur if those portions do not address statistics. If portions of the FOI summary written by the TAD reviewer incorporate or reference the statistics review, then the TAD reviewer should work with the statistician to make sure that the review accurately reflects the statistics (including context). This interaction should take place during the drafting stage, prior to the final action package going to the TAD Team Leader and Division Director. The TAD Team Leader reviews the package for scientific accuracy and completeness and compliance with the regulations and Office procedures. In rare instances where a TAD Team Leader has concerns about any incorporation or reference to statistics, they will direct the TAD reviewer to consult with the Biometrics Team and make changes, as appropriate. Keeping in mind, the first interaction between the TAD reviewer and the statistician should not be at the point a final action package is forwarded to the TAD Team Leader for review. The TAD Division Director focuses on making sure the package is consistent with Office policies.

share a copy of your FOI Summary document with the sponsor and tell the sponsor that they may request changes to correct typographical errors.

Include the complete FOI Summary in Folder A of the approval package.

VIII. CONTENTS OF THE FOI SUMMARY

Use the office template for the NADA FOI Summary. 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.

This section describes the contents of each section of the FOI Summary in more detail than the template. Refer to this section as you use the FOI Summary template.

A. General instructions for using the FOI template

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

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

3. Where you see brackets or shaded areas, you will provide information relating to your specific application.

B. Title Page

1. Date of Approval

   Leave this blank in the final version. The Quality Assurance Team will date stamp the FOI Summary with the same date as the approval letter.

2. Proprietary Name

   The proprietary name is the exclusive name the sponsor or distributor assigns to a drug substance or the drug product. It is more commonly known as the trade name and is often trademarked. For example, different sponsors market amoxicillin as, "AMOXI-SOL", "AMOXI-BOL", and "ROBAMOX-V." To identify the proprietary name refer to the proprietary name box on the most

recently submitted 356V. Use the proprietary name consistently throughout the FOI Summary.[15]

When writing the proprietary name, do not use trademark symbols (® or ™). Write the portion of proprietary name to the left of the trademark symbol in ALL CAPS. If the proprietary name contains words to the right of the trademark symbol, capitalize the first letter of each word. For proprietary names that are not trademarked, capitalize the first letter of each word. For example:

- Quest® Gel would appear as QUEST Gel
- Component® TE-H with Tylan® would appear as COMPONENT TE-H with TYLAN
- Tri-Heart® Plus Chewable Tablets would appear as TRI-HEART Plus Chewable Tablets
- Sentinel® Flavor Tabs® would appear as SENTINEL FLAVOR TABS
- Penicillin G Potassium, USP, which is not trademarked, would appear as Penicillin G Potassium, USP.

3. Established Name

   The United States Adopted Names (USAN) Council usually assigns the established name.[16] Amoxicillin, florfenicol, and roxarsone are some examples of established names. To identify the established name refer to the established name box on the most recently submitted 356V. The established name should be identical to the product label. Use it consistently throughout the FOI Summary.

4. Dosage Form

   The dosage form refers to the physical description of the approved manufactured product. For example, aerosol, enteric-coated capsule, cream, emulsion, granule, implant (pellets), infusion, inhalant, paste, soluble powder, solution for

[15] For a product with an excessively long proprietary name, you may use a shortened proprietary name throughout the FOI Summary provided the full proprietary name (followed by the shortened name in parentheses) is used the first time the proprietary name appears.
[16] See 21 CFR 299.4.

injection, suspension, chewable tablet, or Type A medicated article. If the dosage form is part of the proprietary name, do not include the dosage form line on the title page.

5. Species

   Some approvals apply to a specific class within a species (e.g., lactating dairy cattle). If there is a specific class for the approval, include that information here. If there is no class limitation, enter the species in plain language (e.g. dogs rather than canine).

6. Indication(s) or Effect(s) of Supplement

   The indication(s) or effect(s) of supplement in the FOI Summary refers to the indications (for an original application) or changes (for a supplemental application) being approved in this application. For an original application, the indication(s) you include in the FOI Summary should be identical to those on the label. For supplemental applications, list the change(s) being approved (i.e., describe the new indication, new species, new route(s) of administration, new dosage(s), or label changes). The effect(s) of supplement should be descriptive enough to identify which indication(s) and/or species are affected by the supplemental approval. For example, a supplemental NADA to reduce a withdrawal time from 7 to 0 days would read, "To reduce the withdrawal time from 7 to 0 days in turkeys." For the title page, you may paraphrase the indication(s) or effect(s) of supplement if needed, to ensure that the indication(s) or effect(s) of supplement fit(s) on one page.

7. Sponsor's Name

   Copy the sponsor's name exactly as it appears in 21 CFR 510.600(c).

C. Header

The header will appear on all pages (except the cover page) of the FOI Summary. To insert the NADA number in place of <XXX-XXX> in the Header, select View → select Header and Footer. This will open the header so you can insert the NADA number.

D. Table of Contents

The template automatically generates the Table of Contents (TOC). Only the first two heading levels will appear in the TOC.

After you complete the body of the FOI Summary, update the TOC headings and page numbers. To update the TOC, move the mouse cursor over one of the lines in the TOC and click the right mouse button. Select "Update Field" and choose "Update entire table."

E. General Information

1. Sponsor, their address, Drug Labeler Code, and U.S. Agent

   If this is not the first approval for a sponsor, copy the sponsor name, address, and drug labeler code exactly as it appears in 21 CFR 510.600(c). Use the listing in the electronic CFR to obtain the most recent information.[17] If this is a sponsor's first approval, see your team leader for assistance.

   If the sponsor does not reside or have a place of business within the U.S., insert the name and address of the authorized U.S. agent.[18] Delete the field if not applicable.

2. Proprietary Name(s) and Established Name(s)

   These sections should be the same as described above for the title page.

3. Pharmacological Category

   This section describes the action of the drug product (e.g., anticoccidial, antimicrobial, or antiparasitic).

4. Dosage Form(s)

   This section should be the same as described above for the title page. However, if the dosage form is part of the proprietary name, it means dosage form was not included as a separate line on the title page. If that is the case, you will still include dosage form information in this portion of the table.

[17] The electronic CFR (e-CFR) provides the most up to date information. It is a different site than the online CFR, which is an electronic copy of the most recent printed CFR (issued in April of each year).
[18] 21 CFR §514.1(a).

5. Amount of Active Ingredient(s)

   This section describes the amount of drug(s) per tablet, mL, percentage, or other measure of concentration.

6. How Supplied

   This section describes the size and description of the containers (e.g., 50 and 100 mL vials).

7. How Dispensed

   This section identifies whether this is a prescription (Rx), over-the-counter (OTC), or veterinary feed directive (VFD).

8. Dosage

   This section describes the approved dose, frequency, and duration of treatment as printed on the approved labeling.

9. Route(s) of Administration

   This section describes the way to administer the product. For example, dermal, immersion, implantation, inhalation, intramuscular injection, insertion, instillation, intramammary, intranasal, ocular, oral, otic, or topical.

10. Species/Class(es)

    Some approvals apply to a specific class within a species (e.g., lactating dairy cattle). If there is a specific class for the approval, include that information here. If there is no class limitation, enter the species in plain language (e.g. dogs rather than canine).

11. Indication(s)

    Copy the information for this section exactly from the approved product labeling. For an original approval, list all indications. For supplemental NADAs, you may abbreviate the list to include only the indications to which the supplement applies. If you include all of the previously approved indications with the new or modified indications, then highlight (by bolding) the new or modified indications so that the new or modified indications are readily

distinguishable. In the rare instance that the supplement does not apply to a specific approved indication (e.g., a change in Acceptable Daily Intake [ADI]), include a statement that reads, "There was no change in the approved indications."

12. Effect(s) of Supplement

    If this is a supplemental approval, this section should briefly describe the changes we are approving. For original approvals, delete this row from the General Information table.

F. Effectiveness

1. Introductory paragraph

   You may insert an introductory paragraph before the dosage characterization section if it provides additional relevant information.

2. Dosage Characterization

   Sponsors do not have to demonstrate dosage characterization by substantial evidence. This section should provide a narrative summary of the individual studies, literature, or other information that explains how the dosage or dosage range was selected. For new animal drugs intended to affect the structure or function of an animal (i.e., production drugs) this section should also include a summary of the information provided to characterize the critical aspects of the dose relationship relevant to the dose or dose range selected. Examples of production drugs include melatonin use in mink, follicular stimulating hormone for super ovulation, and monensin for feed efficiency. If individual studies are included, the narrative should include, where applicable, the name(s) of clinical investigator(s), location(s) of study (city and state only), a brief description of the protocol or study design, number of animals, and study results. If you include published literature, list the references at the end of this section.

3. Substantial Evidence

   This section describes the adequate and well-controlled effectiveness study or studies that support FDA's decision to approve the new animal drug. Describe these studies in general terms using an outline format. You may choose to

follow the sample outline in Appendix 1 of this guide. Check with your team leader if you have questions about which studies to include in the FOI Summary.

At a minimum, the study information should include a full identification of the study including name(s) of clinical investigator(s), location(s) of study (city and state only), study type, a brief outline of the protocol, number of animals, and study results. Do not include any information that could lead to identification of the animal owner.

If you include information in the FOI Summary from more than one study, use the same format to summarize each study. Summarize a multi-location field study for which study results are pooled to assess statistical significance as a single study. The best way to provide study results may be in tables. If you use tables, you may number them consecutively throughout the entire document or consecutively within each section.

The level of detail you provide should allow a general understanding of how each study was performed and the results of each study. For example, if a study uses a 6-point scoring system to evaluate an endpoint, provide enough description so that readers who are not familiar with that scoring system can interpret numerical summaries in the results section. It is not necessary to describe all aspects of the study.

4. Supplemental approval information

   Some supplemental NADAs may not include dosage characterization information or new studies to demonstrate effectiveness, because they reference information from previous approvals. In these cases, use the language in the template, and include the NADA number and date of the FOI Summary that contains the information you reference.

G. Target Animal Safety

The Target Animal Safety section describes the safety studies that support FDA's decision to approve the new animal drug. Describe these studies in general terms using an outline format. Check with your team leader if you have questions about which studies to include in the FOI Summary.

The basic study information you provide should include a full identification of the study including name(s) of the study director, location(s) of study (city and state

only), study type, brief outline of the protocol, number of animals, and study results. Do not include any information that could lead to identification of the animal owner.

The best way to provide study results may be in tables. If there is more than one study, use the same format for each of the studies. If you use tables, you may number them consecutively throughout the entire document or consecutively within each section.

As with the effectiveness data, the level of detail you provide for each study should allow the reader to understand how each study was performed and to understand the results of each study. It is not necessary to describe all aspects of the study.

For supplemental NADAs that do not include new target animal safety studies, use the language in the template, and include the NADA number and date of the FOI Summary that contains the information you reference.

H. Human Food Safety

1. Non-food producing animals

   If the product is for use in non-food producing animals, then include the standard language in the template explaining that we did not require human food safety data.

2. Food-producing animals

   If the product is for use in food-producing animals, include information for all four sections (Toxicology, Residue Chemistry, Microbial Food Safety, and Analytical Methods for Residues), or provide the reason(s) a particular section(s) was (were) not pertinent to the approval. For supplemental approvals, include a reference to previous FOI Summaries, as appropriate.

   For supplemental applications that do not include human food safety studies, use the language in the template, and include the NADA number and date of the FOI Summary that contains the information you reference.

   a. Toxicology

      This section will describe the toxicology studies that support FDA's decision to approve the new animal drug. Under the first subheading, summarize

each toxicology study. Sequentially number and individually describe each study with the applicable identifying information: title of study, name of study director, location of study (city and state only), brief outline of the protocol, number of animals, GLP compliance statement, and study results.

The final three subheadings in the toxicology section (subheadings a.2 through a.4 in the template) identify the No Effect Level (NOEL) and provide the calculation of the ADI, Acceptable Single-Dose Intake (ASDI), if applicable, and safe concentrations based on the toxicology studies.

b. Residue Chemistry

This section will describe the residue chemistry studies that support FDA's decision to approve the new animal drug. Under the first subheading, summarize each residue chemistry study. Sequentially number and individually describe each study with the applicable identifying information: title of study, name of study director, location of study (city and state only), brief outline of the protocol, number of animals, GLP compliance statement, and study results.

The final three subheadings in this section (subheadings b.2 through b.4 in the template) identify the target tissue and provide the tolerance assignments and withdrawal times based on the residue chemistry studies.

c. Microbial Food Safety

The Microbial Food Safety Team will provide the text for this section.

d. Analytical Method for Residues

Describe each analytical method individually in the Analytical Method for Residues section.

I. User Safety

Copy the human warnings exactly from the approved product labeling for this section. If there are any specific user safety concerns, provide the basis for the user safety concerns including steps for minimizing the potential harm to humans handling, administering, or exposed to the new animal drug.

J. Agency Conclusions

This section contains a summary of considerations involved in the approval of the subject drug.

In this section you will:

- Provide a detailed discussion of the basis for the approved marketing status (Rx, OTC, or VFD) for the product.[19] For drugs with Rx and VFD status, list each substantial reason why adequate directions for laymen's use cannot be written. Appendix 2 contains sample language.

- Note whether we granted exclusivity or not.[20] Copy the appropriate boilerplate language from the exclusivity P&P into the FOI Summary. The boilerplate language explains why we have or have not granted exclusivity.

- If this is a supplemental application, identify whether the approval is a Category I or Category II change.[21] If this is an original NADA, delete this section of the template.

- Provide available patent information as submitted by the sponsor with the application or with their Labeling technical section, if applicable.

K. Attachments

Typically, you will only need to attach the labeling that the sponsor provides with the NADA. Attach copies of the labeling components in the order you list them in this section. List the names of the labeling components identically to any name listed on the label (for example, pouch versus packet). Make sure that the labels you attach are legible.

If applicable, also attach the Determinative and Confirmatory Method.

IX. DISTRIBUTION COPIES

Send forward only one copy of the FOI Summary with the draft approval package.

[19] See P&P 1240.2220 for further information about classification of OTC and Rx drugs.
[20] See P&P 1243.5780 to support the decision on granting exclusivity.
[21] 21 CFR 514.106(b) defines the category change types.

With the final approval package you will:

- Include all the necessary copies of the FOI Summary;
- Write in the intended recipient of each copy, in pencil, on the title page in the upper right hand corner;
- List the copies for distribution of the FOI Summary and appended labeling in the cc block as follows (Note: Do not include the cc block on FOI Summary copy for the sponsor, FOI Staff, or the Division of Dockets Management):

  cc: Document Control Unit, for the administrative file of:
  N-XXXXXX-X-XXXX-XX
  Courtesy copy for the sponsor
  HFV-12, FOI Staff
  HFV-104, Green Book
  HFA-305, Division of Dockets Management

X. FOI SIGNATURE PAGE

Fill in the fields indicated by carat marks. If the drug is for use in non-food producing animals, insert "NA" on the Division of Human Food Safety (HFV-150) signature line (Line 4). For approvals that the ONADE Office Director signs, insert "NA" on the Center Director signature line (Line 7).

Attach the original FOI signature page to the Document Control Unit copy of the FOI Summary in the approval package.

XI. REFERENCES

Statutes

Federal Food, Drug, and Cosmetic Act

21 USC §301, et seq.

Freedom of Information Act

5 USC 552

Trade Secrets Act

18 USC 1905

Code of Federal Regulations (Title 21)

Part 20 – Public Information

§20.61, Trade secrets and commercial or financial information which is privileged or confidential

Part 299 – Drugs; Official Names and Established Names

§299.4, Established names for drugs

Part 510 – Sponsors of Approved Applications

§510.600, Names, addresses, and drug labeler codes of sponsors of approved applications

Part 514 – New Animal Drug Applications

§514.1, Applications

§514.8, Supplemental new animal drug applications

§514.11, Confidentiality of data and information in a new animal drug application file

§514.106, Approval of supplemental applications

CVM Program Policy and Procedure Manual

1240.2220 - Classification of OTC and Rx Drugs

1243.3010 - Format and Style Conventions for Letters

1243.3030 - Completing Final Action Packages for STARS Submissions

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

XII. 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 update and provide a standard outline format for an NADA FOI Summary using a template, and to reorganize the General Information Section of the NADA FOI Summary.

December 19, 2006 – Revised to correct typographical errors and modify format for Center-wide email announcement of approvals.

December 10, 2007 – Revised to make compatible with ADAA FOI and MRA and to remove information now contained in P&P 1243.3800 (i.e., preparing the Center-wide notification of approval).

March 6, 2008 – Revised to include instructions for using the most recent 356V to determine the established and proprietary name of a product and to clarify that if there is an animal class associated with the approval, that information is included on the Species line of the title page and in the general information table.

May 14, 2008 – Minor adjustments made in formatting of the document.

APPENDIX 1. SAMPLE STUDY SUMMARY OUTLINE

Note: The following is a sample study summary outline. Depending on the type of study, it may be more appropriate to combine several items under a single heading, or further expand a particular heading. Try to avoid more than three levels in the outline of each study summary.

1. Type of Study: <field study, reproductive safety, bioequivalence, etc.>

a. "Title" (Study No.)

b. Investigator(s) or Study Director: *<Provide name of Clinical Investigator(s) (for clinical studies) or Study Director (for non-clinical laboratory studies), and the study location(s) - city and state>*

c. Study Design:

1) Objective: *<description of study objective, include GLP compliance statement, if appropriate: "This study was conducted in accordance with the Good Laboratory Practice Regulations (GLPs; 21 CFR 58)." If a non-clinical laboratory study was not conducted in compliance with GLPs, provide a reason for the non-compliance and explain in what way or why the study is not compliant and why it remains acceptable.>*

2) Study Animals: *<number, breed/class, gender, age, weight, or other pertinent animal information>*

3) Treatment Groups: *<description of treatment group assignments, and dosage regimens; a table may be helpful>*

4) Drug Administration: *<description of test and control articles, treatment group assignments, and dosage regimens>*

5) Measurements and Observations: *<decision variables and other (secondary) variables/observations; include brief description of study schedule; for food safety studies, include a brief description of the method used to analyze drug residues>*

6) Statistical Methods: *<description of the statistical methods, if appropriate>*

d. Results: *<tabular format and/or descriptive>*

e. Adverse Reactions: *<description of adverse reactions, or statement such as, "No adverse reactions were reported in this study." This section does not apply to some studies, such as safety studies.*

f. Conclusion(s): *<study conclusion(s)>*

APPENDIX 2. MARKETING STATUS INFORMATION

Prescription (Rx) products

This product may be dispensed only by or on the lawful order of a licensed veterinarian (Rx marketing status). Adequate directions for lay use cannot be written because <*Provide all reasons, for example, " professional expertise is required to properly administer the injection, provide adequate instructions for post treatment care, or to monitor the safe use of the product, including treatment of any adverse reactions.*">

Over-the-Counter (OTC) products

This product can be marketed over-the-counter (OTC) because the approved labeling contains adequate directions for use by laypersons and the conditions of use prescribed on the label are reasonably certain to be followed in practice.

Veterinary Feed Directive (VFD) products

A valid veterinary feed directive (VFD) is required to dispense this drug. Any animal feed bearing or containing this drug will be fed to animals only by or on a lawful veterinary feed directive issued by a licensed veterinarian in the course of their professional practice. <*State whether the VFDs for this drug are refillable. For example, "In addition, the veterinary feed directives issued for this drug are not refillable." Also, discuss why professional supervision of a licensed veterinarian is needed.*>