OFFICE OF NEW ANIMAL DRUG EVALUATION
REVIEWERS' CHAPTER

FREEDOM OF INFORMATION (FOI) SUMMARY FOR AN ABBREVIATED NEW ANIMAL DRUG APPLICATION (ANADA)

I. PURPOSE

To describe a standardized format for the Freedom of Information Summary for an approved Abbreviated New Animal Drug Application under 21 CFR 514.11(e)(2).[1]

II. PROCEDURE TO FOLLOW

CVM routinely asks a sponsor to prepare an FOI summary for an ANADA approval. CVM reviewers should write the Agency Conclusions section of the FOI Summary. The reviewer should follow the procedures in this guide to make sure that the FOI summary contains necessary information in a consistent format.

The sponsor should submit the draft FOI Summary in an electronically compatible format (MSWORD preferred). If the sponsor has not done so, the primary reviewer should request it electronically (filed as an amendment). The electronic format allows corrections and additions to be made quickly and efficiently during the final review process, especially during processing of the approval package.

[1] In 1985, CVM issued a revised FOI Summary guideline. That guideline needs to be revised, but does contain some useful information. The reviewer should follow the procedures and format outlined in this P&P guide where this guide does not match the 1985 guideline. If the reviewer has questions on any discrepancies, they should consult with their Team Leader or Division Director.

Responsible Office: ONADE Quality Assurance Team (HFV-102).
Date: 11/16/2001

For supplemental applications, the unaffected sections of the summary should refer (by date) to the FOI summary for the original or a previous supplemental approval, as appropriate; for example, "This approval does not affect this section of the summary. Refer to FOI summary dated <*date*> for ANADA/NADA <number.>"

The following illustrates the format that should be used for an FOI summary:

III. FORMAT FOR ANADA FOI SUMMARY

Each FOI summary should include a cover sheet that provides the following information: drug name, proprietary name, file number, sponsor name, general description of approval (species, dose), and date of approval. Reviewers, at their discretion, can include a table of contents.

1. GENERAL INFORMATION:

a. File Number:	*<insert file number e.g., ANADA xxx-xxx>*
b. Sponsor:	*<insert company name>* *<insert company address>* Drug Labeler Code: *<insert code number from 21 CFR 510.600>*
c. Established Name:	*<insert drug's established name>*
d. Proprietary Name:	*<insert product's proprietary name>*
e. Dosage Form:	*<insert dosage form>*
f. How Supplied:	*<insert how supplied>*
g. How Dispensed:	*<insert Rx, OTC, or VFD>*
h. Amount of Active Ingredients:	*<insert the amount of active ingredient>*

i.	Route of Administration:	*<insert route of administration>*
j.	Species/Class:	*<insert species/class>*
k.	Recommended Dosage:	*<insert recommended dosage>*
l.	Pharmacological Category:	*<insert pharmacological category>*
m.	Indications:	*<insert indication(s) verbatim from the label>*
n.	Pioneer Product:	*Trade Name (proprietary name); Established Name; NADA Number; Sponsor Name*

If the summary is for a supplemental approval, include:

o.	Effect of Supplement:	*<insert effect of the action>*

2. TARGET ANIMAL SAFETY AND DRUG EFFECTIVENESS:

This section should contain a summary of the basis for concluding that the product is safe and effective for its intended use. This section (as part of overall safety and effectiveness, depending on the basis of approval) may include:

- *a summary of the basis for the approved Suitability Petition (SP) if the ANADA is the subject of an approved SP.*
- *a summary of the bioequivalence study(ies) or summary of the basis for granting a waiver of the **in vivo** bioequivalence study(ies).*

*In a case in which a waiver of **in vivo** testing has been granted, the Target Animal Safety and Effectiveness section should contain the following:*

Under the provisions of the Federal Food, Drug and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act (GADPTRA) of 1988, an Abbreviated New Animal Drug Application (ANADA) may be submitted for a generic version of an approved new animal drug (pioneer product). New target animal safety and effectiveness data and human food safety data (other than tissue residue data) are not required for approval of an ANADA.

Ordinarily the ANADA Sponsor shows the generic product is bioequivalent to the pioneer, which has been shown to be safe and effective. If bioequivalence is demonstrated through a clinical endpoint study, then a tissue residue study to establish the withdrawal time for the generic product should also be conducted. For certain dosage forms, the agency will grant a waiver from the requirement of an *in vivo* bioequivalence study (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 2000). http://www.fda.cov/cvm/guidance/published.htm#documents

Based on the formulation characteristics of the generic product, <*insert Sponsor's name*> was granted a waiver from the requirement for an *in vivo* bioequivalence study for the generic product <*insert generic and established name of drug product*.> The generic product is administered as an <*insert dosage form granted a waiver; for example, oral solution*,> contains the same active ingredient in the same concentration and dosage form as the pioneer product, and contains no inactive ingredients that may significantly affect the absorption of the active ingredient. The pioneer product <*insert trade and established name,*> the subject of <*insert name of company*> NADA xxx-xxx, was approved on <*date.*>

3. HUMAN SAFETY:

a. *If the product is to be used in a non-food producing animal, include the following language:*

This drug is intended for use in <*insert non-food species,*> which are non-food animals. Because this new animal drug is not intended for use in food-producing animals, data on human safety pertaining to drug residues in food were not required for approval of this NADA.

Human Warnings are provided on the product label as follows: "Not for human use. Keep this and all drugs out of the reach of children." *<Insert any additional human warnings (including user safety concerns) as deemed appropriate.>*

b. *If the product is to be used in a food-producing animal, include the three sections provided below. Provide the rationale for any sections that are not considered appropriate for this approval.*

- **Tolerances for Residues:**
  The tolerances established for the pioneer product apply to the generic product. A tolerance of *<insert>* is established for *<insert>* residues in the uncooked edible tissues of *<insert>* under 21 CFR 556.xxx.

- **Withdrawal Times:**
  The FOI should include a summary of the tissue residue depletion study(ies), if any; or if a waiver of the in vivo bioequivalence study was granted, use the following statements:

  Because a waiver of the *in vivo* bioequivalence study was granted, the withdrawal times are those previously assigned to the pioneer product.

  The withdrawal times are *<insert times.>*

- **Regulatory Method for Residues:**
  The analytical method for detection of residues in tissues is the *<insert.>* This method is found on file at the Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855.

4. AGENCY CONCLUSIONS:

The agency conclusions should include the following statement:
This ANADA submitted under section 512(b) of the Federal Food, Drug, and Cosmetic Act satisfies the requirements of section 512(n) of the act and demonstrates that *<insert product name,>* when used under its proposed conditions of use, is safe and effective for its labeled indications.

This section should include additional conclusions when bioequivalence and tissue residue studies have been conducted in support of the ANADA.

If the approval is for a "hybrid" application, a combination of 512(b)(1) and (b)(2), the reviewer should modify the FOI summary to include relevant NADA FOI information as well as ANADA FOI information. For these rare types of approvals, please confer with the Generic Animal Drug Team for suggested modifications.

5. ATTACHMENTS:

Facsimile Generic Labeling and Currently Approved Pioneer Labeling are attached as indicated below:
List which types of labeling are attached.

IV. DISTRIBUTION COPIES FOR ANADA FOI SUMMARY

Copies should be distributed as follows:

cc: Courtesy copy for the sponsor (no *cc:block* listed on this copy)
HFV-199, NADA Orig. [white copy]
HFV-2, Special Mailing List
HFV-12, FOI Staff (no *cc:block* listed on this copy)
HFV-102, Reserve Copy
HFV-102, Green Book
HFV-120, Labeling Project
HFA-305, Dockets Management Branch (no *cc:block* listed on this copy)
HFR-XXxxx, District Office Copy

Name of Primary Reviewer

<Author's name, HFV-#, date>

NOTES:
Reviewers should send forward only one copy of the FOI Summary with the draft Approval Package.

A copy should be provided to the FDA DO for a sponsor's headquarters and for any FDA DOs identified in the HFV-140 Technical Section Complete letter or Manufacturing Chemistry Review Memoranda (as indicated in the *cc: block*). Guidance on FDA DOs is provided in CVM Policy and Procedures Guide 1243.3300, Copies of Correspondence to FDA District Offices: www.fda.gov/cvm/index/policy_proced/ppindex.html

The reviewer should provide all necessary copies in the final approval package. Copies are designate for distribution on the cover page (upper right hand corner).