APPROVAL LETTERS

I. PURPOSE

This document describes the procedures you use to prepare and route the approval letter for original and supplemental New Animal Drug Applications (NADAs) and Abbreviated New Animal Drug Applications (ANADAs) other than regulatory supplements.[1,2] The Division of Manufacturing Technologies (HFV-140) prepares and routes an approval letter as described in this document when they approve any category I manufacturing supplement.[3]

II. SCOPE OF THE APPROVAL LETTER

The intent of our approval letter is to inform an applicant of the approval and the conditions of approval. It is not intended to provide the details of the basis for our decision to approve. Therefore, the approval letter does not specifically discuss

[1] See P&P 1243.6020 and 1243.6030 for information on regulatory supplements.
[2] For purposes of this document, "you" refers to a reviewer, consumer safety officer (CSO), or other individual from the team or division in the Office of New Animal Drug Evaluation (ONADE) responsible for preparing the approval letter for an application.
[3] Category I manufacturing supplements are supplements that ordinarily do not require a reevaluation of any of the safety or effectiveness data in the original application.

findings relevant to particular sections (e.g., environmental, food safety, effectiveness) of an application.

III. ELEMENTS OF APPROVAL LETTERS

When preparing an approval letter, follow P&P 1243.3010 Format and Style Conventions for Letters. Further specific instructions for how to fill in certain fields of the approval letter template follow.

A. Principal submission identification field:

Refer to P&P 1243.3010.

B. Date:

After the office or center director signs the letter, the Quality Assurance Team adds the date to the paper copies of the approval letter.[4] The CVM ONADE Records mailbox manager adds the date of the approval letter to the electronic file using the date on the paper copy.

C. Inside address:

Refer to P&P 1243.3010. Use the address of the cover letter accompanying the application unless the sponsor has specifically requested that we send the letter to a different address. The address on the cover letter may not be the same as the corporate address listed in 21 CFR 510.600.

D. Reference line:

1. The reference line for an original or supplemental NADA approval letter reads:

   Re: Request for <*insert original or supplemental*> approval of <*proprietary name of the product here, e.g., DRUGEX*>

[4] For manufacturing supplements, after the division director signs the approval letter, the Document Control Unit adds the date to the paper copies.

Note: Information on the formatting for the proprietary is in P&P 1243.3010 Section III. C. and P&P 1243.5741 Section IV. A. 5.

2. The reference line for an ANADA approval letter reads:

Re: Request for <*insert original or supplemental*> generic approval of <*insert the proprietary name of the product here, e.g., DRUGEX*>

E. Salutation:

Refer to P&P 1243.3010.

F. Body of the letter:

1. Opening paragraph

a. The **first sentence** informs the applicant that their application or supplemental application is approved and includes a reference to the proprietary name, date of the application, and the date of any amendments made to the application.[5,6]

b. The **second sentence** of an approval letter for

- an **(A)NADA** includes the drug's proprietary name, established name, the dosage form if not part of the proprietary name, and the indications, species/class(es) and, if applicable, conditions of use for which the drug is approved.

- a **manufacturing supplemen**t describes the nature of the manufacturing changes that we are approving.

If the description of the approved uses and conditions of use are exceptionally long, you may refer to the labeling attached to the Freedom of Information

[5] "Application" as used throughout the rest of the document can refer to an original or supplemental NADA or an original or supplemental ANADA. If we are approving an ANADA, the approval letter specifies ANADA wherever reference is made to the application.

[6] For manufacturing supplements, the first sentence also includes the established name and the dosage form if not part of the proprietary name.

(FOI) Summary rather than restating the description in the letter. An adequate description of what we are approving is critical to ensure that the applicant knows exactly what drug and uses we are approving and that we have a clear record on which to base an enforcement action if the applicant is marketing the drug for unapproved uses.

c. If you are writing an approval letter for an original NADA (except ADAA feed combinations), the **third sentence** specifies the expiration date for the product (including the Type B and C products, if applicable) because it is one of the conditions of use.

If you are writing an approval letter for an original or supplemental ANADA, the **third sentence** specifies the proprietary name, established name, sponsor, and (A)NADA number for the reference product. For an original ANADA, the next sentence specifies the expiration date (including the Type B and C products, if applicable) for the product because it is one of the conditions of use.

In cases where the expiration dating changes as part of a supplemental (A)NADA approval, include the expiration dating sentence in the letter.

d. If we are publishing a FEDERAL REGISTER notice of the approval, the next sentence reads: "We forwarded a notice of this approval for publication in the FEDERAL REGISTER."

e. The last sentence of the opening paragraph of every approval letter informs the applicant that any request to change the conditions of the approval may require the submission of a supplemental application.[7]

2. Second paragraph

This paragraph discusses whether or not we are granting exclusivity. The template includes paragraphs that describe the length of, and basis for, exclusivity. Select the one that applies. The boilerplate language includes the citation for the relevant section of the Federal Food, Drug, and Cosmetic Act

[7] 21 CFR 514.8.

(the act). See P&P 1243.5780 to determine the appropriate exclusivity paragraph.

3. Third paragraph

Choose the paragraph that pertains to the type of labeling submitted with the application.

a. Dosage form products

If the submission includes only facsimile labeling, or if it includes a mix of facsimile labeling and final printed labeling (FPL), use the paragraph that requests submission of FPL prior to marketing and references the date of the facsimile labeling submission and STARS code. This paragraph explains that FPL must be identical to the facsimile labeling approved as part of the application.[8] This paragraph instructs the applicant to submit three copies of each component of the FPL to CVM before distributing and marketing the drug product.[9]

If acceptable FPL for all components was provided with the application, use the paragraph acknowledging acceptability of the FPL.

b. Medicated feeds

In most cases, we approve labeling for the Type A medicated article and representative labeling, commonly referred to as "Blue Bird labeling." for Type B and Type C medicated feeds manufactured from the Type A medicated article If the submission includes facsimile labeling, use the paragraph that instructs the applicant to submit FPL for the Type A medicated article prior to marketing. Because "Blue Bird labeling" for Type B and Type C medicated feeds is representative labeling (i.e., it includes general

[8] You may list only typographical changes in an approval letter. Any other label changes necessitate an amendment to the underlying application.
[9] 21 CFR 514(b)(3)(vi) requires sponsors to submit three copies of their final printed labeling.

information about the feed but varies depending on mixing), the applicant does not need to submit FPL for Type B and Type C medicated feeds.[10]

In those instances in which we are approving an original or supplemental application for a Type C medicated feed other than ADAA combination approvals, the applicant will need to submit FPL. Use the first labeling paragraph in the letter instead.

If acceptable FPL was provided with the application, or if the application is for an ADAA combination, use the paragraph acknowledging acceptability of the FPL.

4. Fourth paragraph Manufacturing

You have two options for the manufacturing paragraph.

Option 1: For supplements or ADAA combination approvals that do not involve a change in the Chemistry, Manufacturing, and Controls (CMC) information, do not put a manufacturing paragraph in the approval letter.

Option 2: For all other NADA and ANADA approval letters, use the manufacturing paragraph provided in the letter.

Type C free-choice feeds. In those instances in which we are approving an original or supplemental application for a Type C free-choice feed that does not require a feed mill license (i.e., manufactured from a Category I Type A medicated article using a formulation that will be published in the CFR), do not put a manufacturing paragraph in the approval letter. In those instances in which we are approving an original or supplemental application for a Type C free-choice feed that does require a feed mill license (i.e., manufactured from a Category II Type A medicated article or using a proprietary feed formulation), use the following alternative manufacturing paragraph:

The manufacture of full scale commercial batches using manufacturing instructions that have been determined to yield a properly mixed medicated

[10] "Blue Bird labeling" generally includes the name of the drug, the indications, the active ingredients, a guaranteed nutrient analysis that must meet the Association of American Feed Control Officials (AAFCO) standards, a list of the ingredients mixed, mixing or feeding directions, warnings, and cautions.

feed product of the specified formulation is not a requirement for approval. However, medicated feed manufacturers must be able to assure that following the manufacturing instructions will result in a properly mixed feed under GMPs for medicated feeds (21 CFR 225.102(b)(1)(iv)).[11] Therefore, the feed mill should document the successful evaluation of multiple full scale batches (usually a minimum of three (3)) of the specific free-choice formulation prior to shipment of the medicated feed product. In addition, adequate cleanout procedures for all equipment used in the manufacture and distribution of medicated feeds are essential to assure proper drug levels and avoid contamination (21 CFR 225.65).

5. Closing paragraph

   Refer to P&P 1243.3010.

G. Complementary closing and signature block:[12]

The center director signs original applications and supplements that would approve a new species, significant new indications, and changes in Rx/OTC status. The ONADE director signs other supplemental applications, except manufacturing supplements.

H. Enclosure notation:

When sending the approval letter, provide the applicant with a copy of the FOI Summary identical to the FOI Summary you are forwarding to the Division of Dockets Management (HFA-305). Include "Freedom of Information Summary" in the enclosure block. Attach a copy of the approved facsimile labeling or Blue Bird labeling to the FOI Summary.

I. Internal administrative tools:

1. cc: block notation

[11] For medicated pet foods, contact the Division of Manufacturing Technologies for the appropriate GMP citation.

[12] You can find the delegations of authority for approval of new animal drug applications, medicated feed mill license applications and their supplements in the Staff Manual Guide, Delegations of Authority (Volume II), Section 1410.502.

For original applications, include in the cc: block a notation of a distribution copy to the FDA District Office (DO) for any FDA DOs identified in the GMP status check email. A DO copy is not needed for products manufactured outside the U.S. or if no new drug will be manufactured, e.g., ADAA feed combinations and concurrent use approvals of previously approved drugs.

2. Concurrence table

   Include a concurrence table to document that the appropriate people have reviewed and concurred with the draft, if applicable, and final letter.

   When preparing the final approval letter, type the name of the individuals who signed the draft and date they signed the draft into the "draft signature & date" column of the concurrence table. When printing the final copies, include the table on only the pink copy. The final approval signatures and dates on the final approval letter will be written in ink in the table on the pink copy as the document circulates.

3. Other administrative information

   This area is used to record additional information such as a preparer line, notation of electronic copies, to document draft tracking, and to record supervisory review, when applicable.[13] The default for this field is "not applicable." Do not delete the box or heading.

IV. AVAILABILITY OF A TEMPLATE

Use the office template for the approval letter when it becomes available. 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.

The appendices provide sample approval letters.

[13] For information regarding supervisory review of CVM work products and dispute resolution, consult P&P 1240.2110 "Procedures for Resolving Scientific/Data Disagreements within CVM."

V. FINAL ROUTING FOR APPROVAL LETTERS

A. Approval Letter for an Original or Supplemental (A)NADA

The approval letter for original or supplemental (A)NADAs will be routed as part of the (A)NADA approval package. Routing for (A)NADA approval packages is described in P&P 1243.3800.

B. Approval Letter for a Manufacturing Supplemental (A)NADA

The director of the Division of Manufacturing Technologies, HFV-140, has signature authority for approval of manufacturing supplements described in 21 CFR 514.8. The approval letter for manufacturing supplemental (A)NADAs will be routed as part of the final action package.

VI. REFERENCES

CVM Program Policy and Procedures Manual

1243.3010 - Format and style conventions for letters

1243.3800 - Preparing and processing an approval package

1243.5741 – Memorandum recommending approval (MRA) for original and supplemental new animal drug applications (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 – original version

August 15, 2003 – revised

December 10, 2007 - revised to incorporate format and style conventions, changes and boilerplate language agreed upon by ONADE Management, incorporating active voice where possible, sample letters, and revised overall format.

March 12, 2008 – revised to clarify what address to use for the inside address and to make grammatical changes.

July 1, 2008 – revised to correct grammar in exclusivity paragraph of sample letter.

November 17, 2008 – Division of Manufacturing Technologies revised the document to add clarifying information regarding the manufacturing paragraph (paragraph 4) of the approval letter and free-choice feeds.

December 4, 2008 – Revised to properly format footnotes 8 and 9.

February 4, 2009 – Revised to correct citation in manufacturing paragraph in sample letters in Appendices 1 and 2. Paragraph now correctly cites Section 501(a). Added a citation to P&Ps 1243.3010 and 1243.5741 for information on how to format the proprietary name.

APPENDIX 1. ORIGINAL AND SUPPLEMENTAL NADA SAMPLE LETTER

N-XXXXXX-A-0000-OT

Drug Company International
Attention: John Doe, DVM, PhD
Manager, Regulatory Affairs
1100 Industrial Drive, Suite 500
Anytown, NJ 55555

Re: Request for <*original or supplemental*> approval of <*proprietary name of the product here. e.g., DRUGEX*>

Dear Dr. Doe:

For original approvals, use this as the first paragraph:
We approve your original new animal drug application (NADA) for <*proprietary name*> dated <*date of cover letter accompanying application*><*if appropriate, insert,* amended <*date(s) of amendment(s)*>> under section 512(c)(1) of the Federal Food, Drug, and Cosmetic Act (the act). <*Use the following as your next sentence, repeating as needed for clarity:* <*proprietary name*> (<*established name*>) <*dosage form if not part of the proprietary name*> is approved for <*indications*> in <*species and class if appropriate*> <*limitations or other conditions of use if appropriate*[14]>. The expiration dating for this new animal drug is <*insert # months/years*>. We forwarded a notice of this approval for publication in the FEDERAL REGISTER. You must notify us of any change to the conditions established in this approval according to 21 CFR 514.8. Any change to the conditions of the approval may require the submission of a supplemental application.

For supplemental approvals, use this as the first paragraph:
We approve your supplemental new animal drug application (NADA) for <*proprietary name*> dated <*date of cover letter accompanying application*><*if appropriate, insert,* amended <*date(s) of amendment(s)*>> under section 512(c)(1) of the Federal Food, Drug,

[14] *If the intended uses and conditions of use are extensive in length or complexity, a reviewer may refer to the approved facsimile labeling so long as a copy of it is enclosed with the approval letter (i.e., attached to the FOI Summary).*

and Cosmetic Act (the act). This supplemental approval of <*insert proprietary name*> (<established name>) <dosage form if not part of the proprietary name> provides for <*indications, species, limitations or other conditions of use, or other changes provided by the supplemental approval*>. <*Insert the following sentence, if applicable:* We forwarded a notice of this approval for publication in the FEDERAL REGISTER>. You must notify us of any change to the conditions established in this approval according to 21 CFR 514.8. Any change to the conditions of the approval may require the submission of a supplemental application.

[*See P&P 1243.5780 to determine the appropriate exclusivity paragraph. For* ***example****,* <*proprietary name*>, as approved in this letter, qualifies for THREE years of marketing exclusivity beginning as of the date of this letter. Your new animal drug qualifies for exclusivity under section 512(c)(2)(F)(iii) of the act because your supplemental application contains effectiveness, animal safety, or human food safety studies that you conducted or sponsored that were required for the approval.]

Choose one of the following three paragraphs depending on the type of labeling submitted.

Your final printed labeling must be identical to the approved labeling submitted < *include all submission information for the approved labeling-the date(s) the labeling was submitted and the STARS code(s) for the submission(s) here, e.g.,* November 31, 2004 (N-XXXXXX-A-0000-OT ,<*if acceptable labeling was compiled from multiple submissions, insert name(s) of labeling component(s) e.g., package insert)*> < *If applicable, include a description of typographical changes needed for the final printed labeling.*> Please submit in triplicate three paper copies (a total of nine copies) of each component of the final printed labeling before distributing and marketing your new animal drug. Any changes to this approved labeling will require a supplemental application (see 21 CFR 514.8(c)).

OR, if facsimile labeling or a mix of facsimile and FPL was submitted for a feed product, use this:

Your final printed labeling of the Type A medicated article must be identical to the approved labeling submitted <*include all submission information for the approved labeling-the date(s) the labeling was submitted and the STARS code(s) for the submission(s) here, e.g.,* November 31, 2004 (N-XXXXXX-A-0000-OT*)*>. < *If applicable, include a description of typographical changes needed for the final printed labeling.*> It is not necessary to resubmit your representative Type B and Type C medicated feed labels (Blue

Bird) submitted *<the date(s) the labeling was submitted and the STARS code(s) for the submission(s) here, e.g.,* November 31, 2004 (N-XXXXXX-A-0000-OT*)*>. Please submit in triplicate three paper copies (a total of nine copies) of each component of the final printed labeling before distributing and marketing your new animal drug. Any changes to this approved labeling will require a supplemental application (see 21 CFR 514.8(c)).

OR, if all labeling submitted was FPL, use this:

Your final printed labeling submitted <*reference the date and submission code for the FPL submitted to the NADA* > is acceptable. Any changes to this approved labeling will require a supplemental application (see 21 CFR 514.8(c)).

<If the approval is for an original NADA, use the following manufacturing paragraph.[15]*>*

Under current good manufacturing practice (cGMP) regulations (21 CFR 211 and 226), you are required to validate your manufacturing processes. This validation provides assurance that the manufacturing processes will reliably meet predetermined specifications. This validation is demonstrated by documenting that the manufacturing processes are adequate to preserve the identity, strength, quality, and purity of the new animal drug. If your validation information was not available or was found deficient at the time of the pre-approval inspection, you should contact FDA after you complete manufacturing validation and before you ship the product. A product that does not conform to cGMP is adulterated under section 501(a) of the act.

If you submit correspondence relating to this approval, your correspondence should reference the date and the principal submission identifier(s) found at the top of this letter. If you have any questions, please contact <*name, position, team or division or office name, and contact number*>.

Sincerely,

[15] *In those rare instances in which we are approving an original or supplemental application for a Type C free choice feed, refer to section III.F.4.*

<signature block for appropriate signature authority>

Enclosure<*s*>:
Freedom of Information Summary *(Delete this if there is no Freedom of Information Summary for this approval.)*

cc: Document Control Unit, for the administrative file of:
N-XXXXXX-A-0000-OT, M-0001 *(This information is a sample; change as needed.)*
HFR-XXX, District Office Copy *(This information is a sample; change as needed.)*

Insert or delete rows and columns and modify management titles in the concurrence table as necessary.

Concurrence	Draft Signature & Date	Final Signature & Date
< *individual name*>, Primary Reviewer, < *name of team*>		
< *individual name*>, Leader, <*insert name of team*>		
< *individual name*>, Director, <*insert name of Division*>		
< *title of signatory and name of specialty team or division* (if appropriate)> (e.g., Director, Division of Human Food Safety; Leader, Biometrics Team)		
< *individual name*>, Leader, Quality Assurance Team		
< *individual name*>, Director, Office of New Animal Drug Evaluation (signs final concurrence if approval letter is signed by Center Director)	N/A	

Other administrative information:
not applicable
<Not applicable is the standard information here. This area is for the preparer line and notation of electronic copies. If you document these things, delete "not applicable" in the field and add the information.

APPENDIX 2. ORIGINAL AND SUPPLEMENTAL ANADA SAMPLE LETTER

A-XXXXXX-A-0000-OT

Drug Company International
Attention: John Doe, DVM, PhD
Manager, Regulatory Affairs
1100 Industrial Drive, Suite 500
Anytown, NJ 55555

Re: Request for <*original generic or supplemental generic*> approval of <*proprietary name of the product here. e.g., DRUGEX*>

Dear Dr. Doe:

For original generic approvals, use this as the first paragraph:
We approve your original abbreviated new animal drug application (ANADA) for <*proprietary name*> dated <*date of cover letter accompanying application*><*if appropriate, insert,* amended <*date(s) of amendment(s)*>> under section 512(c)(2)(A) the Federal Food, Drug, and Cosmetic Act (the act). <*Use the following as your next sentence, repeating as needed for clarity: <proprietary name>* (<*established name if not part of proprietary name*>) <*dosage form if not part of the proprietary name*> is approved for <*indications*> in <*species and class if appropriate*> <*limitations or other conditions of use if appropriate*[16]>.> The reference drug for <*generic proprietary name*> is <*reference product proprietary name*> (<*established name*>) <*dosage form if not part of the proprietary name*>, sponsored by <*reference product sponsor*> under <*reference product (A)NADA number*>. The expiration dating for this new animal drug is <*insert # months/years*>. We forwarded a notice of this approval for publication in the FEDERAL REGISTER. You must notify us of any change to the conditions established in this approval according to 21 CFR 514.8. Any change to the conditions of the approval may require the submission of a supplemental application.

[16] *If the intended uses and conditions of use are extensive in length or complexity, a reviewer may refer to the approved facsimile labeling so long as a copy of it is enclosed with the approval letter (i.e., attached to the FOI Summary).*

For supplemental generic approvals, use this as the first paragraph:
We approve your supplemental abbreviated new animal drug application (ANADA) for <*proprietary name*> dated <*date of cover letter accompanying application*><*if appropriate, insert,* amended <*date(s) of amendment(s)*>> under section 512(c)(2)(A) the Federal Food, Drug, and Cosmetic Act (the act). This supplemental approval of <*proprietary name*> (<*established name if not part of the proprietary name*>) <*dosage form if not part of the proprietary name*> provides for <*indications, species, limitations or other conditions of use, or other changes provided by the supplemental approval*>. The reference drug for <*generic proprietary name*> is <*reference product proprietary name*> (<*established name*>) <*dosage form if not part of the proprietary name*>, sponsored by <*reference product sponsor*>, under <*reference product (A)NADA number*.> <*Insert the following sentence, if applicable:* We forwarded a notice of this approval for publication in the FEDERAL REGISTER>. You must notify us of any change to the conditions established in this approval according to 21 CFR 514.8. Any change to the conditions of the approval may require the submission of a supplemental application.

Choose one of the following three paragraphs depending on the type of labeling submitted.

Your final printed labeling must be identical to the approved labeling submitted < *include all submission information for the approved labeling-the date(s) the labeling was submitted and the STARS code(s) for the submission(s) here, e.g.,* November 31, 2004 (A-XXXXXX-A-0000-OT ,<*if acceptable labeling was compiled from multiple submissions, insert name(s) of labeling component(s) e.g., package insert)*> < *If applicable, include a description of typographical changes needed for the final printed labeling.*> Please submit in triplicate three paper copies (a total of nine copies) of each component of the final printed labeling before distributing and marketing your new animal drug. Any changes to this approved labeling will require a supplemental application (see 21 CFR 514.8(c)).

OR, if facsimile labeling or a mix of facsimile and FPL was submitted for a feed product, use this:

Your final printed labeling of the Type A medicated article must be identical to the approved labeling submitted <*include all submission information for the approved labeling-the date(s) the labeling was submitted and the STARS code(s) for the submission(s) here, e.g.,* November 31, 2004 (A-XXXXXX-A-0000-OT*)*>. < *If applicable, include a description of typographical changes needed for the final printed labeling.*> It is not

necessary to resubmit your representative Type B and Type C medicated feed labels (Blue Bird) submitted *<the date(s) the labeling was submitted and the STARS code(s) for the submission(s) here, e.g.,* November 31, 2004 (A-XXXXXX-A-0000-OT*)*>. Please submit in triplicate three paper copies (a total of nine copies) of each component of the final printed labeling before distributing and marketing your new animal drug. Any changes to this approved labeling will require a supplemental application (see 21 CFR 514.8(c)).

OR, if all labeling submitted was FPL, use this:

Your final printed labeling submitted <*reference the date and submission code for the FPL submitted to the ANADA* > is acceptable. Any changes to this approved labeling will require a supplemental application (see 21 CFR 514.8(c)).

<If the approval is for an original ANADA, use the following manufacturing paragraph.[17]*>*

Under current good manufacturing practice (cGMP) regulations (21 CFR 211 and 226), you are required to validate your manufacturing processes. This validation provides assurance that the manufacturing processes will reliably meet predetermined specifications. This validation is demonstrated by documenting that the manufacturing processes are adequate to preserve the identity, strength, quality, and purity of the new animal drug. If your validation information was not available or was found deficient at the time of the pre-approval inspection, you should contact FDA after you complete manufacturing validation and before you ship the product. A product that does not conform to cGMP is adulterated under section 501(a) of the act.

If you submit correspondence relating to this approval, your correspondence should reference the date and the principal submission identifier(s) found at the top of this letter. If you have any questions, please contact <*name, position, team or division or office name, and contact number*>.

Sincerely,

[17] *In those rare instances in which we are approving an original or supplemental application for a Type C free choice feed, refer to section III.F.4.*

<signature block for appropriate signature authority>

Enclosure<*s*>:
Freedom of Information Summary *(Delete this if there is no Freedom of Information Summary for this approval.)*

cc: Document Control Unit, for the administrative file of:
A-XXXXXX-A-0000-OT, M-0001 *(This information is a sample; change as needed.)*
HFR-XXX, District Office Copy *(This information is a sample; change as needed.)*

Insert or delete rows and columns and modify management titles in the concurrence table as necessary.

Concurrence	Draft Signature & Date	Final Signature & Date
< *individual name*>, Primary Reviewer, < *name of team*>		
< *individual name*>, Leader, <*insert name of team*>		
< *individual name*>, Director, <*insert name of Division*>		
< *title of signatory and name of specialty team or division* (if appropriate)> (e.g., Director, Division of Human Food Safety; Leader, Biometrics Team)		
< *individual name*>, Leader, Quality Assurance Team		
< *individual name*>, Director, Office of New Animal Drug Evaluation (signs final concurrence if approval letter is signed by Center Director)	N/A	

Other administrative information:
not applicable
<Not applicable is the standard information here. This area is for the preparer line and notation of electronic copies. If you document these things, delete "not applicable" in the field and add the information.

APPENDIX 3. ADAA SAMPLE LETTER

N-XXXXXX-A-0000-OT

Drug Company International
Attention: John Doe, DVM, PhD
Manager, Regulatory Affairs
1100 Industrial Drive, Suite 500
Anytown, NJ 55555

Re: Request for <*original, supplemental*> approval of <*proprietary names of the product here. e.g., DRUGEXA and DRUGEXB*>

Dear Dr. Doe:

For original animal drug availability act (ADAA) approvals, use this as the first paragraph:
We approve your original new animal drug application (NADA) for <*proprietary names*> dated <*date of cover letter accompanying application*><*if appropriate, insert*, amended <*date(s) of amendment(s)*>>. Your application for this new animal drug combination was approved according to section 512(d)(4) of the Federal Food, Drug, and Cosmetic Act.> <*Use the following as your next sentence, repeating as needed for clarity:* <*proprietary names*> (<*established names*>) <*dosage forms if not part of the proprietary name*> is approved for <*indications*> in <*species and class if appropriate*> <*limitations or other conditions of use if appropriate*[18]>. We forwarded a notice of this approval for publication in the FEDERAL REGISTER. You must notify us of any change to the conditions established in this approval according to 21 CFR 514.8. Any change to the conditions of the approval may require the submission of a supplemental application.

OR
For supplemental ADAA approvals, use this as the first paragraph:

[18] *If the intended uses and conditions of use are extensive in length or complexity, a reviewer may refer to the approved facsimile labeling so long as a copy of it is enclosed with the approval letter (i.e., attached to the FOI Summary).*

We approve your supplemental new animal drug application (NADA) for <*proprietary names*> dated <*date of cover letter accompanying application*><*if appropriate, insert,* amended <*date(s) of amendment(s)*>>. Your application for this new animal drug combination was approved according to section 512(d)(4) of the Federal Food, Drug, and Cosmetic Act.> This supplemental approval of <*insert proprietary names*> (<established names>) <*dosage forms if not part of the proprietary name*> provides for <*indications, species, limitiations or other conditions of use, or other changes provided by the supplemental approval*>. <*Insert the following sentence, if applicable:* We forwarded a notice of this approval for publication in the FEDERAL REGISTER>. You must notify us of any change to the conditions established in this approval according to 21 CFR 514.8. Any change to the conditions of the approval may require the submission of a supplemental application.

Your final printed labeling submitted <*reference the date and submission code for the FPL submitted to the NADA* > is acceptable. Any changes to this approved labeling will require a supplemental application (see 21 CFR 514.8(c)).

If you submit correspondence relating to this approval, your correspondence should reference the date and the principal submission identifier(s) found at the top of this letter. If you have any questions, please contact <*name, position, team or division or office name, and contact number*>.

Sincerely,

<*signature block for appropriate signature authority*>

Enclosure<*s*>:
Freedom of Information Summary *(Delete this if there is no Freedom of Information Summary for this approval.)*

cc: Document Control Unit, for the administrative file of:

N-XXXXXX-A-0000-OT, M-0001 *(This information is a sample; change as needed.)*

Insert or delete rows and columns and modify management titles in the concurrence table as necessary.

Concurrence	Draft Signature & Date	Final Signature & Date
< *individual name*>, Primary Reviewer, < *name of team*>		
< *individual name*>, Leader, <*insert name of team*>		
< *individual name*>, Director, <*insert name of Division*>		
< *title of signatory and name of specialty team or division* (if appropriate)> (e.g., Director, Division of Human Food Safety; Leader, Biometrics Team)		
< *individual name*>, Leader, Quality Assurance Team		
< *individual name*>, Director, Office of New Animal Drug Evaluation (signs final concurrence if approval letter is signed by Center Director)	N/A	

Other administrative information: not applicable *<Not applicable is the standard information here. This area is for the preparer line and notation of electronic copies. If you document these things, delete "not applicable" in the field and add the information.*

APPENDIX 4. MANUFACTURING SAMPLE LETTER

N-XXXXXX-C-000X-XX

Drug Company International
Attention: John Doe, DVM, PhD
Manager, Regulatory Affairs
1100 Industrial Drive, Suite 500
Anytown, NJ 55555

Re: Request for supplemental approval of <*proprietary name of the product here. e.g., DRUGEX*>

Dear Dr. Doe:

We approve the <*type of manufacturing supplement submitted*> to your <*insert abbreviated if generic*> new animal drug application for <*insert proprietary name*> (<*insert established name*>) <*insert dosage form if not included as part of the proprietary name*> dated <*insert date of cover letter of the current application, or the date of the previously incomplete supplement*><*if appropriate, insert* reactivated <*date(s) of cover letter(s) of the reactivated application*>< *if applicable insert* and> amended <*date(s) of amendment(s)*>>under section <*for original NADAs cite 512(c)(1), for supplemental NADAs cite 512(c)(2)(A)*> of the Federal Food, Drug, and Cosmetic Act. <*Insert a sentence describing the nature of the chemistry/manufacturing changes that are being approved*>. Any request to change the conditions of this approval may require the submission of a supplemental application.

Choose one of the following three paragraphs depending on the type of labeling submitted. If no labeling is submitted, delete these paragraphs.

Your final printed labeling must be identical to the approved labeling submitted <*include all submission information for the approved labeling- the date(s) the labeling was submitted and the STARS code(s) for the submission(s) here, e.g.,* November 31, 2004 (N-XXXXXX-C-000X-XX) ,<*if acceptable labeling was compiled from multiple submissions, insert name(s) of labeling component(s) e.g., package insert*>. < *If applicable, include a*

description of typographical changes needed for the final printed labeling.> Please submit in triplicate three paper copies (a total of nine copies) of each component of the final printed labeling before distributing and marketing your new animal drug. *(Note if this is a CBE30 manufacturing supplement, you will delete the previous wording "before distributing and marketing your new animal drug.")* Any changes to this approved labeling will require a supplemental application (see 21 CFR 514.8(c)).

OR, if facsimile labeling or a mix of facsimile and FPL was submitted for a feed product, use this:

Your final printed labeling of the Type A medicated article must be identical to the approved labeling submitted <*include all submission information for the approved labeling-the date(s) the labeling was submitted and the STARS code(s) for the submission(s) here, e.g.,* November 31, 2004 (N-XXXXXX-C-000X-XX)>. < *If applicable, include a description of typographical changes needed for the final printed labeling.*> It is not necessary to resubmit your representative Type B and Type C medicated feed labels (Blue Bird) submitted <*the date(s) the labeling was submitted and the STARS code(s) for the submission(s) here, e.g.,* November 31, 2004 (N-XXXXXX-C-000X-XX)>. Please submit in triplicate three paper copies (a total of nine copies) of each component of the final printed labeling before distributing and marketing your new animal drug. *(Note if this is a CBE30 manufacturing supplement, you will delete the previous wording "before distributing and marketing your new animal drug.")* Any changes to this approved labeling will require a supplemental application (see 21 CFR 514.8(c)).

OR, if all labeling submitted was FPL, approval, use this:

Your final printed labeling submitted <*reference the date and submission code for the FPL submitted to the (A)NADA* > is acceptable. Any changes to this approved labeling will require a supplemental application (see 21 CFR 514.8(c)).*]*

If you submit correspondence relating to this approval, your correspondence should reference the date and the principal submission identifier(s) found at the top of this letter. If you have any questions, please contact <*name, position, team or division or office name, and contact number*>.

Sincerely,

<signature block for appropriate signature authority>

cc: Document Control Unit, for the administrative file of:
N-XXXXXX-C-000X-XX, S-000X *(This information is a sample; change as needed.)*
HFR-XXX, District Office Copy *(This information is a sample; change or delete as needed.)*

Insert or delete rows and columns and modify management titles in the concurrence table as necessary.

Concurrence	Final Signature& Date
<individual name>, Primary Reviewer, *<name of team>*	
<individual name>, Leader, *<insert name of team>*	

Other administrative information: not applicable *<Not applicable is the standard information here. This area is for the preparer line and notation of electronic copies. If you document these things, delete "not applicable" in the field and add the information.*