OFFICE OF NEW ANIMAL DRUG EVALUATION REVIEWER'S CHAPTER

EXCLUSIVITY AND EXCLUSIVE MARKETING RIGHTS BOILERPLATE FOR USE IN THE FOLLOWING DOCUMENTS: MEMORANDUM RECOMMENDING APPROVAL, LETTER TO APPLICANT, AND FREEDOM OF INFORMATION SUMMARY

I. PURPOSE

This document provides the boilerplate language we (ONADE) use when describing the exclusivity that applies to a new animal drug application (NADA) or abbreviated new animal drug application (ANADA) under section 512(c)(2)(F) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and for conditional approvals under section 571.[1] We use this boilerplate language in our NADA and ANADA approval packages (i.e., the Memorandum Recommending Approval (MRA), approval letter, and Freedom of Information(FOI) summary).

II. ADDITIONAL INFORMATION

When using the boilerplate language in this document in review and approval documentation, always modify the boilerplate language to follow grammar rules when citing the Federal Food, Drug, and Cosmetic Act. This means spelling out the Federal Food, Drug, and Cosmetic Act the first time it is cited within the document and abbreviating it to FD&C Act anywhere else it is referenced.

Sections IV - XII below provide criteria to help you determine when exclusivity applies, and which boilerplate language is appropriate to use. You should carefully read both the descriptive title and the criteria in each section to determine which, if any, exclusivity boilerplate language to use when preparing your approval package.

[1] 21 U.S.C. § 360b(c)(2)(F) and 21 USC 360ccc, respectively.

III. DEFINITIONS

1. Exclusivity (or Marketing Exclusivity): The period of time during which we will not approve a generic copy of the approved new animal drug.

2. Exclusive Marketing Rights:[2] The seven-year period during which we may not approve or conditionally approve another application submitted for a new animal drug with the same intended use as another applicant's designated new animal drug for which we have granted approval or conditional approval.

3. Active Moiety means the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt (including a salt with hydrogen or coordination bonds), or other noncovalent derivative (such as a complex, chelate, or clathrate) of the molecule, responsible for the physiological or pharmacological action of the drug substance.

4. Substantial Evidence[3]: means evidence consisting of one or more adequate and well-controlled investigations, such as

    a. a study in a target species;

    b. a study in laboratory animals;

    c. any field investigation that may be required under section 512 and that meets the requirements of subsection (b)(3) if a presubmission conference is requested by the applicant;

    d. a bioequivalence study; or

    e. an *in vitro* study

    conducted by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and reasonably be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof.

Sections 512(c)(2)(F)(ii), (iii), and (v) of the FD&C Act provide that an original or supplemental application may qualify for three-year exclusivity if it: "contains substantial evidence of the effectiveness of the drug involved, any studies of animal safety, or, in the case of food producing animals, human food safety studies (other than bioequivalence studies or residue depletion studies, except residue depletion studies for minor uses or minor species) required for the approval of the application [or the supplement] and conducted or sponsored by the applicant [or person submitting the supplement] . . . ."

Although bioequivalence studies may be considered to establish "substantial evidence of effectiveness of the drug" and may be conducted by a sponsor to support other approval requirements, as stated above, bioequivalence studies are explicitly excluded from the exclusivity provisions in the FD&C Act. Therefore, FDA may not grant exclusivity based on such studies.

[2] Section 573(c)(1), 21 USC § 360ccc-2(c)(1)
[3] Section 512(d)(3) of the FD&C Act, 21 USC § 360b(d)(3)

IV. ORIGINAL NADA CONTAINS AN ACTIVE MOIETY NOT PREVIOUSLY APPROVED[4]

A. Criteria[5]

If the NADA meets all of the following criteria, it qualifies for FIVE years of exclusivity:

- We **have not** approved (under section 512(b)(1) of the FD&C Act) the active moiety[6] in another application.
- The NADA is an original (not a supplemental) application.
- The NADA contains the following studies (other than bioequivalence or residue depletion studies) the applicant conducted or sponsored and that we required to approve the application: 1) one or more investigations to demonstrate substantial evidence of effectiveness of the drug involved; 2) any studies of animal safety; or 3) human food safety study(ies).

B. If the NADA meets the criteria in section IV. A., use this boilerplate language for the FOI summary, MRA, and approval letter:

<*Insert proprietary name*>, as approved <*insert either "in this letter" or for the MRA and FOI summary "in our approval letter"*>, qualifies for FIVE years of marketing exclusivity beginning as of the date of <*insert either this letter or our approval letter*>. This drug qualifies for exclusivity under section 512(c)(2)(F)(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) because this is the first time we are approving this active moiety in a new animal drug application submitted under section 512(b)(1) of the FD&C Act.

C. If the NADA was submitted to seek approval under section 512(b)(1) for a new animal drug that is already conditionally approved under section 571, use this boilerplate language in the FOI summary, MRA, and approval letter:

<*Insert proprietary name*>, as approved <*insert either "in this letter" or for the MRA and FOI summary "in our approval letter"*>, qualifies for FIVE years of marketing exclusivity beginning as of the date of <*insert either "this letter" or for the MRA and FOI summary "our approval letter"*>. This drug qualifies for exclusivity under section 512(c)(2)(F)(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) because this is the first time we are approving this active moiety in a new animal drug application submitted under section 512(b)(1) of the FD&C Act. Any applicable exclusive marketing rights and exclusivity for this drug run concurrently.

[4] The template language below is written to address drugs with a single active moiety. If the drug product has multiple active moieties, reach out to the ONADE Policy Team.

[5] Section 512(c)(2)(F)(i) of the FD&C Act, 21 USC § 360b(c)(2)(F)(i)

[6] The Ensuring Innovation Act (signed into law on April 23, 2021) amended sections of the FD&C Act (incl. sec. 512(c)(2)(F)(i) and the parallel human drug provisions) by striking the phrase "active ingredient (including any ester or salt of the active ingredient)" and replacing it throughout with "active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)).

D. If the sponsor has a designated new animal drug and submitted the NADA for it, use this boilerplate language in the FOI summary, MRA, and approval letter:

<*Insert proprietary name*>, as approved <*insert either in this letter or for the MRA and FOI summary "in our approval letter"*>, qualifies for SEVEN years of exclusive marketing rights beginning as of the date of <*insert either "this letter" or for the MRA and FOI summary "our approval letter"*>. This drug qualifies for exclusive marketing rights under section 573(c) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) because it is a designated new animal drug under section 573(a) of the FD&C Act. Except as provided in section 573(c)(2) of the FD&C Act, we may not approve or conditionally approve another application submitted for such new animal drug with the same intended use as <*insert proprietary name*>. Because this is the first time we are approving this active moietyin a new animal drug application submitted under section 512(b)(1) of the FD&C Act, this drug also qualifies for five years of exclusivity under section 512(c)(2)(F)(i) of the FD&C Act. The exclusive marketing rights and exclusivity for this drug run concurrently.

V. ORIGINAL NADA CONTAINS AN ACTIVE MOIETY WE HAVE PREVIOUSLY APPROVED

A. Criteria[7]

If the NADA meets all of the following criteria, it qualifies for THREE years exclusivity:

- We **have** approved the active moiety in another application.
- The NADA is an original (not a supplemental) application.
- The NADA contains the following studies (other than bioequivalence or residue depletion studies) the applicant conducted or sponsored and that we required to approve the application: 1) one or more investigations to demonstrate substantial evidence of effectiveness of the drug involved; 2) any studies of animal safety; or 3) human food safety study(ies).

NOTE: An example of when a three-year exclusivity period applies is when we approve a new species or indication for a previously approved drug.

B. If the NADA meets the criteria in section V. A., use this boilerplate language in the FOI summary, MRA, and approval letter:

<*Insert proprietary name*>, as approved <*insert either "in this letter" or for the MRA and FOI summary "in our approval letter"*>, qualifies for THREE years of marketing exclusivity beginning as of the date of <*insert either "this letter" or for the MRA and FOI summary "our approval letter"*>. This drug qualifies for exclusivity under section 512(c)(2)(F)(ii) of the Federal Food, Drug, and Cosmetic Act because <*insert either "you" or for the MRA and FOI summary, "the sponsor"*> submitted an original NADA that contains new studies that demonstrate the <*insert either safety, effectiveness or safety and effectiveness*> *of <insert proprietary name*>.

[7]Section 512(c)(2)(F)(i) of the FD&C Act, 21 USC § 360b(c)(2)(F)(i)

C. If the NADA was submitted under section 512(b)(1) for a designated new animal drug that is already conditionally approved under section 571, use this boilerplate in the FOI summary, MRA, and approval letter:

<*Insert proprietary name*>, as approved <*insert either "in this letter" or for the MRA and FOI summary "in our approval letter"*>, qualifies for THREE years of marketing exclusivity beginning as of the date of <*insert either "this letter" or for the MRA and FOI summary "our approval letter"*>. This drug qualifies for exclusivity under section 512(c)(2)(F)(ii) of the Federal Food, Drug, and Cosmetic Act because <*insert either "you" or for the MRA and FOI summary, "the sponsor"*> submitted an original NADA that contains new studies that demonstrate the effectiveness of <*insert proprietary name*>. The exclusive marketing rights and applicable exclusivity for this drug run concurrently.

D. If the NADA was submitted for a new animal drug that is designated under section 573 of the FD&C Act, use this boilerplate language in the FOI summary, MRA, and approval letter:

<*Insert proprietary name*>, as approved <*insert either "in this letter" or for the MRA and FOI summary "in our approval letter"*>, qualifies for SEVEN years of exclusive marketing rights beginning as of the date of <*insert either "this letter" or for the MRA and FOI summary "our approval letter"*>. This drug qualifies for exclusive marketing rights under section 573(c) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) because it is a designated new animal drug under section 573(a) of the FD&C Act. Except as provided in section 573(c)(2) of the FD&C Act, we may not approve or conditionally approve another application submitted for such new animal drug with the same intended use as <*insert proprietary name*>. Because <*insert either "you" or for the MRA and FOI summary "the sponsor"*> submitted an original NADA that contains new studies that demonstrate the <*insert either safety, effectiveness or safety and effectiveness*> *of* <*insert proprietary name*>, this drug also qualifies for three years of exclusivity under section 512(c)(2)(F)(ii) of the FD&C Act. The exclusive marketing rights and exclusivity for this drug run concurrently.

NOTE: Keep in mind that applications containing human food safety studies that applicants either conduct or sponsor to change the tolerance or withdrawal time are not eligible for exclusivity. In most cases, a new study that the applicant conducts or sponsors that is part of the substantial evidence of effectiveness or a new animal safety study (except for bioequivalence studies), would provide grounds for granting exclusivity. Generally, a human food safety study would not provide grounds for granting exclusivity.

VI. SUPPLEMENTAL NADA CONTAINS A PREVIOUSLY APPROVED ACTIVE MOIETY

NOTE: Exclusivity most frequently applies to supplemental NADAs that add claims or species.

A. Criteria[8]

If the supplemental NADA meets all of the following criteria, it qualifies for exclusivity:

[8] Supplemental NADAs that contain new effectiveness studies, studies of animal safety, or human food safety studies qualify for three-year exclusivity. Section 512(c)(2)(F)(iii) of the FD&C Act, 21 U.S.C. § 360b(c)(2)(F)(iii).

- We approved the active moiety in another application under section 512(b)(1).
- This is not an original NADA.
- The NADA contains the following studies (other than bioequivalence or residue depletion studies) the applicant conducted or sponsored and that we required to approve the application: 1) one or more investigations to demonstrate substantial evidence of effectiveness of the drug involved; 2) any studies of animal safety; or 3) human food safety study(ies).

B. If the NADA meets the criteria in section VI. A. above, use this boilerplate language in the FOI summary, MRA, and approval letter:

This supplemental approval for <*insert proprietary name*> qualifies for THREE years of marketing exclusivity under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act because the supplemental application included <*insert either safety, effectiveness, or safety and effectiveness studies*>. This exclusivity begins as of the date of <*insert either "this letter" or for the MRA and FOI summary "our approval letter"*>and only applies to <*describe the change, e.g., new claim, new species, etc. that is approved in the supplemental application*>.

C. If the supplemental NADA was submitted under section 512(b)(1) for a new animal drug that is already conditionally approved under section 571, use this boilerplate language in the FOI summary, MRA, and approval letter:

This supplemental approval for <*insert proprietary name*> qualifies for THREE years of marketing exclusivity under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act because the supplemental application included effectiveness studies. This exclusivity begins as of the date of <*insert either "this letter" or for the MRA and FOI summary "our approval letter"*> and only applies to <*describe change, e.g., new claim, new species, etc. that is approved in the supplemental application*>. Any applicable exclusive marketing rights and exclusivity for this drug run concurrently.

D. If the sponsor already has an approved new animal drug and gets it designated under section 573, they may submit a supplemental NADA for approval of that designated use. In those cases, use this boilerplate language in the FOI summary, MRA, and approval letter:

This supplemental approval for <*insert proprietary name*> qualifies for SEVEN years of exclusive marketing rights beginning as of the date of <*insert either "this letter" or for the MRA and FOI summary "our approval letter"*>. This drug qualifies for exclusive marketing rights under section 573(c) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) because it is a designated new animal drug under section 573(a) of the FD&C Act. Except as provided in section 573(c)(2) of the FD&C Act, we may not approve or conditionally approve another application submitted for such new animal drug with the same intended use as <*insert proprietary name*>. Because the supplemental application included <*insert either safety, effectiveness, or safety and effectiveness studies*>, this drug also qualifies for three years of exclusivity under section 512(c)(2)(F)(iii) of the FD&C Act. This exclusivity begins as of the date of <*insert either "this letter" or for the MRA and FOI summary "our approval letter"*> and only applies to <*describe change, e.g., new claim, new species, etc. that is approved*

in the supplemental application>. The exclusive marketing rights and applicable exclusivity run concurrently.

E. If the supplemental NADA is for a designated new animal drug that was approved as an original active moiety not previously approved and it is still within its five-year exclusivity period, it does not qualify for any additional exclusivity. Use this boilerplate language in the FOI summary, MRA, and approval letter:

Any applicable exclusive marketing rights and exclusivity under the original approval for this drug continue.

NOTE: Keep in mind that applications containing human food safety studies that applicants either conduct or sponsor to change the tolerance or withdrawal time are not eligible for exclusivity. In most cases, a new study that the applicant conducts or sponsors that is part of the substantial evidence of effectiveness or a new animal safety study (but generally not a human food safety study), would provide grounds for granting exclusivity.

VII. APPLICATION DOES NOT QUALIFY FOR EXCLUSIVITY

A. If the NADA or supplemental NADA does not meet the criteria described in sections IV. A., V. A., or VI. A. above, use the following boilerplate language:

<*Insert proprietary name*>, as approved in <*insert either "this letter" or for the MRA and FOI summary "our approval letter"*>, does not qualify for marketing exclusivity under section 512(c)(2)(F) of the Federal Food, Drug, and Cosmetic Act.

VIII. OTHER RARE SITUATIONS WHERE EXCLUSIVITY MAY BE GRANTED

There are other rare situations for which we may grant exclusivity, for example:

- Five-year exclusivity for the first NADA we approve in a food animal species following a waiver of exclusivity in a non-food-producing animal species (section 512(c)(2)(F)(v)).
- Three-year exclusivity for an original application for a new chemical entity in a non-food animal species when the applicant waives a five-year exclusivity (section 512(c)(2)(F)(iv)).

If an application qualifies for exclusion under one of these provisions, you should consult your team leader or the Policy Team for assistance.

IX. ABBREVIATED NEW ANIMAL DRUG APPLICATION

Abbreviated new animal drug applications (ANADAs), also known as generic new animal drug applications, do not qualify for marketing exclusivity because exclusivity applies only to applications we approve under section 512(b)(1) of the FD&C Act. Original and supplemental new animal drug applications (NADAs) are approved under section 512(b)(1). ANADAs are approved under section 512(b)(2). The purpose of exclusivity is to prevent sponsors from filing generic applications for some period of time after the date of an approval of an original or supplemental NADA under section 512(b)(1). This period of exclusivity provides the sponsor of the original or supplemental NADA time to recoup

research and development costs before someone can copy it in a generic application and encourages the continued development of new animal drugs.

For an ANADA, use this boilerplate language in the FOI summary, MRA, and approval letter:

This ANADA does not qualify for exclusivity. ANADAs are filed under section 512(b)(2) of the Federal Food, Drug, and Cosmetic Act. FDA can only grant exclusivity to new animal drug applications and supplemental new animal drug applications filed under section 512(b)(1).

X. SECTION 512(B)(1) SUPPLEMENTS TO ABBREVIATED NEW ANIMAL DRUG APPLICATIONS

A. A section 512(b)(1) supplement to an ANADA is treated the same as a supplement to an NADA, whether the supplement is submitted following approval of the ANADA or in a hybrid submission.[9]

B. For section 512(b)(1) supplements to an ANADA, you should prepare the FOI summary, MRA, and approval letter as follows:

Use the boilerplate language in section V. that applies to the supplemental application (or supplemental NADA portion of the application). For example, if the supplemental NADA contains animal safety, effectiveness, or human food safety studies (other than bioequivalence or residue studies), the application may qualify for three-year exclusivity.

NOTE: Keep in mind that applications containing human food safety studies that applicants either conduct or sponsor to change the tolerance or withdrawal time are not eligible for exclusivity. In most cases, a new study that the applicant conducts or sponsors that is part of the substantial evidence of effectiveness or a new animal safety study (but generally not a human food safety study), would provide grounds for granting exclusivity.

XI. BIOTECHNOLOGY-DERIVED DRUG PRODUCTS

Section 106 of the Generic Animal Drug and Patent Term Restoration Act (Pub.L. 100-670) states that FDA cannot approve an abbreviated new animal drug application for a new animal drug that is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site-specific gene manipulation techniques.

Therefore, include this boilerplate language in the FOI summary, MRA, and approval letter to explain why the drug is not eligible for exclusivity:

The exclusivity provisions of section 512(c)(2)(F) of the Federal Food, Drug, and Cosmetic Act do not apply to this drug because under section 106 of the Generic Animal Drug and Patent Term Restoration Act (Pub.L. 100-670), FDA cannot approve an abbreviated new animal drug application for a new animal drug that is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific gene manipulation techniques. <*Only include this*

[9] "Hybrid" has historically referred to an application that has both a generic section 512(b)(2) application and a supplemental section 512(b)(1) application component.

last sentence in the FOI summary and MRA: Therefore, a sponsor cannot submit an ANADA to market a generic version of this drug.>

XII. CONDITIONAL APPROVALS

Under section 571, we may grant an applicant conditional approval without their providing substantial evidence demonstrating that the new animal drug is effective for its proposed uses. The applicant need only demonstrate that the new animal drug has a reasonable expectation of effectiveness. The applicant, however, must meet the same safety standards that would be applied to such drugs under section 512(d), i.e., demonstrate target animal and human food safety. We cannot grant conditional approval of a new animal drug that is contained in, or is a product of, a transgenic animal.

A conditional approval is for a one-year period and is renewable for up to four additional one-year terms. It cannot be in effect for more than five years. A conditional approval is not an approval under section 512(b)(1) and does not qualify for marketing exclusivity. A conditional approval under section 571(a)(1)(A)(i) (for a minor use or minor species (MUMS) indication) may qualify for exclusive marketing rights, if designated under section 573. A conditional approval under section 571(a)(1)(A)(ii) (known as expanded conditional approval or XCA) is ineligible to be designated under section 573, and therefore cannot confer exclusive marketing rights or any marketing exclusivity. Once a conditionally approved drug is fully approved under section 512, any applicable exclusive marketing rights and marketing exclusivity run concurrently (see sections III – V above).

A. If the application submitted is for the conditional approval of a designated new animal drug, use the following boilerplate in the FOI summary, MRA, and approval letter:

<*Insert proprietary name*>, as approved <*insert either in this letter or in our approval letter*>, qualifies for SEVEN years exclusive marketing rights beginning as of the date of <*insert either this letter or our approval letter*>. This drug qualifies for exclusive marketing rights under section 573(c) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) because it is a designated new animal drug under section 573(a) of the FD&C Act. Except as provided in section 573(c)(2) of the FD&C Act, we may not approve or conditionally approve another application submitted for such new animal drug with the same intended use as <*insert proprietary name*>.

Use the following boilerplate in the Exclusivity section of the GBAAD form:

Conditionally approved by FDA under application number <*insert application number*>, <*Insert proprietary name*> in the dosage form and for <*insert the intended use(s) being conditionally approved*> qualifies for seven years of exclusive marketing rights beginning as of the date of conditional approval. This new animal drug qualifies for exclusive marketing rights under section 573(c) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) because it has been declared a designated new animal drug by FDA under section 573(a) of the FD&C Act.

B. If the application is for the conditional approval of a new animal drug for a minor use or minor species that has not received designation, use the following boilerplate in the FOI summary, MRA, and approval letter:

<*Insert proprietary name*>, as approved in <*insert either "this letter" or for the MRA and FOI summary "our approval letter"*>, does not qualify for exclusive marketing rights under section 573(c) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) because it is not a designated new animal drug under section 573(a) of the FD&C Act.

XIII. MISCILLANEOUS NOTES

Types of studies that qualify an application for exclusivity include substantial evidence of the effectiveness of the drug involved, any studies of animal safety, or human food safety studies (other than bioequivalence or residue studies).

Because the intent of marketing exclusivity is to reward innovation, exclusivity only applies when we require the investigation for approval and when the applicant conducts or sponsors the study(-ies).

If an applicant has prepared a qualitative risk assessment under Guidance for Industry 152, whether or not we grant exclusivity is based upon whether the applicant conducted or sponsored studies that were reported or referenced in their risk assessment.[10]

Marketing exclusivity does not apply to many supplemental NADA approvals. In these cases, there is no need for exclusivity boilerplate language in the MRA or approval letter to the applicant. An example of a supplemental application where exclusivity does not apply is one that the Director, Division of Manufacturing Technologies approves, that does not require an effectiveness or safety study that could qualify the application for exclusivity under section 512(c)(2)(F) but may contain stability or other studies that do not qualify. In cases where exclusivity does not apply or we are not granting exclusivity, you should also make certain we say that in the exclusivity section of the MRA.

XIV. REFERENCES

Statutes

Federal Food, Drug, and Cosmetic Act (FD&C Act)

Sections 512(b)(1) and (2) of the FD&C Act, 21 USC § 360b(1) and (2)

[10] Guidance for Industry 152 sets forth the recommended approach for assessing the safety of antimicrobial new animal drugs with regard to their microbiological effects on bacteria of human health concern.

Section 512(c)(2)(F) of the FD&C Act, 21 U.S.C. § 360b(c)(2)(F)

Section 512(d)(3) of the FD&C Act, 21 USC § 360b(d)(3)

Section 571 of the FD&C Act, 21 U.S.C. § 360ccc

Section 573 of the FD&C Act, 21 U.S.C. § 360ccc-2

Section 106 of the Generic Animal Drug and Patent Term Restoration Act (Pub.L. 100-670)

Guidance for Industry (GFI)

GFI #152, Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to Their Microbiological Effects on Bacteria of Human Health Concern

XV. VERSION HISTORY

November 16, 2001 – original version

September 30, 2013 – Revised to update references and boilerplate text and add boilerplate text for conditional approvals.

April 7, 2015 – Revised to update boilerplate text, add conditional approval Animal Drugs @ FDA text and other minor editorial changes.

August 2, 2018 – Revised to update the boilerplate to cite the Federal Food, Drug, and Cosmetic Act (FD&C Act) appropriately and to include instruction in a new section II called Additional information that tells reviewers to follow grammar rules when citing the FD&C Act and modifying the boilerplate to do so is appropriate.

March 5, 2020 – Revised to correct typographical errors.

January 6, 2021 – Updated to change “the act” to the FD&C Act. And to fix punctuation errors. Updated to add new exclusivity language for conditional approvals.

June 28, 2021 – Updated to reflect changes to exclusivity provisions of Sec. 512(c)(2)(F) of the FD&C Act.

October 27, 2021 – Revised to remove redundant sentence from the boilerplate for conditional approvals.

November 29, 2023 – Cyclical quality management review of the document completed, and no substantive edits were made. The document was placed into the current office template and format.

February 24, 2024 – Section III had the definition of active moiety added. Edits to clarify limitations on 5-year exclusivity for new chemical entities and section XII revised to clarify application to conditional approvals.