OFFICE OF NEW ANIMAL DRUG EVALUATION REVIEWER'S CHAPTER

ALL OTHER INFORMATION

I. PURPOSE

The purpose of this document is to explain:

- what all other information (AOI) is,
- submission of all further information in support of major technical sections,
- the content of the AOI technical section (M submission), and
- when sponsors should submit the AOI technical section.

II. WHAT IS ALL OTHER INFORMATION (AOI)

Our intent with respect to all other information is for sponsors to submit all information pertinent to an evaluation of safety and effectiveness they receive or otherwise obtain from any source for the new animal drug, as stipulated in 21 CFR 514.1(b)(8)(iv). This includes information from:

- other investigations or commercial marketing (for example, outside the U.S.),
- reports in the scientific literature (an adequate summary may be acceptable in lieu of a reprint of a published report), both favorable and unfavorable, involving the new animal drug that is subject to the application and related new animal drugs, and
- evaluations from the sponsor's veterinary or medical department, expert committees, or consultants.

When this information is included in the Effectiveness, Target Animal Safety, or Human Food Safety technical sections, we refer to it as "all further <effectiveness, target animal safety, or human food safety> information" in our review documentation and any correspondence to sponsors. The term All Other Information should only be used to describe the information in the AOI technical section.

III. ALL FURTHER SAFETY OR EFFECTIVENESS INFORMATION SUBMITTED WITH OR IN SUPPORT OF, MAJOR TECHNICAL SECTIONS

As a general rule, we encourage sponsors to submit any available safety and effectiveness information with the applicable major technical sections. We use it to ensure that we are able to review the safety and effectiveness of the new animal drug in the context of all available studies and information for that new animal drug.

The types of safety and effectiveness information requested for P submissions include:

- reports of studies conducted by or on behalf of the sponsor such as pilot studies of safety or effectiveness, pharmacological or toxicological studies, or other studies that evaluate the safety or effectiveness of the new animal drug,
- abstracts of published manuscripts or proceedings describing studies related to the safety or effectiveness of the new animal drug,
- results of literature searches,
- foreign marketing experiences, and
- adverse drug experience information.

In the context of a phased review process, this information should be submitted for review before a technical section may be considered complete.

Remind the sponsor to submit any safety and effectiveness information with the appropriate major technical section if it is available at the time that technical section is submitted (21 CFR 514.1(b)(8)(i, ii, and iii)). Ask that they submit as part of the AOI technical section any new safety and effectiveness information that becomes available after completion of the applicable technical section. Review such information under the AOI technical section, recognizing our review of the AOI technical section occurs at late stages of the phased review process. This may cause us to reevaluate and subsequently reopen major technical section(s) we previously deemed complete.

IV. CONTENT OF THE AOI TECHNICAL SECTION

If a sponsor follows our recommendation to submit safety and effectiveness information as early in the investigational new animal drug (INAD) process as practical, the AOI technical section is likely to be small in size and scope. If the sponsor follows our recommendation, the AOI technical section will consist of only information the sponsor has not submitted before, and the sponsor may have only recently become aware of it or come into possession of it. The content of the AOI technical section (submitted to either the INAD or new animal drug application (NADA)) includes information such as:

- abstracts of published manuscripts or proceedings
- results of literature searches
- study reports not previously submitted to the INAD or NADA
- foreign marketing experiences, and

- adverse drug experience information.

Discuss the scope, content, and format of the AOI technical section with the sponsor before they submit it. Take into consideration such items as the active ingredient, dosage form, history of the product, species and class of animal administered the new animal drug, and timeframe in which information was published or reported when determining the scope and content of the AOI technical section. Ask that sponsors not include information or study reports previously reviewed in the INAD or NADA. A cross-reference to its previous submission may be appropriate.

Review of new studies included in the AOI technical section yet required by 21 CFR 514.1(b)(8)(i, ii, and iii) that should have been submitted with the applicable technical section(s) may cause us to reevaluate and subsequently reopen a technical section(s).

V. WHEN DO WE INSTRUCT SPONSORS TO SUBMIT THE AOI TECHNICAL SECTION

A sponsor submits the AOI technical section to their INAD as part of the phased review process or as a technical section to their non-administrative original or supplemental application.

When submitted to the INAD as part of phased review, recommend that sponsors submit their AOI technical section (M submission) after submission of the last P submission (that is presumed to result with the issuance of a major technical section complete letter), but no later than Day 80 of the 180-day review clock for the last P submission.[1] This facilitates completion of the AOI technical section at the same time we complete the last major technical section. If the sponsor indicates that they have no additional AOI at this time (i.e., everything was already submitted to the INAD), request that they submit the AOI technical section and indicate in the letter that there is no additional AOI beyond the information already provided in previous submissions to the INAD.

If an M submission is received under an INAD for an Animal Drug Availability Act of 1996 (ADAA) feed use combination that requires no further assessment of the major technical sections (i.e., no P submissions are required) in order to meet the requirements for the submission of a 60-day original ADAA feed use combination NADA,[2] recommend that sponsors submit their AOI technical section at least 100 days before they expect to submit their original ADAA combination NADA. This facilitates completion of the AOI technical section and issuance of the Technical Section Complete letter ahead of the sponsor's submission of the 60-day original ADAA feed use combination NADA, ensuring that the sponsor meets one of the eligibility requirements for the 60-day review process.

AOI technical section complete letters are valid for 90 days from the date the AOI technical section complete letter was issued. Technical section complete letters for all the other major and minor technical sections do not have an expiration date associated with them. If we receive an administrative NADA or 60-day original ADAA feed use combination NADA greater than 90 days after we issue the AOI technical section complete letter, then the review division should take the following actions:

[1] See P&P 1243.4080, "Labeling and All Other Information Technical Sections (Minor Technical Section or M Submissions)."
[2] See P&P 1243.5730, "Review of 60-Day Original Animal Drug Availability Act of 1996 (ADAA) Feed Use Combination NADA," for information on the requirements for a 60-day original ADAA feed use combination NADA.

- Convert the administrative NADA or 60-day original ADAA feed use combination NADA to a non-administrative (traditional) NADA.

- Ask the applicant to amend their administrative NADA to update the AOI technical section.[3] In most situations the amendment will either contain a certification by the sponsor that there is no new information to be added to the AOI technical section or contain minimal new information.

- Note that an amendment to the 60-day original ADAA feed use combination NADA will require conversion of the application to a non-administrative (traditional) NADA, as discussed in P&P 1243.5730.

- Depending on the amount of information and the due date of submission, the review division may determine that it is necessary to reset the review clock.[4]

- If the review of the AOI results in the reopening of a major technical section(s) we previously deemed complete, the technical section complete letter(s) for those technical section(s) are no longer valid, and the review division should refuse to file the administrative NADA.[5]

See P&P 1243.4080 for the business rules related to the AOI technical section (e.g., refusing to review the AOI M submission or updating the due date for the AOI M submission based on changes in the last (referenced) P or Z submission).

VI. REFERENCES

Code of Federal Regulations (Title 21)

Part 514 – New Animal Drug Applications

§514.1, Applications

CVM Program Policies and Procedure Manual – ONADE Reviewers Chapter

1243.2050 - Refuse to File and Refuse to Review

1243.3026 - Assessing Submission Quality and Amending and Resetting the Clock on Submissions

1243.4080 - Labeling and All Other Information Technical Sections (Minor Technical Section or M Submissions)

1243.5730 - Review of 60-day Original Animal Drug Availability Act of 1996 (ADAA) Feed Use Combination New Animal Drug Applications (NADAs)

[3] See P&P 1243.3026, "Assessing Submission Quality and Amending and Resetting the Clock on Submissions," for information about amendments.
[4] See P&P 1243.3026 for information on resetting the clock.
[5] See P&P 1243.2050, "Refuse to File and Refuse to Review."

VII. VERSION HISTORY

March 29, 2011 – Original version

May 3, 2011 – Minor formatting corrected under Section V. April 12, 2012 – Updated P&P document numbers.

October 25, 2017 - Updated to clarify use of the term All Other Information and remove references to the ERA process.

July 5, 2018 – Updated to incorporate changes in processes associated with the review of original ADAA combination medicated feed combination NADA applications within 60 days.

October 1, 2018 - This document has been updated to incorporate changes introduced as a result of the ADUFA IV Goal of reviewing original Animal Drug Availability Act of 1996 (ADAA) feed use combination NADA applications within 60-days.

April 21, 2021 – Revised to update the titles of some references and correct some formatting errors.

October 20, 2023 – Cyclical quality systems review completed, and minor formatting updated. To bring all office quality system documentation into compliance with the FDA Visual Identity Program approved fonts, ONADE has adopted Arial 11-point font. The font of this document was changed from Verdana 10-point font to Arial 11-point font.