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OFFICE OF NEW ANIMAL DRUG EVALUATION REVIEWER'S CHAPTER

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ALL OTHER INFORMATION

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**I. PURPOSE**

The purpose of this document is to explain:

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

**II. WHAT IS 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). All other information 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
- evaluations from the sponsor’s veterinary or medical department, expert committees, or consultants.

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### **III. INFORMATION SUBMITTED WITH, OR IN SUPPORT OF, MAJOR TECHNICAL SECTIONS.**

As a general rule, we encourage sponsors to submit available safety and effectiveness information as early as practical. Depending on when sponsors provide this information to us, we use it to: 1) support activities such as development planning and determine the sponsor's requirements for conducting safety and effectiveness studies, 2) focus review efforts in protocol preparation; 3) review all available studies and information in support of the new animal drug approval process.

The types of safety and effectiveness information requested for early submission include 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. Regardless of the timing of the submission of this information, or whether we determine these studies are pivotal or non-pivotal, we require sponsors to submit this information before approval of their new animal drug (21 CFR 514.1(b)(8)(i, ii, and iii)). In the context of a phased review process, this information should be submitted for review before a technical section may be considered complete.

Other information, required by 21 CFR 514.1(b)(8)(iv) (see Section II above) and also known as 'all other information,' is sometimes submitted during this time period as well. It may be used for the same purposes as the safety and effectiveness information discussed previously in this section. When this information is submitted early, review it in the context of, and as part of, the appropriate major technical section.

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 submission 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 INAD process as practical, the AOI technical section is likely to be small in size and scope. The content of the AOI technical section (submitted to either the INAD or NADA) includes information such as:

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- 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 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 submitted to 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.

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

A sponsor submits their 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. This facilitates completion of the AOI technical section at the same time we complete the last major technical section. Regardless of whether the sponsor has additional AOI at this time (i.e., everything 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.

AOI technical section complete letters are valid for 90 days from the date stamped on the letter. 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

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an administrative NADA greater than 90 days after we issue the AOI technical section complete letter the review division should take the following actions:

- Convert the administrative NADA to a non-administrative NADA.
- Ask the applicant to amend their NADA to update the AOI technical Section. It is likely that many amendments 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.
- 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.
- If the technical section letters for other technical sections are no longer valid, the review division should refuse to file the administrative NADA.

If we request an end-review amendment (ERA) for the last pending major technical section under the INAD, see P&P 1243.4075 for procedures on requesting that sponsors amend their AOI technical section. Similarly, if a sponsor includes their AOI technical section as part of an original or supplemental NADA and we request an ERA for that application, see P&P 1243.5730 for procedures on requesting that sponsors update their AOI technical section as a result of the ERA process. See P&Ps 1243.4080 and 1243.3050 on the process for reassignment and confirmation of adjusted due dates for the AOI technical section as affected by minor amendments or ERAs.

## VI. REFERENCES

Code of Federal Regulations (Title 21)

Part 514 – New Animal Drug Applications

§514.1, Applications

CVM Program Policy and Procedures Manual

1243.4075, Integrating an end-review amendment (ERA) into the investigational new animal drug data (P) submission review process

1243.5730, Integrating an end-review amendment (ERA) into the new animal drug application review process

1243.3050, Documenting and verifying technical sections required for approval.

1243.4080, Labeling and all other information technical sections (minor technical section or “M” submissions).

## **VII. VERSION HISTORY**

March 29, 2011 – original version

May 3, 2011 – Minor formatting corrected under Section V.

April 12, 2012 – Update P&P document numbers.