PHARMACOLOGY AND TOXICOLOGY

DISTRIBUTION OF FINAL REPORTS FROM THE CARCINOGENICITY ASSESSMENT COMMITTEE (CAC) AND EXECUTIVE CAC

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PURPOSE This MAPP establishes the policies and procedures by which the review divisions will provide sponsors with the final reports from the Carcinogenicity Assessment Committee (CAC) and the Executive CAC.

BACKGROUND

The CAC conducts a tertiary review of carcinogenicity studies in accordance with MAPP 7412.1, *Management of CDER Carcinogenicity Assessment Committee (CAC) and Executive CAC*. The CAC review is of interest to sponsors who often request it from the review divisions.

The review divisions are responsible for all direct communication with sponsors, including recommendations from the CAC and Executive CAC. Since carcinogenicity studies submitted to the Center for Drug Evaluation and Research (CDER) should be reviewed by the CAC or Executive CAC, it is important that a mechanism to consistently communicate the CAC recommendations to sponsors is established. To achieve this objective, this guide describes the policy and procedures for releasing CAC final reports.

REFERENCES

- CDER MAPP 7412.1, *Management of CDER Carcinogenicity Assessment Committee (CAC) and Executive Committee*.

POLICY

- This policy applies to all final reports documenting the deliberations and recommendations of the CAC and the Executive CAC. Final reports should be provided to sponsors by the reviewing division upon written request by the sponsor.

- The recommendations in a CAC and Executive CAC final report of the carcinogenicity study results are advisory to the review divisions and office directors. These reports aid in the interpretation of the carcinogenicity study results and the potential relevance of the findings under the conditions of clinical use.

- The final reports generated by the CAC or Executive CAC on the dose selection and study design for proposed carcinogenicity protocols provide Center concurrence and/or recommendations for sponsors and are to be conveyed to the sponsor.

PROCEDURES

Releasing CAC and Executive CAC final reports:

- The review division should inform the sponsor when a proposed carcinogenicity protocol or study results will be reviewed by the CAC or Executive CAC. The final report for the protocol evaluation will be made available 75 days from the CDER receipt stamp date of the protocol.

- Upon written request, the full reports the CAC evaluation of the carcinogenicity study will be made available 30 days after the CAC meeting.

- The final report should be provided with a cover letter from the Division Director (or designate) clearly stating that the recommendations made by the CAC on carcinogenicity study evaluations are advisory and should not be interpreted by the sponsor as a measure of the approvability of their application.

EFFECTIVE DATE

This MAPP is effective upon date of publication.