4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-1620]

Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee. This meeting was announced in the *Federal Register* of May 6, 2019. The amendment is being made to reflect a change in the **DATES**, *Agenda*, and *Procedure* portions of the document. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Lauren Tesh Hotaki, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, Fax: 301-847-8533, email: ODAC@fda.hhs.gov; or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of May 6, 2019 (84 FR 19788), FDA announced that a meeting of the Pediatric Oncology Subcommittee of the

Oncologic Drugs Advisory Committee would be held on June 20, 2019. On page 19788, in the first column, the DATES portion of the document is changed to read as follows:

DATES: The meeting will be held on June 20, 2019, from 9 a.m. to 3:30 p.m.

On page 19789, in the second column, the second paragraph of the *Agenda* portion of the document is changed to read as follows:

During the afternoon session, information will be presented to gauge investigator interest in exploring potential pediatric development plans for one product in early stages of development for adult cancer indications. The subcommittee will consider and discuss issues concerning diseases to be studied, patient populations to be included, and possible study designs in the development of these products for pediatric use. The discussion will also provide information to the Agency pertinent to the formulation of written requests for pediatric studies, if appropriate. The product under consideration is ONC201, presentation by Oncoceutics Inc.

On page 19789, in the third column, the third sentence of the *Procedure* portion of the document is changed to read as follows:

Oral presentations from the public will be scheduled between approximately 10:50 a.m. and 11:20 a.m. and 1:50 p.m. and 2:20 p.m.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to the advisory committees.

Dated: June 14, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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