The draft guidance provides advice on how applicants may use the IID to support the safety of excipients to facilitate application assessment. Topics such as referencing the IID for various excipient grades and ingredients in colors and flavors are addressed. Since the IID is referenced in many types of applications, topics of general concern to all application types and those specific to investigational new drug applications (INDs), new drug applications (NDAs), and abbreviated new drug applications (ANDAs) are described.

Finally, the draft guidance provides information about where and how to contact FDA with questions about excipients and information related to specific IID listings.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Using the Inactive Ingredient Database.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This draft guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520). The collection of information in 21 CFR part 314, including the submission of NDAs and ANDAs, has been approved under OMB control number 0910–0001. The collection of information in 21 CFR part 312, including the submission of INDs, has been approved under OMB control number 0910–0014. The collection of information entitled ''Guidance for Industry on Formal Meetings between FDA and Sponsors and Applicants for PDUFA Products'' has been approved under OMB control number 0910–0429. The collection of information entitled ''Controlled Correspondence Related to Generic Drug Development'' has been approved under OMB control number 0910–0797.

In accordance with the PRA, prior to publication of any final guidance document, FDA intends to solicit public comment and obtain OMB approval for any information collections recommended in this guidance that are new or that would represent material modifications to those previously approved collections of information found in FDA regulations or guidances.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: July 8, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–14780 Filed 7–10–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–2836]

Allergenic Products Advisory Committee; Notice of Meeting; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice entitled ''Allergenic Products Advisory Committee; Notice of Meeting'' that appeared in the **Federal Register** of June 24, 2019. The document announced a forthcoming public advisory committee meeting of the Allergenic Products Advisory Committee. The document was published with the incorrect name of the committee in the Agenda portion of the notice. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Capt. Serina Hunter-Thomas or Ms. Monique Hill, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6338, Silver Spring, MD 20993–0002, 240–402–5771, *serina.hunter-thomas@fda.hhs.gov* or 301–796–4620, *monique.hill@fda.hhs.gov,* respectively; or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area).

SUPPLEMENTARY INFORMATION: In the **Federal Register** of Monday, June 24, 2019, 84 FR 29524, in FR Doc. 2019–13354, the following correction is made:

On page 29525, in the first column, under the headings, **SUPPLEMENTARY INFORMATION** and ''*Agenda*'', the first sentence is corrected to read ''On September 13, 2019, the Center for Biologics Evaluation and Research (CBER) Allergenic Products Advisory Committee (APAC) will meet in open session to discuss and make recommendations on the safety and efficacy of Peanut (*Arachis hypogaea*) Allergen Powder manufactured by Aimmune Therapeutics, Inc., indicated for treatment to reduce the risk of anaphylaxis after accidental exposure to peanut in patients aged 4 to 17 years with a confirmed diagnosis of peanut allergy.''

Dated: July 8, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–14779 Filed 7–10–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the Advisory Committee on Heritable Disorders in Newborns and Children

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces that the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC) has scheduled a public meeting. Information about the ACHDNC and the agenda for this meeting can be found on the ACHDNC website at *https://www.hrsa.gov/advisory-committees/heritable-disorders/index.html.*

DATES: August 1, 2019, 9:00 a.m.–5:00 p.m. Eastern Time (ET) and August 2, 2019, 9:00 a.m.–3:00 p.m. ET.

ADDRESSES: This meeting will be held in person and by webcast. The address for the meeting is 5600 Fishers Lane, Rockville, Maryland 20857. While this meeting is open to the public, advance registration is required. Please visit the ACHDNC website for information on registration: *https://www.hrsa.gov/advisory-committees/heritable-disorders/index.html.* The deadline for online registration is 12:00 p.m. ET on July 29, 2019. Instructions on how to access the meeting via webcast will be provided upon registration.

FOR FURTHER INFORMATION CONTACT: Alaina Harris, Maternal and Child Health Bureau (MCHB), HRSA, 5600 Fishers Lane, Room 18W66, Rockville, Maryland 20857; 301–443–0721; or *ACHDNC@hrsa.gov.*