The draft guidance provides advice on how applicants may use the IID to support the safety of excipients to facilitate application assessment.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Finally, the draft guidance provides information about where and how to contact FDA with questions about excipients and information related to specific IID listings.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Using the Inactive Ingredient Database.''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 This draft guidance is not subject to Executive Order 12866.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This draft guidance refers to previously approved collections of information found in FDA regulations.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.*

SUPPLEMENTARY INFORMATION: ACHDNC provides advice and recommendations to the Secretary of HHS (Secretary) on the development of newborn screening activities, technologies, policies, guidelines, and programs for effectively reducing morbidity and mortality in newborns and children having, or at risk for, heritable disorders. ACHDNC's recommendations regarding inclusion of additional conditions for screening, following adoption by the Secretary, are evidence-informed preventive health services provided for in the comprehensive guidelines supported by HRSA through the Recommended Uniform Screening Panel (RUSP) pursuant to section 2713 of the Public Health Service Act (42 U.S.C. 300gg–13). Under this provision, non-grandfathered group health plans and health insurance issuers offering group or individual health insurance are required to provide insurance coverage without cost-sharing (a co-payment, co-insurance, or deductible) for preventive services for plan years (*i.e.,* policy years) beginning on or after the date that is one year from the Secretary's adoption of the condition for screening.

During the August 1–2, 2019, meeting, ACHDNC will hear from experts in the fields of public health, medicine, heritable disorders, rare disorders, and newborn screening. Agenda items include: (1) Review of the RUSP condition nomination and evidence review process; (2) updates on screening methodologies; (3) rare disease registries; (4) linking data resources; and (5) workgroup updates. Agenda items are subject to changes as priorities dictate. The final meeting agenda will be available on ACHDNC's website: *https://www.hrsa.gov/advisory-committees/heritable-disorders/index.html.* Information about ACHDNC, a roster of members, as well as past meeting summaries are also available on the ACHDNC website.

Members of the public will have the opportunity to provide comments. In addition to general public comments, the ACHDNC is soliciting specific feedback at this meeting from the public on processes for nominating conditions to the RUSP condition and conducting evidence reviews. There will be time reserved on the agenda for public participants to provide comments on the RUSP condition nomination and evidence review process. Requests to offer oral comments will be accepted in the order they are requested and may be limited as time allows. Public participants may also submit written statements as further described below. To submit written comments or request time for an oral comment at the meeting, please register online by 12:00 p.m. ET on July 26, 2019. Visit the ACHDNC website for information on registration *https://www.hrsa.gov/advisory-committees/heritable-disorders/index.html.* Individuals associated with groups or who plan to provide comments on similar topics may be asked to combine their comments and present them through a single representative. No audiovisual presentations are permitted. Written comments should identify the individual's name, address, email, telephone number, professional or organization affiliation, background or area of expertise (*e.g.,* parent, family member, researcher, clinician, public health, etc.), and the topic/subject matter.

Individuals who plan to attend and need special assistance or another reasonable accommodation should notify Alaina Harris, at the contact information listed above, at least 10 business days prior to the meeting. Since this meeting occurs in a federal government building, attendees must go through a security check to enter the building. Non-U.S. Citizen attendees must notify HRSA of their planned attendance at least 20 business days prior to the meeting in order to facilitate their entry into the building. All attendees are required to present government-issued identification prior to entry.

Maria G. Button,

Director, Division of the Executive Secretariat.

[FR Doc. 2019–14758 Filed 7–10–19; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Children's Hospitals Graduate Medical Education Payment Program, OMB No. 0915–0247, Extension

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

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than September 9, 2019.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail them to HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the ICR title for reference.

Information Collection Request Title: Children's Hospitals Graduate Medical Education Payment Program, OMB No. 0915–0247, Extension.

Abstract: In 1999, the Children's Hospitals Graduate Medical Education (CHGME) Payment Program was enacted by Public Law 106–129 and most recently amended by the Dr. Benjy Frances Brooks Children's Hospitals Graduate Medical Education (GME) Support Reauthorization Act of 2018 (Pub. L. 115–241). The purpose of this program is to fund freestanding children's hospitals to support the training of pediatric and other residents in GME programs. The legislation indicates that eligible children's hospitals will receive payments for both direct and indirect medical education. Direct payments are designed to offset the expenses associated with operating approved graduate medical residency training programs; indirect payments are designed to compensate hospitals for expenses associated with the treatment of more severely ill patients and the additional costs relating to teaching residents in such programs.

Need and Proposed Use of the Information: Data based on the number of full-time equivalent (FTE) residents in applicant children's hospital training programs to determine the amount of direct and indirect medical education payments to be distributed to participating children's hospitals. Indirect medical education payments will be derived from a formula that requires the reporting of discharges, beds, and case mix index information from participating children's hospitals.