Section 1: Introduction

- Provides information on regulatory policy and guidance background, purpose, document control, new features of eCTD v4.0, and guidelines for an eCTD v4.0 submission.

Section 2: Submission Contents

- Recommends and provides details on specific topics organized by their placement (by module) in the eCTD submission.

Section 3: Combination Products

- Recommends and provides details on device combination product information organized by their placement in the eCTD submission.

Section 4: Two-Way Communications

- Provides details on the two-way communication process.

Section 5: Rules for Submission Tracking Information

- Provides details on the submission tracking relationships for an FDA eCTD submission.

The FDA eCTD v4.0 Module 1 Implementation Package will provide the detailed specifications to create Module 1 of an eCTD v4.0-based electronic submission for CDER or CBER. The Implementation Package will provide the technical specifications and the necessary components to create a valid FDA eCTD v4.0 submission. The Implementation Package contains the following components:

FDA eCTD Module 1 Implementation Guide

- The technical specification for the FDA eCTD v4.0 Module 1 using the Health Level Seven Regulated Product Submission Release 2, Normative standard.

FDA Regional Genericode Controlled Vocabulary Files

- Includes region-specific vocabulary and the files intended for implementers to use as a computable version of the controlled vocabulary content.

FDA Regional Module XML Samples

- Includes samples of M1 eCTD v4.0 xml.

FDA Object Identifiers (OID) Listing

- Provides the OIDs to be used for the FDA Module 1 controlled vocabulary.

FDA Regional Controlled Vocabulary

- Includes region-specific vocabulary and these files are intended as the human readable version of the controlled vocabulary content.

FDA Regional Controlled Vocabulary for Transition Mapping Message DTD 2.01

- Provides a human readable version of the controlled vocabulary transition mapping for the transition from Module 1 DTD 2.01.

FDA Regional Controlled Vocabulary for Transition Mapping Message DTD 3.3

- Provides a human readable version of the controlled vocabulary transition mapping for the transition from Module 1 DTD 3.3.

II. Electronic Access

Persons with access to the internet may obtain the eCTD v4.0 Technical Conformance Guide and the FDA eCTD v4.0 Module 1 Implementation Package at either *https://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm309911.htm* or *https://www.regulations.gov.*

Dated: February 19, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–03574 Filed 2–21–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–0008]

Allergenic Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Allergenic Products Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public.

DATES: The meeting will be held on May 15, 2020, from 8:30 a.m. to 3 p.m.

ADDRESSES: The meeting will be held at FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For security information, please refer to *https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.* For those unable to attend in person, the meeting will also be webcast and will be available at the following link: *https://collaboration.fda.gov/apac051520/.* Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FOR FURTHER INFORMATION CONTACT: Kathleen Hayes or Monique Hill, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6307C, Silver Spring, MD 20993–0002, 301–796–7864, *Kathleen.Hayes@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). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: On May 15, 2020, the Center for Biologics Evaluation and Research's (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 Extract manufactured by DBV Technologies, S.A for treatment of patients 4 through 11 years old with a confirmed diagnosis of peanut allergy.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material is available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before May 8, 2020. Oral presentations from the public will be scheduled between approximately 11:45 a.m. to 12:45 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before April 30, 2020. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by May 1, 2020.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Kathleen Hayes at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 19, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–03604 Filed 2–21–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

"Low Income Levels" Used for Various Health Professions and Nursing Programs Authorized in Titles III, VII, and VIII of the Public Health Service Act

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

ACTION: Notice.

SUMMARY: HRSA is updating income levels used to identify a ''low income family'' for the purpose of determining eligibility for programs that provide health professions and nursing training to individuals from disadvantaged backgrounds. These various programs are authorized in Titles III, VII, and VIII of the Public Health Service Act.

SUPPLEMENTARY INFORMATION: HHS periodically publishes in the **Federal Register** low-income levels to be used by institutions receiving grants and cooperative agreements to determine eligibility for programs providing training for (1) disadvantaged individuals, (2) individuals from disadvantaged backgrounds, or (3) individuals from low-income families.

Many health professions and nursing grant and cooperative agreement awardees use the low-income levels to determine whether potential program participants are from an economically disadvantaged background and would be eligible to participate in the program, as well as to determine the amount of funding the individual receives. Awards are generally made to accredited schools of medicine, osteopathic medicine, public health, dentistry, veterinary medicine, optometry, pharmacy, allied health, podiatric medicine, nursing, and chiropractic; public or private nonprofit schools which offer graduate programs in behavioral health and mental health practice; and other public or private nonprofit health or education entities to assist the disadvantaged to enter and graduate from health professions and nursing schools. Some programs provide for the repayment of health professions or nursing education loans for disadvantaged students.

A ''low-income family/household'' for workforce training programs included in Titles III, VII, and VIII of the Public Health Service Act is defined as having an annual income that does not exceed 200 percent of the Department's poverty guidelines. A family is a group of two or more individuals related by birth, marriage, or adoption who live together.

Most HRSA programs use the income of a student's parent(s) to compute low income status. However, a ''household'' may potentially be only one person. Other HRSA programs, depending upon the legislative intent of the program, the programmatic purpose related to income level, as well as the age and circumstances of the participant, will apply these low income standards to the individual student to determine eligibility, as long as he or she is not listed as a dependent on the tax form of his or her parent(s). Each program announces the rationale and choice of methodology for determining low-income levels in program guidance.

Low-income levels are adjusted annually based on HHS's poverty guidelines. HHS's poverty guidelines are based on poverty thresholds published by the U.S. Census Bureau, adjusted annually for changes in the Consumer Price Index. The income figures below have been updated to reflect the Department's 2020 poverty guidelines as published in 85 FR 12 (January 17, 2020).

LOW INCOME LEVELS BASED ON THE 2020 POVERTY GUIDELINES FOR THE 48 CONTIGUOUS STATES AND THE DISTRICT OF COLUMBIA

Persons in family/household *	Income level **
1	$25,520
2	34,480
3	43,440
4	52,400
5	61,360
6	70.320
7	79,280
8	88,240

For families with more than 8 persons, add $8,960 for each additional person.

* Includes only dependents listed on federal income tax forms.

** Adjusted gross income for calendar year 2019.

LOW INCOME LEVELS BASED ON THE 2020 POVERTY GUIDELINES FOR ALASKA

Persons in family/household *	Income level **
1	$31,900
2	43,100
3	54,300
4	65,500
5	76,700
6	87,900
7	99,100
8	110,300

For families with more than 8 persons, add $11,200 for each additional person.

* Includes only dependents listed on federal income tax forms.