than 2 business days before the meeting. If FDA is unable to post the background material on its Web site 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 Web site after the meeting. Background material is available at *http://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 September 3, 2014. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 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 August 25, 2014. 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 August 26, 2014.

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 physical disabilities or special needs. If you require special accommodations due to a disability, please contact Kalyani Bhatt at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://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: July 8, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–16358 Filed 7–11–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0001]

Dermatologic and Ophthalmic Drugs Advisory Committee Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Dermatologic and Ophthalmic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on October 20, 2014, from 8 a.m. to 5 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/default.htm;* under the heading ''Resources for You,'' click on ''Public Meetings at the FDA White Oak Campus.'' Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Moon Hee V. Choi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2147, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, *DODAC@fda.hhs.gov,* 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 Web site at *http://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.

Agenda: The committee will discuss biologics license application (BLA) 125504, secukinumab, a human monoclonal antibody, submitted by Novartis, proposed for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy.

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 Web site 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 Web site after the meeting. Background material is available at *http://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 October 3, 2014. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 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 September 25, 2014. 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 September 26, 2014.

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

Dated: July 8, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–16359 Filed 7–11–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Clarifications Regarding the Ryan White HIV/AIDS Program and Reconciliation of Advanced Premium Tax Credits Under the Affordable Care Act; Request for Comment

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

ACTION: Request for Public Comment on Reconciliation of Advanced Premium Tax Credits (APTC or premium tax credit) under the Affordable Care Act and the Ryan White HIV/AIDS Program (RWHAP).

SUMMARY: HRSA's HIV/AIDS Bureau (HAB) recently released HAB Policy Clarification Notice 14–01, which requires RWHAP grantees and subgrantees that use program funds to purchase health insurance in the Marketplace to establish appropriate mechanisms to vigorously pursue any excess premium tax credit a client receives from the Internal Revenue Service (IRS) upon submission of the client's tax return. HRSA now seeks public comment on the operational feasibility for RWHAP grantees and subgrantees to implement a complementary policy that would allow RWHAP grantees and subgrantees to use RWHAP funds to pay the IRS any additional income tax liability a client may owe to the IRS solely based on reconciliation of the premium tax credit. In addition to general comments about the feasibility of implementing such a policy, HRSA would like feedback on the following issues related to this policy:

- Could this proposed policy be easily implemented by a grantee?
- What challenges would grantees and subgrantees face in implementing this proposed policy?
- Will grantees be able to conduct fiscal monitoring of this proposed policy? If so, what level of effort would be required?

DATES: Submit comments no later than August 13, 2014.

ADDRESSES: Comments should be submitted to *RyanWhiteComments@hrsa.gov* by August 13, 2014.

FOR FURTHER INFORMATION CONTACT: Theresa Jumento using the email above or by telephone at (301) 443–5807.

SUPPLEMENTARY INFORMATION: Many RWHAP clients with incomes between 100–400 percent of the federal poverty level (FPL) who do not have minimum essential coverage may be eligible for an APTC to offset the cost of purchasing a qualified health plan through the Marketplace. The amount of the premium tax credit is based on the individual's income, family size, and the cost of the second-lowest cost silver plan available to them in the Marketplace. If an individual qualifies for a premium tax credit, the individual may choose to have some or all of the estimated premium tax credit paid in advance directly to the insurance company to lower the individual's monthly premium or can wait to get all of the premium tax credit when the individual files a tax return at the end of the year.

Taxpayers will reconcile the APTC when they file their tax returns. Individuals will subtract the total of any APTC they receive during the year from the amount of the premium tax credit calculated on their tax return (*i.e.,* ''actual premium tax credit''). If an individual received APTC that exceeds the actual premium tax credit for which the individual is eligible, the individual will owe that amount back to the IRS.

It is important for RWHAP grantees and subgrantees to convey to clients the importance of reporting accurate income information on their Marketplace application and reporting to the Marketplace any income changes as these changes occur throughout the year. Other changes in circumstances that can affect the amount of an individual's premium tax credit, that should be reported as they occur, include: Marriage, divorce, birth or adoption of a child, other changes to household composition, and gaining or losing eligibility for government-sponsored or employer-sponsored health care coverage. Notifying the Marketplace about changes in circumstances will decrease the likelihood of a significant difference between the APTC payments and the actual premium tax credit. For example, if an individual winds up making more money than estimated on the Marketplace application, the individual could have to pay back some or all of the premium tax credit on their next tax return.

It is possible that, despite RWHAP grantees' and subgrantees' best efforts to encourage clients to report changes in circumstances to the Marketplace during the year, a RWHAP client's actual premium tax credit is less than the APTC resulting in the client owing the difference to the IRS. HRSA is considering allowing RWHAP grantees and subgrantees to use RWHAP funds to pay the IRS any additional income tax liability a client may owe to the IRS solely based on reconciliation of the premium tax credit.

Should such a policy be implemented, grantees and subgrantees would be responsible for establishing and maintaining policies and procedures for coordinating such payments to the IRS since RWHAP grantees and subgrantees are prohibited from making any direct payments to clients. HRSA seeks comment from the public regarding this proposed policy, particularly on whether this policy could be easily implemented by the grantees and subgrantees and what challenges grantees and subgrantees might face in implementing such a policy.

Dated: July 3, 2014.

Mary K. Wakefield,

Administrator.

[FR Doc. 2014–16406 Filed 7–11–14; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; A Generic Submission for Theory Development and Validation (NCI)

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI), National Institutes of Health (NIH), will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the