The estimated burden for this information collection has changed since the previous OMB approval. The current burden is based on the number of actual new notifications received including notifications that were counted previously under the OMB approval for the interim final rule entitled “Permanent Discontinuance or Interruption in Manufacturing of Certain Drug or Biological Products” (80 FR 38915, July 8, 2015) (OMB control number 0910–0699).

Dated: July 16, 2018.
Leslie Kux,
Associate Commissioner for Policy.

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Charter Renewal for the Advisory Commission on Childhood Vaccines

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

ACTION: Notice of charter renewal.

SUMMARY: HHS is hereby giving notice that the Advisory Commission on Childhood Vaccines (ACCV) has been rechartered. The effective date of the renewed charter is July 20, 2018.

FOR FURTHER INFORMATION CONTACT: Narayan Nair, MD, MPH, Executive Secretary, Advisory Commission on Childhood Vaccines, Health Resources and Services Administration, Department of Health and Human Services, Room 08N146B, 5600 Fishers Lane, Rockville, MD 20857; phone: (301) 443–6593; fax: (301) 443–8196; email: nnair@hrsa.gov.

SUPPLEMENTARY INFORMATION: The ACCV was established by section 2119 of the Public Health Service Act (the Act) (42 U.S.C. 300aa–19), as enacted by Public Law (Pub. L.) 99–660, and as subsequently amended, and advises the Secretary of Health and Human Services (the Secretary) on issues related to implementation of the National Vaccine Injury Compensation Program (VICP). Other activities of the ACCV include: Recommending changes in the Vaccine Injury Table at its own initiative or as the result of the filing of a petition; advising the Secretary in implementing section 2127 of the Act regarding the need for childhood vaccination products that result in fewer or no significant adverse reactions; surveying federal, state, and local programs and activities related to gathering information on injuries associated with the administration of childhood vaccines, including the adverse reaction reporting requirements of section 2125(b) of the Act; advising the Secretary on the methods of obtaining, compiling, publishing, and using credible data related to the frequency and severity of adverse reactions associated with childhood vaccines; consulting on the development or revision of Vaccine Information Statements; and recommending to the Director of the National Vaccine Program research related to vaccine injuries which should be conducted to carry out the VICP.

The charter renewal for ACCV was approved on July 20, 2018, which will also stand as the filing date. Renewal of the ACCV charter gives authorization for the Commission to operate until July 20, 2020.

A copy of the ACCV charter is available on the VICP website at: https://www.hrsa.gov/advisory-committees/vaccines/index.html. A copy of the charter also can be obtained by accessing the FACA database that is maintained by the Committee Management Secretariat under the General Services Administration. The website address for the FACA database is http://www.facadatabase.gov/.

Amy P. McNulty,
Acting Director, Division of the Executive Secretariat.

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

NAME OF COMMITTEE: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Resource-Related Research Projects (R24).

TIME: 2:00 p.m. to 3:00 p.m.
AGENDA: To review and evaluate grant applications.
PLACE: National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).
CONTACT: Dharmendar Rathore, Ph.D., Senior Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Room 3C30, National Institutes of Health/NIAID, 5601 Fishers Lane, MSC 9823, Bethesda, MD 20892–9823, 240–669–5058, rathored@mail.nih.gov.

NAME OF COMMITTEE: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Clinical Trials Implementation Cooperative Agreement (U01).
DATE: August 24, 2018.
TIME: 11:00 a.m. to 1:00 p.m.
AGENDA: To review and evaluate grant applications.
PLACE: National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

(Catalogue of Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: July 20, 2018.
Natasha M. Copeland,
Program Analyst, Office of Federal Advisory Committee Policy.

BILLING CODE 410–01–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Housing Opportunity Through Modernization Act of 2016: Final Implementation of Public Housing Income Limit

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Notice.

SUMMARY: The Housing Opportunity Through Modernization Act of 2016 (HOTMA) was signed into law on July 29, 2016. One of the statutory amendments made by HOTMA adds an income limit to the Public Housing program. This notice informs the public of how HUD is setting that income limit and makes the income limit effective, while providing information to public
On November 29, 2016, at 81 FR 85996, HUD published a notice soliciting public input on a proposal to determine the over-income limit by using the very low-income (VLI) level for the applicable area as the baseline and multiplying it by 2.4. Because VLI is preliminarily calculated as 50 percent of the estimated AMI for the family, in most cases this would result in a figure matching 120 percent AMI. However, in areas where the VLI has been adjusted to account for high or low housing costs or to prevent it from being lower than 50 percent of the State non-metro median family income, the final amount would result in an adjusted eligibility income limit, as well.

HUD’s income limits were developed by HUD’s Office of Policy Development and Research and are updated annually. Information about HUD’s income limits and HUD’s methodology for adjusting income limits as part of the income limit calculation can be found at https://www.huduser.gov/portal/datasets/il/il16/index_il2016.html.

This notice finalizes how the over-income limit is determined and informs PHAs how to begin implementing the statutory income limit for public housing. However, this notice does not address how a PHA is to determine the monthly subsidy to use in setting rents for over-income families that the PHA has allowed to remain in public housing. Section 103 of HOTMA requires HUD to issue a regulation on that determination, and HUD will follow this notice with a proposed rule, which will also include guidelines for how PHAs are to set their policies for addressing over-income families after the 2-year grace period has ended. Additionally, this notice does not make effective the requirement to submit the annual report on the number of over-income families and the number of families on the public housing waiting lists.HUD intends to make this reporting requirement effective through a forthcoming notice.

The regulations at 24 CFR 960.261 provide discretion to PHAs to evict or terminate assistance to families whose income exceeds the local low-income limit, except for families with a valid Family Self-Sufficiency (FSS) contract, or families where at least one family member is receiving the Earned Income Disregard benefit. The statutory changes in section 103 of HOTMA do not address the treatment of families whose income exceeds the local low-income limit but is below the applicable over-income limit established in HOTMA. As such, the standards and flexibility provided through the regulations at 24 CFR 960.216 continue to apply for families with incomes above the local low-income limit but below the over-income limit established in this notice.

II. Summary of Comments

In response to the November 29, 2017, notice, HUD received 11 comments. Adjustments

1. Commenters stated that HUD should never adjust the over-income limit downward (below 120 percent AMI), but rather use it as a floor for all areas and only adjust upward for high-cost areas. Others stated that it is necessary to keep as many higher-income families in public housing as possible to subsidize the lower-income families, particularly in light of reduced public housing funding.

HUD Response: HUD disagrees with the suggestion that 120 percent of AMI should be a floor for over-income families. Section 16(a)(5) of the 1937 Act provides discretion to HUD to establish income limits higher or lower than 120 percent of AMI to account for several factors including construction costs, family incomes, vacancy rates, or rental costs. HUD’s methodology considers several of these factors and makes proportional adjustments. Were HUD to establish a floor of 120 percent, residents in localities with higher housing costs would receive disproportionate treatment than those in lower housing cost areas. HUD believes its methodology adequately makes proportional adjustments—both upward and downward—to reflect the factors required by the statute.

HUD also recognizes the concern that higher-income families allow PHAs to more deeply subsidize lower-income families. The statute allows PHAs to continue to house over-income families without providing them subsidy, if the PHA opts to do so. HUD will issue further guidance to PHAs on how to set their over-income policies.

2. Commenters asked that HUD include adjustments based on construction costs and vacancy rates, as those are two cost categories included in the statute but not contemplated in HUD’s proposal. Some stated that HUD should include local vacancy rates in adjusting the income limit. Others also asked that HUD should include factors for increasing the limit for larger families and should consider family composition so as not to penalize families with an adult child beginning to work who will soon leave the household.

HUD Response: HUD’s methodology takes into account local housing market factors such as construction costs and vacancy rates by using the metropolitan-
may terminate or raise rents on that household. If a PHA becomes aware, through an annual reexamination or an interim reexamination for an increase in income, that a family has reached the over-income limit, that will be the point in time for which the two-year clock will start.

**Caps on Changes**

Commenters asked if HUD was going to impose a 5 percent cap on changes to the over-income limit that would be on top of caps on changes already in place related to program income limits and, if so, asked HUD to provide additional justification for and examples of this policy. Others stated that HUD should eliminate the 5 percent ceiling for increase in the very low-income limit to account for expensive rental markets, but only for the purpose of determining the over-income limits.

HUD Response: HUD does not intend to impose additional adjustments beyond those adjustments made by HUD to the very low-income limits, which includes a 5 percent cap on annual changes to such income limits. Specifically, HUD’s current cap on income limit increases is the greater of 5 percent or twice the increase in national median income growth. Because there is a two-year process to declare a family ineligible for public housing subsidy under section 16(a)(5) of the 1937 Act, large increases to the over-income limit for higher rental markets may result in families who are over-income in one year not being considered over-income in the second year as the over-income limit is adjusted upward in subsequent years.

**Exemptions**

1. Commenters pointed out that the notice states that PHAs housing families with incomes over 120 percent AMI under section 3(a)(5) of the 1937 Act are exempt from the income limit in HOTMA, but that the statutory provision was directed at individual families and did not seem to encompass the entire PHA.

HUD Response: Section 3(a)(5) of the 1937 Act permits PHAs operating fewer than 250 units that were not admitted under the circumstances included in section 3(a)(5) will be subject to the over-income limit established in HOTMA and made effective by this notice.

2. Commenters recommended that HUD include exemptions from the over-income limit for vulnerable populations, including seniors and disabled individuals and those that face specific financial constraints (e.g., large families). Some stated that HUD should provide an explicit exemption to over-income limits for families participating in self-sufficiency programs. Commenters also stated that PHAs should be required to consider whether evicting a family for having an income that exceeds the over-income limit would create a hardship (such as for a household member caring for a relative close to the home or if a household member is ill). Others asked that HUD allow PHAs the ability to apply for an exception to the over-income limit entirely, based on the local market and conditions.

HUD Response: HUD does not have the authority under HOTMA to permit PHAs to exempt any public housing family from the over-income limitation established by HOTMA. However, PHAs are required to establish policies for continued occupancy in public housing. Through the development of those policies, a PHA is able to consider specific circumstances in which they would provide for flexibility in the administration of over-income requirements, provided such policies are in compliance with the 1937 Act and all applicable fair housing requirements. PHAs are subject to, among other fair housing and civil rights authorities, Section 504 of the Rehabilitation Act (Section 504), the Fair Housing Act, and Title II of the Americans with Disabilities Act (ADA), which include, among other requirements, the obligation to grant reasonable accommodations that may be necessary for persons with disabilities.

**Fair Market Rents (FMRs)**

1. Commenters stated that new guidance on small area fair market rents (SAFMRs) might make calculation of income thresholds administratively cumbersome for PHAs.

HUD Response: For each locality, HUD will publish over-income limits annually. Therefore, there is no associated burden on PHAs to calculate the over-income limits.

2. Commenters stated that FMRs do not accurately reflect rental market prices and that they are too volatile year-to-year, and are therefore
inappropriate to use when determining very low-incomes.

HUD Response: FMRs are HUD’s best estimates of gross rents paid in each locality for which FMRs are published. Therefore, FMRs represent the best known, consistently calculated measurement of housing costs across the country. Furthermore, as required by section 107 of HOTMA, HUD will publish annual notices of proposed material changes in the methodology for estimating FMRs for public comment. The Federal Register notice announcing proposed material changes in the methodology for estimating FY 2018 FMRs, published June 26, 2017, at 82 FR 24377, contains specific proposals to limit the year-to-year volatility in FMR estimates that are concerning to the commenters.

3. Commenters stated that HUD should consider additional changes to the VLI FMR determination only for the purpose of determining the income limit. The commenters asked that HUD increase the annualized two-bedroom FMR from 85 percent to 100 percent to follow the expectation that FMRs allow access to 40–50 percent of the rental market in any given area. The commenters also suggested that HUD change the VLI limit from 35 percent to 30 percent.

HUD Response: The current high housing cost adjustment is that the 4-person very low-income limit is increased if the limit would otherwise be less than the amount at which 35 percent of it equals 85 percent of the annualized two-bedroom 40th percentile rent in the area. This adjusts income limits upward for areas where rental housing costs are unusually high in relation to the median income. The high housing cost adjustment is not meant to mimic programmatic requirements but to increase income limits in areas where the housing cost relative to incomes are extreme high.

Mixed Income Developments

1. Commenters stated that a barrier to implementing the income limit is that many public housing developments use Low-Income Housing Tax Credits, and the tax credit program does not allow PHAs to terminate households from affordable housing programs when household income increases over time. They asked that HUD and the Department of Treasury more closely align their policies.

HUD Response: HUD’s and Treasury’s policies are aligned when it comes to the treatment of over-income families. HUD regulations protect initially qualifying households from being displaced as their income rises, provided that their income remains below 80 percent AMI, which is a statutorily mandated public housing income limit. Similarly, under Treasury’s regulations, the fact that a family is over-income under the Tax Credit program (which generally has a lower income limit than the public housing program) does not by itself amount to good cause for lease termination, although the over-income designation may affect the tax credits.

2. Commenters urged HUD to consider implementing a mechanism where public housing tenants in a mixed-finance building can switch to a market unit if the family’s income exceeds the applicable over-income limit (freeing up an ACC unit), but allowing them to easily access a subsidized unit again should the family’s income drop again.

HUD Response: HUD appreciates the comment and will take it in consideration during the rulemaking stage, which will address how a PHA determines its policies on dealing with over-income families after the 2-year grace period.

Over-Income Tenants

1. Commenters asked whether the decision to require an over-income family to vacate the unit or charge them the greater of FMR or the subsidy amount is a decision that a PHA can make on a unit-by-unit basis or whether it must be an agency-wide policy decision.

HUD Response: As with any other discretion provided to PHAs, PHAs are required to develop policies in their Admissions and Continued Occupancy Policies (ACOP) regarding when families will be permitted to remain in the unit and pay an alternative rent or be terminated. All such decisions must be consistent with applicable non-discrimination and other fair housing requirements. HUD will further address this issue in the rulemaking stage.

2. Commenters stated that the assumption in HOTMA that families with incomes exceeding the applicable over-income limit will be able to find housing in the private market is unrealistic in cities with very expensive housing markets.

HUD Response: HUD recognizes the concern expressed by this commenter, which is the reason that HUD chose to exercise its authority to establish higher over-income limits for such cities.

Utility Allowance

Commenters asked whether, when charging over-income families FMR, the PHA would be allowed to reduce the FMR rent for the utility allowance.

HUD Response: This question is outside of the scope of this notice. In a forthcoming rulemaking, HUD will address the alternative rent options. HUD will specifically address the implications of utility allowances in that rulemaking.

Reports to HUD

Commenters asked for additional guidance on what the report on over-income families (required by HOTMA) would look like.

HUD Response: Under the new requirements in the 1937 Act, PHAs will need to report annually on the number of over-income families residing in public housing and the number of families on the admissions waiting lists for public housing at the end of that year. The report will be in a format specified by HUD in the future.

Temporary Income Decreases

Commenters asked if the two-year over-income clock is restarted if a family has a temporary decrease in income.

HUD Response: If a family requests an interim reexamination, which then demonstrates that a family’s income has dropped below the over-income limit, the family is no longer considered over-income. If a PHA becomes aware, through a subsequent annual reexamination or an interim reexamination that the family’s income has increased to an amount that exceeds the over-income limit, the family would begin a new two-year clock.

Other Questions

1. Commenters asked for additional clarity on how HUD will determine rent structures for over-income families that the PHA allows to stay in their unit.

HUD Response: This question is outside of the scope of this notice. In a forthcoming rulemaking, HUD will address the alternative rent options.

2. Commenters stated that HUD should explicitly require compliance with fair housing and civil rights laws in its implementing regulations.

HUD Response: HUD appreciates the concerns regarding fair housing and civil rights laws. PHAs, in the administration of their public housing program, are always required to comply with fair housing and civil rights laws and their implementing regulations. HUD will consider whether any reference to fair housing and civil rights laws and regulations in forthcoming program regulations would be particularly helpful during the rulemaking stage.
3. Commenters stated that HUD should try to streamline its over-income policies across multiple HUD programs. HUD Response: HUD appreciates the suggestion. However, this comment is outside of the scope of this notice. In many cases, over-income policies vary by program due to program design and funding structures, so HUD is limited in its ability to align such requirements.

III. Implementation

Through this notice, HUD is announcing that as of the date this notice is effective, HUD will be following the provisions of section 16(a)(5) of the 1937 Act, as added by section 103 of HOTMA, using the method of determining the over-income limit as described in the November 29, 2016, notice. PHAs must update their Admissions and Continued Occupancy Policies (ACOP) to implement these changes. Such policies must include the imposition of an over-income limit in the programs, all instances of when the two-year timeframe begins, and notification requirements. If the implementation of this provision requires a significant amendment to a PHA’s annual plan, a PHA should immediately take steps to complete the significant amendment process in order to effectuate the policy change. PHAs must complete all relevant policy and PHA plan changes no later than 6 months after the effective date of this notice.

Once a PHA has completed updates to its ACOP and, if necessary, its PHA plan, when the PHA becomes aware, through an annual reexamination or an interim reexamination for an increase in income, that a family’s income exceeds the applicable income limit, the PHA must, per section 16(a)(5) of the 1937 Act, document that the family exceeds the threshold to compare with the family’s income a year later.

If, one year after the initial determination by the PHA that a family’s income exceeds the over-income limit, the family’s income continues to exceed the over-income limit, the PHA must, as required by section 16(a)(5) of the 1937 Act, provide written notification to the family that their income has exceeded the over-income limit for one year, and that if the family’s income continues to exceed the over-income limit for the next 12 consecutive months, the family will be subject to either a higher rent or termination based on the PHA’s policies. If, however, a PHA discovers through an annual or interim reexamination that a previously over-income family has income that is now below the over-income limit, the family is no longer subject to these provisions. The family is entitled to a new 2-year grace period if the family’s income once again exceeds the over-income limit.

HLD will provide additional information on where to locate applicable income limits, guidelines for PHAs to set alternative rents for over-income families, and any other guidance regarding this provision in a forthcoming notice.

IV. Environmental Impact Certification

This notice involves statutorily required income limits and exclusions with regard to eligibility for or calculation of HUD housing assistance or rental assistance which does not constitute a development decision affecting the physical condition of specific project areas or building sites. Accordingly, under 24 CFR 50.19(c)(6), this notice is categorically excluded from environmental review under the National Environmental Policy Act of 1969 (42 U.S.C. 4321).

Dated: July 9, 2018.

Danielle Bastarache,
Deputy Assistant Secretary for Public and Indian Housing.

[FR Doc. 2018-15941 Filed 7-25-18; 8:45 am]

BILLING CODE 4210–67–P

INTERNATIONAL TRADE COMMISSION

Notice of Receipt of Complaint; Solicitation of Comments Relating to the Public Interest


ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has received a complaint entitled Certain Lithography Machines and Systems and Components Thereof (II), DN 3329; the Commission is soliciting comments on any public interest issues raised by the complaint or complainant’s filing pursuant to the Commission’s Rules of Practice and Procedure.


General information concerning the Commission may also be obtained by accessing its internet server at United States International Trade Commission (USITC) at https://www.usitc.gov. The public record for this investigation may be viewed on the Commission’s Electronic Document Information System (EDIS) at https://edis.usitc.gov. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission’s TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission has received a complaint and a submission pursuant to § 210.8(b) of the Commission’s Rules of Practice and Procedure filed on behalf of Carl Zeiss SMT GmbH on July 20, 2018. The complaint alleges violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain lithography machines and systems and components thereof (II). The complaint names as respondents: Nikon Corporation of Japan; Nikon Research Corporation of America of Belmont, CA; and Nikon Precision Inc. of Belmont, CA. The complainant requests that the Commission issue a limited exclusion order, cease and desist orders and impose a bond upon respondents’ alleged infringing articles during the 60-day Presidential review period pursuant to 19 U.S.C. 1337(j).

Proposed respondents, other interested parties, and members of the public are invited to file comments, not to exceed five (5) pages in length, inclusive of attachments, on any public interest issues raised by the complaint or §210.8(b) filing. Comments should address whether issuance of the relief specifically requested by the complainant in this investigation would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) Explain how the articles potentially subject to the requested remedial orders are used in the United States;

(ii) Identify any public health, safety, or welfare concerns in the United States;