stakeholders (*e.g.,* physicians, pharmacies, outsourcing facilities). Several comments were submitted concerning the implications of the policies described in the revised draft guidance for physicians who compound or repackage drug products or mix, dilute, or repackage FDA-licensed biological products in their offices. In response to these comments, FDA made changes, where appropriate, in the final guidance. The changes include adding a footnote to state that ''processing of beta-lactams'' does not refer to mixing, reconstituting, or other such acts that are performed in accordance with the directions contained in FDA-approved labeling; adding a footnote to reflect that the FDA does not generally object to rapid movement temporary blocking or disruption of first air in the ISO 5 area when necessary for the safe handling of radiopharmaceuticals to minimize radiation exposure, and revising the language in a footnote concerning the scope of physician compounding or repackaging activities to state that FDA generally does not intend to take action under section 501(a)(2)(A) of the FD&C Act against a physician who is compounding a drug product, repackaging an FDA-approved drug product, or who is mixing, diluting, or repackaging an FDA-licensed biological product, provided that it occurs in the physician's office for in-office administration to the physician's patients; and adding recommendations encouraging compounders to use risk evaluation strategies and risk management tools to develop appropriate controls necessary to prevent the occurrence of insanitary conditions at their facilities. In addition, editorial changes were made to the guidance for clarity.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Insanitary Conditions at Compounding Facilities.'' The examples described in the final guidance do not constitute an exhaustive list of conditions FDA considers to be insanitary conditions. 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.

II. Paperwork Reduction Act of 1995

This guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required.

However, this guidance refers to a previously approved FDA collection of information. This collection of information is subject to review by OMB under the PRA. The collections of information in 21 CFR part 7 pertaining to FDA's recall regulations have been approved under OMB control number 0910–0249.

III. Electronic Access

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

Dated: November 3, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–24807 Filed 11–6–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Request for Comments on Draft Recommendation Statement on Preventing Obesity in Midlife Women, as Part of the HRSA-Supported Women's Preventive Services Guidelines

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

ACTION: Notice.

SUMMARY: This notice seeks public comments on a draft recommendation statement on preventing obesity in midlife women, as part of the HRSA-supported Women's Preventive Services Guidelines (''Guidelines''), through a national cooperative agreement, the Women's Preventive Services Initiative (WPSI). The WPSI recommends counseling midlife women, aged 40 to 60 years, with normal or overweight BMI (18.5–29.9 kg/m2) to maintain weight or limit weight gain to prevent obesity. Counseling may include individualized discussion of healthy eating and physical activity. Under Section 2713 of the Public Health Service Act, as added by the Patient Protection and Affordable Care Act, non-grandfathered group health plans and non-grandfathered group and individual health insurance issuers must include coverage, without cost sharing, for certain preventive services under that section, including those provided for in the Guidelines.

DATES: Members of the public are invited to provide written comments no later than December 9, 2020. All comments received on or before this date will be reviewed and considered by the WPSI Multidisciplinary Steering Committee, and provided to HRSA for further consideration in determining the recommended updates that it will support.

ADDRESSES: Members of the public interested in providing comments can do so by accessing the initiative's web page at *https://www.womenspreventivehealth.org/.*

FOR FURTHER INFORMATION CONTACT: Kimberly Sherman, HRSA, Maternal and Child Health Bureau, telephone (301) 443–8283 or email: *wellwomancare@hrsa.gov.*

SUPPLEMENTARY INFORMATION: The HRSA-supported Women's Preventive Services Guidelines were originally established in 2011 based on recommendations from an HHS commissioned study by the Institute of Medicine, now known as the National Academy of Medicine (NAM). Since then, there have been advancements in science and gaps identified in the existing guidelines, including a greater emphasis on practice-based clinical considerations. HRSA awarded a 5-year cooperative agreement in March 2016 (HRSA–16–057) to convene a coalition representing clinicians, academics, and consumer-focused health professional organizations to conduct a rigorous review of current scientific evidence and recommend updates to existing guidelines, in accordance with the framework created by the NAM Clinical Practice Guidelines We Can Trust expert committee. The American College of Obstetricians and Gynecologists was awarded the cooperative agreement and formed an expert panel called the Women's Preventive Services Initiative.

Under section 2713 of the Public Health Service Act, non-grandfathered group health plans and issuers of non-grandfathered group and individual health insurance coverage are required to cover specified preventive services without a copayment, coinsurance, deductible, or other cost sharing, including preventive care and screenings for women as provided for in comprehensive guidelines supported by HRSA for this purpose. Non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual coverage are required to provide coverage without cost sharing for

preventive services listed in the updated HRSA-supported Guidelines.

Under HRSA's cooperative agreement with the American College of Obstetricians and Gynecologists, the WPSI administers processes which assure public input and transparency, as well as participation by patient and consumer representatives, in the development of these Guidelines.

Thomas J. Engels,

Administrator.

[FR Doc. 2020–24819 Filed 11–6–20; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Advisory Council on Alzheimer's Research, Care, and Services; Meeting

AGENCY: Assistant Secretary for Planning and Evaluation, HHS.

ACTION: Notice of meeting.

SUMMARY: This notice announces the public meeting of the Advisory Council on Alzheimer's Research, Care, and Services (Advisory Council). The Advisory Council provides advice on how to prevent or reduce the burden of Alzheimer's disease and related dementias on people with the disease and their caregivers. The Advisory Council will next meet on Monday, November 9, and Tuesday, November 10. On November 9, federal representatives will provide updates on efforts to address Alzheimer's disease since January and a panel will present the results of two VA programs, STAR–VA and REACH–VA. On November 10, an invited panel will discuss past and current initiatives to expand access to long-term services and supports.

DATES: The meeting will be held on November 9 from 1:00 p.m. to 4:00 p.m. EST and November 10 from 1:00 p.m. to 4:00 p.m. EST.

ADDRESSES: The meeting will be virtual and stream live at *http://www.hhs.gov/live.*

Comments: Time is allocated on the agenda to hear public comments from 3:30 p.m. to 4:00 p.m. The time for oral comments will be limited to two (2) minutes per individual. In order to provide a public comment, please register by emailing your name to *napa@hhs.gov* by Thursday, November 5. Registered commenters will receive both a dial-in number and a link to join the meeting virtually; individuals will have the choice to either join virtually via the link, or to call in only by using the dial-in number. Note: There may be a 30–45 second delay in the livestream video presentation of the conference. For this reason, if you have pre-registered to submit a public comment, it is important to connect to the meeting by 3:15 p.m. to ensure that you do not miss your name and allotted time when called. If you miss your name and allotted time to speak, you may not be able to make your public comment. All participant audio lines will be muted for the duration of the meeting and only unmuted by the Host at the time of the participant's public comment. Should you have questions during the session email *napa@hhs.gov* and someone will respond to your message as quickly as possible.

In order to ensure accuracy, please submit a written copy of oral comments for the record by emailing *napa@hhs.gov* by Thursday, November 12. These comments will be shared on the website and reflected in the meeting minutes.

In lieu of oral comments, formal written comments may be submitted for the record by Tuesday, November 10 to Helen Lamont, Ph.D., OASPE, 200 Independence Avenue SW, Room 424E, Washington, DC 20201. Comments may also be sent to *napa@hhs.gov.* Those submitting written comments should identify themselves and any relevant organizational affiliations.

FOR FURTHER INFORMATION CONTACT: Helen Lamont, 202–260–6075, *helen.lamont@hhs.gov.* Note: The meeting will be available to the public live at *www.hhs.gov/live.*

SUPPLEMENTARY INFORMATION: Notice of these meetings is given under the Federal Advisory Committee Act (5 U.S.C. App. 2, section 10(a)(1) and (a)(2)). Topics of the Meeting: An invited panel will present on emergency preparedness for people with dementia with a special focus on the COVID–19 pandemic. The chairs of the subcommittees (Research, Clinical Care, and Long-Term Services and Supports) will present recommendations for adoption by the full Advisory Council.

Procedure and Agenda: The meeting will be webcast at *www.hhs.gov/live* and video recordings will be added to the National Alzheimer's Project Act website when available, after the meeting.

Authority: 42 U.S.C. 11225; Section 2(e)(3) of the National Alzheimer's Project Act. The panel is governed by provisions of Public Law 92–463, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

Dated: October 13, 2020.

Brenda Destro,

Deputy Assistant Secretary for Planning and Evaluation, Office of Human Services Policy.

[FR Doc. 2020–24818 Filed 11–6–20; 8:45 am]

BILLING CODE 4150–05–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA–2020–0033; OMB No. 1660–0026]

Agency Information Collection Activities: Proposed Collection; Comment Request; State Administrative Plan for the Hazard Mitigation Grant Program

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: 60 day notice and request for comments.

SUMMARY: The Federal Emergency Management Agency, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public to take this opportunity to comment on an extension, without change, of a currently approved information collection. In accordance with the Paperwork Reduction Act of 1995, this notice seeks comments concerning the State Administrative Plan for the procedural guide that details how the State will administer the Hazard Mitigation Grant Program (HMGP).

DATES: Comments must be submitted on or before January 8, 2021.

ADDRESSES: Submit comments at *www.regulations.gov* under Docket ID FEMA–2020–0033. Follow the instructions for submitting comments.

All submissions received must include the agency name and Docket ID, and will be posted, without change, to the Federal eRulemaking Portal at *http://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to read the Privacy and Security Notice that is available via a link on the homepage of *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Roselyn Brown-Frei, Section Chief, Hazard Mitigation Division, Federal Insurance and Mitigation Administration, FEMA, *roselyn.brown-frei@fema.dhs.gov,* 202–924–7198. You may contact the Information Management Division for copies of the proposed collection of information at