obtained and comments may be forwarded by emailing *infocollection@acf.hhs.gov.* Alternatively, copies can also be obtained by writing to the Administration for Children and Families, Office of Planning, Research, and Evaluation (OPRE), 330 C Street SW, Washington, DC 20201, Attn: ACF Reports Clearance Officer. All requests, emailed or written, should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: A State Plan is a required comprehensive narrative description of the nature and scope of a state's or Replacement Designee's (RD) Refugee Resettlement Program and provides assurances that the program will be administered in conformity with the specific requirements stipulated in 45 CFR 400.4–400.9. The State Plan must include all applicable state or RD procedures, designations, and certifications for each requirement as well as supporting documentation. The plan assures ORR that the state or RD is capable of administering refugee assistance and coordinating employment and other social services for eligible caseloads in conformity with specific requirements.

Changes proposed to the previously approved State Plan for Grants to States for Refugee Resettlement information collection are described below. ORR is proposing:

- Streamlining/formatting changes to multiple sections of the form including technical corrections to regulatory citations and removing a number of requirements related to the now obsolete Wilson-Fish Alternative Program (superseded by the Wilson-Fish TANF Coordination Program, which will have its own separate reporting requirements).
- adding a number of requirements related to Replacement Designees (RDs) to ensure that they are administering the Refugee Resettlement Program with transparency and equity and to the same standard as a state, including quarterly consultation process, Refugee Medical Assistance, Unaccompanied Refugee Minors (URM), and emergency planning to ensure ORR populations receive all necessary information and services to the extent possible.
- requesting additional information related to the Refugee Support Services (RSS) program; ORR's current template does not provide sufficient detailed information for ORR to ascertain how a grantee intends to provide RSS services to its client base.
- improving the URM section to correct inefficiencies, eliminate unnecessary items, and address the needs of victims of trafficking and Special Immigrant Juveniles now eligible for the URM program. In particular, ORR is soliciting states' and RDs' plans for placing children referred by ORR and ensuring alignment with federal capacity priorities.

Respondents: State agencies and RDs under 45 CFR 400.301(c) administering or supervising the administration of programs.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
State Plan for Grants to States for Refugee Resettlement	62	3	18	3,348	1,116

Estimated Total Annual Burden Hours: 1,116.

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: 8 U.S.C. 1522 of the Immigration and Nationality Act (the Act) [Title IV, Sec. 412 of the Act] for each state agency requesting federal funding for refugee resettlement under 8 U.S.C. 524 [Title IV, Sec. 414 of the Act].

Mary Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2020–24777 Filed 11–6–20; 8:45 am]

BILLING CODE 4184–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–2268]

Insanitary Conditions at Compounding Facilities; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''Insanitary Conditions at Compounding Facilities.'' Drug products compounded under insanitary conditions could become contaminated and cause serious adverse events, including death, in patients. FDA is issuing this guidance to help compounding facilities and State regulatory agencies understand some examples of what FDA considers to be insanitary conditions that could cause a drug to become contaminated or rendered injurious to health. These examples are intended to help compounding facilities take action to prevent the occurrence of these and other insanitary conditions, as well as to implement appropriate corrective actions when such conditions already exist.

DATES: The announcement of the guidance is published in the **Federal Register** on November 9, 2020.

ADDRESSES: You may submit either electronic or written comments on Agency guidances on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such

as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2016–D–2268 for ''Insanitary Conditions at Compounding Facilities.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the final guidance document.

FOR FURTHER INFORMATION CONTACT: Jinhee Lee, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5225, Silver Spring, MD 20993, 301–796–6770.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Insanitary Conditions at Compounding Facilities.'' [1] Under section 501(a)(2)(A) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 351(a)(2)(A)), a drug is adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth or rendered injurious to health. Drug products compounded under insanitary conditions could become contaminated and cause serious adverse events, including death, in patients. Although sections 503A and 503B of the FD&C Act (21 U.S.C. 353a and 353b) provide exemptions for compounded drugs from specified provisions of the FD&C Act if certain conditions are met, neither section provides an exemption from section 501(a)(2)(A) of the FD&C Act. Any drug that is prepared, packed, or held under insanitary conditions is deemed to be adulterated under the FD&C Act, including drugs produced by a compounding facility.

Since the 2012 fungal meningitis outbreak associated with injectable drug products that a pharmacy compounded and shipped to patients and healthcare providers across the country, the Agency has identified insanitary conditions at many of the compounding facilities that it has inspected, and numerous compounders have voluntarily recalled drug products intended to be sterile and also temporarily or permanently ceased sterile operations because of these findings. Generally, State licensed pharmacies do not register with FDA unless they are outsourcing facilities. As a result, the Agency is often not aware of these pharmacies, their conditions and practices, and potential problems with the quality of their drug products. Although FDA does conduct some surveillance inspections, FDA does not inspect the vast majority of State licensed pharmacies in the United States unless, for example, FDA receives a complaint, such as a report of a serious adverse event or product quality issue. FDA does, however, routinely inspect outsourcing facilities registered with FDA.[2] Regardless of whether a facility is routinely inspected by FDA, it is critical that both State licensed pharmacies and outsourcing facilities identify and remediate, as well as work to prevent, the occurrence of insanitary conditions within their facilities. Because insanitary conditions can result in drug contamination and patient injury, corrective action should be implemented expeditiously in order to prevent the recurrence of such conditions.

In the **Federal Register** of September 26, 2018 (83 FR 48631), FDA announced the availability of a revised draft guidance for industry entitled ''Insanitary Conditions at Compounding Facilities.'' The revised draft guidance provided examples of conditions that the Agency has observed at compounding facilities it has inspected and considers to be insanitary conditions. The revised draft guidance also described corrective actions that compounding facilities should take when they identify such conditions and the regulatory actions FDA may take in response to identified insanitary conditions.

FDA received comments on the revised draft guidance from various

[1] For the purpose of this guidance, FDA regards *compounding facilities* as pharmacies, Federal facilities, and outsourcing facilities that compound or repackage drugs, or that mix, dilute, or repackage biological products.

[2] See section 503B(b)(4) of the FD&C Act.

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