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, 240–402–7500.

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

Submit written requests for single copies of this 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; or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, 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 guidance document.

FOR FURTHER INFORMATION CONTACT: Michail Alterman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4245, Silver Spring, MD 20993, 240–402–9355, or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''CMC Postapproval Manufacturing Changes for Specified Biological Products To Be Documented in Annual Reports.'' Applicants must notify FDA of a change to an approved BLA in accordance with all statutory and regulatory requirements—including section 506A of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 356a) and § 601.12 (21 CFR 601.12). Section 506A of the FD&C Act provides requirements for making and reporting manufacturing changes to an approved application or license and for distributing a drug made with such changes. Under § 601.12, each postapproval change in the product, production process, quality controls, equipment, facilities, or responsible personnel established in an approved BLA is categorized into one of three reporting categories:

- *Major change:* Applicants must submit and receive FDA approval of a supplement to the BLA before the product produced with the manufacturing change is distributed.
- *Moderate change:* Applicants must submit a supplement at least 30 days before the product is distributed or, in some cases, the product may be distributed immediately upon FDA's receipt of the supplement.
- *Minor change:* Applicants may proceed with the change but must notify FDA of the change in an annual report.

This guidance provides recommendations for reporting certain changes in an annual report. It discusses the contents of an annual report notification and lists examples of postapproval manufacturing changes for BLAs that FDA generally considers to have a minimal potential to have an adverse effect on the identity, strength, quality, purity, or potency of the product as they may relate to the safety or effectiveness of the product.

This guidance finalizes the draft guidance of the same title issued on August 9, 2017 (82 FR 37232) in the **Federal Register**. FDA considered comments received on the draft guidance as the guidance was finalized. Based on comments received, FDA updated the guidance with additional manufacturing examples and made editorial changes to improve 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 ''CMC Postapproval Manufacturing Changes for Specified Biological Products To Be Documented in Annual Reports.'' 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

While this guidance contains no collection of information, it does refer to previously approved FDA collections 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 for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR 601.12 have been approved under OMB control number 0910–0338; and the collections of information in 21 CFR parts 210 and 211 have been approved under OMB control number 0910–0139.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: December 6, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–26734 Filed 12–9–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Additional Comment Period for Updated HRSA-Supported Women's Preventive Services Guidelines Statement on Breastfeeding Services and Supplies

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

ACTION: Notice.

SUMMARY: On August 20, 2021, HRSA published a notice soliciting public comments regarding proposed updated draft recommendations to the HRSA-Supported Women's Preventive Services Guidelines (Guidelines) in the areas of Well-Women Preventive Visits, Counseling for Sexually Transmitted Infections, and Breastfeeding Services and Supplies, which, when accepted by HRSA, are required to be covered without cost-sharing by certain health insurance issuers under the Public Health Service Act. The updated draft recommendation statements were developed through a national cooperative agreement, the Women's Preventive Services Initiative (WPSI), by

the American College of Obstetricians and Gynecologists (ACOG). Since the publication of that notice, WPSI has further updated its recommendation statement on Breastfeeding Services and Supplies. HRSA encourages members of the public to review this revised updated recommendation statement and provide comments for consideration.

DATES: Members of the public are invited to provide written comments no later than December 20, 2021. All comments received on or before this date will be reviewed and considered by the WPSI Multidisciplinary Steering Committee.

ADDRESSES: Members of the public interested in providing comments on the draft recommendation statements 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, email: *wellwomancare@hrsa.gov.*

SUPPLEMENTARY INFORMATION: HRSA established the Guidelines in 2011 based on a study and recommendations by the Institute of Medicine, now known as the National Academy of Medicine, developed under a contract with the Department of Health and Human Services. Under section 1001(5) of the Patient Protection and Affordable Care Act, Public Law 111–148, which added section 2713 to the Public Health Service Act, 42 U.S.C. 300gg–13, the preventive care and screenings set forth in the Guidelines are required to be covered without cost-sharing by certain health insurance issuers. Since 2011, there have been advancements in science and gaps identified in these guidelines, including a greater emphasis on practice-based clinical considerations. Accordingly, since March 2016, HRSA has supported cooperative agreements with ACOG to convene a coalition representing clinicians, academics, and consumer-focused health professional organizations to conduct a rigorous review of current scientific evidence and make recommendations to HRSA regarding updates to the Guidelines to improve adult women's health across the lifespan. HRSA then decides whether to support, in whole or in part, the recommended updates to the Guidelines. Under the cooperative agreement, ACOG formed WPSI, consisting of an Advisory Panel and two expert committees, the Multidisciplinary Steering Committee (MSC) and the Dissemination and Implementation Steering Committee (DISC), which are comprised of a broad coalition of organizational representatives who are experts in disease prevention and women's health issues. Through oversight by the Advisory Panel, MSC supports the development and implementation of the Guidelines through the review of existing evidence and recommendation development. Specifically, the MSC examines the evidence to develop new and update existing recommendations for women's preventive services. DISC takes the HRSA-approved recommendations, developed by the MSC, and works to disseminate them through the development of implementation tools and resources for both patients and practitioners.

In March 2021, ACOG engaged in a process to consider and review new information and evidence to determine whether to recommend updates to the Guidelines. ACOG bases its recommended updates to the Guidelines on review and synthesis of existing clinical guidelines and new scientific evidence, following the National Academy of Medicine standards for establishing foundations for and rating strengths of recommendations, articulation of recommendations, as well as external reviews. Additionally, ACOG incorporates processes to assure opportunity for public comment, including participation by patients and consumers, in the development of the updated Guideline recommendations.

This notice solicits comments from the public on a revised draft recommendation statement on Breastfeeding Supplies and Services. The updated draft recommendation statement that was published on August 20, 2021 and the revised recommendation statement that HRSA recently received from ACOG are provided below. WPSI will consider and, as necessary, incorporate additional public comment in its recommendation statement. HRSA will then decide whether to support, in whole or in part, the recommended updates to the Guidelines.

Clinical Recommendation Statement as Published on August 20, 2021

The MSC updated clinical recommendation included consultative services to optimize successful initiation and maintenance of breastfeeding: ''The WPSI recommends comprehensive lactation support services (including consultation, counseling, education, and breastfeeding equipment and supplies) during the antenatal, perinatal, and postpartum periods to optimize the successful initiation and maintenance of breastfeeding.''

Revised Clinical Recommendation Statement

The MSC has made two further updates to the clinical recommendation statement for breastfeeding. The first addresses provider type in the provision of breastfeeding services to reflect that breastfeeding education can be provided by clinicians and through peer support services. The second update moves a paragraph on breastfeeding equipment and supplies from the implementation section of the guideline into the clinical recommendation component, making it a substantive addition to the Guidelines with corresponding effect under Section 2713. As revised, the clinical recommendation statement provides: ''The WPSI recommends comprehensive lactation support services (including consultation; counseling; education by clinicians and peer support services; and breastfeeding equipment and supplies) during the antenatal, perinatal, and postpartum periods to optimize the successful initiation and maintenance of breastfeeding. Breastfeeding equipment and supplies include, but are not limited to, double electric breast pumps (including pump parts and maintenance) and breast milk storage supplies. Access to double electric pumps should be a priority to optimize breastfeeding and should not be predicated on prior failure of a manual pump. Breastfeeding equipment may also include equipment and supplies as clinically indicated to support dyads with breastfeeding difficulties and those who need additional services.''

Members of the public can view the complete revised updated draft recommendation statement by accessing the initiative's web page at *https://www.womenspreventivehealth.org/.*

Diana Espinosa,

Acting Administrator.

[FR Doc. 2021–26700 Filed 12–9–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–NEW]

Agency Father Generic Information Collection Request. 30-Day Public Comment Request

AGENCY: Office of the Secretary, Health and Human Service, HHS.

ACTION: Notice and request for comments. Office of the Assistant Secretary for Public Affairs is requesting