www.regulations.gov. Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number: ____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at website address at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–10637 Marketplace Operations
CMS–10501 Healthcare Fraud Prevention Partnership (HFPP) Data Sharing and Information Exchange

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Marketplace Operations; *Use:* The data collections and third-party disclosure requirements will assist HHS in determining Exchange compliance with Federal standards and monitoring QHP issuers in FFEs for compliance with Federal QHP issuer standards. The data collection will also assist HHS in monitoring Web-brokers for compliance with Federal Web-broker standards. The data collected by health insurance issuers and Exchanges will help to inform HHS, Exchanges, and health insurance issuers as to the participation of individuals, employers, and employees in the individual Exchange, the SHOP, and the premium stabilization programs. *Form Number:* CMS–10637 (OMB control number 0938–1353); *Frequency:* Annually; *Affected Public:* Private sector (Business or other for-profits); *Number of Respondents:* 3,902; *Total Annual Responses:* 3,902; *Total Annual Hours:* 2,336,190. (For policy questions regarding this collection contact: Nikolas Berkobien at 301–492–4400.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Healthcare Fraud Prevention Partnership (HFPP) Data Sharing and Information Exchange; *Use:* Section 1128C(a)(2) of the Social Security Act (42 U.S.C. 1320a–7c(a)(2)) authorizes the Secretary and the Attorney General to consult, and arrange for the sharing of data with, representatives of health plans for purposes of establishing a Fraud and Abuse Control Program as specified in Section 1128(C)(a)(1) of the Social Security Act. The result of this authority has been the establishment of the HFPP. The HFPP was officially established by a Charter in the fall of 2012 and signed by HHS Secretary Sibelius and US Attorney General Holder. In December 2020, President Trump signed into law H.R.133—Consolidated Appropriations Act, 2021, which amended Section 1128C(a) of the Social Security Act (42 U.S.C. 1320a–7c(a)) providing explicit statutory authority for the Healthcare Fraud Prevention Partnership including the potential expansion of the public-private partnership analyses.

Data sharing within the HFPP primarily focuses on conducting studies for the purpose of combatting fraud, waste, and abuse. These studies are intended to target specific vulnerabilities within the payment systems in both the public and private healthcare sectors. The HFPP and its committees design and develop studies in coordination with the TTP. The core function of the TTP is to manage and execute the HFPP studies within the HFPP. *Form Number:* CMS–10501 (OMB control number: 0938–1251); *Frequency:* Occasionally; *Affected Public:* Private sector (Business or other for-profits); *Number of Respondents:* 28; *Number of Responses:* 28; *Total Annual Hours:* 120. (For questions regarding this collection, contact Marnie Dorsey at (410–786–5942).

Dated: May 27, 2021.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2021–11591 Filed 6–1–21; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–P–0163]

Determination That SANDOSTATIN (Octreotide Acetate) Injection, Equal to 0.2 Milligrams Base/Milliliter and Equal to 1 Milligrams Base/Milliliter, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) has determined that SANDOSTATIN (octreotide acetate) injection, equal to (EQ) 0.2 milligrams (mg) base/milliliter (mL) and 1 mg base/mL, was not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to this drug product, and it will allow FDA to continue to approve ANDAs that refer to the product as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Stacy Kane, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6236, Silver Spring, MD 20993–0002, 301–796–8363, *Stacy.Kane@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that

the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

SANDOSTATIN (octreotide acetate) injection, EQ 0.2 mg base/mL and EQ 1 mg base/mL, is the subject of NDA 19667, held by Novartis Pharmaceuticals Corporation. NDA 19667 was initially approved on October 21, 1988, and the EQ 0.2 mg base/mL and EQ 1 mg base/mL strengths were approved on June 12, 1991. SANDOSTATIN is indicated to reduce blood levels of growth hormone and IGF–I (somatomedin C) in acromegaly patients who have had inadequate response to or cannot be treated with surgical resection, pituitary irradiation, and bromocriptine mesylate at maximally tolerated doses. SANDOSTATIN is also indicated for the symptomatic treatment of patients with metastatic carcinoid tumors where it suppresses or inhibits the severe diarrhea and flushing episodes associated with the disease. SANDOSTATIN is also indicated for the treatment of profuse watery diarrhea associated with vasoactive intestinal peptide-secreting tumors.

In a letter received by the Agency on May 11, 2020, Novartis Pharmaceuticals Corporation notified FDA that SANDOSTATIN (octreotide acetate) injection, EQ 0.2 mg base/mL and EQ 1 mg base/mL, was being discontinued, and FDA moved the drug product to the ''Discontinued Drug Product List'' section of the Orange Book. Caplin Steriles Limited submitted a citizen petition dated February 5, 2021 (Docket No. FDA–2021–P–0163), under 21 CFR 10.30, requesting that the Agency determine whether SANDOSTATIN (octreotide acetate) injection, EQ 0.2 mg base/mL and EQ 1 mg base/mL, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that SANDOSTATIN (octreotide acetate) injection, EQ 0.2 mg base/mL and EQ 1 mg base/mL, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that SANDOSTATIN (octreotide acetate) injection, EQ 0.2 mg base/mL and EQ 1 mg base/mL, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of SANDOSTATIN (octreotide acetate) injection, EQ 0.2 mg base/mL and EQ 1 mg base/mL, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list SANDOSTATIN (octreotide acetate) injection, EQ 0.2 mg base/mL and EQ 1 mg base/mL, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to this drug product. Additional ANDAs for this drug product may also be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: May 26, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–11575 Filed 6–1–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Rural Health Care Coordination Program Performance Improvement and Measurement System Database, OMB No. 0906–0024—Reinstate With Changes

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

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than July 2, 2021.

ADDRESSES: Submit your comments, including the ICR Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Rural Health Care Coordination Program Performance Improvement and Measurement System Database, OMB No. 0906–0024—Reinstate with Changes.

Abstract: The Rural Health Care Coordination (Care Coordination) program is authorized under Section 330A(e) of the Public Health Service (PHS) Act (42 U.S.C. 254(e)), as amended, to ''improve access and