

notice appears in the **Federal Register**, and the Commission requests that comments be submitted within 7 days on agreements that request expedited review. Copies of agreements are available through the Commission's website (www.fmc.gov) or by contacting the Office of Agreements at (202) 523-5793 or tradeanalysis@fmc.gov.

Agreement No.: 201307-001.

Agreement Name: Crowley/Sealand Space Charter Agreement.

Parties: Crowley Latin America Services, LLC; Maersk A/S DBA Sealand.

Filing Party: Wayne Rohde; Cozen O'Connor.

Synopsis: The amendment deletes Haiti from the geographic scope of the agreement and adjusts the amount of space being chartered.

Proposed Effective Date: 11/16/2023.

Location: <https://www2.fmc.gov/FMC.Agreements.Web/Public/AgreementHistory/22408>.

Dated: November 17, 2023.

Carl Savoy,

Federal Register Alternate Liaison Officer.

[FR Doc. 2023-25815 Filed 11-21-23; 8:45 am]

BILLING CODE 6730-02-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10418]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including any of the following subjects: the necessity and utility of the proposed information

collection for the proper performance of the agency's functions; the accuracy of the estimated burden; ways to enhance the quality, utility, and clarity of the information to be collected; and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by the OMB desk officer by December 22, 2023.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing>.

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

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (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 30-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 that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Annual MLR and Rebate Calculation Report and MLR Rebate Notices; *Use:* Under section 2718 of the Affordable Care Act and

implementing regulation at 45 CFR part 158, a health insurance issuer (issuer) offering group or individual health insurance coverage must submit a report to the Secretary concerning the amount the issuer spends each year on claims, quality improvement expenses, non-claims costs, Federal and State taxes and licensing and regulatory fees, the amount of earned premium, and beginning with the 2014 reporting year, the amounts related to the transitional reinsurance and risk adjustment programs established under sections 1341 and 1343, respectively, of the Affordable Care Act. An issuer must provide an annual rebate if the amount it spends on certain costs compared to its premium revenue (excluding Federal and States taxes and licensing and regulatory fees) does not meet a certain ratio, referred to as the medical loss ratio (MLR). Each issuer is required to submit annually MLR data, including information about any rebates it must provide, on a form prescribed by CMS, for each State in which the issuer conducts business. Each issuer is also required to provide a rebate notice to each policyholder that is owed a rebate and each subscriber of policyholders that are owed a rebate for any given MLR reporting year. Additionally, each issuer is required to maintain for a period of seven years all documents, records and other evidence that support the data included in each issuer's annual report to the Secretary.

Based upon CMS' experience in the MLR data collection and evaluation process, CMS is updating its annual burden hour estimates to reflect the actual numbers of submissions, rebates and rebate notices.

The 2022 MLR Reporting Form and Instructions reflect changes for the 2020 reporting year and beyond. For 2022, it is expected that issuers will submit fewer reports and on average, send fewer notices and rebate checks in the mail to policyholders and subscribers, which will reduce burden on issuers. *Form Number:* CMS-10418 (OMB control number: 0938-1164); *Frequency:* Annually; *Affected Public:* Private Sector, Business or other for-profit and not-for-profit institutions; *Number of Respondents:* 480; *Number of Responses:* 1,677; *Total Annual Hours:* 170,091. For policy questions regarding this collection contact Jiyun Lim at 667-290-9650.

Dated: November 17, 2023.

William N. Parham, III,

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

[FR Doc. 2023-25861 Filed 11-21-23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-P-4223]

Determination That BUPRENEX (Buprenorphine Hydrochloride) Injection, 0.3 Milligram/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, the Agency, or we) has determined that BUPRENEX (buprenorphine hydrochloride) Injection, 0.3 milligram (mg)/milliliter (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: Caitlin Callahan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6269, Silver Spring, MD 20993-0002, 301-796-3600, Caitlin.Callahan@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act 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.

BUPRENEX (buprenorphine hydrochloride) Injection, 0.3 mg/mL, is the subject of NDA 018401, held by Indivior, Inc., and initially approved on December 29, 1981. BUPRENEX is indicated for the management of pain severe enough to require an opioid analgesic and for which alternate treatments are inadequate.

BUPRENEX (buprenorphine hydrochloride) Injection, 0.3 mg/mL, is currently listed in the “Discontinued Drug Product List” section of the Orange Book. Odin Pharmaceuticals LLC submitted a citizen petition dated September 27, 2023 (Docket No. FDA-2023-P-4223), under 21 CFR 10.30, requesting that the Agency determine whether BUPRENEX (buprenorphine hydrochloride) Injection, 0.3 mg/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 BUPRENEX (buprenorphine hydrochloride) Injection, 0.3 mg/mL, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that this drug product was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of BUPRENEX (buprenorphine hydrochloride) Injection, 0.3 mg/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 BUPRENEX (buprenorphine hydrochloride) Injection, 0.3 mg/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: November 17, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023-25857 Filed 11-21-23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-D-4719]

Translation of Good Laboratory Practice Study Reports: Questions and Answers; Draft 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 draft guidance for industry entitled “Translation of GLP Study Reports: Questions and Answers.” This guidance provides information to sponsors and nonclinical laboratories regarding the translation of study reports for studies conducted in compliance with good laboratory practice (GLP) regulations. GLP studies are nonclinical safety studies that include, but are not limited to nonclinical toxicology studies, safety pharmacology studies, and device safety studies. When study reports of GLP studies are translated from the original language into English, adequate documentation is critical to ensure