supporting data, including payroll records, that the contracting officer may reasonably require.

Contracting officers use the information to establish the contract's construction requirements price adjustment to reflect the contractor's actual increase or decrease in wages and fringe benefits.

C. Annual Burden

Respondents: 405.
Total Annual Responses: 405.
Total Burden Hours: 16,200.

D. Public Comment

A 60-day notice was published in the **Federal Register** at 89 FR 26149, on April 15, 2024. No comments were received.

Obtaining Copies: Requesters may obtain a copy of the information collection documents from the GSA Regulatory Secretariat Division by calling 202–501–4755 or emailing *GSARegSec@gsa.gov.* Please cite OMB Control No. 9000–0154, Construction Wage Rate Requirements—Price Adjustment (Actual Method).

Janet Fry,

Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2024–13771 Filed 6–21–24; 8:45 am]

BILLING CODE 6820–EP–P

GENERAL SERVICES ADMINISTRATION

[Notice–IEB–2024–07; Docket No. 2024–0002; Sequence No. 28]

Privacy Act of 1974; System of Records

AGENCY: General Services Administration (GSA).

ACTION: Rescindment of a system of records notice.

SUMMARY: Pursuant to the provisions of the Privacy Act of 1974, notice is given that the General Services Administration (GSA) proposes to rescind a System of Records Notice, GSA/GOVT–8, Excluded Parties List System. This system of records contains information entered by Federal agencies that identifies individuals excluded from Federal Government procurement and nonprocurement programs and the applicable authority for the exclusion.

DATES: This system of records stopped being maintained in 2013.

ADDRESSES: Comments may be submitted to the Federal eRulemaking Portal, *http://www.regulations.gov.* Submit comments by searching for GSA/GOVT–8.

FOR FURTHER INFORMATION CONTACT: Call or email Richard Speidel, Chief Privacy Officer at (202) 969–5830 and *gsa.privacyact@gsa.gov.*

SUPPLEMENTARY INFORMATION: GSA proposes to rescind a System of Records Notification, GSA/GOVT–8. For procedural background, GSA initially published this SORN in 2006 with two numbers, ''GSA/GOVT–8'' and ''GSA/GOV–8.'' The text of the original SORN (71 FR 70515) clearly intends the number to be GSA/GOVT–8 while a typo in a header introduces the incorrect GSA/GOV–8. GSA filed a ''cancellation'' of a separate system of records in 2007 (72 FR 9337) that identified GSA/GOVT–8 as the number of the present SORN. An update in 2008 (73 FR 22374) continues the error in the header, identifying the SORN as GSA/GOV–8. In 2013, an attempt was made to ''cancel'' the SORN (78 FR 22880) that also identified the SORN as GSA/GOV–8. The present action is intended to clarify GSA's intent around the now-former system of records operating under GSA/GOVT–8 and/or GSA/GOV–8.

This Notice is being rescinded due to the records of GSA/GOVT–8 being integrated into the wider System for Award Management SORN, GSA/GOVT–9 beginning in 2012. Both systems of records were maintained until 2013, when all of the GSA/GOVT–8 records were fully integrated into GSA/GOVT–9.

SYSTEM NAME AND NUMBER:

Excluded Parties List System, GSA/GOVT–8.

HISTORY:

This system was previously published under two numbers, GSA/GOVT–8 and GSA/GOV–8. The initial publication was on December 5, 2006 (71 FR 70515), a revised version was published on April 25, 2008 (73 FR 22374), and a ''cancellation'' was published on April 17, 2013 (78 FR 22880).

Richard Speidel,

Chief Privacy Officer, Office of Enterprise Data & Privacy Management, General Services Administration.

[FR Doc. 2024–13749 Filed 6–21–24; 8:45 am]

BILLING CODE 6820–AB–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Performance Review Board Membership

AGENCY: Centers for Medicare & Medicaid Services.

ACTION: Notice of Performance Review Board membership.

SUMMARY: The U.S. Code of Federal Regulations requires each agency to establish, in accordance with regulations prescribed by the Office of Personnel Management, one or more Senior Executive Service (SES) Performance Review Boards (PRBs).

FOR FURTHER INFORMATION CONTACT: Lei Lonni Giroux, 410–786–4175 or *leilonni.giroux@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION: The PRB shall review and evaluate the initial summary rating of a senior executive's performance, the executive's response, and the higher-level official's comments on the initial summary rating. In addition, the PRB will review and recommend executive performance bonuses and pay increases.

5 U.S.C. 4314(c)(4) requires the appointment of board members to be published in the **Federal Register**. The following persons comprise a standing roster to serve as members of the SES PRB for the Centers for Medicare & Medicaid Services:

Jonathan Blum, Principal Deputy Administrator and Chief Operating Officer (serves as the Chair)
Stephanie Bovell, Acting Director, Office of Human Capital (serves as co-chair)
John Czajkowski, Deputy Chief Operating Officer
Elizabeth Fowler, Deputy Administrator and Director, Center of Medicare and Medicaid Innovation
Timothy Engelhardt, Director, Federal Coordinated Health Care Office
George Hoffman, Deputy Director, Office Information Technology and Deputy Chief Information Officer
Kathleen Cantwell, Office of Strategic Operations and Regulatory Affairs
Jean Moody-Williams, Deputy Director, Center for Clinical Standards and Quality
Ing-Jey Cheng, Director, Chronic Care Policy Group, Center for Medicare
Boulanger, Jennifer, Deputy Director Office of Legislation

The Deputy Administrator and Chief Operating Officer of the Centers for Medicare & Medicaid Services (CMS), Jonathan Blum, having reviewed and

approved this document, authorizes Vanessa Garcia, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Vanessa Garcia,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2024–13696 Filed 6–21–24; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–P–2272]

Determination That INVEGA (Paliperidone) Extended-Release Tablet, 1.5 Milligrams, 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 INVEGA (paliperidone) extended-release tablet, 1.5 milligrams (mg), 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: 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.

INVEGA (paliperidone) extended-release tablet, 1.5 mg, is the subject of NDA 021999, held by Janssen Pharmaceuticals, Inc. NDA 021999 was initially approved on December 19, 2006, for the INVEGA paliperidone extended-release 3 mg, 6 mg, 9 mg, and 12 mg dose tablets, and the supplement for the INVEGA paliperidone extended-release 1.5 mg dose tablet was approved on August 26, 2008. INVEGA is indicated for the treatment of schizophrenia and schizoaffective disorder.

In a letter dated February 9, 2023, Janssen Pharmaceuticals, Inc., notified FDA that INVEGA (paliperidone) extended-release tablet, 1.5 mg, was being discontinued, and FDA moved the drug product to the ''Discontinued Drug Product List'' section of the Orange Book.

Aurobindo Pharma USA, Inc., submitted a citizen petition dated May 7, 2024 (Docket No. FDA–2024–P–2272), under 21 CFR 10.30, requesting that the Agency determine whether INVEGA (paliperidone) extended-release tablet, 1.5 mg, 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 INVEGA (paliperidone) extended-release tablet, 1.5 mg, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that INVEGA (paliperidone) extended-release tablet, 1.5 mg, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of INVEGA (paliperidone) extended-release tablet, 1.5 mg, 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 INVEGA (paliperidone) extended-release tablet, 1.5 mg, 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: June 18, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–13803 Filed 6–21–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–1668]

Chemistry, Manufacturing, and Controls in Support of Recombinant Protein Products for Veterinary Medicinal Use; 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 (GFI) #288 entitled ''Chemistry, Manufacturing, and Controls in Support of Recombinant Protein Products for Veterinary Medicinal Use.'' This draft guidance