12. The final risk evaluation for DIBP entitled, ''Risk Evaluation for Diisobutyl Phthalate.''

III. Unreasonable Risk Determination

EPA determined that BBP presents an unreasonable risk of injury to human health and the environment driven by 7 of the 38 conditions of use (COUs). EPA has determined that the unreasonable risk to human health presented by BBP is driven by 2 COUs based on non-cancer risks associated with inhalation exposure to workers. The unreasonable risk to the environment is driven by 7 COUs due to chronic exposure of aquatic organisms through surface water. EPA did not identify unreasonable risk of injury to consumers or the general population under any COUs for BBP, nor do cumulative exposures contribute to unreasonable risks.

EPA determined that DBP presents an unreasonable risk of injury to human health and the environment driven by 6 of the 44 COUs. EPA has determined that the unreasonable risk to human health presented by DBP is driven by 5 COUs based on non-cancer risks driven by inhalation and aggregate exposure to workers. The unreasonable risk to the environment is driven by 1 COU due to chronic exposure of aquatic vertebrates, and exposure of aquatic plants and algae, through surface water. EPA did not identify unreasonable risk of injury to consumers or the general population under any COUs for DBP, nor do cumulative exposures contribute to unreasonable risks.

EPA determined that DCHP presents an unreasonable risk of injury to human health driven by 2 of the 24 COUs. EPA has determined that the unreasonable risk to human health presented by DCHP is driven by 2 COUs based on non-cancer risks associated with acute inhalation exposures to workers. EPA did not identify unreasonable risk to the environment under any COUs. EPA did not identify unreasonable risk of injury to consumers or the general population under any COUs for DCHP, nor do cumulative exposures contribute to unreasonable risks.

EPA determined that DEHP presents an unreasonable risk of injury to human health and the environment driven by 20 of the 44 COUs. EPA has determined that the unreasonable risk to human health presented by DEHP is driven by 10 COUs based on non-cancer risks associated with exposure to workers. The unreasonable risk to the environment is driven by 20 COUs due to chronic exposure of aquatic organisms through surface water with a subset of 18 of these COUs also driven by risk due to chronic exposure of sediment-dwelling organisms through sediment pore water. EPA did not identify unreasonable risk of injury to consumers or the general population under any COUs for DEHP, nor do cumulative exposures contribute to unreasonable risks.

EPA determined that DIBP presents an unreasonable risk of injury to human health and the environment driven by 9 of the 28 COUs. EPA has determined that the unreasonable risk to human health presented by DIBP is driven by 4 COUs based on non-cancer risks associated with inhalation exposure to workers. The unreasonable risk to the environment is driven by 7 COUs due to exposure of algae and chronic exposure of aquatic vertebrates through surface water. EPA did not identify unreasonable risk of injury to consumers or the general population under any COUs for DIBP, nor do cumulative exposures contribute to unreasonable risks.

IV. Next Step Is Risk Management

Consistent with TSCA section 6(a), EPA will propose risk management regulatory actions to the extent necessary so that BBP, DBP, DCHP, DEHP, and DIBP no longer present an unreasonable risk. EPA expects to focus its risk management actions on the conditions of use that significantly contribute to the unreasonable risks. In proposing rules and selecting among requirements, consistent with TSCA section 6(c)(2), EPA will consider and factor in, to the extent practicable: (i) the effects of BBP, DBP, DCHP, DEHP, and DIBP on health and the environment; (ii) the magnitude of exposure to BBP, DBP, DCHP, DEHP, and DIBP of human beings and the environment; (iii) the benefits of BBP, DBP, DCHP, DEHP, and DIBP for various uses; and (iv) the reasonably ascertainable economic consequences of the rule.

Additional information received may inform the risk management of the phthalates and, like the prioritization and risk evaluation processes, there will be an opportunity for public comment on any proposed risk management actions.

Authority: 15 U.S.C. 2601 *et seq.*

Dated: December 31, 2025.

Nancy B. Beck,

Principal Deputy Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2025–24290 Filed 1–5–26; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2024–E–1294; FDA–2024–E–1295; FDA–2024–E–1296; and FDA–2024–E–1297]

Determination of Regulatory Review Period for Purposes of Patent Extension; ZURZUVAE

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for ZURZUVAE is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by March 9, 2026. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by July 6, 2026. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of March 9, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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 Nos. FDA–2024–E–1294; FDA–2024–E–1295; FDA–2024–E–1296; and FDA–2024–E–1297 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; ZURZUVAE.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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, 240–402–7500.

• 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 § 10.20 (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.

FOR FURTHER INFORMATION CONTACT: Jack Dan, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6200, Silver Spring, MD 20993, 240–402–6940.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug or biological product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product.

Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product, ZURZUVAE (zuranolone), indicated for the treatment of postpartum depression (PPD) in adults. Subsequent to this approval, the USPTO received patent term restoration applications for ZURZUVAE (U.S. Patent Nos. 9,512,165; 10,172,871; 10,342,810; and 11,236,121) from Sage Therapeutics, Inc. and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated June 27, 2025, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of ZURZUVAE represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for ZURZUVAE is 2,959 days. Of this time, 2,628 days occurred during the testing phase of the regulatory review period, while 331 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(i)) became effective:* September 26, 2015. The applicant claims November 23, 2016, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was September 26, 2015, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* December 5, 2022. FDA has verified the applicant's claim that the new drug application (NDA) for ZURZUVAE (NDA 217369) was initially submitted on December 5, 2022.

3. The date of issuance of the interim final rule controlling the drug under section 201(j) of the Controlled Substances Act: October 31, 2023. FDA has verified the applicant's claim that NDA 217369 was approved on August 4, 2023, and that the Drug Enforcement

Agency issued an interim final rule controlling the product under section 201(j) of the Controlled Substances Act on October 31, 2023.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application(s) for patent extension, this applicant seeks 69, 954, 1,045, or 1,294 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Brian Fahey,

Associate Commissioner for Legislation.

[FR Doc. 2026–00026 Filed 1–5–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Current List of HHS-Certified Laboratories and Instrumented Initial Testing Facilities Which Meet Minimum Standards To Engage in Urine and Oral Fluid Drug Testing for Federal Agencies

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) provides notice of the laboratories and Instrumented Initial Testing Facilities (IITFs) currently certified to meet the standards of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines) using Urine and the laboratories currently certified to meet the standards of the Mandatory Guidelines using Oral Fluid.

FOR FURTHER INFORMATION CONTACT: Anastasia Flanagan, Division of Workplace Programs, SAMHSA/CSAP, 5600 Fishers Lane, Room 16N06B, Rockville, Maryland 20857; 240–276–2600 (voice); *Anastasia.Flanagan@samhsa.hhs.gov* (email).

SUPPLEMENTARY INFORMATION: The Department of Health and Human Services (HHS) publishes a notice listing all HHS-certified laboratories and Instrumented Initial Testing Facilities (IITFs) in the **Federal Register** monthly, in accordance with Section 9.19 of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines) using Urine and Section 9.17 of the Mandatory Guidelines using Oral Fluid. If any laboratory or IITF certification is suspended or revoked, the laboratory or IITF will be omitted from subsequent lists until such time as it is restored to full certification under the Mandatory Guidelines.

If any laboratory or IITF has withdrawn from the HHS National Laboratory Certification Program (NLCP) during the past month, it will be listed at the end and will be omitted from the monthly listing thereafter.

This notice is also available on the internet at *https://www.samhsa.gov/workplace/drug-testing-resources/certified-lab-list.*

The Mandatory Guidelines using Urine were first published in the **Federal Register** on April 11, 1988 (53 FR 11970), and subsequently revised in the **Federal Register** on June 9, 1994 (59 FR 29908); September 30, 1997 (62 FR 51118); April 13, 2004 (69 FR 19644); November 25, 2008 (73 FR 71858); December 10, 2008 (73 FR 75122); April 30, 2010 (75 FR 22809); January 23, 2017 (82 FR 7920); and on October 12, 2023 (88 FR 70768).

The Mandatory Guidelines using Oral Fluid were first published in the **Federal Register** on October 25, 2019 (84 FR 57554) with an effective date of January 1, 2020, and subsequently revised in the **Federal Register** on October 12, 2023 (88 FR 70814).

The Mandatory Guidelines were initially developed in accordance with Executive Order 12564 and section 503 of Public Law 100–71 and allowed urine drug testing only. The Mandatory Guidelines using Urine have since been revised, and new Mandatory Guidelines allowing for oral fluid drug testing have been published. The Mandatory Guidelines require strict standards that laboratories and IITFs must meet in order to conduct drug and specimen validity tests on specimens for Federal agencies. HHS does not allow IITFs to conduct oral fluid testing.

To become certified, an applicant laboratory or IITF must undergo three rounds of performance testing plus an on-site inspection. To maintain that certification, a laboratory or IITF must participate in a quarterly performance testing program plus undergo periodic, on-site inspections.

Laboratories and IITFs in the applicant stage of certification are not to be considered as meeting the minimum requirements described in the HHS Mandatory Guidelines using Urine and/or Oral Fluid. An HHS-certified laboratory or IITF must have its letter of certification from HHS/SAMHSA (formerly: HHS/NIDA), which attests that the test facility has met minimum standards.

HHS-Certified Laboratories Approved To Conduct Oral Fluid Drug Testing

In accordance with the Mandatory Guidelines using Oral Fluid effective October 10, 2023 (88 FR 70814), the following HHS-certified laboratories meet the minimum standards to conduct drug and specimen validity tests on oral fluid specimens:

At this time, there are no laboratories certified to conduct drug and specimen validity tests on oral fluid specimens.

HHS-Certified Instrumented Initial Testing Facilities Approved To Conduct Urine Drug Testing

In accordance with the Mandatory Guidelines using Urine effective February 1, 2024 (88 FR 70768), the following HHS-certified IITFs meet the minimum standards to conduct drug and specimen validity tests on urine specimens:

Dynacare, 6628 50th Street NW, Edmonton, AB Canada T6B 2N7, 780–784–1190 (Formerly: Gamma-Dynacare Medical Laboratories)

Note: DOT does not allow IITFs to test DOT-regulated specimens.

HHS-Certified Laboratories Approved To Conduct Urine Drug Testing

In accordance with the Mandatory Guidelines using Urine effective February 1, 2024 (88 FR 70768), the