

other aspect of this collection of information, including 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 on the collection(s) of information must be received by the OMB desk officer by October 24, 2024.

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 (44 U.S.C. 3506(c)(2)(A)) 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:* Extension of a currently approved collection; *Title of Information Collection:* Program

Integrity: Exchange, Premium Stabilization Programs, and Market Standards; Amendments to the HHS Notice of Benefit and Payment Parameters for 2014; Final Rule II; *Use:* On March 23, 2010, the Patient Protection and Affordable Care Act (PPACA; Pub. L. 111-148) was signed into law and on March 30, 2010, the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152) was signed into law. The two laws implement various health insurance policies. On June 19, 2013, the Department of Health and Human Services (HHS) published proposed rule CMS-9957-P: Program Integrity: Exchanges, SHOP, Premium Stabilization Programs, and Market Standards (78 FR 37302) (Program Integrity Proposed Rule) which, among other things, contained third party disclosure requirements and data collections that supported the oversight of premium stabilization programs, State Exchanges, and qualified health plan (QHP) issuers in Federally-facilitated Exchanges (FFE)s. Parts of the proposed rule were finalized as Patient Protection and Affordable Care Act; Program Integrity: Exchange, Premium Stabilization Programs, and Market Standards; Amendments to the HHS Notice of Benefit and Payment Parameters for 2014; Final Rule (Program Integrity Final Rule II), 78 FR 25326 (October 24, 2013). This ICR relates to a portion of the information collection request (ICR) requirements set forth in the final rule. *Form Number:* CMS-10516 (OMB control number: 0938-1277); *Frequency:* Annually; *Affected Public:* Private Sector, State, Local, or Tribal Governments; Business or other for-profits, and Not-for-Profits; *Number of Respondents:* 457; *Number of Responses:* 457; *Total Annual Hours:* 42,771. (For questions regarding this collection, contact Andrea Honig at (301) 492-4147.)

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2024-21732 Filed 9-23-24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-E-2079]

Determination of Regulatory Review Period for Purposes of Patent Extension; BRAVECTO; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA or the Agency) published a notice in the **Federal Register** of February 12, 2018, for the determination of the regulatory review period for the animal drug BRAVECTO. In accordance with the Court's order in *Nissan Chemical Corp., et al. v. FDA, et al.*, No. 22-01598 (D.D.C.), this document revises the **SUPPLEMENTARY INFORMATION** section of that notice by adjusting the start date of the testing phase for BRAVECTO. This notice supersedes the June 11, 2021, **Federal Register** document revising the February 12, 2018, notice.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301-796-3600.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 12, 2018 (83 FR 6033), in FR Doc. 2018-02761, in the first column, the first two paragraphs under the section "II. Determination of Regulatory Review Period," the following revision is made on page 6034:

FDA has determined that the applicable regulatory review period for BRAVECTO is 1,548 days. Of this time, 1,510 days occurred during the testing phase of the regulatory review period, while 38 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 512(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360b(j)) became effective:* February 19, 2010. Pursuant to the Court's order in *Nissan Chemical Corp., et al. v. FDA, et al.*, No. 22-01598 (D.D.C.), the start date of the testing phase for BRAVECTO was February 19, 2010.

Dated: September 19, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024-21841 Filed 9-23-24; 8:45 am]

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