in state and federal benefit programs through NDNH data matching. DFS provides states with data to help them locate parents, establish fair and equitable child support obligations, process income withholding and payments, collect and enforce past-due child support, and communicate effectively and efficiently. DFS provides outreach, technical support, and training to child support agencies, employers, insurers, financial institutions, and other private and government partners to ensure that the FPLS systems are used to their maximum benefit.

DFS is responsible for automation of data and timeliness of transactions. Other responsibilities include, but are not limited to, oversight of collaborations with the Social Security Administration (SSA) on technical aspects of their use of OCSE's data and OCSE's use of SSA data center resources; conduct analyses and feasibility assessments; develop requirements; and design, develop, and implement system enhancements to increase efficiencies and support users of FPLS information. DFS also ensures that all IT projects are managed according to OMB/HHS/ACF standards for architecture, capital planning, security, and privacy, and fall within tolerances for acceptance.

Additionally, DFS provides guidance, analysis, technical assistance, and oversight to state and tribal child support programs regarding performance measurement; statistical, policy, and program analysis; synthesis and dissemination of data sets to inform the program; and application of emerging technologies, such as business intelligence and data analytics to improve and enhance the effectiveness of programs and service. DFS is also responsible for collection, compilation, analysis, and dissemination of state and tribal data to Congress and the general public. The Division also provides statistical and budgeting support in coordination with other divisions. DFS is responsible for promoting public access and understanding of data; managing academic/research projects; and providing support for researchers. DFS provides technical assistance to states in developing their self-assessment capabilities and implementing the annual reporting requirements contained in the Personal Responsibility and Work Opportunity Reconciliation Act of 1996.

Division of State and Tribal Systems (KFB10): The Division of State and Tribal Systems (DSTS) reviews, analyzes, and approves/disapproves state and tribal requests for Federal Financial Participation for automated systems development and operations activities that support the child support program. DSTS is headed by a Division Director who directly reports to the Deputy Commissioner. DSTS provides assistance to states and tribes in developing or modifying automation plans to conform to federal requirements. DSTS monitors approved state and tribal systems development activities; certifies state-wide automated systems; and conducts periodic reviews to assure state and tribal compliance with regulatory requirements applicable to automated systems supported by Federal Financial Participation. DSTS provides guidance to states and tribes on functional requirements for these automated information systems, and works with federal, state, local, and tribal health and human services agencies to foster and promote interoperability and collaboration across the automated systems that support their programs. The Division promotes interstate and tribal transfer of existing automated systems and provides assistance and guidance to improve ACF's programs through the use of automated systems and technology. It provides development support and guidance to tribes on the installation, implementation, and maintenance of the Model Tribal System.

II. Continuation of Policy. Except as inconsistent with this reorganization, all statements of policy and interpretations with respect to organizational components affected by this notice within ACF, heretofore issued and in effect on this date of this reorganization are continued in full force and effect.

III. Delegation of Authority. All delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegations, provided they are consistent with this reorganization.

IV. Funds, Personnel, and Equipment. Transfer of organizations and functions affected by this reorganization shall be accompanied in each instance by direct and support funds, positions, personnel, records, equipment, supplies, and other resources.

This reorganization became effective upon completion of a Congressional notification period.

Robert F. Kennedy, Jr.,

Secretary, Department of Health and Human Services.

[FR Doc. 2025–23471 Filed 12–18–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–P–1304]

Determination That EFFEXOR XR (Venlafaxine Hydrochloride) Extended-Release Capsule, 100 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 or Agency) has determined that EFFEXOR XR (venlafaxine hydrochloride) extended-release capsule, 100 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.

EFFEXOR XR (venlafaxine hydrochloride) extended-release capsule, 100 mg, is the subject of NDA 020699, held by Upjohn US, and initially approved on October 20, 1997. EFFEXOR XR is indicated in adults for the treatment of major depressive disorder, generalized anxiety disorder, social anxiety disorder and panic disorder. EFFEXOR XR (venlafaxine hydrochloride) extended-release capsule, 100 mg, is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

SciRegs International, Inc., on behalf of Inventia Healthcare Limited, submitted a citizen petition dated May 16, 2025 (Docket No. FDA–2025–P–1304) under 21 CFR 10.30, requesting that the Agency determine whether EFFEXOR XR (venlafaxine hydrochloride) extended-release capsule, 100 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 EFFEXOR XR (venlafaxine hydrochloride) extended-release capsule, 100 mg, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that EFFEXOR XR (venlafaxine hydrochloride) extended-release capsule, 100 mg, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of EFFEXOR XR (venlafaxine hydrochloride) extended-release capsule, 100 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 EFFEXOR XR (venlafaxine hydrochloride) extended-release capsule, 100 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.

Lowell M. Zeta,

Acting Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–23408 Filed 12–18–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2024–N–5603; FDA–2024–N–4731; FDA–2024–N–5468; FDA–2024–N–5234; FDA–2025–N–0123; FDA–2025–N–0383; FDA–2025–N–0338; FDA–2025–N–0183; FDA–2025–N–0349; FDA–2025–N–0082]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Amber Barrett, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at *https://www.reginfo.gov/public/do/PRAMain.* An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
New Animal Drug and Veterinary Master Files	0910–0032	9/30/2028
Administrative Detention and Banned Medical Devices	0910–0114	9/30/2028
Food and Drug Administration's Adverse Event and Product Experience Reporting Program	0910–0291	9/30/2027
Notification Procedures for Statements of Dietary Supplements	0910–0331	9/30/2028
Substances Generally Recognized as Safe (GRAS): Notifications and Convening Panels	0910–0342	9/30/2028
Public Health Service Guideline on Infectious Disease Issues in Xenotransplantation	0910–0456	9/30/2028
Export Notification and Recordkeeping Requirements	0910–0482	9/30/2028
Establishing and Maintaining Lists of United States Establishments With Interest in Exporting Human Food Program-Regulated Products	0910–0509	9/30/2028
Foreign Supplier Verification Programs for Importers of Food for Humans and Animals	0910–0752	9/30/2028
Compounding Animal Drugs From Bulk Drug Substances	0910–0904	9/30/2028