

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2024-07504 Filed 4-8-24; 8:45 am]

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GENERAL SERVICES ADMINISTRATION

[Notice-IE-2024-03; Docket No. 2024-0001; Sequence No. 9]

Privacy Act of 1974; Rescindment of a System of Records

AGENCY: Office of the Chief Privacy Officer; General Services Administration, (GSA).

ACTION: Rescindment of a system of records notice.

SUMMARY: Pursuant to the Privacy Act of 1974 and Office of Management and Budget (OMB) Circular No. A-108, notice is hereby given that the GSA proposes to rescind the GSA/Transit-1, Transportation Benefits Records, System of Records Notice (SORN). This system of records contains information entered by GSA and provides transportation fringe benefits to employees who use mass transportation to commute to and from work.

DATES: Effective immediately.

ADDRESSES: Comments may be submitted to the Federal eRulemaking Portal, <http://www.regulations.gov>. Submit comments by searching for Notice-IE-2024-03, GSA/Transit-1.

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, GSA/Transit-1. This Notice is being rescinded due to the records of GSA/Transit-1 being maintained under DOT/ALL-8, Parking and Transit Benefit System, managed by the Department of Transportation (DOT). The records under GSA/Transit-1 were transitioned to the DOT in 2017 and are now being maintained under DOT/ALL-8.

SYSTEM NAME AND NUMBER:

Transportation Benefits Records, GSA/TRANSIT-1.

HISTORY:

A SORN was previously published in the **Federal Register** at 76 FR 56762 on October 14, 2011.

Richard Speidel,

Chief Privacy Officer, Office of the Deputy Chief Information Officer, General Services Administration.

[FR Doc. 2024-07430 Filed 4-8-24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2024-N-1569]

Determination That NALFON (Fenoprofen Calcium) Oral Capsules, Equivalent to 300 Milligram Base, and Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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 the drug products listed in this document were 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 these drug products, and it will allow FDA to continue to approve ANDAs that refer to the products 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 generally known as the “Orange Book.” Under FDA regulations, a drug is 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).

Under § 314.161(a) (21 CFR 314.161(a)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) before an ANDA that refers to that listed drug may be approved, (2) whenever a listed drug is voluntarily withdrawn from sale and ANDAs that refer to the listed drug have been approved, and (3) when a person petitions for such a determination under 21 CFR 10.25(a) and 10.30. Section 314.161(d) provides that if FDA determines that a listed drug was withdrawn from sale for safety or effectiveness reasons, the Agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug.

FDA has become aware that the drug products listed in the table are no longer being marketed.

Application No.	Drug name	Active ingredient(s)	Strength(s)	Dosage form/route	Applicant
NDA 017604	NALFON	Fenoprofen Calcium	Equivalent to (EQ) 300 Milligrams (mg) Base.	Capsule; Oral	Xspire Pharma.
NDA 017087	ETHRANE	Enflurane	99.9%	Liquid; Inhalation	Baxter Healthcare Corp.
NDA 018801	STERILE WATER FOR INJECTION.	Sterile Water For Injection	100% (1 Milliliter (mL)); 100% (5.2 mL).	Liquid; N/A	Hospira, A Pfizer Company.
NDA 019152	CALAN SR	Verapamil Hydrochloride	120 mg; 180 mg, 240 mg	Tablet, Extended Release; Oral.	Pfizer Inc.
NDA 019885	ACCUPRIL	Quinapril Hydrochloride	EQ 5 mg Base; EQ 10 mg Base; EQ 20 mg Base; EQ 40 mg Base.	Tablet; Oral	Pfizer Pharmaceuticals Ltd.