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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-1664]

RIN 1117-ZA08

Schedules of Controlled Substances; Removal of Exemption Status for Inactive Butalbital Products

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final determination.

SUMMARY: The Drug Enforcement Administration (DEA) is revoking the exempted status for certain nonnarcotic prescription products that are currently on DEA's Table of Exempted Prescription Products, but whose National Drug Codes (NDC) are inactive because they are no longer available and/or the company that applied for the exemption no longer exists. These products will be removed from DEA's Table of Exempted Prescription Products and will no longer be considered exempt prescription products under the Controlled Substances Act. This action does not impact exempted prescription products with active NDC numbers.

DATES: This final determination is effective on [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Terrence L. Boos, Ph.D., Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 362-3249.

SUPPLEMENTARY INFORMATION:

Legal Authority

The Controlled Substances Act (CSA) authorizes the Attorney General, by regulation, to exempt from certain provisions of the CSA any compound, mixture, or preparation

containing certain nonnarcotic controlled substances if he finds that it is both (1) approved for prescription use, and (2) contains one or more other active ingredients which are not listed in any schedule and which are included in such combinations, quantity, proportion, or concentration as to vitiate the potential for abuse.[1] The Attorney General has delegated this authority to the Administrator of DEA (Administrator).[2] The Administrator may also revoke a previously granted exemption by following the same procedures that are used to evaluate an application for exemption—namely, by publishing in the *Federal Register* a general notice of the proposed rulemaking (NPRM) for revoking the exemption, permitting interested persons to file written comments on or objections to the proposed revocation, considering any comments submitted, and publishing a final order in the *Federal Register* that sets forth the findings of fact and conclusions of law upon which the order is based.[3]

This final determination revokes the exemption status for certain prescription products previously granted exemption because the National Drug Codes (NDC) of these products are no longer active and/or the companies that originally filed for their exemption no longer exist. This action revokes the exemption status for a number of products and removes them from DEA's Table of Exempted Prescription Products. While this action revokes the exemption status, this action will have no effect on these products because they are no longer marketed.

Background: Exempted Prescription Products

DEA has exempted prescription drug products from certain parts of the CSA when the products meet the requirements for exemption, including the requirement to contain active ingredients believed to vitiate the potential for abuse. The current table of products

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[1] 21 U.S.C. 811(g)(3)(A); 21 CFR 1308.31, 1308.32.
[2] 28 CFR 0.100
[3] *See* 21 CFR 1308.31(c), (d).

that have been granted exempted prescription product status, pursuant to 21 CFR 1308.31 and 1308.32, can be found on the DEA Diversion Control Division website.[4]

Butalbital is classified as an intermediate acting barbiturate. Butalbital is a schedule III nonnarcotic controlled substance that falls under DEA Controlled Substances Code Number 2100, as it is a derivative of barbituric acid.[5] Originally, some butalbital prescription products were exempted by the Bureau of Drug Abuse Control (BDAC) of the Food and Drug Administration (FDA), the predecessor to the Bureau of Narcotics and Dangerous Drugs and later DEA. A panel of public health physicians and FDA medical officers developed the criteria used to exempt butalbital prescription products by BDAC in 1967. These criteria were based upon the expectation that combining the controlled substance with an amount of counteractive drug sufficient to cause early deterrent side effects would vitiate the potential for abuse. For products containing long or intermediate acting barbiturates in combination with analgesics, the criteria provided that an exemption would be granted if, for every 15 mg of barbiturate, the product contained at least (1) 188 mg aspirin; (2) 375 mg salicylamide; or (3) 70 mg phenacetin, acetanilid, or acetaminophen.

Following the establishment of the criteria, DEA approved subsequent applications by new manufacturers based upon the same criteria, whereby the inclusion of these other active ingredients was thought to be in sufficient quantities to vitiate the potential for abuse. The criteria developed in 1967 was originally found to meet the standard for exemption currently described in 21 U.S.C. 811(g)(3)(A), such that if a prescription drug was found to meet the 1967 criteria for exemption, then it also met the test to contain an ingredient that vitiated the potential for abuse under the CSA standard.

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[4] *Available at* https://www.deadiversion.usdoj.gov/schedules/exempt/exempt_rx_list.pdf.
[5] 21 CFR 1308.13(c)(3)

Currently, there are 189 butalbital products listed by their NDC on DEA's Table of Exempted Prescription Products. Using the FDA's National Drug Code Directory[6] and the U.S. National Institute of Health (NIH)–National Library of Medicines DailyMed database,[7] DEA determined that 160 of the NDCs correlating to butalbital products on the exempt prescription product list are no longer active and marketed. DEA confirmed with FDA these products are no longer marketed. Thereafter, on May 26, 2026, DEA published an NPRM in the *Federal Register* proposing to remove these inactive products from the exempted prescription product list to accurately portray which products are currently on the market.[8]

Comments Received

DEA received one comment in response to the NPRM for the removal of butalbital products on the exempt prescription product table that are no longer active and marketed.

Comment: One commenter was concerned about the use of FDA's National Drug Code Directory and the NIH DailyMed database to identify products that are no longer marketed to remove them from the DEA Exempted Prescription Product table. The commentor mentioned that a drug product manufactured by a contract manufacturing organization and labeled for a private label distributor may have NDCs that do not appear on the NDC directory or in the DailyMed database. The commenter proposed that all drug

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[6] FDA's NDC directory contains information about finished, unfinished (e.g., active pharmaceutical ingredients) and compounded drugs. The NDC Directory contains product listing data submitted for all finished drugs including prescription and over-the-counter drugs, approved and unapproved drugs as well as repackaged and relabeled drugs. Drug establishments are required to provide FDA with a current list of all drugs, including active pharmaceutical ingredients manufactured, prepared, propagated, compounded, or processed for sale in the United States at their facilities. Drugs are identified and reported using a unique NDC, which serves as the FDA's identifier for drugs. FDA publishes the listed NDC numbers in the NDC directory, which is updated daily. Database queried January 27 – February 3, 2026.

[7] The DailyMed database contains labeling, submitted to the FDA by companies, for the following products: FDA-approved products, including prescription drug and biological products for human use (labeling includes Prescribing Information, patient labeling, and carton and container labeling); drug products and biological products; nonprescription (e.g., over-the-counter) drug and biological products for human use; certain medical devices for human use; medical gases for human and animal use; and prescription and nonprescription drugs for animal use. Also, additional products regulated, but not approved, by the FDA may be found on DailyMed, such as certain medical devices; cosmetics; dietary supplements; medical foods; and unapproved prescription and nonprescription products. Database queried January 27 – February 3, 2026.

[8] *Schedules of Controlled Substances; Removal of Exemption Status for Inactive Butalbital Products,* 91 FR 30527 (May 26, 2026).

products with currently certified NDC numbers remain on the DEA Exempted Prescription Product Table, and that DEA should utilize FDA's complete drug listing.

DEA Response: DEA appreciates the comment submitted. Items on the DEA Exempted Prescription Product Table are NDC number specific, and the prescription product must be labeled with the exempted NDC number for identification purposes. According to the FDA National Drug Code Directory website, "The NDC Directory contains information on active and certified, finished and unfinished drugs submitted to FDA in structured product labeling electronic listing files by labelers. The NDC Directory contains product listing data submitted for all finished drugs including prescription and over-the-counter drugs, approved and unapproved drugs, as well as repackaged and relabeled drugs."[9] Because the NDC directory contains the information for the certified finished drugs, in line with the request by the commenter, this directory was used to search for active pharmaceutical products that contain the NDCs of those butalbital products on DEA's exempt prescription product list.

The NIH–National Library of Medicines DailyMed database contains labeling information and product information that has been submitted to FDA by companies. This database was also searched in conjunction with FDA's NDC directory to confirm products are no longer being marketed.

DEA also reached out directly to FDA prior to the publication of the NPRM as well as in response to the commenter to confirm if these products were active and currently being marketed. DEA confirmed with FDA these products are no longer marketed.

Lastly, there were no comments received from any of the parties that would be directly affected by the removal of these NDCs from the Table of Exempted Prescription Products. Likewise, any product that is no longer exempted under the CSA may still be

[9] https://www.fda.gov/drugs/drug-approvals-and-databases/national-drug-code-directory

manufactured and sold, so long as the company and the product conform to all DEA regulations and the CSA.

Therefore, the final determination is being published without any changes.

List of Products to Be Removed from the Table of Exempted Prescription Products

For reasons detailed above, DEA is removing the following prescription products from DEA's Table of Exempted Prescription Products, as set forth below:

Company	Trade Name	NDC Code	Form	Controlled Substance	(mg or mg/ml)
Alpha Scriptics Inc	Butacet Capsules	53121-0133	CA	Butalbital	50
Alphagen Laboratories, Inc.	Butalbital and Acetaminophen Capsules 50mg/ 650mg	00603-2542	CA	Butalbital	50
Alphagen Laboratories, Inc.	Geone Capsules	59743-0004	CA	Butalbital	50
Altana, Inc.	Axocet (Butalbital and Acetaminophen)	0281-0389	TB	Butalbital	50
Althon Pharmaceuticals, Inc.	Butalbital, Acetaminophen and Caffeine Tablets USP	66813-074	TB	Butalbital	50
Alvogen, Inc.	Butalbital and Acetaminophen Tablets USP 50/325	47781-0535	TB	Butalbital	50
Alvogen, Inc.	Butalbital, Acetaminophen and Caffeine Tablets USP 50/325/40	47781-0536	TB	Butalbital	50
Alvogen, Inc.	Butalbital and Acetaminophen Tablets 50/325	47781-0628	TB	Butalbital	50
Alvogen, Inc.	Butalbital, Acetaminophen and Caffeine Tablets (50/325/40)	47781-0625	TB	Butalbital	50
Alvogen, Inc.	Butalbital and Acetaminophen Tablets (50/300)	47781-0644	TB	Butalbital	50
American Pharmaceuticals, Inc.	AMERICET Tablets	58605-0501	TB	Butalbital	50
American Urologicals Inc	Butace	00539-0906	CA	Butalbital	50
Amerisource Health Services Corporation	Butalbital, Acetaminophen and Caffeine Tablets 50/325/40mg	68084-0396	TB	Butalbital	50
Aphena Pharma Solutions	Butalbital, Acetaminophen and Caffeine Tablets (50/325/40mg	71610-0042	TB	Butalbital	50
Atland Pharmaceuticals	Butalbital and Acetaminophen Tablets (25 mg/325 mg)	71993-301	TB	Butalbital	25
Atley Pharmaceuticals	Butalbital, Acetaminophen and Caffeine Tablets	59702-661	TB	Butalbital	50
AvKare, Inc.	Butalbital, Acetaminophen and Caffeine Tablets USP 50/325/40	50268-139	TB	Butalbital	50
Baucum Laboratories Inc	Butalbital, Acetaminophen and Caffeine Tablets	54696-0513	TB	Butalbital	50
Blansett Pharm Co	Anolor 300 Capsules	51674-0009	CA	Butalbital	50
Cardinal Health	Butalbital, Acetaminophen and Caffeine Tablets 50mg/325mg/40mg	55154-7988	TB	Butalbital	50
Cardinal Health	Butalbital, Acetaminophen and Caffeine Tablets 50mg/325mg/40mg	55154-7147	TB	Butalbital	50
Cardinal Health	Butalbital, Acetaminophen and Caffeine Tablets 50mg/325mg/40mg	0904-6538	TB	Butalbital	50
Carnrick Labs Inc	Phrenilin	00086-0050	TB	Butalbital	50
Carpenter Pharmacal Co	ALAGESIC Tablets	55726-0300	TB	Butalbital	50
Cody Laboratories, Inc	BU-TAB AC	65893-100	TB	Butalbital	50
Columbia Drug Co	Isopap Capsules	11735-0400	CA	Butalbital	50
CTEX Pharmaceuticals, Inc.	Butex Forte Capsules	62022-0070	CA	Butalbital	50
CTEX Pharmaceuticals, Inc.	Butex Forte Capsules	62022-0074	CA	Butalbital	50

D.M. Graham Laboratories, Inc.	Butalbital, Acetaminophen and Caffeine Tablets	00756-0111	TB	Butalbital	50
Diversified Health Care Services	Geone Capsules	59743-004	CA	Butalbital	50
Dunhall Pharmacal Inc	Triaprin	00217-2811	CA	Butalbital	50
Duramed Pharmaceuticals	Butalbital, Acetaminophen and Caffeine Tablets	51285-0849	TB	Butalbital	50
EconoMed Pharmaceuticals, Inc.	ARCET Capsules	38130-0325	CA	Butalbital	50
EconoMed Pharmaceuticals, Inc.	ARCET Compound Tablets	38130-0111	TB	Butalbital	50
Equipharm Corp	EQUI-CET Tablets	57779-0111	TB	Butalbital	50
Everett Laboratories, Inc	Repan Capsules	00642-0164	CA	Butalbital	50
Everett Laboratories, Inc	Repan Capsules	00642-0163	CA	Butalbital	50
Everett Laboratories, Inc	Repan Tablets	00642-0162-10	TB	Butalbital	50
Forest Pharmacal Inc	Acetaminophen 325 mg/Butalbital 50 mg	00456-0674	TB	Butalbital	50
Forest Pharmacal Inc	Acetaminophen 500 mg/Butalbital 50 mg	00456-0671	TB	Butalbital	50
Forest Pharmacal Inc	Bancap	00456-0546	CA	Butalbital	50
Forest Pharmacal Inc	Esgic Capsules	00456-0631	CA	Butalbital	50
Forest Pharmacal Inc	ESGIC PLUS Capsules	00456-0679	CA	Butalbital	50
Forest Pharmacal Inc	Esgic Tablets	00456-0630	TB	Butalbital	50
Forest Pharmacal Inc	ESGIC-PLUS	00456-0678	TB	Butalbital	50
Genetco Inc	Butalbital, Apap and Caffeine	00302-0490	TB	Butalbital	50
Geneva Pharmaceuticals, Inc.	Butalbital, Acetaminophen and Caffeine Tablets	00781-1901	TB	Butalbital	50
GM Pharmaceuticals (Manufactured by Mikart, Inc.)	Vanatol S (Butalbital, Acetaminophen, & Caffeine Soln 50/325/40	58809-359	LQ	Butalbital	50
GM Pharmaceuticals (Manufactured by Mikart, Inc.)	Vanatol LQ (Butalbital, Acetaminophen, & Caffeine Soln 50/325/40	58809-820	LQ	Butalbital	50
Goldline Laboratories	Butalbital, APAP and Caffeine Tablets	00182-1274	TB	Butalbital	50
GSMS Incorporated	Butalbital, Acetaminophen and Caffeine Tablets USP (50/325/40)	60429-589	TB	Butalbital	50
GSMS Incorporated	Butalbital, Acetaminophen and Caffeine Capsules USP (50/300/40)	51407-200	CA	Butalbital	50
Halsey Drug Co Inc	Blue Cross Butalbital, APAP and Caffeine Tablets	00879-0567	TB	Butalbital	50
Halsey Drug Co Inc	Butalbital and Acetaminophen Tablets	00879-0543	TB	Butalbital	50

Hyrex Pharmaceutical	Two-Dyne Revised	00314-2229	TB	Butalbital	50
International Ethical Laboratories, Inc.	Tencon Tablets	11584-029-01	TB	Butalbital	50
Interstate Drug Exchange	IDE-Cet Tablets	00814-3820	TB	Butalbital	50
Intetlab	CON-TEN	11584-1029	CA	Butalbital	50
Inwood Laboratories, Inc.	Butalbital, Acetaminophen and Caffeine Tablets, USP	0258-3657	TB	Butalbital	50
Keene Pharmacal Inc	Endolar	00588-7777	CA	Butalbital	50
Kenco	Axotal	00013-1301	TB	Butalbital	50
Landry Pharmacal Inc	Febridyne Plain Capsules	05383-001	CA	Butalbital	50
Larken Laboratories, Inc.	Butalbital and Acetaminophen Tablets (25 mg/325 mg)	68047-722	TB	Butalbital	25
Lasalle Laboratories	Pacaps Modified Formula	48534-0884	CA	Butalbital	50
Lemmon Company	Acetaminophen/Butalbital/Caffeine Tablets	00093-0854	TB	Butalbital	50
LGM Pharma Solutions, LLC	Butalbital, Acetaminophen and Caffeine Capsules (50/300/40 mg)	79739-7029	CA	Butalbital	50
LGM Pharma Solutions, LLC	Butalbital and Acetaminophen Tablets (50/300 mg)	79739-7075	TB	Butalbital	50
Lunsco Inc	Pacaps Capsules	10892-0116	CA	Butalbital	50
Major Pharmaceuticals	Fabophen Tablets	00904-3280	TB	Butalbital	50
Mallard Consumer Products	Anaquan Tablets	59441-0343	TB	Butalbital	50
Mallard Inc	Anoquan Modified Formula	00166-0881	CA	Butalbital	50
Mallinckrodt Inc.	Butalbital, Acetaminophen, and Caffeine ("BAC") Tablets USP	00406-0970	TB	Butalbital	50
Marlop Pharmacal Inc	Dolmar	12939-0812	CA	Butalbital	50
Marnel Pharmaceuticals	Margesic Capsules	00682-0804	CA	Butalbital	50
Marnel Pharmaceuticals	Marten-Tab Tablets	00682-1400	TB	Butalbital	50
Martec Pharmacal Inc	Butalbital, Acetaminophen and Caffeine Tablets	52555-0079	TB	Butalbital	50
Mayne Pharma	Butalbital, Acetaminophen, & Caffeine Capsules 50/300/40	51862-542	CA	Butalbital	50
Mayrand Pharmaceuticals, Inc	Sedapap-10 Tablets	00259-1278	TB	Butalbital	50
Midlothian Laboratories (Manufactured by Mikart, Inc.)	Esgic (Butalbital, Acetaminophen, & Caffeine Capsules 50/325/40	68308-219	CA	Butalbital	50
Midlothian Laboratories (Manufactured by Mikart, Inc.)	Esgic (Butalbital, Acetaminophen, & Caffeine Tablets 50/325/40	68308-220	TB	Butalbital	50

Midlothian Laboratories (Manufactured by Mikart, Inc.)	Zebutal (Butalbital, Acetaminophen, & Caffeine Capsules 50/325/40	68308-554	CA	Butalbital	50
Mikart, Inc.	Alagesic Capsules	50991-302	CA	Butalbital	50
Mikart, Inc.	Bupap	00095-0240	TB	Butalbital	50
Mikart, Inc.	Butalbital and Acetaminophen Tablets 50/325	46672-0099	TB	Butalbital	50
Mikart, Inc.	Butalbital and Acetaminophen Tablets 50/650	11584-0029	TB	Butalbital	50
Mikart, Inc.	Butalbital and Acetaminophen Tablets 50/650	46672-0098	TB	Butalbital	50
Mikart, Inc.	Butalbital, Acetaminophen and Caffeine Capsules	46672-0228	CA	Butalbital	50
Mikart, Inc.	Butalbital, Acetaminophen and Caffeine Capsules	00588-7788	CA	Butalbital	50
Mikart, Inc.	Butalbital, Acetaminophen and Caffeine Eilixer	46672-0633	EL	Butalbital	50
Mikart, Inc.	Butalbital, Acetaminophen and Caffeine Tablets	52555-0647	TB	Butalbital	50
Mikart, Inc.	Butalbital, Acetaminophen and Caffeine Tablets USP	49884-0811	TB	Butalbital	50
Mikart, Inc.	Butalbital, Acetaminophen and Caffeine Tablets USP	00258-3665	TB	Butalbital	50
Mikart, Inc.	Butalbital, Acetaminophen and Caffeine Tablets USP (50/325/40)	51862-540	TB	Butalbital	50
Mikart, Inc.	Butalbital, Acetaminophen and Caffeine Tablets, USP	0591-3416	TB	Butalbital	50
Mikart, Inc.	Butalbital and Acetaminophen Capsules 50/300	46672-286	CA	Butalbital	50
Mikart, Inc.	Butalbital and Acetaminophen Tablets 50/300	46672-856	TB	Butalbital	50
Mikart, Inc.	Butalbital, Acetaminophen and Caffeine Tablets, USP	46672-184	TB	Butalbital	50
Mikart, Inc.	Butalbital, Acetaminophen, and Caffeine Oral Solution	66813-073	LQ	Butalbital	50
Mikart, Inc.	Butalbital, Acetaminophen, and Caffeine Tablets	51432-0034	TB	Butalbital	50
Mikart, Inc.	Butalbital, Acetaminophen, and Caffeine Tablets	46672-0059	TB	Butalbital	50
Mikart, Inc.	Capacet (Butalbital, Acetaminophen, and Caffeine 50/325/40)	58407-534	CA	Butalbital	50
Mikart, Inc.	Cephadyn Tablets	59702-0650	TB	Butalbital	50
Mikart, Inc.	Dolgic Plus Tablets	68453-074	TB	Butalbital	50
Mikart, Inc.	Dolgic Tablets	62022-0073	TB	Butalbital	50
Mikart, Inc.	DOLMAR Tablets	12939-0811	TB	Butalbital	50
Mikart, Inc.	Esgic Capsules	00535-0012	CA	Butalbital	50
Mikart, Inc.	Esgic Tablets	00535-0011	TB	Butalbital	50
Mikart, Inc.	Promacet	58605-524	TB	Butalbital	50

Mikart, Inc.	Sedapap Tablets	00259-0392	TB	Butalbital	50
Mikart, Inc. (on behalf of Mayne Pharma)	Butalbital and Acetaminophen Capsules 50/300	51862-544	CA	Butalbital	50
Mikart, Inc. (on behalf of Mayne Pharma)	Butalbital and Acetaminophen Tablets 50/300	51862-538	TB	Butalbital	50
Mikart, Inc. (on behalf of Monarch PCM, LLC)	Vtol LQ (Butalbital, Acetaminophen, Caffeine Oral Solution)	70154-111	LQ	Butalbital	50
Mikart, Inc./Shionogi, Inc.	Dolgic Plus Tablets	59630-074	TB	Butalbital	50
Moore Medical Corporation	Butalbital, Acetaminophen and Caffeine Tablets	00839-7831	TB	Butalbital	50
Nexgen Pharma	BUPAP (Butalbital and Acetaminophen 50mg/300mg)	0095-3000	TB	Butalbital	50
Nexgen Pharma	Butalbital with Acetaminophen and Caffeine Tablets	0722-7029	TB	Butalbital	50
Nexgen Pharma	Butalbital, Acetaminophen and Caffeine Tablets(50mg/325mg/40mg)	0722-7320	TB	Butalbital	50
Northampton Medical, Inc.	FEMCET	58436-0703	TB	Butalbital	50
PD-Rx Pharmaceuticals, Inc.	Butalbital/APAP/Caffeine Tablets (50mg/325mg/40mg)	55289-0879	TB	Butalbital	50
Pharmaceutical Basics Inc	Butalbital, Acetaminophen and Caffeine Tablets	00832-1102	TB	Butalbital	50
Phlight Pharma, LLC.	Allzital (Butalbital and Acetaminophen Tablets (25 mg/325 mg))	70569-150	TB	Butalbital	25
Poly Pharmaceuticals, Inc.	Alagesic	50991-0302	CA	Butalbital	50
Private Formula Inc	Sangesic	00511-1627	TB	Butalbital	30
ProficientRx	Butalb/Acet/Caffeine 50mg/300mg/40mg	71205-962	CA	Butalbital	50
Qualitest Pharmaceuticals, Inc.	Butalbital, Acetaminophen and Caffeine Tablets 50/325/40mg	0603-2544	TB	Butalbital	50
Qualitest Pharmaceuticals, Inc.	Butalbital, Acetaminophen and Caffeine Tablets USP	0603-2547	TB	Butalbital	50
Qualitest Pharmaceuticals, Inc.	Butalbital, Acetaminophen and Caffeine Tablets, USP	0603-2551	TB	Butalbital	50
Qualitest Products Inc	Butalbital, Acetaminophen and Caffeine Tablets	52446-0544	TB	Butalbital	50
Redi-Med	Butalbital Compound Capsules	53506-0103	CA	Butalbital	50
Roberts Pharmaceutical Corporation	Anoquan	54092-0178	TB	Butalbital	50
Roberts Pharmaceutical Corporation	Tencet Tablets	59441-0153	TB	Butalbital	50
Rotex Pharmaceuticals, Inc.	Rogesic Capsules	31190-0008	CA	Butalbital	50
Rugby Laboratories Inc	Butalbital, Acetaminophen and Caffeine Tablets, USP	0536-5567	TB	Butalbital	50
Rugby Laboratories Inc	ISOCET Tablets	00536-3951	TB	Butalbital	50
Russ Pharmaceuticals, Inc.	FEMCET Capsules	50474-0703	CA	Butalbital	50

Savage Laboratories	AXOTAL	00281-1301	TB	Butalbital	50
Shoals Pharmaceuticals, Inc.	Tencet	47649-0370	TB	Butalbital	50
Shoals Pharmaceuticals, Inc.	Tencet Capsules	47649-0560	CA	Butalbital	50
Skylar Laboratories, LLC	Allzital (Butalbital and Acetaminophen Tablets) (25 mg/325 mg)	70362-722	TB	Butalbital	25
Skylar Laboratories, LLC	Butalbital and Acetaminophen Tablets (50 mg/325 mg)	70362-721	TB	Butalbital	50
Solubiomix	Butalbital and Acetaminophen Tablets (50 mg/325 mg)	69499-302	TB	Butalbital	50
Solubiomix	Butalbital and Acetaminophen Capsules (50 mg/300 mg)	69499-342	CA	Butalbital	50
Stewart Jackson Pharmacal, Inc.	Ezol	45985-0578	CA	Butalbital	50
STI Pharma, LLC	Butalbital and Acetaminophen Tablets (50 mg/325 mg)	54879-026	TB	Butalbital	50
Tedor Pharma, Inc.	Butalbital and Acetaminophen Tablets (50 mg/300 mg)	47781-534	TB	Butalbital	50
Tedor Pharma, Inc.	Butalbital and Acetaminophen Tablets (50 mg/325 mg)	43199-053	TB	Butalbital	50
Tedor Pharma, Inc. (Manufactured for Xspire Pharma)	Butalbital, Acetaminophen and Caffeine Caps (50mg/300mg/40mg)	42195-955	CA	Butalbital	50
Trimen Labs	Amaphen Capsules (reformulated)	11311-0954	CA	Butalbital	50
U.S. Pharmaceuticals	Medigesic Capsules	52747-0600	CA	Butalbital	50
UAD Laboratories Inc	Bucet Capsules	00785-2307	CA	Butalbital	50
US Pharmaceuticals Inc	Medigesic Tablets	52747-0311	TB	Butalbital	50
Valeant Pharmaceuticals	Phrenilin Forte	0187-0844	CA	Butalbital	50
Victory Pharma Inc. (Manuf. By West-Ward Pharmaceutical)	Zebutal Brand Butalbital, Acetaminophen, and Caffeine Capsules	68453-170	CA	Butalbital	50
WE Hauck Inc	G-1 Capsules	43797-0244	CA	Butalbital	50
West-Ward Pharmaceutical Corp.	Butalbital with Acetaminophen and Caffeine Tablets	00143-1787	TB	Butalbital	50
West-Ward Pharmaceutical Corp.	Butalbital, Acetaminophen and Caffein Capsules	00143-3001	CA	Butalbital	50
West-Ward Pharmaceutical Corp.	Butalbital, Acetaminophen, and Caffeine Tablets, USP	00143-1115	TB	Butalbital	50
West-Ward Pharmaceutical Corp.	Zebutal Brand Butalbital, Acetaminophen, and Caffeine Capsules	59630-0170	CA	Butalbital	50
Wraser Pharmaceuticals	Phrenilin Forte (Butalbital, Acetaminophen and Caffeine) 50/300/40	66992-955	CA	Butalbital	50
Zenith Goldline Pharmaceuticals	Butalbital, Acetaminophen and Caffeine Tablets	00182-2659	TB	Butalbital	50

Regulatory Analyses

Executive Orders 12866, 13563, 14192, and 14294

DEA has determined that this rulemaking is not a "significant regulatory action" under section 3(f) of E.O. 12866, Regulatory Planning and Review. This rule has been drafted and reviewed in accordance with E.O. 12866, "Regulatory Planning and Review," section 1(b), Principles of Regulation and E.O. 13563, "Improving Regulation and Regulatory Review," section 1(b), General Principles of Regulation. This action is also not subject to E.O. 14192, "Unleashing Prosperity Through Deregulation," or E.O 14294, "Fighting Overcriminalization in Federal Regulations.".

Executive Order 12988, Civil Justice Reform

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132, Federalism

This rulemaking does not have federalism implications warranting the application of E.O. 13132. The rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination with Indian Tribal Governments

This rule does not have tribal implications warranting the application of E.O. 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.

Regulatory Flexibility Act

The Administrator, in accordance with the Regulatory Flexibility Act,[10] has reviewed this rule and, by approving it, certifies that it will not have a significant economic impact on a substantial number of small entities. There would be no economic impact because the products being removed from DEA's prescription product exempt list are no longer marketed.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995,[11] DEA has determined and certifies that this action would not result in any Federal mandate that may result "in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year . . . ." Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

Paperwork Reduction Act of 1995

This rule would not impose a new collection of information under the Paperwork Reduction Act of 1995.[12] Also, this rule would not impose new or modify existing recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations.

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SIGNING AUTHORITY

This document of the Drug Enforcement Administration was signed on October 6, 2026, by DEA Administrator Terrance C. Cole. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with

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[10] 5 U.S.C. 601–602.
[11] 2 U.S.C. 1501 *et seq.*
[12] 44 U.S.C. 3501–3521.

requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the Federal Register.

Heather Achbach,
Federal Register Liaison Officer,
Drug Enforcement Administration.

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