Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

Paragraph 6002 Class E Airspace Designated as Surface Areas.

* * * * *

ANM ID E2 Coeur D'Alene, ID [Amended]

Coeur D'Alene—Pappy Boyington Field
(Lat. 47°46′28″ N, long. 116°49′11″ W)

That airspace within a 4.4-mile radius of the Coeur D'Alene—Pappy Boyington Field, and within 1 mile each side of the 193° bearing extending from the 4.4-mile radius to 5.5 miles south of the airport, and that airspace 1.5 miles west and 3.5 miles east of the 019° bearing extending from the 4.4-mile radius to 5.2 miles northeast of the airport. This Class E airspace is effective during the specific dates and times established in advance by a Notice to Air Missions. The effective date and time will thereafter be continuously published in the Chart Supplement.

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

ANM ID E5 Coeur D'Alene, ID [Amended]

Coeur D'Alene—Pappy Boyington Field
(Lat. 47°46′28″ N, long. 116°49′11″ W)

That airspace within a 4.4-mile radius of the Coeur D'Alene—Pappy Boyington Field, and within 2.2 miles each side of the 193° bearing from the airport extending from the 4.4-mile radius to 9 miles south of the airport, and that airspace 4.4 miles each side of the 251° bearing from the Coeur D'Alene—Pappy Boyington Field extending from the 4.4-mile radius to 16 miles west of the airport and that airspace 1.8 miles west and 4 miles east of the 013° bearing from the Coeur D'Alene—Pappy Boyington Field extending from the 4.4-mile radius to 8.5 miles northeast from the airport.

Issued in Des Moines, Washington, on April 5, 2022.

B.G. Chew,

Acting Group Manager, Operations Support Group, Western Service Center.

[FR Doc. 2022–07745 Filed 4–11–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–384]

RIN 1117–AB75

Schedules of Controlled Substances; Exempted Prescription Products

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Drug Enforcement Administration proposes to revoke the exempted prescription product status for all butalbital products previously granted exemptions. Upon publication of a final rule, these products shall become subject to all schedule III controls under the Controlled Substances Act. If finalized, this action would impose the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule III controlled substances on persons who handle (manufacture, distribute, import, export, engage in research, conduct instructional activities or chemical analysis, or possess) or propose to handle butalbital products. This rulemaking also proposes to make changes to our regulations to clarify that DEA may revoke ''(either individually or categorically)'' any previously granted exemptions, and adds regulations to clarify that products exempted from application of all or any part of the Controlled Substances Act are listed in the Table of Exempted Prescription Products available on the DEA Diversion Control website (*https://www.deadiversion.usdoj.gov/*).

DATES: Comments must be submitted electronically or postmarked on or before May 12, 2022.

ADDRESSES: Interested persons may file written comments on this proposal in accordance with 21 CFR 1308.43(g). Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period. To ensure proper handling of comments, please reference ''Docket No. DEA–384'' on all correspondence, including any attachments.

- *Electronic comments:* The Drug Enforcement Administration (DEA) encourages that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or to attach a file for lengthier comments. Please go to *https://www.regulations.gov* and follow the online instructions at that site to submit comments. Upon completion of your submission, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on *Regulations.gov*. If you have received a Comment Tracking Number, you have successfully submitted your comment, and there is no need to resubmit the same comment.
- *Paper comments:* Paper comments that duplicate the electronic submission are not necessary. Should you wish to mail a paper comment *in lieu of* an electronic comment, send via regular or express mail to: Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: Terrence L. Boos, Ph.D., Chief (DOE), Diversion Control Division, Drug Enforcement Administration; Telephone: (202) 362–3249.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received in response to this docket are considered part of the public record. The Drug Enforcement Administration (DEA) will make comments available for public inspection online at *https://www.regulations.gov,* unless reasonable

cause is given. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter. The Freedom of Information Act applies to all comments received. If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want to make it publicly available, you must include the phrase ''PERSONAL IDENTIFYING INFORMATION'' in the first paragraph of your comment. You must also place all of the personal identifying information you do not want made publicly available in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want to make it publicly available, you must include the phrase ''CONFIDENTIAL BUSINESS INFORMATION'' in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment.

DEA will make publicly available in redacted form comments containing personal identifying information and confidential business information identified as directed above. If a comment has so much confidential business information or personal identifying information that DEA cannot redact it effectively, all or part of that comment may not be made publicly available. Comments posted to *https://www.regulations.gov* may include any personal identifying information (such as name, address, and phone number) included in the text of your electronic submission that is not identified, as directed above, as confidential.

An electronic copy of this document and supplemental information to this proposed rule are available at *https://www.regulations.gov* for easy reference.

Legal Authority

Pursuant to the Controlled Substances Act (CSA), under 21 U.S.C. 811(g)(3), 21 CFR 1308.31, and 21 CFR 1308.32, the Attorney General (and thus the Administrator of DEA by delegation) may, by regulation, exempt any compound, mixture, or preparation containing a nonnarcotic controlled substance from the application of all or any part of this subchapter if he finds that it is approved for prescription use, and that it 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. By regulation, the Administrator may 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 in revoking the exemption, permitting interested persons to file written comments on or objections to the revocation, considering any comments submitted, and publishing in the **Federal Register** a final order on the proposal to revoke the exemption. *See* 21 CFR 1308.31(c), (d).

This rulemaking proposes to make changes to 21 Code of Federal Regulations (CFR) 1308.21(d) to clarify that DEA may revoke ''(either individually or categorically)'' any previously granted exemptions, and adds § 1308.31(e) to clarify that products exempted from application of all or any part of the Controlled Substances Act pursuant to section 201(g)(3)(A), of the Act (21 U.S.C. 811(g)(3)(A)) are listed in the Table of Exempted Prescription Products available on the DEA Diversion Control website. In addition, this rulemaking proposes the removal of exempted prescription product status for butalbital products previously granted exemption. If finalized, this action would impose the regulatory controls and administrative, civil, and criminal sanctions of schedule III controlled substances on any person who handles or proposes to handle butalbital products that were previously exempted from control under 21 CFR 1308.31 and 1308.32.

Background: Exempted Prescription Products

Over time, 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 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 at *https://www.deadiversion.usdoj.gov/schedules/exempt/exempt_rx_list.pdf.* The list, dated February 11, 2022, contains 189 prescription products containing butalbital. These butalbital products were granted exempted status due to the quantity of acetaminophen in the formulation, which was believed at the time to vitiate the potential for abuse.

Many of the preparations granted exempted prescription product status were excepted 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 by BDAC in 1967. Following the establishment of the criteria, DEA approved subsequent applications by new manufacturers over the years based upon the same criteria, whereby the inclusion of other active ingredients was thought to be in sufficient quantities to vitiate the potential for abuse. These criteria developed in 1967 were 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 exception, then it also met the test to contain an ingredient that vitiated the potential for abuse under the CSA standard.

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 exception would be granted if for every 15 mg of barbiturate the product contained at least (a) 188 mg aspirin; (b) 375 mg salicylamide; or (c) 70 mg phenacetin, acetanilid or acetaminophen.

Butalbital is classified as an intermediate acting barbiturate. Butalbital is a schedule III controlled substance that falls under Administration Controlled Substances Code Number 2100 as it is a derivative of barbituric acid. 21 CFR 1308.13(c)(3). In 1967, products such as Fioricet, which contained butalbital (50 mg) in combination with acetaminophen (300 mg) and caffeine (40 mg), qualified for the exception under the above criteria. However, products such as Fiorinal, which contained butalbital (50 mg) in combination with aspirin (325 mg) and caffeine (40 mg), did not contain sufficient quantities of aspirin to meet the exception criteria, and therefore did not qualify for the exception. As such, Fiorinal was a schedule III controlled product, while Fioricet and similar butalbital combination products containing sufficient amounts of acetaminophen were automatically granted exempted prescription product status under the BDAC criteria once an application under 21 CFR 1308.31 was received. The rationale behind the difference between Fiorinal and Fioricet was that the acetaminophen quantity in

Fioricet would deter the product's abuse due to the potential liver toxicity resulting from the ingestion of high doses of acetaminophen.

However, subsequent experience has shown that the presence of acetaminophen in these butalbital products has not adequately deterred abuse and diversion. DEA has observed a pattern of diversion, online distribution, and abuse of exempted butalbital products. In particular, DEA has observed exploitation of the exempted prescription product status of butalbital combination products to enable abuse. Therefore, because the inclusion of acetaminophen has not vitiated the abuse potential of these products, DEA has concluded that these products do not meet the exemption criteria found in 21 U.S.C. 811(g)(3)(A).

Sellers have utilized websites to exploit the exempted prescription product status to make butalbital/acetaminophen and butalbital/acetaminophen/caffeine combination products available over the internet. In addition, DEA has documented a significant number of law enforcement encounters with butalbital/acetaminophen and butalbital/acetaminophen/caffeine products. DEA is actively investigating cases where individuals are exploiting the exempted prescription product status and are using such products to provide the controlled substance butalbital for drug abuse purposes. DEA, therefore, proposes to revoke the previously issued exempted prescription product status of all butalbital products. Upon publication of a final rule, these products shall become subject to the schedule III regulatory controls under the CSA.

Increase in Website Activity Relating to Exempted Prescription Products

The Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (Pub. L. 110–425) (Ryan Haight Act) was enacted on October 15, 2008 and became effective on April 13, 2009. The Ryan Haight Act amended the CSA to prevent the illegal distribution and dispensing of controlled substances by means of the internet and made it illegal under Federal law to ''deliver, distribute, or dispense a controlled substance by means of the internet, except as authorized by [the CSA]'' or to aid or abet such activity. 21 U.S.C. 841(h)(1). The Ryan Haight Act applies to all controlled substances in all schedules.

Under the Ryan Haight Act, for every controlled substance that is delivered, distributed, or sold, there must be a ''valid prescription.'' This means not only that the prescription must comply with the longstanding requirement of being issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice, but also that the prescribing practitioner must either (i) have conducted at least one in-person medical evaluation of the patient or (ii) meet the definition of a ''covering practitioner.'' 21 U.S.C. 829(e)(2)(A). Alternatively, a practitioner may write a prescription when engaged in the practice of telemedicine under the limited circumstances enumerated at 21 U.S.C. 802(54). 21 U.S.C. 829(e)(3)(A). Any practitioner who writes a prescription for a controlled substance that fails to comply with this provision of the CSA, as well as any pharmacy that knowingly or intentionally fills such a prescription, violates 21 U.S.C. 841(h)(1).

Hence, the Ryan Haight Act makes it unambiguous that, except in limited and specified circumstances, it is a per se violation of the CSA for a practitioner to issue a prescription for a controlled substance by means of the internet without having conducted at least one in-person medical evaluation.

After the Ryan Haight Act became effective, online pharmacies could no longer deliver, distribute, or dispense controlled substances without registering with DEA as online pharmacies and complying with associated laws and regulations, including the requirement of a prescription issued after an in-person medical evaluation of the patient in most circumstances. In response, DEA has seen a significant increase in the number of online pharmacies highlighting the availability of exempted prescription products containing butalbital/acetaminophen and butalbital/acetaminophen/caffeine and providing online dispensing. These sites are thereby exploiting the exempted prescription product status so customers can obtain butalbital. Thus, DEA finds a need to remove the exempted prescription product status for these products. If this proposed rule goes into effect, online pharmacies will be required to cease the sale and distribution of the products containing butalbital unless they comply with all relevant CSA requirements, including the requirements of the Ryan Haight Act and associated regulations.

DEA does not have data for the volume of exempted butalbital products dispensed via the internet. Therefore, DEA requests that online pharmacies/websites provide such volume data in their comments, so DEA can assess the potential impact of this proposed rulemaking.

Seizure Data

The National Forensic Laboratory Information System (NFLIS),[1] System to Retrieve Information from Drug Evidence (STRIDE), and STARLiMS databases [2] indicate that there were 3,122 butalbital drug reports identified that were submitted to Federal, state, and local forensic laboratories from January 1, 2010 to December 31, 2020.[3] In 2010, there were 402 butalbital reports, 420 reports in 2011, 363 reports in 2012, 328 reports in 2013, 330 reports in 2014, 340 reports in 2015, 302 reports in 2016, 252 reports in 2017, 148 reports in 2018, 132 reports in 2019 and 105 reports in 2020.

For the majority of butalbital exhibits, analytical laboratories only identify the active ingredient butalbital. Only a portion of the exhibits identifies the other secondary product ingredients. However, when secondary ingredients are reported, combinations of butalbital and acetaminophen greatly exceed the number of combination products containing butalbital and aspirin (or other ingredients) reported. (See chart below.)

SUMMARY TABLE

Calendar year	Percent of reports butalbital/acetaminophen	Percent of reports butalbital/aspirin
2010	29.4	6.0
2011	40.6	4.3
2012	40.6	4.4
2013	37.0	3.7
2014	25.3	2.0
2015	23.7	2.3
2016	21.5	2.9
2017	22.9	1.8
2018	16.2	5.1
2019	21.7	3.3
2020	33.0	2.1

Therefore, DEA concludes, based on the data mentioned above, that the mere presence of acetaminophen or acetaminophen/caffeine in butalbital combination products does not serve to vitiate the potential for abuse.

[1] NFLIS is a national drug forensic laboratory reporting system that systematically collects results from drug chemistry analyses conducted by state and local forensic laboratories across the country. The NFLIS participation rate, defined as the percentage of the national drug caseload represented by laboratories that have joined NFLIS, is over 97 percent. NFLIS includes drug chemistry results from completed analyses only.

[2] STRIDE is a database of drug exhibits sent to DEA laboratories for analysis. Exhibits from the database are from DEA, other Federal agencies, and law enforcement agencies. On October 1, 2014, STARLiMS replaced STRIDE as the DEA laboratory drug evidence data system of record.

[3] NFLIS database was queried on August 19, 2021, by date of submission, all drugs reported; STRIDE and STARLiMS databases were queried August 19, 2021, by date of collection, all drug records analyzed.

State Regulatory Controls on Butalbital Products

At least 15 states have seen a need to place additional regulatory requirements on the butalbital products for which DEA has granted exempted prescription product status. Alabama, Alaska, California, Georgia, Hawaii, Idaho, Illinois, Indiana, Kentucky, Maryland, Mississippi, New Mexico, Oklahoma, Pennsylvania, and Utah all subject these products to schedule III controls.

Ability To Reapply for Exempted Prescription Product Status

Any manufacturer of a butalbital/acetaminophen or butalbital/acetaminophen/caffeine combination product that is subject to this rulemaking may reapply for exempted prescription product status by following the application procedures specified in 21 CFR 1308.31 if they believe that their formulation contains unique attributes which demonstrate that their product meets the exemption criteria (*e.g.,* it contains one or more 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). However, DEA wishes to clarify that the mere presence of acetaminophen in the formulation in quantities of greater than 70 mg per 15 mg of barbiturate will no longer automatically qualify a butalbital product for an exemption unless the applicant can further demonstrate that the formulation vitiates the potential for abuse.

Requirements for Handling Schedule III Controlled Substances

If this proposed rule is adopted in final form, butalbital products formerly subject to automatic exemption will become subject to the CSA's schedule III regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, dispensing, importing, exporting, research, and conduct of instructional activities and chemical analysis with, and possession involving, schedule III substances, including the following (as of the date a final rule becomes effective):

1. *Registration.* Any person who handles (manufactures, distributes, dispenses, imports, exports, engages in research, or conducts instructional or chemical analysis with, or possesses) butalbital products, or who desires to handle butalbital products, would be required to be registered with DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958 and in accordance with 21 CFR parts 1301 and 1312.

2. *Disposal of Stocks.* Any person who does not desire or is not able to obtain a schedule III registration would be required to surrender all quantities of currently held butalbital products. Alternately, they may transfer all quantities of currently held butalbital products to a person registered with DEA in accordance with 21 CFR part 1317, in addition to all other applicable Federal, state, local, and tribal laws.

3. *Security.* Butalbital products would be subject to schedule III–V security requirements and must be handled and stored pursuant to 21 U.S.C. 821, 823, 871(b) and in accordance with 21 CFR 1301.71–1301.93.

4. *Labeling and Packaging.* All labels, labeling, and packaging for commercial containers of butalbital products would be required to comply with 21 U.S.C. 825 and 958(e) and be in accordance with 21 CFR part 1302.

5. *Inventory.* Every DEA registrant who possesses any quantity of butalbital products would be required to take an inventory of butalbital products on hand, pursuant to 21 U.S.C. 827 and 958 and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

Any person who becomes registered with DEA must take an initial inventory of all stocks of controlled substances (including butalbital products) on hand on the date the registrant first engages in the handling of controlled substances, pursuant to 21 U.S.C. 827 and 958 and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

After the initial inventory, every DEA registrant must take a new inventory of all controlled substances (including butalbital products) on hand at least every two years, pursuant to 21 U.S.C. 827 and 958 and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

6. *Records and Reports.* Every DEA registrant would be required to maintain records and submit reports for butalbital products, or products containing butalbital products, pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR parts 1304, 1312, and 1317.

7. *Prescriptions.* All prescriptions for butalbital products would be required to comply with 21 U.S.C. 829 and be issued in accordance with 21 CFR parts 1306 and 1311, subpart C.

8. *Importation and Exportation.* All importation and exportation of butalbital products would be required to be in compliance with 21 U.S.C. 952, 953, 957, and 958 and in accordance with 21 CFR part 1312.

9. *Liability.* Any activity involving butalbital products not authorized by, or in violation of, the CSA or its implementing regulations, would be unlawful and may subject the person to administrative, civil, and/or criminal sanctions.

List of Butalbital Products To Be Removed From the Table of Exempted Prescription Products

For reasons detailed above, DEA proposes the removal of Exempted Prescription Product status for all butalbital products, to include the products listed below:

Company	Trade name	NDC code	Form	Controlled substance	(mg or mg/ml)
Actavis Pharma, Inc	Butalbital, Acetaminophen and Caffeine Capsules USP 50/300/40.	0591–2640	CA	Butalbital	50
Actavis Pharma, Inc	Butalbital, Acetaminophen and Caffeine Tablets USP 50/325/40.	0591–3369	TB	Butalbital	50
Actavis Pharma, Inc	Fioricet (Butalbital, Acetaminophen and Caffeine USP 50/300/40).	52544–080	CA	Butalbital	50
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 AcetaminophenTablets 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

Company	Trade name	NDC code	Form	Controlled substance	(mg or mg/ml)
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 (25mg/325mg)	71993–301	TB	Butalbital	25
Atley Pharmaceuticals	Butalbital, Acetaminophen and Caffeine Tablets	59702–661	TB	Butalbital	50
Aurobindo Pharma Inc	Butalbital, Acetaminophen and Caffeine Capsules USP 50/325/40.	13107–075	CA	Butalbital	50
AvKare, Inc	Butalbital, Acetaminophen and Caffeine Tablets USP 50/325/40.	50268–139	TB	Butalbital	50
AvKare, Inc	Butalbital, Acetaminophen and Caffeine Capsules USP 50/300/40.	42291–181	CA	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.	55154–3356	TB	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.	55154–3356	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 325mg/Butalbital 50mg	00456–0674	TB	Butalbital	50
Forest Pharmacal Inc	Acetaminophen 500mg/Butalbital 50mg	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
Granules Pharmaceuticals Inc.	Butalbital, Acetaminiphen and Caffeine Capsules 50mg/300mg/40mg.	70010–044	CA	Butalbital	50
Granules Pharmaceuticals Inc.	Butalbital and Acetaminiphen Capsules 50mg/300mg	70010–054	CA	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

Company	Trade name	NDC code	Form	Controlled substance	(mg or mg/ml)
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
KVK Tech	Butalbital, Acetaminophen & Caffeine Tablets (50mg/325mg/40mg).	10702–253	TB	Butalbital	50
Landry Pharmacal Inc	Febridyne Plain Capsules	05383–001	CA	Butalbital	50
Lannett Company, Inc	Butalbital, Acetaminophen & Caffeine Tablets (50mg/325mg/40mg).	00527–1695	TB	Butalbital	50
Lannett Company, Inc	Butalbital, Acetaminophen & Caffeine Capsules (50mg/325mg/40mg).	00527–4094	CA	Butalbital	50
Lannett Company, Inc	Butalbital, Acetaminophen & Caffeine Capsules (50mg/300mg/40mg).	00527–4095	CA	Butalbital	50
Larken Laboratories, Inc	Allzital Butalbital and Acetaminophen Tablets (25mg/325mg).	68047–752	TB	Butalbital	25
Larken Laboratories, Inc	Butalbital and Acetaminophen Tablets (25mg/325mg)	68047–722	TB	Butalbital	25
Larken Laboratories, Inc	Butalbital and Acetaminophen Tablets (50mg/325mg)	68047–721	TB	Butalbital	50
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 Tablets (50/325/40mg).	79739–7320	TB	Butalbital	50
LGM Pharma Solutions, LLC	Butalbital, Acetaminophen and Caffeine Capsules (50/300/40mg).	79739–7029	CA	Butalbital	50
LGM Pharma Solutions, LLC	Butalbital and Acetaminophen Tablets (50/300mg)	79739–7075	TB	Butalbital	50
Libertas Pharma, Inc	Butalbital, Acetaminophen and Caffeine Capsules USP	51862–179	CA	Butalbital	50
Lunsco Inc	Pacaps Capsules	10892–0116	CA	Butalbital	50
Major Pharmaceuticals	Butalbital, Acetaminophen and Caffeine Tablets (50/325/40mg).	0904–6938	TB	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	46672–0053	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

Company	Trade name	NDC code	Form	Controlled substance	(mg or mg/ml)
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	Tencon (Butalbital and Acetaminophen 50mg/325mg)	11584–0030	TB	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
NorthStar	Butalbital, Acetaminophen and Caffeine Capsules (50mg/300mg/40mg).	16714–170	CA	Butalbital	50
Oceanside Pharmaceuticals (Manufactured by Nexgen).	Butalbital and Acetaminophen Tablets (50mg/300mg)	68682–306	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/325mg/40mg	63187–933	TB	Butalbital	50
ProficientRx	Butalb/Acet/Caffeine 50mg/300mg/40mg	71205–962	CA	Butalbital	50
ProficientRx	Butalb/Acet/Caffeine 50mg/325mg/40mg	71205–981	TB	Butalbital	50
ProficientRx	Butalb/Acet/Caffeine 50mg/325mg/40mg	71205–510	TB	Butalbital	50
Qualitest Pharmaceuticals, Inc.	Butalbital and Acetaminophen Tablets	0603–2540	TB	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) (25mg/325mg).	70362–722	TB	Butalbital	25
Skylar Laboratories, LLC	Butalbital and Acetaminophen Tablets (50mg/325mg)	70362–721	TB	Butalbital	50
Solubiomix	Butalbital and Acetaminophen Tablets (50mg/325mg)	69499–302	TB	Butalbital	50
Solubiomix	Butalbital and Acetaminophen Capsules (50mg/300mg)	69499–342	CA	Butalbital	50
Stewart Jackson Pharmacal, Inc.	Ezol	45985–0578	CA	Butalbital	50
STI Pharma, LLC	Butalbital and Acetaminophen Tablets (50mg/325mg)	54879–026	TB	Butalbital	50
Sunrise Pharmaceuticals, Inc	Butalbital, Acetaminophen, Caffeine Capsules (50mg/300mg/40mg).	11534–187	CA	Butalbital	50
Taro Pharmaceuticals U.S.A., Inc.	Butalbital, Acetaminophen and Caffeine Caps (50mg/300mg/40mg).	51672–4222	CA	Butalbital	50
Tedor Pharma, Inc	Butalbital and Acetaminophen Tablets (50mg/300mg)	47781–534	TB	Butalbital	50
Tedor Pharma, Inc	Butalbital and Acetaminophen Tablets (50mg/325mg)	43199–053	TB	Butalbital	50

Company	Trade name	NDC code	Form	Controlled substance	(mg or mg/ml)
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
Westminster Pharmaceuticals	Butalbital, Acetaminophen and Caffeine Tablets (50mg/325mg/40mg).	69367–203	TB	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 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review)

This proposed rule was developed in accordance with the principles of Executive Orders (E.O.) 12866 and 13563. E.O. 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects; distributive impacts; and equity). E.O. 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in E.O. 12866. E.O. 12866 classifies a ''significant regulatory action'' requiring review by the Office of Management and Budget (OMB) as any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the E.O.

The economic, interagency, budgetary, legal, and policy implications of this proposed rule have been examined, and it has been determined that it is a significant regulatory action under E.O. 12866.

Benefits

The removal of exempted prescription product status for butalbital products previously granted exemption would impose the regulatory controls and administrative, civil, and criminal sanctions of schedule III controlled substances on any person who handles or proposes to handle butalbital products that were previously exempted from control under 21 CFR 1308.31 and 1308.32. Controlling previously exempt butalbital prescription products as schedule III controlled substances is expected to prevent, curtail, and limit the questionable distribution and dispensing of these products, including the distribution and dispensing via the internet. One of DEA's primary concerns is the prevalence of questionable online websites that promote the sale of exempted butalbital products ''without a prescription.'' Such questionable sales practices exploit the current regulatory status of these exempted prescription products. These questionable websites are not to be equated with ''mail order pharmacies,'' which serve a valuable role in legitimate U.S. health care. This proposal is directed in particular to such questionable websites and is not intended to adversely affect legitimate mail order or retail pharmacies. This proposed rule is expected to impact these online sales practices, resulting in fewer individuals abusing these products and potentially becoming addicted to these or similar products.

Additionally, DEA anticipates benefits from reduced societal costs (*i.e.,* health care costs, criminal justice system costs, opportunity costs, etc.) due to abuse and addiction. While this proposed rule is expected to lower the abuse of currently exempt butalbital products, DEA has no basis to quantify the amount of abuse that will be prevented, and the societal cost savings result of this rule. However, DEA anticipates that removal of exempted prescription product status for butalbital products will reduce the amount of abuse of these products, and lead to societal cost savings.

Costs

Below is an Economic Impact Analysis which summarizes the costs associated with this proposed rule.

Affected Persons

The removal of exempted prescription product status for previously exempted butalbital products will affect all persons who handle (manufacture, distribute, dispense, engage in research, conduct instructional activities, or possess) or propose to handle these products. The exempt butalbital products are prescription drug products

used for the treatment of tension headaches. While some hospitals or clinics may hold some exempt butalbital products in inventory, quantities are expected to be minimal and the economic impact on hospitals is expected to be minimal. Therefore, DEA does not anticipate this proposed rule will affect hospitals. Additionally, while prescribers would need a DEA registration to prescribe these products, nearly all individual practitioners are expected to be registered with DEA already or otherwise have authority to prescribe controlled substances but are exempt from registration. Therefore, for the purposes of this analysis, DEA assumes this proposed rule primarily affects manufacturers, distributors, and pharmacies.

The ''Table of Exempted Prescription Products'' includes the National Drug Code (NDC), which serves as a universal product identifier for the exempt prescription products, among other information. While the list of products that have been granted exempted prescription product status contains 189 prescription products containing butalbital (as of February 11, 2022), not all are actively marketed in the United States. By comparing the NDC of the 189 products that were granted exempt status to the current NDC Directory,[4] coupled with recent exemption approvals, DEA estimates 49 exempt butalbital products are actively marketed in the United States. DEA believes many of the remainder of these 189 products have been discontinued; there is no requirement to inform DEA of discontinuation of products that have been granted exempt prescription product status. From review of applicant information in the application for exempt prescription product status and NDC labeler information from the NDC Directory, DEA estimates the 49 exempt butalbital products are manufactured by 30 manufacturers.

The number of DEA registrations forms the basis of the number of distributors and pharmacies. Because exempted butalbital products are widely prescribed, DEA assumes that all DEA-registered distributors and pharmacies are exempted butalbital product handlers. Also, for the purposes of this analysis, DEA assumes all legally operating distributors and pharmacies that handle exempted butalbital products are registered with DEA. Based on DEA records, as of June 5, 2020, there are 627 distributor registrations and 70,672 pharmacies authorized to handle schedule III controlled substances.

In summary, DEA estimates 71,329 establishments (30 manufacturers, 627 distributors, and 70,672 pharmacies) are affected by this proposed rule.

Costs Associated With Requirements

DEA considered various costs associated with handling exempt butalbital products as a schedule III controlled substance for each of the business activities (manufacturer, distributor, prescriber, and pharmacy) anticipated to handle butalbital and be impacted by this proposed rule. The costs include costs associated with various requirements, such as: Registration, physical security, labeling and packaging, inventory and recordkeeping, and disposal.

The registration requirements impact all manufacturers that do not hold a DEA manufacturer registration. DEA conducted a search of its registration records for the 30 manufacturer establishments identified as handling exempt butalbital. DEA estimates there are 19 manufacturers that would need DEA registrations if this proposed rule were promulgated. The 19 non-registered manufacturers would incur an initial registration and an annual renewal fee of $3,699 for the manufacturer registration for a total of $70,281 per year. DEA assumes all legally operating distributors and pharmacies that handle exempted butalbital products are already registered with DEA. Therefore, DEA estimates distributors and pharmacies would not incur additional registration-related costs if this proposed rule were promulgated. In summary, the estimated cost of the registration requirements associated with this proposed rule is the cost of the initial registration and annual renewal registration fees for the 19 manufacturers, $70,281 per year.

DEA estimated the costs associated with physical security requirements for manufacturers and distributors. Many states already control butalbital as a schedule III controlled substance under state law. As state requirements for schedule III controlled substances generally meet or exceed DEA requirements, only the establishments located in states where the exempt butalbital products are not controlled as schedule III controlled substances under state law are estimated to incur costs associated with physical security. Based on review of publicly available information regarding the locations of the manufacturers and registered locations of distributors, DEA estimates 17 manufacturer establishments and 399 distributors are located in states where exempt butalbital products are not already subject to controls equivalent to Federal schedule III handling requirements under state law. Based on a review of manufacturing data of a largely prescribed controlled substance and review of commercially available industry reports of exempt butalbital products, DEA estimates 3 of the 17 manufacturers (located in states where the exempt butalbital products are not controlled as schedule III controlled substances under state law) will need a large secure area and 14 of 17 will require a small secure area. DEA estimates the three large manufacturers would each need to secure 20,000 square feet (sq. ft.) of space and 14 small manufacturers would each need to secure 10,000 sq. ft. of space, at a cost of $112,000 and $79,196 for a large and small manufacturer, respectively, for a total of $1,444,744.

As with manufacturers, DEA anticipates a concentration of market share with a small number of large distributors distributing the majority of exempt butalbital products in the U.S. DEA estimates the market distribution of exempt butalbital products is similar to that of a largely prescribed controlled substance. Based on estimates that 20 large, 60 medium, and 319 small distributors would need to secure 4,000 sq. ft., 250 sq. ft., and 16 sq. ft. of space, respectively, DEA estimates a cost of $35,418, $8,854, and $2,217 for large, medium, and small distributors, respectively, for a total of $1,946,823. In summary, DEA estimates the requirements associated with physical security controls will have a one-time cost of $1,444,744 for all manufacturers combined and a one-time cost of $1,946,823 for all distributors combined, for a grand total of $3,391,567.

DEA estimates pharmacies are already handling other schedule III controlled substances and have the controls and procedures in place to store exempt butalbital products in a secure area at a minimal cost. Pharmacies and institutional practitioners may disperse such substances throughout the stock of non-controlled substances in such a manner as to obstruct the theft or diversion of controlled substances. 21 CFR 1301.75(b). DEA believes these

[4] ''The Drug Listing Act of 1972 requires registered drug establishments to provide FDA with a current list of all drugs manufactured, prepared, propagated, compounded, or processed by it for commercial distribution. (See Section 510 of the Federal Food, Drug, and Cosmetic Act (Act) (21 U.S.C. 360)). Drug products are identified and reported using a unique, three-segment number, called the National Drug Code (NDC), which serves as a universal product identifier for drugs. FDA publishes the listed NDC numbers and the information submitted as part of the listing information in the NDC Directory which is updated daily.'' *https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm.* (accessed March 18, 2020)

facilities possess adequate physical security controls and any cost associated with physical security requirements as a result of this rule is minimal.

In accordance with the CSA, every DEA registrant must maintain, on a current basis, a complete and accurate record of each controlled substance manufactured, received, sold, delivered, or otherwise disposed of. 21 U.S.C. 827(a). These records must be maintained separately from all other records of the registrant, or alternatively, in the case of non-narcotic controlled substances, be in such a form that required information is readily retrievable from the ordinary business records of the registrant. 21 U.S.C. 827(b)(2). The records must be kept and be available for at least two years for inspection and copying by officers or employees of the Attorney General. 21 U.S.C. 827(b)(3). To fulfill its regulatory responsibilities, DEA assumes for the purpose of this analysis that exempt butalbital product handlers already maintain detailed records of exempt butalbital product transactions and those records can be maintained separately or readily retrievable at minimal cost. DEA estimates that there will be no economic impact beyond the inventory of exempted prescription status butalbital product stock pursuant to the initial and biennial inventory requirements in 21 CFR 1304.11.

Following the finalization of this scheduling action, registrants would be required to take an inventory of all stocks of exempted prescription status butalbital products on hand and continue to conduct inventories biennially. DEA estimates the inventories for manufacturers and distributors will be conducted by a warehouse first-line supervisor and administrative personnel and will take one-half hour to complete. Additionally, DEA estimates inventories for pharmacies will be conducted by a pharmacist and a pharmacy technician and will take 6 minutes (0.1 hour) to complete. Based on U.S. Bureau of Labor Statistics hourly wage data and load for benefits, DEA estimates the cost of initial and biennial inventory for manufacturers, distributors, and pharmacies is $33.03, $33.03, and $11.12 per occurrence, respectively.[5] Total inventory cost for 30 manufacturers, 627 distributors and 70,672 pharmacies is $807,573 initially, in the first year, and biennially, thereafter.

If this rule is finalized, labeling and packaging requirements pursuant to 21 CFR part 1302 would apply to currently exempted prescription status butalbital products. Printed labels would need to indicate their status as a schedule III controlled substance. For example, the printed label would need to include ''CIII'' or ''C–III.'' DEA assumes that the activity of manufacturers making labeling changes is routine and in their normal course of business. Therefore, DEA assumes that the cost of making this change is minimal. Accordingly, DEA estimates that the cost of the labeling and packaging requirements of this proposed rule is minimal.

A reverse distributor generally performs the disposal of controlled substances by registrants. DEA recognizes that removing the exempt status for previously exempt butalbital products may increase the volume of material that registrants will need to dispose through a reverse distributor. However, as exempted prescription status butalbital products are currently not controlled, DEA does not have information on the volume of exempt butalbital products currently disposed of, and thus cannot determine what the increase in schedule III controlled substance disposal will be or how it will affect the fees charged by reversed distributors. Therefore, DEA is unable to quantify the costs associated with the disposal of exempt butalbital products. However, since DEA assumes the affected establishments are already disposing of controlled substances, the disposal of previously exempted prescription status butalbital products will be incorporated into existing business processes. DEA believes that any cost increase, if one exists, will be minimal.

In summary, DEA estimates the economic impact of this proposed rule is due to the costs associated with registration requirements, the costs associated with storage requirements, and the costs associated with inventory requirements. The registration cost is an initial registration fee and an annual renewal fee of $70,281 (for the 19 non-registered manufacturer establishments). The cost associated with storage requirements is a one-time cost of $3,391,567 for all affected establishments combined (17 manufacturers and 399 distributors located in states where exempted prescription status butalbital products are not controlled under State law). The costs associated with inventory and recordkeeping are an initial inventory cost of $807,573 and a biennially recurring inventory cost of $807,573 for all manufacturer, distributor, and pharmacy establishments combined.

DEA determined the annualized cost of the proposed rule by calculating the present value of the costs utilizing the discounted cash flow method at 3 percent and 7 percent and converting the present value into equal annual payments over 20 years at the 3 percent and 7 percent discount rates.[6] The present value of the costs associated with the proposed rule is $10,434,492 and $8,336,626 at 3 percent and 7 percent discount rates, respectively. The annualized costs are $701,362 and $786,918 at 3 percent and 7 percent discount rates, respectively. Conservatively, using the 7 percent rate, the estimated annualized cost of the proposed rule is $786,918 per year. The estimated highest cost in any given year is $4,269,421, which represents the year of implementation of the rule (Year 1). Although DEA currently is unable to quantify the societal cost savings resulting from the placement of butalbital products in schedule III, DEA believes such savings will exceed the costs associated with this proposed rule.

Discussion of Uncertainties

This analysis evaluates the economic impact of controlling pharmaceuticals that are currently exempt from control. Therefore, DEA does not have a strong basis to estimate some of the costs or other impacts to affected persons. DEA welcomes all comments that would narrow the uncertainties in the presented analysis, and specifically asks potentially affected persons the following questions (specific and quantified responses are more helpful):

1. DEA does not have data on (a) the volume of butalbital products dispensed via online pharmacies and websites; (b) the number of physicians impacted that do not have DEA registrations; (c) the number of pharmacies impacted that do not have DEA registrations; and (d) the impact on patients that are unable to

[5] Bureau of Labor Statistics, Occupational and Employment and Wages, May 2019, *https://www.bls.gov/oes/current/oes_nat.htm.* Bureau of Labor Statistics, ''Employer Costs for Employee Compensation—December 2019'' reports that benefits for private industry is 29.9 percent of total compensation. The 29.9 percent of total compensation equates to a 42.7 percent (29.9/70.1) load on wages and salaries. *https://www.bls.gov/news.release/pdf/ecec.pdf.* 0.5 hour × [$26.47 per hour + $19.82 per hour] × 1.427 load = $33.03. 0.1 hour × [$61.58 per hour + $16.32 per hour] × 1.427 load = 11.12.

[6] The use of 7 percent and 3 percent rates for present value calculation, annual payment calculation, and analysis time horizon is based on OMB Circular A–4, September 17, 2003. *See also* ''Regulatory Impact Analysis: A Primer'' and ''Regulatory Impact Analysis: Frequently Asked Questions (FAQ)'' February 7, 2011, Office of Information and Regulatory Affairs (OIRA). DEA used a 20-year time horizon for this analysis as there is no predetermined end to this rule.

seek face-to-face guidance from a provider. DEA requests comments that help to identify the extent of the impact this rulemaking may impose.

2. DEA estimates that hospitals and clinics would be minimally affected by this proposed rule because most hospitals and clinics are expected to hold minimal inventory. Distributions of exempt butalbital products to hospitals and clinics are expected to be minimal, while a large majority of distributions are to pharmacies. Will hospitals and clinics be materially affected by this proposed rule? If so, please explain with specific and quantified information as possible.

3. DEA estimates 19 manufacturers would need to obtain a DEA registration to continue manufacturing exempt butalbital products. Is this a reasonable estimate? Would any manufacturer cease manufacturing exempt butalbital products rather than obtaining a DEA registration to continue manufacturing of exempt butalbital products?

4. How much time would be required to conduct an inventory of exempt butalbital products for a typical manufacturer, distributor, and pharmacy? Who (what occupation) usually conducts the inventory?

5. If this rule is finalized, commercial packaging would require, with some exceptions, a printed label a symbol designating the schedule, *i.e.,* ''CIII'' or ''C–III.'' DEA assumes that the activity of manufacturers making labeling changes is routine and in their normal course of business. What is the cost of adding the required symbol to the commercial packaging?

Executive Order 12988, Civil Justice Reform

This proposed 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 proposed rulemaking does not have federalism implications warranting the application of E.O. 13132. The proposed 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 proposed 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 (RFA) (5 U.S.C. 601–612), has reviewed this proposed rule and by approving it, certifies that the proposed rule, if promulgated, will not have a significant economic impact on a substantial number of small entities.

Below is a summary of the threshold analyses conducted by the DEA to support the certification statement above.

In accordance with the RFA, DEA evaluated the impact of this proposed rule on small entities. DEA estimates that this proposed rule will affect 31,187 entities, of which 30,593 are small entities (17 manufacturers, 406 distributors, and 30,170 pharmacies). The number of affected small entities for each business activity is compared to the number of small entities in each corresponding North American Industry Classification System (NAICS) code to determine whether a substantial number of small entities are affected. Additionally, the annualized cost of the proposed rule for each affected entity is compared to its estimated annual revenue to determine whether this proposed rule will have a significant economic impact on small entities. Since DEA does not collect revenue information on its registrants, to estimate the number of entities ''significantly'' impacted by the proposed rule, DEA relied on publicly available information. Combining the two criteria, substantial number and significant economic impact, DEA determined that this proposed rule will not have a significant economic impact on a substantial number of small entities.

Specifically, DEA examined the registration, physical security, labeling and packaging, inventory and recordkeeping, and disposal requirements for the small entities estimated to be affected by the proposed rule. Based on DEA's understanding of its registrants' operations and facilities, and research of publicly available information regarding size and location, DEA estimates that the annualized cost of this proposed rule would vary. Entities already registered to handle schedule III controlled substances would not incur any additional registration costs, and manufacturers and distributors located in the states that control exempt butalbital products as a schedule III controlled substance under state law would not incur any additional costs associated with physical security as state requirements for schedule III controlled substances generally meet or exceed Federal requirements. DEA estimates the following annualized costs:

- $10,703 per establishment for costs associated with registration, physical security, and inventory requirements: Non-registered manufacturers located in a state where exempt butalbital products are not already subject to controls equivalent to Federal schedule III handling requirements under state law.
- $7,004 per establishment for costs associated with physical security and inventory requirements: Registered manufacturers located in a state where exempt butalbital products are not already subject to controls equivalent to Federal schedule III handling requirements under state law.
- $3,716 per establishment for costs associated with registration and inventory requirements: Non-registered manufacturers located in a state where exempt butalbital products are already subject to controls equivalent to Federal schedule III handling requirements under state law.
- $17 per establishment for costs associated with inventory requirements: Registered manufacturers located in a state where exempt butalbital products are already subject to controls equivalent to Federal schedule III handling requirements under state law.
- $213 per establishment for costs associated with physical security and inventory requirements: Distributors located in a state where exempt butalbital products are not already subject to controls equivalent to Federal schedule III handling requirements under state law.
- $17 per establishment for costs associated with inventory requirements: Distributors located in a state where exempt butalbital products are already subject to controls equivalent to Federal schedule III handling requirements under state law.
- $6 per establishment for costs associated with inventory requirements: All pharmacies.

DEA estimates manufacturer, distributor, and pharmacy business activities best correspond to the following NAICS codes:

- Manufacturer: 325412—Pharmaceutical Preparation Manufacturing
- Distributor: 424210—Drugs and Druggists' Sundries Merchant Wholesalers
- Pharmacy: 446110—Pharmacies and Drug Stores

DEA researched publicly available information for each of the 17 affected manufacturer small entities and estimated each of their annual revenues. The annualized cost corresponding to their registration and location were compared with the estimated annual revenue for each of the 17 manufacturer small entities. DEA considers the economic impact is ''significant'' if the annual impact is greater than 3 percent of annual revenue. The economic impact is estimated to be significant for one of the small manufacturers. In conclusion, DEA estimates there are 930 small firms in NAICS code 325412—Pharmaceutical Preparation Manufacturing, of which 17 small entities are affected by this proposed rule, and one small entity in NAICS code 325412 will have a significant economic impact.

Regarding physical security and inventory costs to distributors, the U.S. Census Bureau's Statistics on U.S. Businesses (SUSB) data contains estimated annual revenue, the number of establishments, and the number of firms for each NAICS code at various revenue ranges, *i.e.,* less than $100,000, $100,000–499,000, $500,000–999,999, etc. The estimated annualized cost of $213 and $17 per distributor establishment was compared to the average annual revenue of the smallest of small firms in NAICS code 424210—Drugs and Druggists' Sundries Merchant Wholesalers. From SUSB data, there are 585 firms in the smallest firm size category, ''Less than $100,000,'' for a combined estimated annual receipts of $31,248,000, or an average of $53,415 per firm.[7] The annualized cost of $213 and $17 are 0.4 percent and 0.03 percent of the average annual receipt of $53,415 per firm. Because DEA does not expect this proposed rule to have a significant economic impact on the smallest of small entities, DEA does not expect it to have a significant economic impact on any small entity. DEA estimates there are 6,663 small firms in NAICS code 424210—Drugs and Druggists' Sundries Merchant Wholesalers, of which 406 distributor small entities are affected by this proposed rule, and no small entities in NAICS code 424210 will have a significant economic impact.

Regarding inventory requirement costs for pharmacies, the estimated annualized cost of $6 per pharmacy establishment was compared to the average annual revenue of the smallest of small firms in NAICS code 446110—Pharmacies and Drug Stores. From SUSB data, there are 751 firms in the smallest firm size category, ''Less than $100,000,'' for a combined estimated annual receipts of $36,066,000 or an average of $48,024 per firm.[8] The annualized cost of $6 is approximately 0.01 percent of the average annual receipt of $48,024 per firm. Because DEA does not expect this proposed rule to have a significant economic impact on the smallest of small entities, DEA does not expect it to have a significant economic impact on any small entity. While DEA estimates this proposed rule to affect a substantial number of pharmacy small entities in NAICS code 446110—Pharmacies and Drug Stores, the proposed rule is not expected to have a significant economic impact on any pharmacy small entity.

In conclusion, DEA's assessment of economic impact by size category indicates that the proposed rule, if promulgated, will not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

The estimated highest cost in any given year is $4,269,421; thus, DEA has determined in accordance with the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1501 *et seq.,* 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 for inflation) in any one year. Therefore, neither a Small Government Agency Plan nor any other action is required under provisions of UMRA.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information under the Paperwork Reduction Act of 1995. 44 U.S.C. 3501–3521. This action would not impose recordkeeping or reporting requirements on state or local governments, individuals, businesses, or organizations. 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.

List of Subjects 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Exports, Imports, Reporting and recordkeeping requirements.

Accordingly, for the reasons set forth in the preamble, DEA proposes to amend 21 CFR part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), 956(b), unless otherwise noted.

■ 2. In § 1308.31, revise paragraph (d) and add paragraph (e) to read as follows:

§ 1308.31 Application for exemption of nonnarcotic prescription product.

* * * * *

(d) The Administrator may revoke (either individually or categorically) any exemption granted pursuant to section 201(g)(3)(A) of the Act (21 U.S.C. 811(g)(3)(A)) by following the procedures set forth in paragraph (c) of this section for handling an application for an exemption which has been accepted for filing. The Administrator has categorically revoked exemptions for the following products:

(1) Effective as of [effective date of final rule], the previous exemptions approved for butalbital products are revoked and such products become subject to the statutory and regulatory restrictions applicable to schedule III controlled substances.

(2) [Reserved]

(e) The compounds, mixtures, or preparations that the Administrator has exempted from application of all or any part of the Act pursuant to section 201(g)(3)(A), of the Act (21 U.S.C. 811(g)(3)(A)) are listed in the Table of Exempted Prescription Products available on the DEA Diversion Control website at *www.deadiversion.usdoj.gov/schedules.*

Anne Milgram,

Administrator.

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[7] *https://www2.census.gov/programs-surveys/susb/tables/2012/us_6digitnaics_r_2012.xlsx.* (accessed June 3, 2020).

[8] Ibid.