TABLE 2—EXECUTIVE ORDER 13771 SUMMARY TABLE

[in $ Millions 2016 Dollars, Over an Infinite Time Horizon]

Item	Primary estimate (7%)	Lower estimate (7%)	Upper estimate (7%)
Present Value of Costs			
Present Value of Cost Savings			
Present Value of Net Costs			
Annualized Costs			
Annualized Cost Savings			
Annualized Net Costs			

We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the final rule. The full analysis of economic impacts is available in the docket for this final rule (Ref. 1) and at *https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations*.

VII. Analysis of Environmental Impact

We have determined under 21 CFR 25.31(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

IX. Federalism

We have analyzed this final rule in accordance with the principles set forth in Executive Order 13132. We have determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the Executive Order and, consequently, a federalism summary impact statement is not required.

X. Consultation and Coordination With Indian Tribal Governments

We have analyzed this rule in accordance with the principles set forth in Executive Order 13175. We have determined that the rule does not contain policies that 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. Accordingly, we conclude that the rule does not contain policies that have tribal implications as defined in the Executive Order and, consequently, a tribal summary impact statement is not required.

XI. Reference

The following reference is on display at the Dockets Management Staff (see **ADDRESSES**) and is available for viewing by interested persons between 9 a.m. and 4 p.m. Monday through Friday; it is also available electronically at *https://www.regulations.gov*. FDA has verified the website address, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. FDA/Economics Staff, ''Elimination of the 21 CFR 610.30 Test for *Mycoplasma* Preliminary Regulatory Impact Analysis, Preliminary Regulatory Flexibility Analysis, Unfunded Mandates Reform Act Analysis,'' 2018. (Available at *https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations*.)

List of Subjects in 21 CFR part 610

Biologics, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 610 is amended as follows:

PART 610—GENERAL BIOLOGICAL PRODUCTS STANDARDS

■ 1. The authority citation for part 610 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360, 360c, 360d, 360h, 360i, 371, 372, 374, 381; 42 U.S.C. 216, 262, 263, 263a, 264.

Subpart D—[Removed and Reserved]

■ 2. Remove and reserve subpart D, consisting of § 610.30.

Dated: July 29, 2020.

Stephen M. Hahn,

Commissioner of Food and Drugs.

[FR Doc. 2020–17085 Filed 8–20–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1308 and 1312

[Docket No. DEA–500]

RIN 1117–AB53

Implementation of the Agriculture Improvement Act of 2018

AGENCY: Drug Enforcement Administration (DEA), Department of Justice.

ACTION: Interim final rule with request for comments.

SUMMARY: The purpose of this interim final rule is to codify in the Drug Enforcement Administration (DEA) regulations the statutory amendments to the Controlled Substances Act (CSA) made by the Agriculture Improvement Act of 2018 (AIA), regarding the scope of regulatory controls over marihuana, tetrahydrocannabinols, and other marihuana-related constituents. This interim final rule merely conforms DEA's regulations to the statutory amendments to the CSA that have already taken effect, and it does not add additional requirements to the regulations.

DATES: Effective August 21, 2020. Electronic comments must be submitted, and written comments must be postmarked, on or before October 20, 2020. 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.

ADDRESSES: To ensure proper handling of comments, please reference ''RIN 1117–AB53/Docket No. DEA–500'' on all correspondence, including any attachments.

• *Electronic comments:* The Drug Enforcement Administration 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 attach a file for lengthier comments. Please go to *http://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon completion of your submission, you will receive a Comment Tracking Number for your comment. Please be aware that submitted comments are not instantaneously available for public view on *http://www.regulations.gov.* If you have received a Comment Tracking Number, your comment has been successfully submitted, and there is no need to resubmit the same comment.

• *Paper comments:* Paper comments that duplicate the electronic submission are not necessary and are discouraged. Should you wish to mail a paper comment *in lieu* of an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, Diversion Control Division; Mailing Address: 8701 Morrissette Drive, Springfield, VA 22152.

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598–2596.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received are considered part of the public record. They will, unless reasonable cause is given, be made available by the Drug Enforcement Administration (DEA) for public inspection online at *http://www.regulations.gov.* Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter. The Freedom of Information Act (FOIA) 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 it to be made 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 it to be made publicly available, you must include the phrase ''CONFIDENTIAL BUSINESS INFORMATION'' in the first paragraph of your comment. You must also prominently identify the confidential business information to be redacted within the comment.

Comments containing personal identifying information and confidential business information identified as directed above will generally be made publicly available in redacted form. If a comment has so much confidential business information or personal identifying information that it cannot be effectively redacted, all or part of that comment may not be made publicly available. Comments posted to *http://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 the complete Economic Impact Analysis, to this interim final rule are available in their entirety under the tab ''Supporting Documents'' of the public docket of this action at *http://www.regulations.gov* under FDMS Docket ID: DEA–500 (RIN 1117–AB53/Docket Number DEA–500) for easy reference.

Executive Summary

The Agriculture Improvement Act of 2018, Public Law 115–334 (the AIA), was signed into law on December 20, 2018. It provided a new statutory definition of ''hemp'' and amended the definition of marihuana under 21 U.S.C. 802(16) and the listing of tetrahydrocannabinols under 21 U.S.C. 812(c). The AIA thereby amends the regulatory controls over marihuana, tetrahydrocannabinols, and other marihuana-related constituents in the Controlled Substances Act (CSA).

This rulemaking makes four conforming changes to DEA's existing regulations:

• It modifies 21 CFR 1308.11(d)(31) by adding language stating that the definition of ''Tetrahydrocannabinols'' does not include ''any material, compound, mixture, or preparation that falls within the definition of hemp set forth in 7 U.S.C. 1639*o*.''

• It removes from control in schedule V under 21 CFR 1308.15(f) a ''drug product in finished dosage formulation that has been approved by the U.S. Food and Drug Administration that contains cannabidiol (2-[1R-3-methyl-6R-(1-methylethenyl)-2-cyclohexen-1-yl]-5-pentyl-1,3-benzenediol) derived from cannabis and no more than 0.1% (w/w) residual tetrahydrocannabinols.''

• It also removes the import and export controls described in 21 CFR 1312.30(b) over those same substances.

• It modifies 21 CFR 1308.11(d)(58) by stating that the definition of ''Marihuana Extract'' is limited to extracts ''containing greater than 0.3 percent delta-9-tetrahydrocannabinol on a dry weight basis.''

This interim final rule merely conforms DEA's regulations to the statutory amendments to the CSA that have already taken effect, and it does not add additional requirements to the regulations. Accordingly, there are no additional costs resulting from these regulatory changes. However, as discussed below, the changes reflected in this interim final rule are expected to result in annual cost savings for affected entities.

Changes to the Definition of Marihuana

The AIA amended the CSA's regulatory controls over marihuana by amending its definition under the CSA. Prior to the AIA, marihuana was defined in 21 U.S.C. 802(16) as follows:

> The term ''marihuana'' means all parts of the plant Cannabis sativa L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin. Such term does not include the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination.

The AIA modified the foregoing definition by adding that the ''term 'marihuana' does not include hemp, as defined in section 1639*o* of Title 7.'' 21 U.S.C. 802(16)(B). Furthermore, the AIA added a definition of ''hemp'' to 7 U.S.C. 1639*o,* which reads as follows:

> The term 'hemp' means the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.

Taken together, these two changes made by the AIA limit the definition of marihuana to only include cannabis or cannabis-derived material that contain more than 0.3% delta-9-tetrahydrocannabinol (also known as Δ^9-THC) on a dry weight basis. Thus, to fall within the current CSA definition of

marihuana, cannabis and cannabis-derived material must both fall within the pre-AIA CSA definition of marihuana and contain more than 0.3 percent Δ^9-THC on a dry weight basis. Pursuant to the AIA, unless specifically controlled elsewhere under the CSA, any material previously controlled under Controlled Substance Code Number 7360 (marihuana) or under Controlled Substance Code Number 7350 (marihuana extract), that contains 0.3% or less of Δ^9-THC on a dry weight basis—*i.e.,* ''hemp'' as that term defined under the AIA—is not controlled. Conversely, any such material that contains greater than 0.3% of Δ^9-THC on a dry weight basis remains controlled in schedule I.

In order to meet the AIA's definition of hemp, and thus qualify for the exception in the definition of marihuana, a cannabis-derived product must itself contain 0.3% or less Δ^9-THC on a dry weight basis. It is not enough that a product is labeled or advertised as ''hemp.'' The U.S. Food and Drug Administration (FDA) has recently found that many cannabis-derived products do not contain the levels of cannabinoids that they claim to contain on their labels.[1] Cannabis-derived products that exceed the 0.3% Δ^9-THC limit do not meet the statutory definition of ''hemp'' and are schedule I controlled substances, regardless of claims made to the contrary in the labeling or advertising of the products.

In addition, the definition of hemp does not automatically exempt any product derived from a hemp plant, regardless of the Δ^9-THC content of the derivative. In order to meet the definition of ''hemp,'' and thus qualify for the exemption from schedule I, the derivative must not exceed the 0.3% Δ^9-THC limit. The definition of ''marihuana'' continues to state that ''*all* parts of the plant Cannabis sativa L.,'' and ''*every* compound, manufacture, salt, derivative, mixture, or preparation of such plant,'' are schedule I controlled substances unless they meet the definition of ''hemp'' (by falling below the 0.3% Δ^9-THC limit on a dry weight basis) or are from exempt parts of the plant (such as mature stalks or non-germinating seeds). *See* 21 U.S.C. 802(16) (emphasis added). As a result, a cannabis derivative, extract, or product that exceeds the 0.3% Δ^9-THC limit is a schedule I controlled substance, even if the plant from which it was derived contained 0.3% or less Δ^9-THC on a dry weight basis.

[1] *See* FDA, Warning Letters and Test Results for Cannabidiol-Related Products, *https://www.fda.gov/NewsEvents/PublicHealthFocus/ucm484109.htm.*

Finally, nothing in the AIA or in these implementing regulations affects or alters the requirements of the Food, Drug, & Cosmetic Act (FD&C Act). *See* 7 U.S.C. 1639r(c). Hemp products that fall within the jurisdiction of the FD&C Act must comply with its requirements. FDA has recently issued a statement regarding the agency's regulation of products containing cannabis and cannabis-derived compounds, and DEA refers interested parties to that statement, which can be found at *https://www.fda.gov/newsevents/Newsroom/PressAnnouncements/ucm628988.htm.*

Changes to the Definition of Tetrahydrocannabinols

The AIA also modified the listing for tetrahydrocannabinols under 21 U.S.C. 812(c) by stating that the term tetrahydrocannabinols does not include tetrahydrocannabinols in hemp. Specifically, 21 U.S.C. 812(c) Schedule I now lists as schedule I controlled substances: ''Tetrahydrocannabinols, except for tetrahydrocannabinols in hemp (as defined under section 1639*o* of Title 7).''

Therefore, the AIA limits the control of tetrahydrocannabinols (for Controlled Substance Code Number 7370). For tetrahydrocannabinols that are naturally occurring constituents of the plant material, Cannabis sativa L., any material that contains 0.3% or less of Δ^9-THC by dry weight is not controlled, unless specifically controlled elsewhere under the CSA. Conversely, for tetrahydrocannabinols that are naturally occurring constituents of Cannabis sativa L., any such material that contains greater than 0.3% of Δ^9-THC by dry weight remains a controlled substance in schedule I.

The AIA does not impact the control status of synthetically derived tetrahydrocannabinols (for Controlled Substance Code Number 7370) because the statutory definition of ''hemp'' is limited to materials that are derived from the plant Cannabis sativa L. For synthetically derived tetrahydrocannabinols, the concentration of Δ^9-THC is not a determining factor in whether the material is a controlled substance. All synthetically derived tetrahydrocannabinols remain schedule I controlled substances.

This rulemaking is modifying 21 CFR 1308.11(d)(31) to reflect this statutory change. By this rulemaking, 21 CFR 1308.11(d)(31) is being modified via the addition of subsection (ii), which reads: ''Tetrahydrocannabinols does not include any material, compound, mixture, or preparation that falls within the definition of hemp set forth in 7 U.S.C. 1639*o*.''

Removal of Schedule V Control of FDA-Approved Products Containing Cannabidiol

Previously DEA, pursuant to 21 CFR 1308.15, separately controlled in Schedule V drug products in finished dosage formulations that have been approved by FDA and that contain cannabidiol (CBD) derived from cannabis and no more than 0.1 percent (w/w) residual tetrahydrocannabinols (under Controlled Substance Code Number 7367). The FDA-approved substances described under Drug Code 7367 are no longer controlled, by virtue of the AIA. As a result, DEA is removing the listing for ''Approved cannabidiol drugs'' under schedule V in 21 CFR 1308.15.

Note that CBD in a mixture with a Δ^9-THC concentration greater than 0.3% by dry weight is not exempted from the definition of ''marihuana'' or ''tetrahydrocannabinols.'' Accordingly, all such mixtures exceeding the 0.3% limit remain controlled substances under schedule I.

Removal of Import/Export Provisions Involving FDA-Approved Products Containing CBD

Previously DEA, pursuant to 21 CFR 1312.30, required import and export permits pursuant to 21 U.S.C. 811(d)(1), 952(b)(2), and 953(e)(3) for the import and export of drug products in finished dosage formulations that have been approved by FDA and that contain CBD derived from cannabis and no more than 0.1 percent (w/w) residual tetrahydrocannabinols. Because such substances are no longer controlled substances, DEA is likewise removing the import and export permit requirement for these substances. The regulation is revised to delete § 1312.30(b).

Drug Code 7350 for Marihuana Extract

The current control status of marihuana-derived constituents depends upon the concentration of Δ^9-THC in the constituent. DEA is amending the scope of substances falling within the Controlled Substances Code Number for marihuana extract (7350) to conform to the amended definition of marihuana in the AIA. As amended, the Drug Code 7350 definition reads:

Marihuana Extract—meaning an extract containing one or more cannabinoids that has been derived from any plant of the genus Cannabis, containing greater than 0.3 percent delta-9-tetrahydrocannabinol on a dry weight

basis, other than the separated resin (whether crude or purified) obtained from the plant.

21 CFR 1308.11(d)(58). The drug code 7350 became effective on January 13, 2017. 81 FR 90194.

Regulatory Analysis

Administrative Procedure Act

An agency may find good cause to exempt a rule from certain provisions of the Administrative Procedure Act (APA) (5 U.S.C. 553), including those requiring the publication of a prior notice of proposed rulemaking and the pre-promulgation opportunity for public comment, if such actions are determined to be unnecessary, impracticable, or contrary to the public interest.

DEA finds there is good cause within the meaning of the APA to issue these amendments as an interim final rule and to delay comment procedures to the post-publication period, because these amendments merely conform the implementing regulations to recent amendments to the CSA that have already taken effect. DEA has no discretion with respect to these amendments. This rule does no more than incorporate the statutory amendments into DEA's regulations, and publishing a notice of proposed rulemaking or soliciting public comment prior to publication is unnecessary. *See* 5 U.S.C. 553(b)(B) (relating to notice and comment procedures). ''[W]hen regulations merely restate the statute they implement, notice-and-comment procedures are unnecessary.'' *Gray Panthers Advocacy Committee* v. *Sullivan,* 936 F.2d 1284, 1291 (D.C. Cir. 1991); *see also United States* v. *Cain,* 583 F.3d 408, 420 (6th Cir. 2009) (contrasting legislative rules, which require notice-and-comment procedures, ''with regulations that merely restate or interpret statutory obligations,'' which do not); *Komjathy* v. *Nat. Trans. Safety Bd.,* 832 F.2d 1294, 1296 (D.C. Cir. 1987) (when a rule ''does no more than repeat, virtually verbatim, the statutory grant of authority'' notice-and-comment procedures are not required).

In addition, because the statutory changes at issue have already been in effect since December 20, 2018, DEA finds good cause exists to make this rule effective immediately upon publication. *See* 5 U.S.C. 553(d). Therefore, DEA is issuing these amendments as an interim final rule, effective upon publication in the **Federal Register**.

Although publishing a notice of proposed rulemaking and soliciting public comment prior to publication are unnecessary in this instance because these regulations merely implement statutory changes over which the agency has no discretion, DEA is soliciting public comment on this rule following its publication. For that reason, DEA is publishing this rule as an interim final rule and is establishing a docket to receive public comment on this rule. To the extent required by law, DEA will consider and respond to any relevant comments received.

Executive Orders 12866 (Regulatory Planning and Review), 13563 (Improving Regulation and Regulatory Review), and 13771 (Reducing Regulation and Controlling Regulatory Cost)

This interim final rule was developed in accordance with the principles of Executive Orders (E.O.) 12866, 13563, and 13771. 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 interim final rule have been examined and it has been determined that it is not a significant regulatory action under E.O. 12866 because it is a non-discretionary action that is dictated by the statutory amendments to the CSA enacted by the AIA. While not determined to be a significant regulatory action, this action has been reviewed by the OMB.

As explained above, DEA is obligated to issue this interim final rule to revise its regulations so that they are consistent with the provisions of the CSA that were amended by the AIA. In issuing this interim final rule, DEA has not gone beyond the statutory text enacted by Congress. Thus, DEA would have to issue this interim final rule regardless of the outcome of the agency's regulatory analysis. Nonetheless, DEA conducted this analysis as discussed below.

Summary of Benefits and Costs

This analysis is limited to the provisions of the AIA that are being directly implemented by this DEA interim final rule. DEA has reviewed these regulatory changes and their expected costs and benefits. Benefits, in the form of cost savings realized by DEA registrants handling previously controlled substances, will be generated as a direct result of the publication of this interim final rule. DEA does not expect there to be any costs associated with the promulgation of this interim final rule. The following is a summary; a detailed economic analysis of the interim final rule can be found in the rulemaking docket at *http://www.regulations.gov.*

The AIA's revised definitions of marihuana and tetrahydrocannabinols effectively decontrol hemp as defined under the AIA. DEA's regulatory authority over any plant with less than 0.3% THC content on a dry weight basis, and any of the plant's derivatives under the 0.3% THC content limit, is removed as a result. It is important to note, however, that this does not mean that hemp is not under federal regulatory oversight. The AIA directs the U.S. Department of Agriculture (USDA) to review and approve commercial hemp production plans developed by State, territory, and Indian tribal agencies and to develop its own production plan. 7 U.S.C. 1639p, 1639q. Until these regulations are finalized, State commercial hemp pilot programs authorized under the 2014 Farm Bill are still in effect and current participants may proceed with plans to grow hemp while new regulations are drafted.[2] DEA expects the USDA to assess the costs and benefits of this new regulatory apparatus once those rules are finalized. For these reasons, DEA considers any potential costs or benefits broadly related to changes in the domestic industrial hemp market due to the

[2] *See* USDA, Hemp Production Program Questions and Answers, *https://www.ams.usda.gov/publications/content/hemp-production-program-questions-and-answers.*

decontrol of hemp, including but not limited to the expansion in the number of producers, consumer products, and the impact on supply chains to be outside the scope of this analysis.

To determine any cost savings resulting from this decontrol action, DEA analyzed its registration, import, and export data. The removal of DEA's regulatory authority over hemp as defined under the AIA will impact only DEA registrants that currently import viable hemp seed intended for germination. Viable hemp seed was classified as a schedule I controlled substance prior to the amendments to the CSA enacted by the AIA. The importation and exportation of controlled substances requires an importer or exporter to first register with DEA, and then apply and obtain a permit to import or export controlled substances for each shipment.[3] The decontrol of hemp with this interim final rule means that viable hemp seed is no longer subject to those schedule I requirements, as long as the material contains less than the 0.3% limit.

Based on the number of import and export permits issued, DEA estimated the number of import and export permit applications that would no longer be needed. DEA reviewed internal data tracking the number of imports and exports for hemp seed over a three year period beginning January 1, 2016 and ending December 31, 2018.[4] During this three year period, there was an average of 88 import permits issued for hemp seed per year, and no exports. These import permits were issued only to participants in state commercial hemp pilot programs, including state departments of agriculture and higher education institutions, which are considered ''fee exempt'', and do not pay the $1,523 annual importer registration fee.[5] However, fee-exempt institutions are still required to obtain a DEA registration and renew that registration annually by filling out and submitting DEA form 225a. DEA expects these institutions to relinquish their schedule I importer registrations as a result of the promulgation of this interim final rule.

DEA estimates the average annual cost savings attributable to the elimination of import permits for hemp seed, and the elimination of annual registration renewals for hemp seed importers to be $3,225.[6] This cost savings is realized entirely by DEA registrants. Since the anticipated reduction in import permits and registration renewals being processed is negligible relative to the total amount of permits and renewals processed by DEA annually, DEA is not expected to experience a measurable decrease in workflow or use of resources, and therefore, will incur no cost savings. The results of this analysis are summarized below:

Average Annual Import Permit Application (DEA Form 357) Cost Savings	
Estimated hourly wage ($/hour):[7]	$45.54
Load for benefits (percent of labor rate):[8]	*43%*
Loaded labor rate ($/hour):[9]	$65.06
Average hourly burden, per application:	0.25
Average annual # of import permit applications for hemp seed:	88
Average annual hemp seed import permit application labor costs:[10]	$1,431.32
Average annual mailing cost of hemp seed import permit applications:[11]	$1,579.50
Annual Registration Renewal Application (DEA Form 225a) Cost Savings	
Estimated hourly wage ($/hour):[12]	$59.56
Load for benefits (percent of labor rate):[13]	*43%*
Loaded labor rate ($/hour):[14]	$85.09
# of Importers no longer requiring registration:	21
Average hourly burden, per application:[15]	0.12
Average annual registration renewal application labor cost:[16]	$214.43
Total Annual Cost Savings:	$3,225.25

This interim final rule removes FDA-approved products containing CBD from schedule V control, including controls over the importation and exportation of this class of drugs. There is currently only one drug that meets these criteria for decontrol.[17] To determine any cost savings resulting from this decontrol action, DEA analyzed its registration, import, and export data. DEA believes all entities that currently handle FDA-approved CBD products also handle other controlled substances. This means the decontrol of this product will not allow these DEA registrants to benefit from any registration-related cost savings. However, like importers of viable hemp seed, importers and exporters of FDA-approved CBD products will no longer be required to obtain import and export permits from DEA.

DEA analyzed its internal import and export data to identify the average

[3] *See* 21 CFR 1312.11(a), 1312.21(a).

[4] DEA import data is organized by drug code. Hemp seed falls within drug code ''7360—Marihuana''.

[5] *See* 21 CFR 1301.21(a)(1).

[6] Rounded down to the nearest whole dollar.

[7] Median hourly wage, Bureau of Labor Statistics, Occupational and Employment and Wages, May 2018, 11–3071 Transportation, Storage, and Distribution Managers (*http://www.bls.gov/oes/current/oes_nat.htm*). The DEA considers this occupational category to be representative of the type of employee that is likely to fill out and submit import permits on behalf of a DEA registered importer.

[8] Bureau of Labor Statistics, ''Employer Costs for Employee Compensation—March 2019'' (ECEC) reports that average benefits for private industry is 30% of total compensation. The 30% of total compensation equates to 42.86% (30% / 70%) load on wages and salaries.

[9] $45.54 × (1 + 0.4286) = $65.06.

[10] ($65.06 × 0.25) × 88 = $1,431.32.

[11] 91% of import permits are submitted via paper form and delivered to DEA by an express carrier with respondent-paid means for return delivery. The estimated cost burden is $19.50 per response: 2 × $9.75 = $19.50. $9.75 is based on a major express carrier's national 3-day flat rate for envelopes. The DEA assumes that 91% of import permits submitted in any given year incur this mailing cost.

[12] Estimates are based on the population of the regulated industry participating in these business activities. The DEA assumes that a general and operations manager (11–1021, 2018 Standard Occupational Classification) will complete the form on behalf of the applicant or registrant.

[13] Bureau of Labor Statistics, ''Employer Costs for Employee Compensation—March 2019'' (ECEC) reports that average benefits for private industry is 30% of total compensation. The 30% of total compensation equates to 42.86% (30% / 70%) load on wages and salaries.

[14] $59.56 × (1 + 0.4286) = $85.09.

[15] The DEA assumes all forms are submitted online.

[16] ($85.09 × 0.5) × 21 = $214.43.

[17] *See* FDA, Regulation of Cannabis and Cannabis-Derived Products: Questions and Answers, *https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-questions-and-answers#approved*.

number of permits issued for FDA-approved CBD products over a three year period beginning January 1, 2016 and ending December 31, 2018. During this period there was an average of 52 import permits and one export permit issued per year, the elimination of which will result in an average annual cost savings of $1,814.[18] This cost savings is realized entirely by DEA registrants. Since the anticipated reduction in import and export permits being processed is negligible relative to the total number of permits processed by DEA annually, DEA is not expected to experience a measurable decrease in workflow or use of resources, and therefore, will incur no cost savings. The results of this analysis are summarized below:

Average Annual Import Permit Application (DEA Form 357) Cost Savings	
Estimated hourly wage ($/hour):[7]	$45.54
Load for benefits (percent of labor rate):[8]	*43%*
Loaded labor rate ($/hour):[9]	$65.06
Average hourly burden, per application:	0.25
Average annual # of import permit applications for FDA-approved CBD:	52
Average annual FDA-approved CBD import permit application labor costs:[19]	$845.74
Average annual mailing cost for import permit applications:[11 20]	$916.50
Average Annual Export Permit Application (DEA Form 161) Cost Savings	
Estimated hourly wage ($/hour):[7]	$45.54
Load for benefits (percent of labor rate):[8]	*43%*
Loaded labor rate ($/hour):[9]	$65.06
Average hourly burden, per collection:	0.5
Average annual # of export permit applications for FD-approved CBD:	1
Average annual FDA-approved CBD export permit application labor costs:[21]	$32.53
Average annual mailing cost of export permit applications:[11]	$19.50
Total Annual Cost Savings:	$1,814.27

This interim final rule amends the definition of marihuana extract to conform to the revised definitions of marihuana and tetrahydrocannabinols. This revised definition now includes the 0.3%-THC content limit for the extract, meaning hemp-derived extracts containing less than 0.3%-THC content are also decontrolled along with the plant itself. As discussed previously, the production of hemp and its extracts as defined under the AIA now falls under the same regulatory oversight shared between the States, territories, and Indian tribal agencies, and the USDA. The FDA also affirms its regulatory oversight over cannabis-derived compounds, such as CBD, whether or not these compounds are ''classified as hemp under the 2018 Farm Bill.'' [22] For these reasons, DEA considers any potential costs or benefits broadly related to changes in the markets for domestic hemp extracts due to their decontrol, including but not limited to the expansion in the number of producers, consumer products, and the impact on supply chains to be outside the scope of this analysis.

Like FDA-approved CBD products and viable hemp seeds, entities no longer require a DEA registration or import and export permits to handle hemp extract that does not exceed the statutory 0.3% THC limit. DEA's import and export data does capture a minimal number of instances of the importation and exportation of CBD; however, this data does not detail whether or not the CBD was derived from Cannabis sativa L. plants containing less than 0.3% THC content. For this reason, DEA does not have a good basis to estimate the annual number of imported or exported hemp-derived extracts that no longer require permits as a result of the promulgation of this interim final rule, but after reviewing its data, believes this number to be minimal. Therefore, DEA concludes that this provision of the interim final rule is likely to result in a minimal benefit to DEA registrants, but DEA does not have a good basis to quantify this amount.

As part of its core function, DEA's Diversion Control Division is responsible for managing over 1.8 million DEA registrations, processing new and renewal registration applications, processing registration modification requests, issuing certificates of registration, issuing import and export permits, issuing renewal notifications, conducting due diligence, maintaining and operating supporting information systems, etc. Therefore, DEA does not anticipate it will realize any measurable cost savings to the government as a result of the negligible decreases in registrant services resulting from the promulgation of this interim final rule.

As described above, DEA estimates the average annual benefit in the form of cost savings to DEA registrants as a result of the promulgation of this interim final rule to be $5,039.[23] DEA calculated the present value of this cost savings over a 20 year period at a 3 percent and 7 percent discount rate. At a 3 percent discount rate, the present value of benefits is $74,968, while the present value of costs is $0, making the net present value (NPV) $74,968. At a 7 percent discount rate, the present value of benefits is $53,383, the present value of costs is $0, making the NPV is $53,383.[24] The table below summarizes the present value and annualized benefit calculations.

Discount Rate	3%	7%
Annual benefit ($)	5,039	5,039
Present value of benefits ($)	74,968	53,383
Present value of costs ($)	0	0
Years	20	20

[18] Rounded down to the nearest whole number.

[19] ($65.06 × 0.25) × 52 = $845.74.

[20] 52 × .91 = 47 (rounded down) permits mailed per year; 47 × $19.50 = $916.50.

[21] ($65.06 × 0.5) × 1 = $32.53.

[22] Ibid.

[23] The total average annual cost savings resulting from the decontrol of viable hemp seed ($3,225) and FDA-approved CBD products ($1,814).

[24] *See* Office of Mgmt. & Budget, Exec. Office of the President, OMB Circular A–4, Regulatory Analysis (2003).

Net present value ($)	74,968	53,383

Figures are rounded.

E.O. 13771 deregulatory actions are final actions that have totals costs less than zero. Also, under E.O. 13771, regulatory actions that expand production options, which are considered to be ''enabling rules,'' generally qualify as E.O. 13771 deregulatory actions. This interim final rule decontrols hemp, hemp extracts and FDA-approved products containing CBD, and it results in cost savings to the public, as discussed above. Accordingly, DEA has determined that this interim final rule is an E.O. 13771 Deregulatory Action.

Executive Order 12988

This interim final rule meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988, Civil Justice Reform, to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burdens.

Executive Order 13132

This rulemaking does not preempt or modify any provision of State law, impose enforcement responsibilities on any State, or diminish the power of any State to enforce its own laws. Accordingly, this rulemaking does not have federalism implications warranting the application of E.O. 13132.

Executive Order 13175

This interim final rule is required by statute, and will not have tribal implications or impose substantial direct compliance costs on Indian tribal governments.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) applies to rules that are subject to notice and comment under section 553(b) of the Administrative Procedure Act (5 U.S.C. 553). As explained in the interim final rule, DEA determined that there was good cause to exempt this interim final rule from pre-publication notice and comment. Consequently, the RFA does not apply to this interim final rule.

Paperwork Reduction Act of 1995

This interim final rule does not involve a collection of information within the meaning of the Paperwork Reduction Act of 1995, 44 U.S.C. 3501–21.

Unfunded Mandates Reform Act of 1995

This interim final rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $136,000,000 or more (adjusted for inflation) in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995. 2 U.S.C. 1532.

Congressional Review Act

This interim final rule is not a major rule as defined by the Congressional Review Act (CRA) (5 U.S.C. 804). DEA is submitting the required reports with a copy of this interim final rule to both Houses of Congress and to the Comptroller General.

List of Subjects

21 CFR Part 1308

Administrative practice and procedure; Drug traffic control; Reporting and recordkeeping requirements.

21 CFR Part 1312

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

For the reasons set forth above, 21 CFR parts 1308 and 1312 are amended 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).

■ 2. In § 1308.11, paragraphs (d)(31) and (58) are revised to read as follows:

§ 1308.11 Schedule I.

* * * * *

(d) * * *

(31) Tetrahydrocannabinols 7370

(i) Meaning tetrahydrocannabinols, except as in paragraph (d)(31)(ii) of this section, naturally contained in a plant of the genus Cannabis (cannabis plant), as well as synthetic equivalents of the substances contained in the cannabis plant, or in the resinous extractives of such plant, and/or synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activity to those substances contained in the plant, such as the following:

1 cis or trans tetrahydrocannabinol, and their optical isomers

6 cis or trans tetrahydrocannabinol, and their optical isomers

3, 4 cis or trans tetrahydrocannabinol, and its optical isomers

(Since nomenclature of these substances is not internationally standardized, compounds of these structures, regardless of numerical designation of atomic positions covered.)

(ii) Tetrahydrocannabinols does not include any material, compound, mixture, or preparation that falls within the definition of hemp set forth in 7 U.S.C. 1639*o*.

* * * * *

(58) Marihuana Extract 7350

Meaning an extract containing one or more cannabinoids that has been derived from any plant of the genus Cannabis, containing greater than 0.3% delta-9-tetrahydrocannabinol on a dry weight basis, other than the separated resin (whether crude or purified) obtained from the plant.

* * * * *

§ 1308.15 [Amended]

■ 3. In § 1308.15, paragraph (f) is removed.

PART 1312—IMPORTATION AND EXPORTATION OF CONTROLLED SUBSTANCES

■ 4. The authority citation for part 1312 continues to read as follows:

Authority: 21 U.S.C. 821, 871(b), 952, 953, 954, 957, 958.

§ 1312.30 [Amended]

■ 5. In § 1312.30, paragraph (b) is removed and reserved.

Timothy J. Shea,

Acting Administrator.

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DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

32 CFR Part 625

[Docket ID: USA–2020–HQ–0010]

RIN 0702–AA98

Surface Transportation—Administrative Vehicle Management

AGENCY: U.S. Army Corps of Engineers, Department of Defense (DoD).