manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2013–N–0013 for ''Sanitary Transportation of Human and Animal Food: What You Need to Know About the FDA Regulation—Small Entity Compliance Guide.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

See the **SUPPLEMENTARY INFORMATION** section for electronic access to the SECG.

FOR FURTHER INFORMATION CONTACT: Carrol Burgundy, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2158.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of April 6, 2016 (81 FR 20091), we issued a final rule entitled ''Sanitary Transportation of Human and Animal Food'' (the final rule) that establishes requirements for shippers, loaders, carriers by motor vehicle and rail vehicle, and receivers engaged in the transportation of food, including food for animals, to use sanitary transportation practices to ensure the safety of the food they transport. The final rule, which is codified at 21 CFR part 1, subpart O, became effective June 6, 2016, and has compliance dates that started April 6, 2017.

We examined the economic implications of the final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612) and determined that the final rule will have a significant economic impact on a substantial number of small entities. In compliance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Pub. L. 104–121, as amended by Pub. L. 110–28), we are making available the SECG to reduce the burden of determining how to comply by further explaining and clarifying the actions that a small entity must take to comply with the rule.

We are issuing the SECG consistent with our good guidance practices regulation (21 CFR 10.115(c)(2)). The SECG represents the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in part 1, subpart O have been approved under OMB control number 0910–0773.

III. Electronic Access

Persons with access to the internet may obtain the SECG at either *https://www.fda.gov/FoodGuidances* or *https://www.regulations.gov*. Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

Dated: November 16, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–25204 Filed 11–21–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–344]

Schedules of Controlled Substances: Placement of FDA-Approved Products of Oral Solutions Containing Dronabinol [(-)-delta-9-trans-tetrahydrocannabinol (delta-9-THC)] in Schedule II

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: This final rule adopts without changes an interim final rule with request for comments published in the **Federal Register** on March 23, 2017. On July 1, 2016, the U.S. Food and Drug Administration (FDA) approved a new drug application for Syndros, a drug product consisting of dronabinol [(-)-delta-9-*trans*-tetrahydrocannabinol (delta-9-THC)] oral solution. The Drug Enforcement Administration (DEA) maintains FDA-approved products of oral solutions containing dronabinol in schedule II of the Controlled Substances Act.

DATES: The effective date of this final rulemaking is November 22, 2017.

FOR FURTHER INFORMATION CONTACT: Michael J. Lewis, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701

Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598–8953.

SUPPLEMENTARY INFORMATION:

Background

On March 23, 2017, the DEA published an interim final rule to make FDA-approved products containing dronabinol in an oral solution a schedule II controlled substance. 82 FR 14815. The interim final rule provided an opportunity for interested persons to file written comments as well as a request for hearing or waiver of hearing, on or before April 24, 2017.

Comments Received

In response to the interim final rule, the DEA received 10 comments.

1. Support for rulemaking: Four commenters supported the interim final rule.

• *DEA Response:* The DEA appreciates the comments supporting the interim final rule.

2. Opposition for rulemaking: One commenter indicated that FDA-approved products of oral solutions containing dronabinol are in schedule II, but marijuana is in schedule I. Two commenters expressed concern that pharmaceutical companies are making a profit from approved drugs containing marijuana constituents. One commenter indicated that FDA should not approve drugs containing constituents of marijuana because, as the commenter alleged, of the lethality of those drugs.

• *DEA Response:* The DEA notes that FDA-approved products of oral solutions containing dronabinol have an approved medical use, whereas marijuana does not have an approved medical use and therefore remains in schedule I. Regarding the comments related to pharmaceutical companies and the approval of FDA drugs, these comments are outside the scope of this rulemaking because they do not relate to the factors determinative of control of a substance [21 U.S.C. 811(c)] or the criteria for placement of a substance in a particular schedule [21 U.S.C. 812(b)].

3. Request for clarification: One other commenter wanted clarification of the approval process, including effectiveness on a long-term basis. One commenter indicated hope that the regulation would clarify hiring practices for people testing positive for THC.

• *DEA Response:* The DEA notes that the comment regarding the approval process is written in vague terms; we interpret the comment to pertain to the FDA-approved drug product Syndros, rather than the regulatory process for the interim final rule, and respond accordingly. As such, the DEA notes that the FDA approved a New Drug Application (NDA) for Syndros which is an oral product containing dronabinol and provided the DEA with a scheduling recommendation for Syndros. The scheduling recommendation by HHS and the FDA approval of the NDA initiated the DEA review and scheduling action. As stated in the interim final rule, after careful consideration of data from preclinical and clinical studies, the DEA concurred with the HHS recommendation that Syndros has abuse potential comparable to other schedule II substances and therefore supported—and continues to support in this final rule—placement of FDA-approved products containing dronabinol in an oral solution in Schedule II under the Controlled Substances Act (CSA). Regarding the commenter seeking clarification on hiring practices, this comment is outside the scope of this rulemaking because it does not relate to the factors determinative of control of a substance [21 U.S.C. 811(c)] or the criteria for placement of a substance in a particular schedule [21 U.S.C. 812(b)].

The DEA did not receive any requests for hearing or waiver. Based on the rationale set forth in the interim final rule, the DEA adopts the interim final rule, without change.

Requirements for Handling FDA-Approved Products Containing Dronabinol in an Oral Solution

As DEA stated in the interim final rule, it should be noted as a preliminary matter that any form of dronabinol other than in an FDA-approved drug product remains a schedule I controlled substance, and those who handle such material remain subject to the regulatory controls, and administrative, civil, and criminal sanctions, applicable to schedule I controlled substances set forth in the CSA and DEA regulations. However, for those who handle dronabinol oral solution exclusively in the form of an FDA-approved drug product, the following is a summary of the schedule II regulatory requirements that remain in effect as a result of this final rule.

FDA-approved products containing dronabinol in an oral solution have been controlled as a schedule II controlled substance since March 23, 2017. With publication of this final rule, such products remain subject to the CSA's schedule II 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 II substances, including the following:

1. *Registration.* Any person who handles (manufactures, distributes, reverse distributes, dispenses, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses) FDA-approved products containing dronabinol in an oral solution, or who desires to handle such products, must be registered with the 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. *Quota.* Only registered manufacturers are permitted to manufacture FDA-approved products containing dronabinol in an oral solution in accordance with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303.

3. *Disposal of stocks.* Upon obtaining a schedule II registration to handle FDA-approved products containing dronabinol in an oral solution, any person who does not desire or is not able to maintain such registration must surrender all quantities of such products, or may transfer all quantities of such products to a person registered with the DEA in accordance with 21 CFR part 1317, in addition to all other applicable federal, state, local, and tribal laws.

4. *Security.* FDA-approved products containing dronabinol in an oral solution are subject to schedule II security requirements and must be handled and stored pursuant to 21 U.S.C. 821, 823, and in accordance with 21 CFR 1301.71–1301.93.

5. *Labeling and Packaging.* All labels, labeling, and packaging for commercial containers of FDA-approved products containing dronabinol in an oral solution must comply with 21 U.S.C. 825 and 958(e), and be in accordance with 21 CFR part 1302.

6. *Inventory.* Every DEA registrant who possesses any quantity of FDA-approved products containing dronabinol in an oral solution must take an inventory of such 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.

7. *Records and Reports.* Every DEA registrant must maintain records and submit reports for FDA-approved products containing dronabinol in an oral solution, pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR parts 1304, 1312, and 1317.

8. *Order Forms.* Every DEA registrant who distributes FDA-approved products containing dronabinol in an oral solution is required to comply with

order form requirements, pursuant to 21 U.S.C. 828, and in accordance with 21 CFR part 1305.

9. *Prescriptions.* All prescriptions for FDA-approved products containing dronabinol in an oral solution must comply with 21 U.S.C. 829, and be issued in accordance with 21 CFR parts 1306 and 1311, subpart C.

10. *Manufacturing and Distributing.* In addition to the general requirements of the CSA and DEA regulations that are applicable to manufacturers and distributors of schedule II controlled substances, such registrants should be advised that (consistent with the foregoing considerations) any manufacturing or distribution of FDA-approved products containing dronabinol in an oral solution may only be for the legitimate purposes authorized by the FDCA and CSA.

11. *Importation and Exportation.* All importation and exportation of FDA-approved products containing dronabinol in an oral solution must be in compliance with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312.

12. *Liability.* Any activity involving FDA-approved products containing dronabinol in an oral solution not authorized by, or in violation of, the CSA or its implementing regulations, is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Analyses

Administrative Procedure Act

This final rule, without change, affirms the amendment made by the interim final rule that is already in effect. Section 553 of the Administrative Procedure Act (APA) (5 U.S.C. 553) generally requires notice and comment for rulemakings. However, Public Law 114–89 was signed into law, amending 21 U.S.C. 811. This amendment provides that in cases where a new drug is (1) approved by the Department of Health and Human Services (HHS) and (2) HHS recommends control in CSA schedule II–V, the DEA shall issue an interim final rule scheduling the drug within 90 days. This action was taken March 23, 2017. Additionally, the law specifies that the rulemaking shall become immediately effective as an interim final rule without requiring the DEA to demonstrate good cause.

Executive Orders 12866, Regulatory Planning and Review, and 13563, Improving Regulation and Regulatory Review

In accordance with 21 U.S.C. 811(j), this scheduling action is subject to formal rulemaking procedures performed ''on the record after opportunity for a hearing,'' which are conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The CSA sets forth the procedures and criteria for scheduling a drug or other substance. Such actions are exempt from review by the Office of Management and Budget (OMB) pursuant to section 3(d)(1) of Executive Order 12866 and the principles reaffirmed in Executive Order 13563.

Executive Order 12988, Civil Justice Reform

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

Executive Order 13132, Federalism

This rulemaking does not have federalism implications warranting the application of Executive Order 13132. The rule does not 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.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This rule does not have tribal implications warranting the application of Executive Order 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 Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612) applies to rules that are subject to notice and comment under section 553(b) of the APA. As noted in the above discussion regarding applicability of the Administrative Procedure Act, the DEA was not required to publish a general notice of proposed rulemaking prior to this final rule. Consequently, the RFA does not apply.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 *et seq.,* the DEA has determined 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 UMRA of 1995.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information requirement 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.

Congressional Review Act

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act (CRA)). This rule will not result in: An annual effect on the economy of $100,000,000 or more; a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of U.S.-based companies to compete with foreign based companies in domestic and export markets. However, pursuant to the CRA, the DEA has submitted a copy of this final rule to both Houses of Congress and to the Comptroller General.

List of Subjects in 21 CFR Part 1308

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

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ Accordingly, the interim final rule amending 21 CFR part 1308, published on March 23, 2017 (82 FR 14815), is adopted as a final rule without change.

Dated: November 6, 2017.

Robert W. Patterson,

Acting Administrator.

[FR Doc. 2017–25275 Filed 11–21–17; 8:45 am]

BILLING CODE 4410–09–P