CBNMS, NOAA learned from U.S. Coast Guard (USCG) that the discharge regulations had the potential to impair the operations of USCG vessels and aircraft conducting law enforcement and on-water training exercises in GFNMS and CBNMS expansion areas. The USCG supports national marine sanctuary management by providing routine surveillance and dedicated law enforcement of the National Marine Sanctuaries Act (NMSA) and sanctuary regulations. To ensure that the March 12, 2015, rule did not undermine USCG's ability to perform its duties, at that time, NOAA postponed the effectiveness of the discharge requirements in both sanctuaries' regulations with regard to USCG activities in the expansion areas for six months. Four additional six-month postponements of the effectiveness of the discharge requirements were published in the **Federal Register** on December 1, 2015 (80 FR 74985), May 31, 2016 (81 FR 34268), December 6, 2016 (81 FR 87803), and June 7, 2017 (82 FR 26339) to provide adequate time for completion of an environmental assessment and to determine NOAA's next steps. Without further NOAA action, the discharge regulations will become effective, with regard to USCG activities, on December 9, 2017.

However, NOAA is currently considering whether, among other things, to exempt certain USCG activities in sanctuary regulations and is concurrently publishing a proposed rule and draft environmental analysis to seek comment on the potential exemption. NOAA is therefore postponing the effectiveness of the discharge requirements in the expansion areas of both sanctuaries with regard to USCG activities for one year until December 9, 2018, or 30 days after publication of a final rule, whichever comes first, to provide adequate time for completion of a final environmental assessment and final rule, as appropriate. The proposed rule and related environmental analysis associated with this action will give the public, other federal agencies, and interested stakeholders an opportunity to comment on various alternatives that are being considered.

II. Classification

A. National Environmental Policy Act

NOAA previously conducted an environmental analysis under the National Environmental Policy Act (NEPA) as part of the rulemaking process leading to the expansion of CBNMS and GFNMS, which addressed regulations regarding the discharge of any matter or material in the sanctuaries. Potential environmental impacts of the decision to postpone effectiveness are sufficiently encompassed within the impacts analysis of the environmental baseline and the no action alternative presented in that analysis. Should NOAA decide to amend the regulations governing discharges for USGS activities in CBNMS and GFNMS, any additional environmental analysis required under NEPA would be prepared and released for public comment.

B. Executive Order 12866: Regulatory Impact

This action has been determined to be not significant under Executive Order 12866.

C. Executive Order 13771: Regulatory Reform

This action is not expected to be an Executive Order 13771 regulatory action because this action is not significant under Executive Order 12866.

D. Administrative Procedure Act

The Assistant Administrator of National Ocean Service (NOS) finds good cause pursuant to 5 U.S.C. 553(b)(B) to waive the notice and comment requirements of the Administrative Procedure Act (APA) because this action is administrative in nature. This action postpones the effectiveness of the discharge requirements in the regulations for CBNMS and GFNMS in the areas added to the sanctuaries' boundaries in 2015, that underwent notice and comment review, with regard to USCG activities for one year to provide adequate time for public scoping, completion of an environmental assessment, and concurrent rulemaking on how to address the USCG activities, as appropriate. The substance of the underlying regulations currently remains unchanged. Therefore, providing notice and opportunity for public comment under the APA would serve no useful purpose. For the reasons above, the Assistant Administrator also finds good cause under 5 U.S.C. 553(d) to waive the 30-day delay in effectiveness and make this action effective immediately upon publication.

Authority: 16 U.S.C. 1431 *et seq.*

Dated: November 14, 2017.

Nicole R. LeBoeuf,

Deputy Assistant Administrator for Ocean Services and Coastal Zone Management, National Ocean Service.

[FR Doc. 2017–25104 Filed 11–21–17; 8:45 am]

BILLING CODE 3510–NK–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. FDA–2013–N–0013]

Sanitary Transportation of Human and Animal Food: What You Need to Know About the Food and Drug Administration Regulation; Small Entity Compliance Guide; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the availability of a guidance for industry entitled ''Sanitary Transportation of Human and Animal Food: What You Need to Know About the FDA Regulation—Small Entity Compliance Guide.'' The small entity compliance guide (SECG) is intended to help small entities comply with the final rule entitled ''Sanitary Transportation of Human and Animal Food.''

DATES: The announcement of the guidance is published in the **Federal Register** on November 22, 2017.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov*.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the

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