

ADDRESSES section for the address and phone number). You may also submit comments through the internet at <https://www.regulations.gov>.

Persons wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed stamped postcard on which the following statement is made: "Comments to FAA Docket No. FAA-2021-0028; Airspace Docket No. 21-ASO-41." The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this document may be changed in light of the comments received. All comments submitted will be available for examination in the public docket both before and after the comment closing date. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at <https://www.regulations.gov>. Recently published rulemaking documents can also be accessed through the FAA's web page at https://www.faa.gov/air_traffic/publications/airspace_amendments/.

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined between 8:00 a.m. and 4:30 p.m., Monday through Friday, except federal holidays at the office of the Eastern Service Center, Federal Aviation Administration, Room 350, 1701 Columbia Avenue, College Park, GA 30337.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA proposes an amendment to 14 CFR part 71 to amend Class E surface airspace at Dyersburg Regional Airport, Dyersburg, TN, due the decommissioning of the Nally Dunston NDB and cancellation of associated approaches. This action would also update the airport name (formerly Dyersburg Municipal Airport) and geographic coordinates to coincide with the FAA's database.

This action would also replace the outdated term Airport/Facility Directory with the term Chart Supplement in the airport description.

Controlled airspace is necessary for the safety and management of instrument flight rules (IFR) operations in the area.

Class E airspace designations are published in Paragraph 6002 of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document would be published subsequently in FAA Order JO 7400.11.

FAA Order JO 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) Is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT 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 proposed rule, when promulgated, will 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.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, 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 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 Federal Aviation Administration 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 Surface Airspace.
* * * * *

ASO TN E2 Dyersburg, TN [Amended]

Dyersburg Regional Airport, TN
(Lat. 35°59'53" N, long. 89°24'24" W)

That airspace upward from the surface within a 4.7-mile radius of the Dyersburg Regional Airport. This Class E airspace is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Chart Supplement.

Issued in College Park, Georgia, on January 27, 2022.

Andree C. Davis,

Manager, Airspace & Procedures Team South, Eastern Service Center, Air Traffic Organization.

[FR Doc. 2022-02342 Filed 2-3-22; 8:45 am]

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DEPARTMENT OF COMMERCE

Census Bureau

15 CFR Part 30

[Docket Number 220124-0033]

RIN 0607-AA58

Foreign Trade Regulations (FTR): Electronic Export Information (EEI) Filing Requirements for Shipments Between the United States and Puerto Rico and the U.S. Virgin Islands (USVI)

AGENCY: Census Bureau, Commerce Department.

ACTION: Advance Notice of Proposed Rulemaking; withdrawal.

SUMMARY: The Census Bureau published an Advance Notice of Proposed Rule Making (ANPRM) in the **Federal Register** on September 17, 2020 to request comments on the overall impact of the removal of the Electronic Export Information (EEI) filing requirements for shipments between the United States, Puerto Rico and the U.S. Virgin Islands. The Census Bureau has decided to continue the current EEI filing requirement for Puerto Rico and the USVI and continue to publish the U.S. Trade with Puerto Rico and U.S. Possessions (FT-895) Publication Series. This decision was made after careful consideration based on the feedback received from the ANPRM and discussions between the Census Bureau and several stakeholders. The Census Bureau will continue to collect the EEI because there is no alternative data source that yields the same high-quality data for Puerto Rico and the U.S. Virgin Islands. The EEI data meets the Census Bureau's statistical objectives and the needs of its data users, including the Bureau of Economic Analysis (BEA), who produces the Gross Domestic Product estimates for Puerto Rico and the U.S. Virgin Islands, which is a Principal Federal Economic Indicator. Both the Census Bureau and BEA are open to considering proposed alternative data sources which will be evaluated, tested, and verified to determine whether the data meet the statistical objectives of the current EEI.

FOR FURTHER INFORMATION CONTACT: Lisa E. Donaldson, Division Chief, Economic Management Division (EMD), Census Bureau, by phone (301) 763-7296 or by email at lisa.e.donaldson@census.gov or Kiesha Downs, Chief, Trade Regulations Branch, EMD, Census Bureau, by phone (301) 763-7079 or by email at kiesha.downs@census.gov.

SUPPLEMENTARY INFORMATION:

Background

The Census Bureau is responsible for collecting, compiling, and publishing export trade statistics for the United States under the provisions of Title 13, United States Code (U.S.C.), Chapter 9, Section 301. Collecting and compiling trade statistics between the United States, Puerto Rico, and other territories is part of the U.S. Census Bureau's monthly processing of EEI. Ultimately, these statistics are sourced from the EEI filings in the Automated Export System (AES) and published in the FT-895 Publication Series. This FT-895 monthly program presents total quantity and value of detailed commodities shipped between the United States, Puerto Rico, and U.S. territories,

including the U.S. Virgin Islands (USVI).

The ANPRM published in the **Federal Register** on September 17, 2020, (85 FR 58016) received 93 comments on the overall impact of the removal of the EEI filing requirements for shipments between the United States, Puerto Rico and the USVI. The Census Bureau received 50 comments in support of maintaining the current EEI filing requirement and 43 comments supporting the removal of the EEI filing requirement. A summary of the comments is provided below.

Comments provided in support of removing the EEI filing requirement to Puerto Rico and the USVI fell under the following themes:

1. *Inequality:* Several commenters support removing the EEI filing requirement were concerned about unfair treatment of U.S. territories. While Puerto Rico and the USVI are not states, they are territories of the United States and exports to and from these territories are considered domestic, not international shipments. Several commenters believe federal agencies should employ consistent treatment of Puerto Rico and the USVI for statistical data. Another commenter indicated, other agencies under the Department of Commerce (DOC), such as the Bureau of Industry and Security (BIS) and the International Trade Administration do not treat shipments to and from Puerto Rico and the USVI as exports. Another commenter stated that the requirement of EEI is the reason many businesses deny service to the trade community located in U.S. Caribbean territories. Another commenter indicated the EEI filing requirement hinders trade competitiveness and negatively impacts job creation.

2. *Increased cost and burden:* Several commenters were concerned that requiring EEI filing to U.S. territories has increased the cost and time of the shipping process for U.S. exporters and freight forwarders. Some commenters indicate the need to dedicate staff and/or hire additional personnel to manage EEI filings has increased labor cost for businesses. Commenters were also concerned that the requirement to file EEI between the mainland U.S., Puerto Rico and the USVI imposes substantial regulatory and economic burden on exporters. Several commenters stated that the Department of Commerce should minimize any governmental paperwork burden (electronic or otherwise) on U.S. citizens engaged in lawful commercial transactions within the U.S. Several commenters also indicated the EEI filing process imposes unnecessary burden on commerce by

impeding the flow of trade and economic development in these territories due to the additional paperwork and administrative costs imposed by the EEI filing requirement. Several commenters stated that the costs are significant in terms of time lost, human resources required; many shippers and manufacturers in the U.S. have decided not to ship to these territories due to these additional steps in the shipping process and restrictions on trade. Additionally, some commenters pointed out that the cost of the EEI filing limits sourcing of U.S. products and increases the cost of goods in Puerto Rico and the USVI.

3. *Possible alternative data sets:* Several commenters identified the possibility of alternative methods for collecting export statistics data. One commenter stated that Puerto Rico is a part of the same U.S. Customs system and should use the same data collection methods as the other 50 states. Other commenters suggested that EEI is viable through data that already exists from multiple sources. One commenter suggested that EEI filing is repetitive and duplicative to manifest requirements of other agencies. Several commenters suggested specific alternative data sets such as the DOC's Bureau of Economic Analysis (BEA) data, which collects trade data that is used to calculate U.S. Gross Domestic Product (GDP) activity, state-to-state activity, and U.S. international transactions. Several commenters also proposed the use of Customs and Border Protection (CBP) manifest data, Puerto Rico's Sistema Unificado de Rentas Internas (SURI), Puerto Rico Port Authority data, monthly reporting similar to the current pipeline reporting, and the FT-895 report as alternative data sources.

Comments provided for maintaining the EEI filing requirement to Puerto Rico and USVI fell under the following themes:

1. *Statistical purposes:* The EEI reporting requirement yields high quality data for Puerto Rico and the USVI that serve several specific statistical objectives. Eliminating the mandatory requirement would remove an additional step in the shipping process. However, there would be several statistical implications associated with this change. Statistical data provides insight on policy decisions, GDP estimates, business development and marketing, economic recovery, research and academia as well as historical data and methodology, critical in measuring economic growth for Puerto Rico and the USVI.

A. Public Policy Decisions: Several commenters noted, EEI is utilized by the Government of Puerto Rico to produce statistical reports, gauge economic activity, and assist in sound policy making. A federal agency commented that it uses the data in its initiative to estimate Puerto Rico GDP statistics. Specifically, the agency commented that reliable GDP statistics for U.S. territories contribute to a better understanding of economic development, such as the impact of federal disaster relief spending in these areas. For example, to date, Congress has appropriated more than \$60 billion for Puerto Rico recovery efforts following hurricanes in 2017 and earthquakes in 2020. Without high-quality GDP statistics, it is difficult for policy makers to gauge the impact of such funding on the Puerto Rican economy. Additionally, another federal agency has concerns about the loss of data, specifically, petroleum trade between the United States and Puerto Rico. This federal agency uses the data for calculation of the total shipped volumes of petroleum and other fuels. There is currently no other source of information or method for tracking trade flows of oil and other energy-related commodities between the United States and Puerto Rico. There is no alternative data source to collect this information because Puerto Rico does not locally collect the data and these data are not included in any other U.S. Census Bureau economic surveys. Commenters are concerned because this information can aid federal agencies in developing strategic plans to ensure Puerto Rico has resilient power generation systems for the future, as the current Administration starts to steer away from oil and towards sustainable energy and information.

B. Business Development and Marketing: One commenter stated that accurate and precise data is critical for the development of small businesses in Puerto Rico and to develop and update business and marketing plans to move Puerto Rico's economy forward. Another commenter noted that businesses in these territories and the U.S. mainland use this detailed data to inform choices and services around new and existing markets, which allows for more competition and better consumer options.

C. Economic Recovery: Several commenters noted, keeping the EEI filing requirement for Puerto Rico and the USVI allows these territories to rebuild their economies and accurately measure, project, and plan economic development. One commenter noted, the lack of reliable statistics is the worst scenario for a country in economic crisis as they work towards restructuring their

debt and attaining a sustainable economy. Several other commenters noted that without a viable and tested alternative data source, the proposal to remove the requirements will make it impossible to measure and analyze Puerto Rico's economy. Other commenters noted that an economic development plan is urgent, and it cannot be attained without having complete, accurate and confident data that includes the information for shipments between the United States and Puerto Rico and USVI.

D. Research and Academic Importance: Several commenters were concerned that the proposed rule to eliminate the EEI filing requirement to Puerto Rico and the USVI will have a significant impact on research and academia. Commenters noted that without the filing requirement, economic students, scholars, entrepreneurs and citizens will not be able to access updated Census Bureau data for research policy purposes. One scholar specifically noted that the Census Bureau's statistical information for economic and agricultural economic courses is useful to students completing projects and thesis papers within their master's program. Another commenter was also concerned that the loss of this data will directly impact the agricultural industry with current global economic and climatic change.

2. Enforcement Purposes: We received several comments against removing the EEI filing requirement for export control and enforcement purposes. One commenter noted that without the collection of data from the U.S. mainland to Puerto Rico and USVI, enforcement agencies lose visibility on potential criminal activity. The Census Bureau consulted with one federal agency on this comment. This agency noted that the removal of the EEI filing requirements for shipments from the U.S. to those territories would adversely impact the agency's ability to ensure the effective enforcement of items subject to the Export Administration Regulations, potentially diverted to foreign countries.

3. No valid alternative data set: Though commenters presented potential alternative data sets, one commenter noted that the level of detail would not be similar to that obtained through the EEI requirement, and the data would not be compiled with the rigor as that by the Census Bureau. One federal agency also noted that the EEI is high-quality economic data which is not typical for the U.S. territories because the U.S. territories are not included in most federal surveys. Territory-level surveys and administrative data are limited. Several commenters noted,

there is currently no substitute for EEI that is routinely available, continuous, current, high frequency and published with documentation and technical support. Without an alternative data source that meets the same statistical objectives, it is not possible to continue to produce GDP estimates for Puerto Rico or the USVI. Should the broader FT-895 report be eliminated as a result of the discontinuation of the EEI-sourced data, GDP estimates for the territory of American Samoa will also be at risk.

4. Cost Benefit: Several commenters noted that the Automated Export System (AES) is a mature system the trade industry understands and knows how to operate. There is concern that creating an entirely new system to capture the same data in today's current environment is an unnecessary burden. Additionally, creating a new system would come at a significant cost to the U.S. Government during a time of increased strain on Government funding, as well as costs to the industry. One commenter noted that many EEI filers for Puerto Rico's data also use the AES for international shipments to foreign countries and adding an alternative system would add a burden to their current operations and workflow. Several economists commented that the requirement to file EEI does not add significant burden on business and the cost and value of the EEI data is greater than the inconvenience to the trade compared to the potential sales acquired, the current information technologies and the fact that the bulk of the shipments to the U.S. are done by large U.S. corporations.

5. GDP Estimates: Several commenters noted that the Census Bureau's FT-895 reports and other statistical trade documents provide routine, consistent, and continuous monthly and annual data that is necessary and relevant for statistical and time-series compatibility. These commenters also added that consistent definitions are critical to ensure GDP estimates and the loss of the FT-895 and EEI reporting will adversely affect the computations of GDP estimates. One commenter specifically stated that the methodology should include a monthly total of the value of goods between the U.S., Puerto Rico and the USVI rather than presenting it on an annual frequency. Another commenter who has used the data for many years is concerned that interruptions or inconsistencies with the current dissemination of the Census Bureau data would create problems. Additionally, one federal agency noted that they significantly rely on trade data

from the FT–895 in constructing reliable and consistent economic statistics, including GDP for U.S. territories. Such statistics provide key insight into the territorial economies, and meaningful information to businesses and decision makers alike. Territorial GDP are highly reliant on export and import data provided from the Census Bureau’s FT–895. The direct concern is that an elimination of EEI reporting requirements could directly impact the availability of import data used in the USVI GDP statistics. To illustrate the significance of this information loss, in 2018 exports reported in the FT–895 accounted for 59-percent and 9-percent of American Samoa and the USVI GDP, respectively. The direct and indirect impact associated to the elimination of the EEI reporting requirements could severely affect the usefulness of American Samoa, Northern Mariana Islands, Guam and USVI GDP as time series statistics. Should the reporting requirement be eliminated, it remains unclear if the Census Bureau will continue to make non-EEI-sourced trade data available for these territories. Other commenters stated that the lack of data with no other avenue for gathering the information would be harmful and unfortunate if such a longtime source of information were to disappear. Similarly, a commenter noted that the FT–895 constitutes an excellent and unique tool benefitting individuals, businesses, academia, etc. and for which there is no viable substitute available.

Robert L. Santos, Director, Census Bureau, approved the publication of this notice of proposed rulemaking in the **Federal Register**.

Dated: January 31, 2022.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2022–02341 Filed 2–3–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 203

[Docket No. FDA–2020–N–1819]

RIN 0910–AH56

Certain Requirements Regarding Prescription Drug Marketing

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is proposing to amend certain prescription drug marketing regulations to reflect changes to affected provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) resulting from enactment of the Drug Supply Chain Security Act (DSCSA), Title II of the Drug Quality and Security Act (DQSA). This action, if finalized, will remove or revise outdated and conflicting regulatory requirements to align with changes to affected provisions of the FD&C Act following enactment of the DSCSA.

DATES: Submit either electronic or written comments on the proposed rule by April 5, 2022.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 5, 2022. Electronic comments must be submitted on or before that date. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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–2020–N–1819 for “Certain Requirements Regarding Prescription Drug Marketing.” Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly available at <https://www.regulations.gov>, or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- **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.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments