



DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1300, 1301, 1302, 1303, 1304, 1308, 1309, 1310, 1312, 1313, 1314, 1315, 1316, and 1321

[Docket No. DEA-403]

RIN 1117-AB41

Revision of Import and Export Requirements for Controlled Substances, Listed Chemicals, and Tableting and Encapsulating Machines, Including Changes to Implement the International Trade Data System (ITDS); Revision of Reporting Requirements for Domestic Transactions in Listed Chemicals and Tableting and Encapsulating Machines; and Technical Amendments

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule; delay of effective date.

SUMMARY: On December 30, 2016, the Drug Enforcement Administration published a final rule to implement requirements associated with the International Trade Data System (ITDS) that will help streamline the export/import of tableting and encapsulating machines, controlled substances, and listed chemicals. That rule is scheduled to become effective January 30, 2017. In accordance with the memorandum of January 20, 2017, from the Assistant to the President and Chief of Staff, entitled “Regulatory Freeze Pending Review,” this action hereby temporarily delays until March 21, 2017, the effective date of the final rule entitled “Revision of Import and Export Requirements for

Controlled Substances, Listed Chemicals, and Tableting and Encapsulating Machines, Including Changes to Implement the International Trade Data System (ITDS); Revision of Reporting Requirements for Domestic Transactions in Listed Chemicals and Tableting and Encapsulating Machines; and Technical Amendments” (RIN 1117-AB41) published in the Federal Register on December 30, 2016, at 81 FR 96992. The temporary delay in the effective date will allow Department of Justice officials an opportunity to review any potential questions of fact, law and policy raised by this regulation, consistent with the Chief of Staff’s memorandum of January 20, 2017.

DATES: Effective Dates: This Final Rule is effective January 30, 2017. The effective date of the Final Rule amending 21 CFR Parts 1300, 1301, 1302, 1303, 1304, 1308, 1309, 1310, 1312, 1313, 1314, 1315, 1316, and 1321 published in the Federal Register December 30, 2016, at 81 FR 96992 is delayed to March 21, 2017. However, compliance with the revisions to DEA regulations made by this rule is not required until [INSERT DATE 180 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Michael J. Lewis, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812.

SUPPLEMENTARY INFORMATION:

The Drug Enforcement Administration (DEA) is updating its regulations for the import and export of tableting and encapsulating machines, controlled substances, and listed chemicals, and its regulations relating to reports required for domestic transactions in listed chemicals, gamma-hydroxybutyric acid, and tableting and encapsulating

machines. In accordance with Executive Order 13563, the DEA has reviewed its import and export regulations and reporting requirements for domestic transactions in listed chemicals (and gamma-hydroxybutyric acid) and tableting and encapsulating machines, and evaluated them for clarity, consistency, continued accuracy, and effectiveness. The amendments clarify certain policies and reflect current procedures and technological advancements. The amendments also allow for the implementation, as applicable to tableting and encapsulating machines, controlled substances, and listed chemicals, of the President's Executive Order 13659 on streamlining the export/import process and requiring the government-wide utilization of the International Trade Data System (ITDS). This rule additionally contains amendments that implement recent changes to the Controlled Substances Import and Export Act for reexportation of controlled substances among members of the European Economic Area made by the Improving Regulatory Transparency for New Medical Therapies Act. The rule also includes additional substantive and technical and stylistic amendments.

On July 15, 2016, the DEA published a general notice in the Federal Register announcing, in coordination with U.S. Customs and Border Protection (CBP), a pilot test of the ITDS involving the electronic submission of data related to the importation and exportation of controlled substances and listed chemicals. (81 FR 46058). The pilot program is testing the electronic transmission through CBP's ACE system, of data, forms and documents required by the DEA using the Partner Government Agency (PGA) Message Set and the Document Image System (DIS). The data, forms, and documents are transmitted for review by the DEA. The PGA Message Set and DIS enable importers, exporters, and brokers to electronically transmit data required by the DEA directly

through ACE; this electronic process replaces certain paper-based processes that are used outside of the pilot program. The test commenced on August 1, 2016, and will continue until publication of a notice in the Federal Register. Any party seeking to participate in the test was instructed to contact their CBP client representative. The pilot program will be concluded as of the effective date of the final rule. At that time, all importers, exporters, and brokers will be able to use ACE to electronically file required data and documentation associated with the importation and exportation of controlled substances and listed chemicals.

The DEA's implementation of this action without opportunity for public comment is based on the good cause exceptions in 5 U.S.C. 553(b)(B) because seeking public comment is impracticable, unnecessary and contrary to the public interest. The temporary delay in the effective date will allow Department of Justice officials an opportunity to review any potential questions of fact, law and policy raised by this regulation, consistent with the Chief of Staff's memorandum of January 20, 2017. Given the imminence of the rule's effective date, seeking prior public comment on this temporary delay would have been impractical, as well as contrary to the public interest in the orderly promulgation and implementation of regulations. For the foregoing reasons, the good cause exceptions in 5 U.S.C. 553(d)(3) also apply to DEA's decision to make today's action effective immediately.

In accordance with the memorandum of January 20, 2017, from the Assistant to the President and Chief of Staff, entitled "Regulatory Freeze Pending Review" this action hereby temporarily delays until March 21, 2017, the effective date of the final rule entitled "Revision of Import and Export Requirements for Controlled Substances, Listed

Chemicals, and Tableting and Encapsulating Machines, Including Changes to Implement the International Trade Data System (ITDS); Revision of Reporting Requirements for Domestic Transactions in Listed Chemicals and Tableting and Encapsulating Machines; and Technical Amendments” (RIN 1117-AB41) published in the Federal Register on December 30, 2016, at 81 FR 96992.

Dated: January 25, 2017.

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Chuck Rosenberg
Acting Administrator

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