(1) Aid to families with Dependent Children under title IV–A of the Social Security Act (the Act);  
(2) Foster Care under title IV–E of the Act;  
(3) Refugee Cash Assistance pursuant to section 412(e) of the Immigration and Nationality Act;  
(4) Cuban and Haitian Entrant Assistance pursuant to section 501(a) of Pub. L. 96–422; and  
(5) Bureau of Indian Affairs general assistance and child welfare assistance pursuant to 42 Stat. 208 as amended.  
This final rule amends § 416.420(b) of the current regulations to include this statutory change.

Justification for Dispensing With Rulemaking Procedures

The Department, even when not required by statute, as a matter of policy, generally follows the Administrative Procedure Act (APA) notice of proposed rulemaking and public comment procedures specified in 5 U.S.C. 553 in the development of its regulations. The APA provides exceptions to its notice and comment procedures when an agency finds there is good cause for dispensing with such procedures. Section 553(b)(3)(B) of the APA exempts application of notice and comment rulemaking procedures “when the agency for good cause finds * * * that notice and public procedures thereon are impracticable, unnecessary, or contrary to the public interest.” We are dispensing with notice and comment rulemaking in the case of this rule because such rulemaking is unnecessary since this rule merely reflects the provisions of section 1611c(c) of the Social Security Act as added by section 9106 of Pub. L. 100–203, and does not contain any policies established by the Secretary.

Regulatory Procedures

Executive Order No. 12291

The Secretary has determined that this is not a major rule under Executive Order 12291, because program and administrative costs are entirely the result of legislation and not this rule. The program and administrative costs will be insignificant and savings are estimated at less than $1 million a year. Therefore, a regulatory impact analysis is not required.

Regulatory Flexibility Act

We certify that this regulation will not have a significant economic impact on a substantial number of small entities because it affects only individuals. Therefore, a regulatory flexibility analysis as provided in Pub. L. 96–354, the Regulatory Flexibility Act, is not required.

Paperwork Reduction Act of 1980

This regulation imposes no reporting and recordkeeping requirements necessitating clearance by the Office of Management and Budget.

(Catalog of Federal Domestic Assistance Program No. 13–807, Supplemental Security Income Program)

List of Subjects in 20 CFR Part 416

Administrative practice and procedure, Aged, Blind, Disability benefits, Public assistance programs, Supplemental Security Income.


Dorcas R. Hardy, Commissioner of Social Security.  
Approved: July 5, 1989.

Louis W. Sullivan, Secretary of Health and Human Services.

Part 416 of Title 20 of the Code of Federal Regulations is amended as follows:

PART 416—[AMENDED]

1. The authority citation for Subpart D of Part 416 continues to read as follows:

Authority: Secs. 1102, 1611 (e), (b), (c), and (e), 1612, 1617, and 1631 of the Social Security Act; 42 U.S.C. 1302, 1382 (a), (b), (c), and (e), 1382a, 1382f, and 1383.

2. In § 416.420, a new paragraph (b)(4) is added to read as follows:

§ 416.420 Determination of benefits; general.

(b) Exceptions to the general rule.—

(4) Income derived from certain assistance payments. We use your income in the current month from the programs listed below to determine your benefit amount for that same month. The assistance programs are as follows:

(i) Aid to Families with Dependent Children under title IV–A of the Social Security Act (the Act);

(ii) Foster Care under title IV–E of the Act;

(iii) Refugee Cash Assistance pursuant to section 412(e) of the Immigration and Nationality Act;

(iv) Cuban and Haitian Entrant Assistance pursuant to section 501(a) of Pub. L. 96–422; and

(v) Bureau of Indian Affairs general assistance and child welfare assistance pursuant to 42 Stat. 208 as amended.

[FR Doc. 89–17845 Filed 7–31–89; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1310 and 1313

Records, Reports, Imports, and Exports of Precursor and Essential Chemicals, Tabulating Machines and Encapsulating Machines

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Final rule.

SUMMARY: This final rule establishes procedures designed to implement the requirements of the Chemical Diversion and Trafficking Act of 1988. The rule contains the requirements for the recordkeeping, reporting, importing, and exporting of precursor and essential chemicals and recordkeeping and reporting on tabulating machines and encapsulating machines.

EFFECTIVE DATE: Part 1310 (the format required on records and reports) will be effective August 31, 1989; Part 1313 will be effective October 30, 1989; except §§ 1313.15(a) and 1313.24(a) which will be effective on August 1, 1989.

FOR FURTHER INFORMATION CONTACT: Mr. G. Thomas Gitchel, Chief, State and Industry Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Telephone (202) 307–7297.

SUPPLEMENTARY INFORMATION:

Introduction

On February 8, 1989, a notice of proposed rulemaking designed to implement the Chemical Diversion and Trafficking Act of 1988 (the “Act”) was published in the Federal Register (54 FR 8144–8151). The proposed rule provided the opportunity for interested parties to submit comments on these proposed regulations on or before March 27, 1989.

The numbering system for Parts 1310 and 1313 has been revised from the proposed regulations to be consistent with the numbering in existing regulations in 21 CFR Part 1300.

Thirty-four interested parties filed comments. A section-by-section analysis of the comments and the DEA’s consideration of them are set forth below.

Part 1310—Records and Reports of Listed Chemicals and Certain Machines

Several comments were received stating that the Piperidine Report (DEA Form 420) and its relevant regulations be deleted from this section. To avoid any confusion, DEA wishes to clarify that the previous Part 1310, to include the
DEA Form 420, the seven-day and the semiannual reports, is deleted and replaced by the current Part 1310.

Definitions (§ 1310.01)

Fourteen comments addressed the definitions of “regulated person” and “retrievable” and the exemptions to a “regulated transaction” as being unclear, confusing, or not in compliance with the Act. The DEA has redefined the term “regulated person” to more closely parallel the definition of “person”, as used elsewhere in Title 21 (See 21 CFR 1301.02(j)).

One comment stated that the definition of “regulated person” should be expanded to include the parent and subsidiaries, affiliates and related companies. However, it is DEA’s view that companies that are separate legal entities will be treated for the purposes of these regulations as separate “regulated persons”.

Four comments asked whether a licensed customs broker is in any sense a “regulated person” and also expressed concern about the role of common carriers. The broker becomes a regulated person only when it meets the definition of a chemical importer or exporter, as explained in §1310.01(f)(1) (ii), §1313.02(b) and §1313.02(f).

Several comments took exception to §1313.01(f)(4)(i), which establishes the exemption for certain domestic, lawful transactions for “agents and employees”. The comments stated that the proposed exemption would add confusion to the clear language of the Act, would create the need for excessive, unnecessary and unintended recordkeeping and reporting and would be redundant. It is the intent of the regulation to ensure that records are available and that the ability exists to assign specific responsibility. As such, specific definition of those persons who are covered by the exemption is necessary.

One comment objected to §1310.01(f)(1)(i) by addressing the unrelated topic of warehouses and public terminals. Exemptions which apply to warehouses and public terminals are specifically covered under §1313.01(f)(1)(ii).

One comment noted the incorrect reference mentioned at the end of §1310.01(f)(1)(i) and (iii); “this section” and “this title or title III”. DEA concurs and the wording has been changed to reflect the proper reference.

It was noted by DEA that part of the exemption relating to labeling machines and encapsulating machines specified under §1310.01(f)(2) had been inadvertently omitted from the proposed regulations. The missing language has been incorporated into this subsection.

One comment requested a clarification of the term “manufacture”. Three comments questioned if the Act applied to chemicals “used in the manufacture” of products manufactured under the approval of the Federal Food, Drug, and Cosmetic Act. It was not the intent to regulate “use or consumption in manufacturing”. A regulated transaction does not cover receipt of listed chemicals, except by a regulated person. Also, a specific exemption from the term regulated transaction is provided for a “chemical mixture” as set forth in §1310.01(g).

Two comments took exception to the use of “readily” in the definition of "retrievable" (§1310.01(h)), stating that timeliness should not be a primary concern and that it adds nothing to the definition. Clearly, one of the purposes of the Act is to provide law enforcement access to information which is accurate and can be responded to in a timely manner. Therefore, timeliness is a major concern.

Three comments addressed the need to define the terms “tabulating” and “encapsulating” machines, as regulated by the Act. DEA has incorporated the definitions into the final regulations (§1310.01(l) and (j)). One comment asked for specific clarification of the status of a specific encapsulating machine which is addressed with this added definition. The proposed §1310.01(l)(i) is redesignated as paragraph (k).

Substances Covered (§1310.02)

Several comments addressed the 30 days advance notice of additions of substances as listed chemicals, specified in §1310.02(c), as being insufficient, inadequate, and in need of improvement. These parties have misinterpreted this subsection. Prior to implementing the addition or deletion of substances as listed chemicals, DEA will publish in the Federal Register a proposed rule allowing 30 days for comments. It has been and will continue to be this agency’s practice to provide for reasonable effective dates and sufficient time to establish compliance with the regulations at the time any final order is published adding a new chemical.

One comment suggested that DEA adopt a similar mechanism described in Section 6053(b) of the Act for adding new chemicals to the list. That section provides for the Attorney General to forward to the Office of Management and Budget (OMB) any proposed regulations for OMB’s comments and recommendations. DEA currently forwards all proposed rules and final rules to OMB for review pursuant to E.O. 12291, except those required to be made “on the record.” Since this is not an “on the record” rulemaking, all proposals for adding or deleting chemicals from the list of listed chemicals will be reviewed by OMB.

One comment requested DEA to include a period of time for establishing “regular customers” and “regular suppliers” after adding a substance as a listed chemical. Although the Act does not contain a provision for this additional period, DEA recognizes the usefulness of this suggestion and intends to provide an opportunity for such submissions under any final order which may be issued under §1310.02(h).

Several comments addressed the need for DEA to specifically identify the listed chemicals by means of a numbering system already in use by the chemical industry to minimize the uncertainty regarding which chemicals are regulated. DEA has reviewed the three numbering systems specifically mentioned in the comments (CAS, TSUS, and Schedule B) and has determined that they were designed for other purposes and do not specifically meet the needs of the Act. In addition, there are overlaps and repetitions within each of these systems which may cause additional confusion.

However, DEA will produce a reference guide as an aid to the regulated industry.

Persons Required To Keep Records and File Reports (§1310.03)

Three comments addressed a reference missing from §1310.03. This section should end “* * * shall keep a record of the transaction as specified by §1310.04 and file reports as specified by §1310.05.” DEA agrees with these comments and has made the appropriate modifications.

Maintenance of Records (§1310.04)

Several comments requested further explanation of the phrase “the principal place of business”, as specified in the proposed §1310.04(c). DEA has inserted additional language into this subsection clarifying that any regulated person who conducts regulated transactions at more than one location shall keep records at each location. To allow flexibility to companies with multiple locations, a provision for a single central recordkeeping location is provided. However, each regulated person operating at multiple locations where records are stored must devise a system to ensure that the recordkeeping and reporting requirements are not being
evaded. This subsection was subdivided to facilitate a better understanding of its purpose.

One comment suggested that records be maintained for at least five to seven years. This recommendation would be inconsistent with the specific time limits for keeping records established by the Act.

**Reports (§ 1310.05)**

Several comments requested further clarification of the terms “extraordinary quantity,” “uncommon method of payment,” and “unusual or excessive losses.” These terms apply to situations which appear to be outside the framework of a normal business transaction. The chemical industry is expected to understand the nature of its legitimate business transactions and must make informed decisions as to whether the above terms apply to any of their transactions. DEA intends to make available informal guidance, as opposed to regulations, to assist the chemical industry in meeting this requirement.

Two comments requested clarification of the term “nearest” DEA office mentioned in §§ 1310.05(a) and (b). This regulation has been reworded to reflect that contacts are to be made to the DEA Divisional office for the area in which the regulated person making the report is located. DEA office locations are available in telephone directories and will be available in DEA guidelines.

Sixteen comments addressed the reporting requirements for quantitative and cumulative thresholds as being vague and ambiguous and also requested further clarification. The threshold limits apply only to the maintenance of records under Part 1310 and for import/export transactions under Part 1313 and do not automatically trigger the filing of reports on regulated transactions. It was not the intent of DEA to imply that reporting was required for virtually every chemical transaction that exceeds the quantitative or cumulative thresholds. To avoid the unintentional confusion concerning the application of quantitative and cumulative thresholds, DEA has removed subsection (c) from § 1310.05 and placed it under § 1310.04(f) where it is more appropriate. Reports are still required for any transactions which meet the specific reporting requirements of § 1310.05.

Several comments addressed the level of the threshold quantities. One comment requested that these quantitative thresholds be replaced with percentage amounts, relative to the previous year’s experience. Comments from law enforcement agencies expressed that the proposed thresholds were too high for chemicals not used in the production of pharmaceuticals and suggested a zero threshold for these chemicals. Among the comments, there was no consensus nor were any alternatives provided. The figures outlined in the regulations were arrived at after substantial internal study and discussions with industry. DEA intends to be flexible with experience regarding thresholds, but these thresholds will remain for the initial implementation of the Act.

One comment requested DEA to establish an upper threshold limit in which shipments which exceed these thresholds are not regulated. This is not provided for in the Act and cannot otherwise be justified at this time.

As suggested by several comments and to assist in the structuring of an industry monitoring system, the cumulative threshold provision (§ 1310.04(f)) has been revised to assess the quantities involved on the basis of a calendar month, rather than on a 30-day period as originally proposed.

One comment proposed that DEA consider having each supplier send in monthly compilations of all chemical shipments in a format similar to the reporting currently required for pharmaceuticals under control of the Controlled Substances Act. DEA cannot levy this as a requirement as it is not authorized by the Act.

DEA has added a sentence to § 1310.05(a)(3) clarifying which regulated person is responsible for reporting an in-transit loss. The supplier is responsible for reporting the loss to DEA. Section 1310.05(a)(4) specifies reporting requirements for domestic transactions only for tableting machines and encapsulating machines. DEA will propose the export reporting requirements at a later date.

**Contents of Records and Reports (§ 1310.06)**

To avoid confusion, DEA has deleted the reference to “reports” in § 1310.06(a). Also, six comments were received concerning the telephone number requirement, identification of customers, and the reporting burden. DEA has deleted the telephone number as required information on the record, but the telephone number, where obtainable, is required on reports made to DEA and on the declarations for exports of listed chemicals.

Three comments stated that DEA has substantially underestimated the reporting burden on regulated persons. Several of the comments referenced above will serve to reduce the reporting burden and DEA deems the estimate to be accurate. As provided, future comments regarding this burden estimate should be directed to OMB, as specified in § 1310.06.

**Proof of Identity (§ 1310.07)**

Fifteen comments were received regarding the requirement to “identify the other party” involved in a regulated transaction specified in § 1310.07. A distinction has been made between elements of proof of identity for domestic transactions and export transactions. To further clarify when this requirement must occur, the phrase “at the time the order is placed” has been added to § 1310.07(a).

Several comments addressed the need for alternatives to obtaining the signature of a purchaser or the purchaser’s agent due to the ever increasing number of orders generated electronically, the blanket purchase orders negotiated at the beginning of each year, and the fact that in most sales the seller does not receive a document signed by the buyer.

This section has been modified to provide flexibility to firms in meeting the requirement based upon normal business practices, but maintaining the need for the clear and provable establishment of the identity of the other party. The rule provides that prior to an initial transaction with a new customer, the parties document the proof of identity and authorized signature. This authorized signature can be maintained on file but must be updated annually. The initial transaction record must reflect a unique identification number and the signature of the authorized agent. If a firm chooses, subsequent transactions need not have the signature of the authorized agent; however, the supplier must ensure that the purchaser/authorization has not changed.

Also, this section has been modified to include acceptable identification for domestic electronic orders, such as computer passwords.

**Part 1313—Importation and Exportation of Precursors and Essential Chemicals**

Two comments recommended that throughout this Part the word “notification” be used rather than “declaration” in describing DEA Form 486. The DEA Form 486, Precursor and Essential Chemical Import/Export Declaration, is the required method of notification which the Administrator has established for chemical imports and exports.

One comment requested an exemption to filing reports of precursors and essential chemicals for activities between companies and foreign subsidiaries within the same
corporation. Such an exception would be inconsistent with the requirements of the Act.

Several comments suggested that DEA be consistent in the wording used to describe when to file a DEA Form 486. Therefore, the subsections throughout this Part that contain the words “provided”, “furnished”, and “filed” have been changed to “received”. However, for transactions covered by § 1313.12 and § 1313.21, a DEA Form 486 must still be received at DEA not later than 15 days prior to the date of importation or exportation.

Based on numerous comments regarding the compromising of confidentiality, the difficulty in keeping the form with the shipment, and the form’s utility in the foreign country, the five-part DEA-486 has been changed to a three-part form, eliminating foreign distribution for both import and export. The Act provides the Attorney General authority to require such form as he deems appropriate for the purpose of notification, and DEA Form 486 meets this requirement.

Two comments challenged the language of § 1313.13(a) and 1313.22(a) that imports (or exports) of chemicals must be for “medical, commercial, scientific, or other legitimate uses”. DEA cannot conceive of another purpose for such importation or exportation, other than for illicit purposes. This is the very concept for which this legislation was created, and the wording remains unchanged. Also, the terms “the regulated chemical importer” under § 1313.13(c)(1) and the regulated chemical exporter” under § 1313.22(c)(1) were considered unclear. The proposed phrases are redundant, and the word “regulated” has been deleted from both subsections.

Several comments discussed possible variances in amounts reported on DEA Form 486 and the actual quantity imported/exported, due to, for example, evaporation or seepage during shipping. Historical knowledge of any losses does not relieve the regulated person from reporting the amount received or shipped. Companies should be able to document normal experiences and the actual quantity exported from the United States or foreign country shall be reported on DEA Form 486.

Two comments requested DEA consider using existing import/export documents required by other federal agencies in lieu of a DEA form. Several federal agencies regulate imports and exports, each with different authority and jurisdiction. However, DEA does not operate within the mandates and regulations of these other agencies. The Act clearly provides DEA the authority to promulgate its own regulations independent of other federal agencies. Two comments asked that DEA allow the use of telefax equipment to file necessary declarations. Although not an item for inclusion in the regulations, DEA has already established this capability in anticipation of the Act. The DEA telex number for import/export transactions is (202) 307–6870.

Scope (§ 1313.01)

One comment stated that the term “those sections” in § 1313.01 was unclear. This section has been clarified to read “that section”, specifically referring to Section 1016 of the Act (21 U.S.C. 971).

Definitions (§ 1313.02)

Two comments urged that the definitions of “regulated person” and “regulated transaction” outlined in Part 1310 either be included or incorporated by reference in Part 1313. DEA agrees that such a modification would clarify that those terms also apply in Part 1313 and therefore the definitions have been restated in § 1313.02.

Four comments suggested that the word “article” in the definitions of “chemical export” and “chemical import” in §§ 1313.02 (a) and (c) be changed to conform with the language in the Act. DEA has substituted the term “listed chemical” wherever the word “article” is mentioned.

Two comments addressed the phrase “that is not in conflict with the laws of the country to which it is intended for import” as part of the definition of “chemical export”. A new definition has been added which deletes this phrase. A new section (§ 1313.25) has been added in which DEA will publish a notice of foreign import restrictions on listed chemicals of which the DEA has knowledge.

One comment recommended the “exporter of record” be considered the exporter and that the “importer of record”, as defined in the U.S. Customs Consumption Summary, be the chemical importer. These definitions have been modified to ensure specific and clear responsibility is assigned. The importer/exporter of record as defined in the comment may not have all of the facts relevant to the transaction. The revised definition has been modified based on comments and input from the U.S. Customs Service and now specifies the responsibility for submission of the export declaration to meet the requirements of the Act.

Several comments questioned the criteria used in determining “an established business relationship” and suggested that in defining an established business relationship DEA accept previous transactions in non-regulated products as sufficient to establish a business relationship for purposes of the Act. Some of these comments also addressed the phrase “and accepted by”, mentioned in the term “regular customer”. All comments were reviewed carefully and many changes were made in this area. The term “established business relationship” has been defined separately for imports and exports and incorporated into § 1313.02. Only previous transactions in the specific listed chemical apply in meeting an established business relationship. Also, the phrase “and accepted by” has been deleted from the definition of regular customer.

One comment stated that the definition of “chemical importer” was ambiguous as it relates to the jurisdiction and customs territory of the United States. The appropriate definitions have been modified with input from the U.S. Customs Service.

One comment found the statement “* * * from the jurisdiction of the United States into the customs territory of the United States * * *” as ambiguous. This is a standard definition used in distinguishing tariff laws from all other applicable laws.

Importation of Precursor and Essential Chemicals Requirement of Authorization to Import (§ 1313.12)

§§ 1313.12(a) and (b) have been rewritten to clarify when the filing of DEA Form 486 must be accomplished. Subsection (c) was created to address the waiver of the 15-day notification requirement as it pertains to filing a DEA Form 486. These modifications were made based on comments DEA addressed previously under Part 1313.

Contents of Import Declaration (§ 1313.13)

One comment recommended that DEA permit the regulated community to use bonded warehouses to store listed precursor and essential chemicals if the appropriate import notice either has not been given in a timely manner or is deemed insufficient. The use of a bonded warehouse has no bearing on the requirement to submit a DEA Form 486 for any importation meeting or exceeding the quantitative thresholds. Any importation meeting or exceeding the quantitative thresholds and found not to contain the appropriate documentation would be in violation of the Act and subject to the penalties outlined in the Act.

Several comments addressed the requirement in § 1313.13(c)(4) to include
the license number for importers on the DEA Form 486 emphasizing the unavailability of this information. This requirement has been deleted from the regulations and the DEA Form 486.

Distribution of Import Declaration (§ 1313.14)

The five-part Precursor and Essential Chemical Import/Export Declaration (DEA Form 486) was changed to a three-part form, as previously mentioned under Part 1313. Previously designated copies 1 and 2 for foreign distribution have been eliminated and copies 3, 4, and 5 have been renumbered, with the new copy 1 being the regulated person's copy, the new copy 2 being DEA's copy, and the new copy 3 being the U.S. Customs Service copy.

One comment suggested that the DEA From 486 was contrary to the U.S. Customs Service's program to require electronic or "paperless transfers" of forms, etc., by 1990. This Act responds to a current specific law enforcement need. Future administrative provisions will be considered as experience dictates.

Waiver of 15-day Advance Notice for Chemical Importers (§ 1313.15)

The question was raised concerning provisions for "emergency shipments" for new customers. DEA cannot foresee any life threatening emergency which could render the 15-day notice established by the Act as impractical. DEA, as has been its practice, will attempt to provide assistance to the regulated industry in truly exigent circumstances.

Several companies proposed different scenarios which they believe would make it difficult, if not impossible, to file the DEA Form 486 15 days prior to importation. The law is very clear on this issue and this requirement is unchanged.

DEA's authority was questioned concerning the statutory notice function which was described as a "premarket clearance and registration." DEA does not recognize this as a premarket clearance, only as a 15-day notification period in order for this agency to perform the responsibilities formally envisioned in the Act.

One comment objected to the use of the word "grant" in § 1313.15(b) and § 1313.24(b), as it relates to regular supplier and regular customer status, on the ground that its use was not authorized by Congress. These subsections have been rewritten to parallel the language of the Act.

Three comments were received concerning DEA's authority to require information specified in § 1313.15(c)(1-8) and the confidentiality of the information. This subsection has been rewritten keeping in mind the concerns of the industry and the needs of DEA. DEA will take action to ensure confidentiality is maintained within DEA. This agency has handled proprietary information under the Controlled Substances Act for years and has established procedures and experience in this area.

One comment expressed concern about the requirement that chemical importers must supply the identity of each foreign chemical supplier within 30 days from the promulgation of these regulations. This requirement is clearly outlined in the Act.

Five comments questioned the relevancy of the requirements of § 1313.15(g) and § 1313.24(f). DEA agrees that these subsections are covered by Part 1310 and has deleted both from the final regulations.

One comment recognized inconsistencies of § 1313.15(b) with previously stated sections. To correct these inconsistencies, the referenced citation was changed to § 1313.12, and the phrase "for all chemical imports" was eliminated.

One comment stated DEA does not have the authority to rescind regular supplier status. DEA has determined that §§ 1313.15 (i) and (j) were redundant as this information is already specified in § 1313.15 and has been deleted. These changes will make the regular supplier determination more workable.

The subsections within § 1313.15 have been renumbered to reflect the above changes.

Exportation of Precursors and Essential Chemicals Requirement of Authorization to Export (§ 1313.21)

Two comments addressed the phrase "that is not in conflict with the laws of the country to which it is intended for export" as expressed in § 1313.21(b). DEA will publish a notice of countries which have imposed restrictions for listed chemicals. Section 1313.25 has been created for this purpose. It will be the obligation of the regulated industry to review the Federal Register for these notices. Where such notices have been published, there is a presumption that the regulated persons have made good faith efforts to familiarize themselves with these restrictions and will abide by them.

Contents of Export Declaration (§ 1313.22)

Two comments requested that the phrase "authorized to export" be deleted since the remaining language is sufficient for DEA's purposes. DEA agrees with these comments and has deleted this phrase from § 1313.22(b).

Five comments were directed to the complex and time-consuming procedures involved in the return of exported chemicals which were refused, rejected or otherwise undeliverable. The procedures have been reevaluated, and new procedures have been established to expedite the return of the listed chemicals. The shipment must be returned to the regulated person as soon as possible. A written notification outlining the circumstances must be forwarded to DEA following the return within a reasonable time.

Distribution of Export Declaration (§ 1313.23)

The modifications to DEA Form 486 are explained under Distribution of Import Declaration. In regard to exports, the new copy 3 must be presented to the U.S. Customs Service along with a copy of the Shippers Export Declaration.

Waiver of 15-day Advance Notice for Chemical Exporters (§ 1313.24)

One comment requested that a mechanism be provided to give the U.S. Customs Service notice that the 15-day notification requirement has been waived. This suggestion has been incorporated into the DEA Form 486.

One comment suggested that filing DEA Form 486 for each shipment to regular customers would be unmanageable and recommended quarterly or yearly regular customer reports. This suggestion is not in accordance with the Act.

One comment recommended that at the time of initial notification an exporter be permitted to apply for "regular customer" status for all listed chemicals, even if within the preceding two-year period the customer has not purchased all of the listed chemicals. DEA will not recognize regular customer status without a business relationship having been established for each specified chemical.

One comment recommended adding the words "if known" to the end of § 1313.24(d)(3). DEA concurs with this requested addition and has moved this section to a new definition contained in § 1313.02(j).

One comment recommended that DEA allow up to 120 days to supply complete customer lists to the Administrator after publication of these regulations. The Act specifically states that the regular customer list shall be received not later than 30 days after the publication of the final regulations.
One comment stated that DEA does not have the authority to disqualify a regular customer. Section 1018(c)(1) of the Act states specifically that the Attorney General "may disqualify any regular customer" as specified in the Act.

Two comments stated DEA had no authority to limit the 15-day advance notice waiver for listed precursor chemicals based on the Convention Against Illicit Trafficking in Narcotic Drugs and Psychotropic Substances. Section 1313.24(j) has been deleted from the final regulations.

Transshipment and In-Transit Shipment of Precursors and Essential Chemicals
Advance Notice of Importation for Transshipment or Transfer (§ 1313.31)

Five comments were received addressing this section. Two comments asked for clarification of "regulated person" as it relates to transshipments that originate from foreign countries. The party who caused the transshipment or transfer is responsible for notification.

Two comments discussed the need for waiver requirements. Providing a waiver of the reporting requirements would only encourage diversion into the illicit market. To prevent the United States from having its borders facilitate the transfer of chemicals for illicit operations, the United States needs the time to determine the legitimacy of the customer.

Suspension of Shipments (§ 1313.41)

One comment requested clarification on how this authority will be exercised. The comment also pointed out that the Act states the "legal and factual basis" for suspension must be provided by the Administrator. The Act specifies the requirements for the suspension of a shipment and the wording of the regulation has been changed to parallel the language of the Act.

Request for Hearing (§ 1313.54)

Two subsections have been added to clarify the procedures governing hearings.

Miscellaneous

Two comments requested DEA to include in the regulations the penalties pertaining to noncompliance with the Act. Regulations are not the appropriate forum for listing penalties; they are clearly set forth in the Act. The Piperidine Report (DEA Form 420), OMB approval 1117–0017, is eliminated.

The Administrator of the Drug Enforcement Administration hereby certifies that this final rule will have no significant impact upon entities whose interests must be considered under the Regulatory Flexibility Act, 5 U.S.C. 601 et seq. This rule is not a major rule for purposes of Executive Order (E.O.) 12291 of February 17, 1981. Pursuant to sections 3(c)(3) and 3(e)(2)(C) of E.O. 12291 and section 6053(b) of Pub. L. 100–690, this rule has been reviewed by the Office of Management and Budget. The information collection requirements in the proposed rule were approved by the Office of Management and Budget on February 3, 1989. Modifications of the information collection requirements, set forth in this final rule, were approved on July 19, 1989.

This action has been analyzed in accordance with the principles and criteria contained in E.O. 12612, and it has been determined that the rule does not have significant federalism implications to warrant the preparation of a Federalism Assessment.

List of Subjects

21 CFR Part 1310
Drug enforcement administration, Drug traffic control, Reporting and recordkeeping requirements.

21 CFR Part 1311
Drug enforcement administration, Drug traffic control, Exports, Imports, Reporting requirements.

For reasons set out in the preamble, Chapter II, Title 21, Code of Federal Regulations is amended as follows. Part 1310 is revised to read as follows:

PART 1310—RECORDS AND REPORTS OF LISTED CHEMICALS AND CERTAIN MACHINES

Sec.
1310.01 Definitions.
1310.02 Substances covered.
1310.03 Persons required to keep records and file reports.
1310.04 Maintenance of records.
1310.05 Reports.
1310.06 Content of records and reports.
1310.07 Proof of identity.


§ 1310.01 Definitions.

As used in this part, the following terms shall have the meanings specified:
(b) The term "listed chemical" means any listed precursor chemical or listed essential chemical.
(c) The term "listed precursor chemical" means a chemical specifically designated by the Administrator in § 1310.02(a) that, in addition to legitimate uses, is used in manufacturing a controlled substance in violation of this title and is critical to the creation of a controlled substance.
(d) The term "listed essential chemical" means a chemical specifically designated by the Administrator in § 1310.02(b) that, in addition to legitimate uses, is used as a solvent, reagent, or catalyst in manufacturing a controlled substance in violation of this title.
(e) The term "regulated person" means any individual, corporation, partnership, association, or other legal entity who manufactures, distributes, imports, or exports a listed chemical, a tableting machine, or an encapsulating machine.
(f) The term "regulated transaction" means:
(i) A distribution, receipt, sale, importation or exportation of a threshold amount as determined by the Administrator which includes a cumulative threshold amount for multiple transactions of a listed chemical, except that such term does not include:
(ii) A delivery of a listed chemical to or by a common or contract carrier for carriage in the lawful and usual course of business of the common or contract carrier, or to or by a warehouseman for storage in the lawful and usual course of business of the warehouseman, except that if the carriage or storage is in connection with the distribution, importation, or exportation of a listed chemical to a third person, this paragraph does not relieve a distributor, importer, or exporter from compliance with this part of Part 1313 of this chapter;
(iii) Any category of transaction specified by regulation of the Administration as excluded from this definition as unnecessary for enforcement of the Act;
(iv) Any transaction in a listed chemical that is contained in a drug that may be marketed or distributed lawfully in the United States under the Federal Food, Drug, and Cosmetic Act; or
(v) Any transaction in a chemical mixture.
(2) A distribution, importation, or exportation of a tableting machine or encapsulating machine except that such
The term does not include a domestic lawful distribution in the usual course of business between agents and employees of a single regulated person; in this context, agents or employees means individuals under the direct management and control of the regulated person.

(g) The term "chemical mixture" means a combination of two or more chemical substances, at least one of which is not a listed precursor chemical or listed essential chemical, except that such term does not include any combination of a listed precursor chemical or a listed essential chemical with another chemical that is present solely as an impurity or which has been created to evade the requirements of the Act.

(h) The term "retrievable" means that records required by this section are kept by automatic data processing systems or other electronic or mechanized recordkeeping systems in such a manner that they can be readily retrieved and separated out from all other records in a reasonable time and/or records are kept on which the listed chemicals, tableting machines, and encapsulating machines are asterisked, redlined, or in some other manner visually identifiable apart from other items appearing on the records or the maintained separate from all other records.

(i) The term "tableting machine" means any manual, semi-automatic, or fully automatic equipment which may be used for the compaction or molding of powdered or granular solids, or semi-solid material, to produce coherent solid tablets.

(j) The term "encapsulating machine" means any manual, semi-automatic, or fully automatic equipment which may be used to fill shells or capsules with any powdered, granular, semi-solid, or liquid material.

(k) Any term not defined in this section shall have the definition set forth in section 102 and 1001 of the Act (21 U.S.C. 802 and 951) and §1301.02 of this chapter.

§ 1310.02 Substances covered.

The following chemicals have been specifically designated by the Administrator of the Drug Enforcement Administration as the listed chemicals subject to the provisions of this part and Part 1313 of this chapter.

(a) Listed Precursor Chemicals:

(1) Anthranilic acid and its salts
(2) Benzyl cyanide
(3) Ephedrine, its salts, optical isomers, and salts of optical isomers
(4) Ergonovine and its salts
(5) Ergotamine and its salts
(6) N-Acetylantianilic acid and its salts
(7) Norpseudoephedrine, its salts, optical isomers, and salts of optical isomers
(8) Phenylacetic acid and its salts
(9) Phenypropanolamine, its salts, optical isomers, and salts of optical isomers

(10) Piperidine and its salts
(11) Pseudoephedrine, its salts, optical isomers, and salts of optical isomers
(12) 3,4-Methylenedioxyphenyl-2-propanone
(b) Listed Essential Chemicals:

(1) Acetic anhydride
(2) Acetone
(3) Benzyl chloride
(4) Ethyl ether
(5) Hydrochloric acid
(6) Potassium permanganate
(7) 2-Butanone (or Methyl Ethyl Ketone or MEK)
(8) Toluene
(c) The Administrator may add or delete a substance as a listed chemical by publishing a final rule in the Federal Register following a proposal which shall be published at least 30 days prior to the final rule.
(d) Any person may petition the Administrator to have any substance added or deleted from paragraphs (a) or (b) of this section.
(e) Any petition under this section shall contain the following information:

(1) The name and address of the petitioner;
(2) The name of the chemical to which the petition pertains;
(3) The name and address of the manufacturer(s) of the chemical (if known);
(4) A complete statement of the facts which the petitioner believes justifies the addition or deletion of the substance from paragraphs (a) or (b) of this section;
(5) The date of the petition.
(f) The Administrator may require the petitioner to submit such documents or written statements of fact relevant to the petition as he deems necessary in making a determination.
(g) Within a reasonable period of time after the receipt of the petition, the Administrator shall notify the petitioner of his decision and the reason therefor. The Administrator need not accept a petition if any of the requirements prescribed in paragraph (e) of this section or requested pursuant to paragraph (f) of this section are lacking or are not clearly set forth as to be readily understood. If the petitioner desires, he may amend and resubmit the petition to meet the requirements of paragraphs (c) and (f) of this section.
(h) If a petition is granted or the Administrator, upon his own motion, proposes to add or delete substances as listed chemicals as set forth in paragraph (c) of this section, he shall issue and publish in the Federal Register a proposal to add or delete a substance as a listed chemical. The Administrator shall permit any interested person to file written comments regarding the proposal within 30 days of the date of publication of his order in the Federal Register. The Administrator will consider any comments filed by interested persons and publish a final rule in accordance with his decision in the matter.

§1310.03 Persons required to keep records and file reports.

Each regulated person who engages in a regulated transaction involving a listed chemical, a tableting machine, or an encapsulating machine shall keep a record of the transaction as specified by §1310.04 and file reports as specified by §1310.05.

§ 1310.04 Maintenance of records.

(a) Every record required to be kept subject to §1310.03 for a listed precursor chemical, a tableting machine, or an encapsulating machine shall be kept by the regulated person for four years after the date of the transaction.
(b) Every record required to be kept subject to §1310.03 for a listed essential chemical shall be kept by the regulated person for two years after the date of the transaction.
(c) A record under this section shall be kept at the regulated person's place of business where the transaction occurred, except that records may be kept at a single, central location of the regulated person if the regulated person has notified the Administrator of the intention to do so. Written notification must be submitted by registered or certified mail, return receipt requested, to the Special Agent in Charge of the DEA Divisional Office for the area in which the records are required to be kept.
(d) The records required to be kept under this section shall be readily retrievable and available for inspection and copying by authorized employees of the Administration under the provisions of 21 U.S.C. 860.
(e) The regulated person with more than one place of business where records are required to be kept shall devise a system to detect any party purchasing from several individual locations of the regulated person thereby seeking to avoid the application of the cumulative threshold or evading the requirements of the Act.
(f) The quantitative threshold or the cumulative amount for multiple
transactions within a calendar month to be utilized in determining whether a receipt, sale, importation or exportation is a regulated transaction is as follows:

<table>
<thead>
<tr>
<th>Chemical</th>
<th>Threshold by base weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>(i) Anthranilic acid and its salts</td>
<td>30 kilograms</td>
</tr>
<tr>
<td>(ii) Benzyl cyanide</td>
<td>1 kilogram</td>
</tr>
<tr>
<td>(iii) Ephedrine, its salts, optical isomers, and salts of optical isomers</td>
<td>10 grams</td>
</tr>
<tr>
<td>(iv) Ergonovine and its salts</td>
<td>20 grams</td>
</tr>
<tr>
<td>(v) Ergotamine and its salts</td>
<td>40 kilograms</td>
</tr>
<tr>
<td>(vi) N-Acetylanthranilic acid and its salts</td>
<td>2.5 kilograms</td>
</tr>
<tr>
<td>(vii) Norpseudoephedrine, its salts, optical isomers, and salts of optical isomers</td>
<td>1 kilogram</td>
</tr>
<tr>
<td>(viii) Phenylacetic acid and its salts</td>
<td>2.5 kilograms</td>
</tr>
<tr>
<td>(ix) Phenylpropanolamine, its salts, optical isomers, and salts of optical isomers</td>
<td>1 kilogram</td>
</tr>
<tr>
<td>(x) Piperidine and its salts</td>
<td>500 grams</td>
</tr>
<tr>
<td>(xi) Pseudoephedrine, its salts, optical isomers, and salts of optical isomers</td>
<td>20 kilograms</td>
</tr>
<tr>
<td>(xii) 3,4-Methylenedioxyphenyl-2-propanone</td>
<td></td>
</tr>
</tbody>
</table>

(2) Listed Essential Chemicals:

(i) Imports and Exports

<table>
<thead>
<tr>
<th>Chemical</th>
<th>Threshold by volume</th>
<th>Threshold by weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>(A) Acetic anhydride</td>
<td>250 gallons</td>
<td>1,023 kilograms</td>
</tr>
<tr>
<td>(B) Acetone</td>
<td>500 gallons</td>
<td>1,500 kilograms</td>
</tr>
<tr>
<td>(C) Benzyl chloride</td>
<td>N/A</td>
<td>4 kilograms</td>
</tr>
<tr>
<td>(D) Ethyl ether</td>
<td>500 gallons</td>
<td>1,364 kilograms</td>
</tr>
<tr>
<td>(E) Hydric acid</td>
<td>40 liters (57%)</td>
<td>22.8 kilograms</td>
</tr>
<tr>
<td>(F) Potassium permanganate</td>
<td>500 gallons</td>
<td>1,455 kilograms</td>
</tr>
<tr>
<td>(G) 2-Butanone (MEK)</td>
<td>500 gallons</td>
<td>1,591 kilograms</td>
</tr>
</tbody>
</table>

(ii) Domestic Sales

<table>
<thead>
<tr>
<th>Chemical</th>
<th>Threshold by volume</th>
<th>Threshold by weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>(A) Acetic anhydride</td>
<td>250 gallons</td>
<td>1,023 kilograms</td>
</tr>
<tr>
<td>(B) Acetone</td>
<td>50 gallons</td>
<td>150 kilograms</td>
</tr>
<tr>
<td>(C) Benzyl chloride</td>
<td>N/A</td>
<td>1 kilogram</td>
</tr>
<tr>
<td>(D) Ethyl ether</td>
<td>50 gallons</td>
<td>135.8 kilograms</td>
</tr>
<tr>
<td>(E) Hydric acid</td>
<td>10 liters (57%)</td>
<td>5.7 kilograms</td>
</tr>
<tr>
<td>(F) Potassium permanganate</td>
<td>N/A</td>
<td>55 kilograms</td>
</tr>
<tr>
<td>(G) 2-Butanone (MEK)</td>
<td>50 gallons</td>
<td>145 kilograms</td>
</tr>
<tr>
<td>(H) Toluene</td>
<td>50 gallons</td>
<td>159 kilograms</td>
</tr>
</tbody>
</table>

(iii) The cumulative threshold is not applicable to domestic sales of Acetone, 2-Butanone (MEK), and Toluene.

§ 1310.05 Reports.

(a) Each regulated person shall report to the Special Agent in Charge of the DEA Divisional Office for the area in which the regulated person making the report is located, as follows:

(1) Any regulated transaction involving an extraordinary quantity of a listed chemical, an uncommon method of payment or delivery, or any other circumstance that the regulated person believes may indicate that the listed chemical will be used in violation of this part.

(2) Any proposed regulated transaction with a person whose description or other identifying characteristic the Administration has previously furnished to the regulated person.

(3) Any unusual or excessive loss or disappearance of a listed chemical under the control of the regulated person. The regulated person responsible for reporting a loss in transit is the supplier.

(4) Any domestic regulated transaction in a tableting machine or an encapsulating machine.

(b) Each report submitted pursuant to paragraph (a) of this section shall, whenever possible, be made orally to the DEA Divisional Office for the area in which the regulated person making the report is located at the earliest practicable opportunity after the regulated person becomes aware of the circumstances involved and as much in advance of the conclusion of the transaction as possible. Written reports of transactions listed in paragraphs (a)(1), (a)(3) and (a)(4) of this section will subsequently be filed as set forth in § 1310.06 within 15 days after the regulated person becomes aware of the circumstances of the event. A transaction may not be completed with a person whose description or identifying characteristic has previously been furnished to the regulated person by the Administration unless the transaction is approved by the Administration.

§ 1310.06 Content of records and reports.

(a) Each record required by § 1310.03 shall include the following:

(1) The name and address of each party to the regulated transaction.

(2) The date of the regulated transaction.

(3) The name, quantity and form of packaging of the listed chemical or a description of the tableting machine or encapsulating machine.
encapsulating machine (including make, model and serial number).

(a) The method of transfer (company truck, picked up by customer, etc.).

(b) The type of identification used by the purchaser and any unique number on that identification.

(c) Each report required by § 1310.05 shall include the information as specified by § 1310.06(a) and, where obtainable, the telephone number of the other party. A report submitted pursuant to § 1310.05(a)(1) or (a)(3) must also include a description of the circumstances leading the regulated person to make the report, such as the reason that the method of payment was uncommon or the loss unusual. If the report is for a loss or disappearance under § 1310.05(a)(3), the circumstances of such loss must be provided (in transit, theft from premises, etc.).

(d) A suggested format for the reports is provided below:

Supplier:
Name
Business Address
City
State
Zip
Business Phone
Purchaser:
Name
Business Address
City
State
Zip
Business Phone
Identification
Shipping Address [if different than purchaser address]:
Street
City
State
Zip
Date of Shipment:
Name of Listed Chemical(s):
Quantity and Form of Packing
Description of Machine:
Make:
Model:
Serial #
Method of Transfer:
If Loss or Disappearance:
Date of Loss:
Type of Loss
Description of Circumstances

Public reporting burden for this collection of information is estimated to average ten minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Drug Enforcement Administration, Records Management Section, Washington, DC 20537; and to the Office of Management and Budget, Paperwork Reduction Project No. 1117-0024, Washington, DC 20503.

§ 1310.07 Proof of Identity.

(a) Each regulated person who engages in a regulated transaction must identify the other party to the transaction. For domestic transactions, this shall be accomplished by having the other party present documents which would verify the identity of the other party to the regulated person at the time the order is placed. For export transactions, this shall be accomplished by good faith inquiry through reasonably available research documents or publicly available information which would indicate the existence of the foreign customer. No proof of identity is required for foreign suppliers.

(b) The regulated person must verify the existence and apparent validity of a business entity ordering a listed chemical, tabling machine or encapsulating machine. For domestic transactions, this may be accomplished by such methods as checking the telephone directory, the local credit bureau, the local Chamber of Commerce or the local Better Business Bureau. For export transactions, a good faith inquiry to verify the existence and apparent validity of a foreign business entity may be accomplished by such methods as verifying the business telephone listing through international telephone information, the firm’s listing in international or foreign national chemical directories or other commerce directories or trade publications, confirmation through foreign subsidiaries of the U.S. regulated person, verification through the country of destination’s embassy Commercial Attache, or official documents provided by the purchaser which confirm the existence and apparent validity.

(c) When transacting business with a new representative of a firm, the regulated person must verify the claimed agency status of the representative.

(d) For sales to individuals or cash purchasers, the type of documents and other evidence of proof must consist of at least a signature of the purchaser, a driver’s license and one other form of identification. Any exports to individuals or exports paid in cash are suspect and should be handled as such. For such exports, the regulated person shall diligently obtain from the purchaser or independently seek to confirm clear documentation which proves the person is properly identified such as through foreign identity documents, driver’s license, passport information and photograph, etc. Any regulated person who fails to adequately prove the identity of the other party to the transaction may be subject to the specific penalties provided for violations of law related to regulated transactions in listed chemicals.

(e) For a new customer who is not an individual or cash customer, the regulated person shall establish the identity of the authorized purchasing agent or agents and have on file that person’s signature, electronic password, or other identification. Once the authorized purchasing agent has been established, the agent list may be updated annually rather than on each order. The regulated person must ensure that shipments are not made unless the order is placed by an authorized agent of record.

(f) With respect to electronic orders, the identity of the purchaser shall consist of a computer password, identification number or some other means of identification consistent with electronic orders and with § 1310.07(e).

For reasons set out in the preamble, Title 21, Code of Federal Regulations, Part 1313 is added to read as follows.

PART 1313—IMPORTATION AND EXPORTATION OF PRECURSORS AND ESSENTIAL CHEMICALS

Sec.
1313.01 Scope.
1313.02 Definitions.

Importation of Precursors and Essential Chemicals
1313.12 Requirement of authorization to import.
1313.13 Contents of import declaration.
1313.14 Distribution of import declarations.
1313.15 Waiver of 15-day advance notice for chemical importers.

Exportation of Precursors and Essential Chemicals
1313.21 Requirement of authorization to export.
1313.22 Contents of export declaration.
1313.23 Distribution of export declaration.
1313.24 Waiver of 15-day advance notice for chemical exporters.
1313.25 Foreign import restrictions.

Transshipment and In-Transit Shipment of Precursors and Essential Chemicals
1313.31 Advance notice of importation for transshipment or transfer.
1313.41 Suspension of shipments.

Hearings
1313.51 Hearings generally.
1313.52 Purpose of hearing.
1313.53 Waiver of modification of rules.
§ 1313.01 Scope.

Procedures governing the importation, exportation, transshipment and in-transit shipment of precursors and essential chemicals pursuant to section 1018 of the Act (21 U.S.C. 971) are governed generally by this section and specifically by the sections of this part.

§ 1313.02 Definitions.

(a) The term "chemical export" means transferring ownership or control, or the sending or taking of threshold quantities of listed chemicals out of the United States (whether or not such sending or taking out constitutes an exportation within the meaning of the Customs and related laws of the United States).

(b) The term "chemical exporter" is a regulated person who, as the principal party in interest in the export transaction, has the power and responsibility for determining and controlling the sending of the listed chemical out of the United States.

(c) The term "regulated person" means any individual, corporation, partnership, association, or other legal entity who manufactures, distributes, imports, or exports a listed chemical, a tableting machine, or an encapsulating machine.

(d) The term "regulated transaction" means:

(1) A distribution, receipt, sale, importation or exportation of a threshold amount as determined by the Administrator which includes a cumulative threshold amount for multiple transactions of a listed chemical, except that such term does not include:

(i) A domestic lawful distribution in the usual course of business between agents or employees of a single regulated person; in this context, agents or employees means individuals under the direct management and control of the regulated person.

(ii) A delivery of a listed chemical to or by a common or contract carrier for carriage in the lawful and usual course of the business of the common or contract carrier, or to or by a warehouseman for storage in the lawful and usual course of the business of the warehouseman, except that if the carriage or storage is in connection with the distribution, importation, or exportation of a listed chemical to a third person, this paragraph does not relieve a distributor, importer, or exporter from compliance with this part of Part 1310;

(iii) Any category of transaction specified by regulation of the Administration as excluded from this definition as unnecessary for enforcement of the Act;

(iv) Any transaction in a listed chemical that is contained in a drug that may be marketed or distributed lawfully in the United States under the Federal Food, Drug, and Cosmetic Act; or

(v) Any transaction in a chemical mixture.

(2) A distribution, importation, or exportation of a tableting machine or encapsulating machine except that such term does not include a domestic lawful distribution in the usual course of business between agents and employees of a single regulated person; in this context, agents or employees means individuals under the direct management and control of the regulated person.

(e) The term "chemical import" means with respect to a listed chemical, any bringing in or introduction of such listed chemical into either the jurisdiction of the United States or into the Customs territory of the United States (whether or not such bringing in or introduction constitutes an importation within the meaning of the tariff laws of the United States).

(f) The term "chemical importer" is a regulated person who, as the principal party in interest in the import transaction, has the power and responsibility for determining and controlling the bringing in or introduction of the listed chemical into the United States.

(g) The term "regular customer" means a person with whom the regulated person has an established business relationship for a specified listed chemical or chemicals that has been reported to the Administration subject to the criteria established in § 1313.02(i).

(h) The term "regular supplier" means a supplier with whom the regulated person has an established business relationship that has been reported to the Administration subject to the criteria established in § 1313.02(i).

(i) The term "established business relationship with a regular supplier" means the regulated person has purchased a listed chemical from a foreign supplier at least once within the past six months, or twice within the past twelve months. The term also means that the regulated person has provided the Administration with the following information in accordance with the Waiver of 15-day advance notice requirements of § 1313.15:

(1) The name, street address, telephone number, telex number and, where available, the facsimile number of the chemical importer and of each regular supplier; and

(2) The frequency and number of transactions occurring during the preceding 12-month period.

(j) The term "established business relationship with a foreign customer" means the regulated person has exported a listed chemical at least once within the past six months, or twice within the past twelve months to a foreign manufacturer, distributor, or end user of the chemical that has an established business in the foreign country with a fixed street address. A person or business which functions as a broker or intermediary is not a customer within the meaning of this section. The term also means that the regulated person has provided the Administration with the following information in accordance with the Waiver of 15-day advance notice requirements of § 1313.24:

(1) The name and street address of the chemical exporter and of each regular customer;

(2) The telephone number, telex number, contact person, and where available, the facsimile number for the chemical exporter and for each regular customer;

(3) The nature of the regular customer's business (i.e., importer, exporter, distributor, manufacturer, etc.), and if known, the use to which the listed chemical or chemicals will be applied;

(4) The duration of the business relationship;

(5) The frequency and number of transactions occurring during the preceding 12-month period;

(6) The amounts and the listed chemical or chemicals involved in regulated transactions between the chemical exporter and the regular customer;

(7) The method of delivery (direct shipment or through a broker or forwarding agent); and

(8) Other information that the chemical exporter considers relevant for determining whether a customer is a regular customer.

(k) The term "Customs territory of the United States" means the several states, the District of Columbia, and Puerto Rico.

(l) The term "jurisdiction of the United States" means the Customs territory of the United States, the Virgin Islands, the Canal Zone, Guam, American Samoa, and Palau.

(m) Any term not defined in this section shall have the definition set...
forth in sections 102 and 1001 of the Act (21 U.S.C. 802 and 951), and §1301.02 and § 1310.01 of this chapter.

Importation of Precursors and Essential Chemicals

§ 1313.12 Requirement of authorization to import.

(a) Each regulated person who imports a listed chemical that meets or exceeds the threshold quantities identified in § 1310.04(f) of this chapter shall notify the Administrator of the importation not later than 15 days before the transaction is to take place.

(b) A completed DEA Form 486 must be received at the following address not later than 15 days prior to the importation:

Drug Enforcement Administration, P.O. Box 28346, Washington, DC 20038.

A copy of the completed DEA Form 486 may be transmitted directly to the Drug Enforcement Administration, Drug Control Section, through electronic facsimile media not later than 15 days prior to the importation.

(c) The 15-day advance notification requirement for listed chemical imports may be waived for any regulated person who has satisfied the requirements for reporting to the Administration an established business relationship with a foreign supplier. For such imports, the DEA Form 486 must be received by the Drug Enforcement Administration, Drug Control Section on or before the date of importation through use of the mailing address listed in § 1313.12(b) or through use of electronic facsimile media.

§ 1313.13 Contents of import declaration.

(a) Any precursor or essential chemical listed in § 1310.02 of this chapter may be imported if that chemical is necessary for medical, commercial, scientific, or other legitimate uses within the United States. Chemical importations into the United States for immediate transfer/transshipment outside the United States must comply with the procedures set forth in § 1313.31.

(b) Any regulated person who desires to import a threshold or greater quantity of a listed chemical shall notify the Administration through procedures set forth in § 1313.12 and distribute three copies of DEA Form 486 as directed in § 1313.14.

(c) The DEA Form 486 must be executed in triplicate and must include the following information:

(1) The name, address, telephone number, telex number, and, where available, the facsimile number of the broker or forwarding agent (if any); and

(2) The name and description of each listed chemical as it appears on the label or container, the name of each chemical as it is designated in 1310.02 of this chapter, the size or weight of container, the number of containers, the net weight of each listed chemical given in kilograms or parts thereof; and the gross weight of the shipment given in kilograms or parts thereof; and

(3) The proposed import date, the foreign port of exportation and the first U.S. Customs Port of Entry; and

(4) The name, address, telephone number, telex number, and, where available, the facsimile number of the consignor in the foreign country of exportation.

§ 1313.14 Distribution of import declaration.

The required three copies of the precursor and essential chemical import declaration (DEA Form 486) will be distributed as follows:

(a) Copy 1 shall be retained on file by the regulated person as the official record of import. Import declaration forms involving a listed precursor chemical must be retained for four years; declaration forms for listed essential chemicals must be retained for two years.

(b) Copy 2 is the Drug Enforcement Administration copy used to fulfill the notification requirements of Section 6053 of the Chemical Diversion and Trafficking Act of 1998, as specified in § 1313.12.

(c) Copy 3 shall be presented to the U.S. Customs Service along with the customs entry. If the import is a regulated transaction for which the 15-day advance notice requirement has been waived, the regulated person shall declare this information to the U.S. Customs Service Official by checking the block on the DEA Form 486 designated for this purpose.

§ 1313.15 Waiver of 15-day advance notice for chemical importers.

(a) Each regulated person shall provide to the Administration the identity of any regular supplier of the regulated person not later than August 31, 1989, along with the information required by § 1313.02(i) for documenting an established business relationship with a regular supplier.

(b) Not later than October 30, 1989, each regular supplier so identified in notifications made under paragraph (a) of this section shall be a regular supplier for purposes of waiving the 15-day advance notice requirement, unless the regulated person is otherwise notified in writing by the Administration.

(c) A supplier identified on an initial DEA Form 486 submitted after October 30, 1989, shall, after the expiration of the 15-day period, qualify as a regular supplier; unless the Administration otherwise notifies the regulated person in writing.

(d) All chemical importers shall be required to file a DEA Precursor and Essential Chemical Import/Export Declaration (DEA Form 486) as required by § 1313.12.

Exportation of Precursors and Essential Chemicals

§ 1313.21 Requirement of authorization to export.

(a) No person shall export of cause to be exported from the United States any chemical listed in § 1310.02 of this chapter, which meets or exceeds the threshold quantities identified in § 1310.04(f) of this chapter until such time as the Administrator has been notified. Notification must be made not later than 15 days before the transaction is to take place. In order to facilitate the export of listed chemicals and implement the purpose of the Act, regulated persons may wish to provide notification to the Administration as far in advance of the 15 days as possible.

(b) A completed DEA Form 486 must be received at the following address not later than 15 days prior to the exportation:

Drug Enforcement Administration, P.O. Box 28346, Washington, DC 20038.

A copy of the completed DEA Form 486 may be transmitted directly to the Drug Enforcement Administration, Drug Control Section, through electronic facsimile media not later than 15 days prior to the exportation.

(c) The 15-day advance notification requirement for listed chemical exports may be waived for any regulated person who has satisfied the requirements of § 1313.24 for reporting to the Administration an established business relationship with a foreign customer as defined in § 1313.02(j). A DEA Form 486 export declaration to a foreign customer must be received by the Drug Enforcement Administration, Drug Control Section, on or before the date of exportation through use of the mailing address listed in § 1313.21(b) or transmitted directly through use of electronic facsimile media.

(d) No person shall knowingly or intentionally export or cause to be exported a listed chemical in violation of the law of the country to which the chemical is exported. Likewise, no
person shall export or cause to be exported any listed chemical when that person has reasonable cause to believe the regulated transaction is in violation of the law of the country to which the chemical is exported. The Administration will publish a notice of foreign import restrictions for listed chemicals of which DEA has knowledge as provided in §1313.23.

§1313.22 Contents of export declaration.
(a) Any precursor or essential chemical listed in §1310.02 of this chapter which meets or exceeds the quantitative threshold criteria established in §1310.04(f) of this chapter may be exported if that chemical is needed for medical, commercial, scientific, or other legitimate uses.
(b) Any regulated person who desires to export a threshold or greater quantity of a listed chemical shall notify the Administration through procedures outlined in §1313.21 and distribute three copies of DEA Form 486 as directed in §1313.23.
(c) The DEA Form 486 must be executed in triplicate and must include all the following information:
(1) The name, address, telephone number, telex number, and, where available, the facsimile number of the chemical exporter; the name, address, telephone number, telex number, and, where available, the facsimile number of the export broker, if any;
(2) The name and description of each listed chemical as it appears on the label or container, the name of each listed chemical as it is designated in §1310.02 of this chapter, the size or weight of container, the number of containers, the net weight of each listed chemical given in kilograms or parts thereof, and the gross weight of the shipment given in kilograms or parts thereof;
(3) The proposed export date, the U.S. Customs port of exportation, and the foreign port of entry; and
(4) The name, address, telephone, telex, and where available, the facsimile number of the consignee in the country where the chemical shipment is destined; the name(s) and address(es) of any intermediate consignee(s).
(d) Notwithstanding the time limitations included in paragraph (b) of this section, a regulated person may receive a waiver of the 15-day advance notification requirement following the procedures outlined in §1313.24.
(e) Declared exports of listed chemicals which are refused, rejected, or otherwise deemed undeliverable may be returned to the U.S. chemical exporter of record. A brief written notification (this does not require a DEA Form 486) outlining the circumstances must be sent to the Drug Enforcement Administration, P.O. Box 28346, Washington, DC 20036, following the return within a reasonable time. This provision does not apply to shipments that have cleared foreign customs, been delivered, and accepted by the foreign consignee. Returns to third parties in the United States will be regarded as imports.

§1313.23 Distribution of export declaration.
The required three copies of the precursor and essential chemical export declaration (DEA Form 486) will be distributed as follows:
(a) Copy 1 shall be retained on file by the chemical exporters as the official record of export. Export declaration forms involving a listed precursor chemical must be retained for four years; declaration forms for listed essential chemicals must be retained for two years.
(b) Copy 2 is the Drug Enforcement Administration copy used to fulfill the notification requirements of Section 8053 of the Chemical Diversion and Trafficking Act of 1988, as specified in §1313.21.
(c) Copy 3 shall be presented to the U.S. Customs Service at the port of exit along with the Shippers Export Declaration for each export of a listed chemical or chemicals.

§1313.24 Waiver of 15-day advance notice for chemical exporters.
(a) Each regulated person shall provide to the Administration the identity and information listed in §1313.02(f) for an established business relationship with a foreign customer not later than August 31, 1989.
(b) Not later than October 31, 1989, each regular customer so identified in notifications made under §1313.24(a) shall be a regular customer for purposes of waiving the 15-day advance notice requirement, unless the regulated person is otherwise notified in writing by the Administration.
(c) Each foreign customer identified on an initial DEA Form 486 submitted after the effective date of the implementation of Part 1313 shall, after the expiration of the 15-day period, qualify as a regular customer, unless the Administration otherwise notifies the regulated person in writing.
(d) The Administrator may notify any chemical exporter that a regular customer has been disqualified or that a new customer for whom a notification has been submitted is not to be accorded the status of a regular customer. In the event of a disqualification of an established regular customer, the chemical exporter will be notified in writing of the reasons for such action.

Public reporting (one-time) burden for this collection of information is estimated to average four hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to the Drug Enforcement Administration, Records Management Section, Washington, DC 20537; and to the Office of Management and Budget, Paperwork Reduction Project No. 1117-0025, Washington, DC 20503.

§1313.25 Foreign import restrictions.
Any export from the United States in violation of the law of the country to which the chemical is exported is subject to the penalties of Title 21 United States Code 960(d).

§1313.31 Advance notice of importation for transshipment or transfer.
(a) A quantity of a chemical listed in §1310.02 of this chapter that meets or exceeds the threshold reporting requirements found in §1310.04(f) of this chapter may be imported into the United States for transshipment, or may be transferred or transshipped within the United States for immediate exportation, provided that advance notice is given to the Administration.
(b) Advance notification must be provided to the Drug Enforcement Administration, P.O. Box 28346, Washington, DC 20036, not later than 15 days prior to the proposed date the listed chemical will transship or transfer through the United States. The written notification (not a DEA Form 486) shall contain the following information:
(1) The date the notice was executed;
(2) The complete name and description of the listed chemical as it appears on the label or container.
(3) The name of the listed chemical as designated by §1310.02 of this chapter.
(4) The number of containers and the size or weight of the container for each listed item:
(5) The new weight of each listed chemical given in kilograms or parts thereof;
(6) The gross weight of the shipment given in kilograms or parts thereof;
(7) The name, address, telephone number, telex number, business of the

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foreign exporter and, where available, the facsimile number;

(8) The foreign port of exportation;
(9) The approximate date of exportation;
(10) The complete identification of the exporting carrier;
(11) The name, address, business, telephone number, telex number, and, where available, the facsimile number of the importer, transferor, or transshipper;
(12) The U.S. port of entry;
(13) The approximate date of entry;
(14) The name, address, telephone number, telex number, business of the consignee and, where available, facsimile number of the consignee at the foreign port of entry;
(15) The shipping route from the U.S. port of exportation to the foreign port of entry at final destination;
(16) The approximate date of receipt by the consignee at the foreign port of entry; and
(17) The signature of the importer, transferor or transshipper, or his agent, accompanied by the agent’s title.

(c) Unless notified to the contrary prior to the expected date of delivery, the importation for transshipment or transfer is considered approved.

(d) No waiver of the 15-day advance notice will be given for imports of listed chemicals in quantities meeting or exceeding threshold quantities for transshipment or transfer outside the United States.

§ 1313.41 Suspension of shipments.
(a) The Administrator may suspend any importation or exportation of a chemical listed in § 1310.02 of this chapter based on evidence that the chemical proposed to be imported or exported may be diverted to the clandestine manufacture of a controlled substance. If the Administrator so suspends, he shall provide written notice of such suspension to the regulated person. Such notice shall contain a statement of the legal and factual basis for the order.

(b) Upon service of the order of suspension, the regulated person to whom the order applies under paragraph (a) of this section must, if he desires a hearing, file a written request for a hearing pursuant to §§ 1313.51–1313.57.

Hearings

§ 1313.51 Hearings generally.

In any case where a regulated person requests a hearing regarding the suspension of a shipment of a listed chemical, the procedures for such hearing shall be governed generally by the procedures set forth in the Administrative Procedure Act (5 U.S.C. 551–559) and specifically by section 6053 of the Chemical Diversion and Trafficking Act (Pub. L. 100–680), by 21 CFR 1313.52–1313.57, and by the procedures for administrative hearings under the Controlled Substances Act set forth in §§ 1316.41–1316.87 of this chapter.

§ 1313.52 Purpose of hearing.

If requested by a person entitled to a hearing, the Administrator shall cause a hearing to be held for the purpose of receiving factual evidence regarding the issues involved in the suspension of shipments within 45 days of the date of the request, unless the requesting party requests an extension of time.

§ 1313.53 Waiver of modification of rules.

The Administrator or the presiding officer (with respect to matters pending before him) may modify or waive any rule in this part by notice in advance of the hearing, if he determines that no party in the hearing will be unduly prejudiced and the ends of justice will thereby be served. Such notice of modification or waiver shall be made a part of the record of the hearing.

§ 1313.54 Request for hearing.

(a) Any person entitled to a hearing pursuant to § 1313.52 and desiring a hearing shall, within 30 days after receipt of the notice to suspend the shipment, file with the Administrator a written request for a hearing in the form prescribed in § 1316.47 of this chapter.

(b) If any person entitled to a hearing or to participate in a hearing pursuant to § 1313.41 fails to file a request for a hearing or a notice of appearance, or if he so files and fails to appear at the hearing, he shall be deemed to have waived his opportunity for the hearing or to participate in the hearing, unless he shows good cause for such failure.

(c) If all persons entitled to a hearing or to participate in a hearing waive or are deemed to waive their opportunity for the hearing or to participate in the hearing, the Administrator may cancel the hearing, if scheduled, and issue his final order pursuant to § 1313.57.

§ 1313.55 Burden of proof.

At any hearing regarding the suspension of shipments, the Agency shall have the burden of proving that the requirements of this part for such suspension are satisfied.

§ 1313.56 Time and place of hearing.

(a) If any regulated person requests a hearing on the suspension of shipments, a hearing will be scheduled no later than 45 days after the request is made, unless the regulated person requests an extension to this date.

(b) The hearing will commence at the place and time designated in the notice given pursuant to paragraph (a) of this section, but thereafter it may be moved to a different place and may be continued from day to day or recessed to a later day without notice other than announcement thereof by the presiding officer at the hearing.

§ 1313.57 Final order.

As soon as practicable after the presiding officer has certified the record to the Administrator, the Administrator shall issue his order regarding the suspension of shipment. The order shall include the findings of fact and conclusions of law upon which the order is based. The Administrator shall serve one copy of his order upon each party in the hearing.

John C. Lown, Administrator, Drug Enforcement Administration.

Date: July 7, 1989.

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21 CFR Part 1316

Exemption From Civil Prosecution for Investigative and Law Enforcement Personnel of the Drug Enforcement Administration

AGENCY: Drug Enforcement Administration (DEA).

ACTION: Final rule.

SUMMARY: This final rule is issued by the Administrator of the Drug Enforcement Administration (DEA) to implement a provision of the Chemical Diversion and Trafficking Act of 1988 which exempts certain employees of the DEA from civil prosecution in the event that they make an unauthorized disclosure of information referred to in paragraph (c)(1) of Section 310 of the Controlled Substances Act (21 U.S.C. 830).

EFFECTIVE DATE: August 1, 1989.

FOR FURTHER INFORMATION CONTACT: G. Thomas Gitchel, Chief, State and Industry Section, Office of Diversion Control, Drug Enforcement Administration, United States Department of Justice, Washington, DC 20537, Telephone: (202) 307–7297.

SUPPLEMENTARY INFORMATION: On January 25, 1988, in a notice of proposed rulemaking published in the Federal Register (54 FR 3622) the Administrator of the DEA proposed to clarify a provision of the Chemical Diversion and Trafficking Act which specifies that.
although any person who is aggrieved by a disclosure of information in violation of Section 310 of the Controlled Substances Act may bring a civil action against the violator for appropriate relief, a civil action may not be brought against investigative or law enforcement personnel of the DEA who make such a disclosure. The proposed rule provided the opportunity for interested parties to submit comments and objections to the proposed rulemaking. Three chemical suppliers, the Chemical Manufacturers Association (CMA) and the National Association of Chemical Distributors (NACD), expressed concern that the DEA exceeded its Congressional authority by making the definition of "investigative personnel" contained in 21 CFR 1316.21 overly broad. They felt that the proposed definition of "investigative personnel" could be construed as including any employee of DEA. The Administrator of the DEA is convinced that the definition of "investigative personnel" is consistent with the intent of Congress as it pertains only to those managers, Diversion Investigators, attorneys, analysts, and support personnel employed by DEA who are involved in the processing, reviewing and analyzing of declarations and other relevant documents or data relative to regulated transactions or who are involved in conducting investigations initiated pursuant to the receipt of such declarations, documents or data. Clearly, this excludes the majority of DEA personnel. Two chemical suppliers, the CMA and the NACD, felt that the definition of "law enforcement personnel" contained in 21 CFR 1318.21 is too broad. In response to these comments, additional language has been added to this definition to restrict the exemption from civil prosecution for unauthorized disclosure of information to those Special Agents of the DEA who, in the course of their official duties, gain knowledge of such confidential information. Due to a conflict in numbering, the new sections of 21 CFR set forth in this final rule which were previously numbered 1316.91 and 1316.92 in the proposed rule of January 25, 1989 have been renumbered 1316.23 and 1316.24.

The Administrator of the DEA hereby certifies that this matter will have no significant impact upon entities whose interests must be considered under the Regulatory Flexibility Act (5 U.S.C. 601).

This rule is not a major rule for purposes of O.C. 12291 of February 17, 1981. Pursuant to sections 3(c)(3) and 3(e)(2)(c) of O.C. 12291, this final rule has been reviewed by the Office of Management and Budget.

This action has been analyzed with the principles and criteria contained in E.O. 12016, and it has been determined that the final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

List of Subjects in 21 CFR Part 1316

Administrative practice and procedure, Drug enforcement administration, Drug traffic control, Research, Seizures and forfeiture.

For reasons set out above, Title 21, Code of Federal Regulations, Part 1316, is amended as follows:

PART 1316—ADMINISTRATIVE FUNCTIONS, PRACTICES AND PROCEDURES

Subpart B—Protection of Researchers, Research Subjects, Investigative Personnel and Law Enforcement Personnel

1. The authority citation for Subpart B is revised to read as follows:


2. Part 1316 is amended redesignating existing section 1318.21 as 1318.23, redesignating existing section 1318.22 as 1318.24 and by adding Sections 1318.21 and 1318.22 to read as follows:

§ 1316.21 Definitions.

As used in this part, the following terms shall have the meanings specified: (a) The term "investigative personnel" includes managers, Diversion Investigators, attorneys, analysts and support personnel employed by the Drug Enforcement Administration who are involved in the processing, reviewing and analyzing of declarations and other relevant documents or data relative to regulated transactions or are involved in conducting investigations initiated pursuant to the receipt of such declarations, documents or data.

(b) The term "law enforcement personnel" means Special Agents employed by the Drug Enforcement Administration who, in the course of their official duties, gain knowledge of information which is confidential under such section.

§ 1316.22 Exemption.

(a) Any person who is aggrieved by a disclosure of information in violation of subsection (c)(1) of Section 310 of the Controlled Substances Act (21 U.S.C. 830) may bring a civil action against the violator for appropriate relief.

(b) Notwithstanding the provision of paragraph (a), a civil action may not be brought under such paragraph against investigative or law enforcement personnel of the Drug Enforcement Administration.

Date: July 7, 1989.

John C. Lawn, Administrator, Drug Enforcement Administration.

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