

an insured depository institution) that is a savings and loan holding company. A company has control over a saving association if it: directly or indirectly, or acting through one or more other persons owns, controls, or has the power to vote 25 percent or more of any class of voting securities; or would be deemed to control the company under § 574.4(a) of this chapter or presumed to control the company under § 574.4(b) of this chapter, and in the latter case, control has not been rebutted. Notwithstanding any other provision of this section, no company shall be deemed to own or control another by virtue of its ownership or control of shares in a fiduciary capacity. When used to refer to a subsidiary of a savings association, the term *subsidiary* means a "subsidiary" that is controlled by the savings association within the meaning of 12 CFR part 574 of this chapter.

(e) References to the Reserve Bank or the Comptroller shall be deemed to include the Director of OTS; and

\* \* \* \* \*

Dated: September 29, 2003.

By the Office of Thrift Supervision.

**James E. Gilleran,**  
Director.

[FR Doc. 03-25217 Filed 10-6-03; 8:45 am]

BILLING CODE 6720-01-P

## CONSUMER PRODUCT SAFETY COMMISSION

### 16 CFR Part 1000

#### Statement of Organization and Functions

**AGENCY:** Consumer Product Safety Commission.

**ACTION:** Final rule.

**SUMMARY:** The Consumer Product Safety Commission is amending its statement of organization and functions to reflect the transfer of the National Injury Information Clearinghouse from the Directorate for Epidemiology to the Office of the Secretary.

**EFFECTIVE DATE:** October 7, 2003.

**FOR FURTHER INFORMATION CONTACT:** Stephen Lemberg, Office of the General Counsel, Consumer Product Safety Commission, Washington, DC 20207, telephone (301) 504-7630, email [slemberg@cpsc.gov](mailto:slemberg@cpsc.gov).

**SUPPLEMENTARY INFORMATION:** The reference to the Clearinghouse in section 1000.27, Directorate for Epidemiology, is being moved to section 1000.16, Office of the Secretary.

Since this rule relates solely to internal agency management, pursuant

to 5 U.S.C. 553(b) notice and other public procedures are not required and it is effective immediately upon publication in the **Federal Register**. Further, this action is not a rule as defined in the Regulatory Flexibility Act, 5 U.S.C. 601-612, and, thus, is exempt from the provisions of the Act.

#### List of Subjects in 16 CFR Part 1000

Organization and functions (government agencies).

■ Accordingly, part 1000 is amended as follows:

#### PART 1000—[AMENDED]

■ 1. The authority citation for part 1000 continues to read as follows:

Authority: 5 U.S.C. 552(a).

#### § 1000.27 [Amended]

■ 2. In § 1000.27, remove the last sentence.

#### § 1000.16 [Amended]

■ 3. In § 1000.16, add at the end the sentence "It administers the National Injury Information Clearinghouse."

Dated: September 30, 2003.

**Todd A. Stevenson,**  
Secretary, Consumer Product Safety Commission.

[FR Doc. 03-25297 Filed 10-6-03; 8:45 am]

BILLING CODE 6335-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 172

[Docket No. 1987F-0179]

#### Food Additives Permitted for Direct Addition to Food for Human Consumption; Olestra; Correction

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule; correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a final rule that appeared in the **Federal Register** of August 5, 2003 (68 FR 46403). The document denied the requests for a hearing and response to objections it has received on the final rule that amended the food additive regulations to provide for the safe use of sucrose esterified with medium and long chain fatty acids (olestra) as a replacement for fats and oils in savory snacks. The document was published with inadvertent errors. This document corrects those errors.

#### FOR FURTHER INFORMATION CONTACT:

Mary Ditto, Center for Food Safety and Applied Nutrition (HFS-255), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 202-418-3102.

**SUPPLEMENTARY INFORMATION:** In FR Doc. 03-19509, appearing on page 46403 in the **Federal Register** of Tuesday, August 5, 2003, the following corrections are made:

1. On page 46408, in the second column, under the heading "*D. Adequacy of Olestra's Label Statement*" the first sentence is corrected to read "In its fifth objection and request for a hearing, CSPI challenges the label statement required by the 1996 final rule, claiming that it is not sufficient to protect the public from adverse effects associated with consumption of olestra."

2. On page 46408, in the third column, under the heading "*E. Alleged Procedural Problems in the Olestra Proceeding*" the first sentence is corrected to read "In its sixth objection and hearing request, CSPI claims that there were a number of problems with the procedures utilized by FDA to reach a decision about the safety of olestra."

3. On page 46408, in the third column, under heading "*E. Alleged Procedural Problems in the Olestra Proceeding*" the second to the last sentence on that page is corrected to read "As in the case with its fifth objection and hearing request, CSPI specifically identifies no factual issue underlying any of its six procedural complaints."

Dated: September 30, 2003.

**Jeffrey Shuren,**  
Assistant Commissioner for Policy.  
[FR Doc. 03-25198 Filed 10-6-03; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

#### 21 CFR Parts 1300, 1309, and 1310

[Docket No. DEA-210F]

RIN 1117-AA69

#### Implementation of the Methamphetamine Anti-Proliferation Act; Thresholds for Retailers and for Distributors Required To Submit Mail Order Reports; Changes to Mail Order Reporting Requirements

**AGENCY:** Drug Enforcement Administration (DEA), Justice.

**ACTION:** Final rule.

**SUMMARY:** This regulation implements the new threshold requirements and mail order reporting requirements of the Methamphetamine Anti-Proliferation Act of 2000 (MAPA), which was enacted on October 17, 2000. DEA is amending its regulations to reduce the thresholds for pseudoephedrine and phenylpropanolamine for retail distributors and for distributors required to submit mail order reports. Also, DEA is amending its regulations to require mail order reports for certain export transactions. DEA is codifying exemptions from the mail order reporting requirements for certain distributions to nonregulated persons and certain export transactions. This rule is consistent with the intent of MAPA to prevent the diversion of drug products to the clandestine manufacture of methamphetamine and amphetamine, and simultaneously reduce the industry reporting burden.

**EFFECTIVE DATE:** November 6, 2003.

**FOR FURTHER INFORMATION CONTACT:**

Patricia M. Good, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Telephone (202) 307-7297.

**SUPPLEMENTARY INFORMATION:**

**What Is DEA's Legal Authority for This Rule?**

DEA implements the Controlled Substances Act (21 U.S.C. 801-971), as amended by the Chemical Diversion and Trafficking Act, the Domestic Chemical Diversion Control Act, the Comprehensive Methamphetamine Control Act, and the recent Methamphetamine Anti-Proliferation Act (Pub. L. 106-310, 114 Stat. 1101), among others. DEA publishes the implementing regulations for these statutes in title 21 of the Code of Federal Regulations (21 CFR) parts 1300 to end. The regulations are designed to prevent the diversion of controlled substances and listed chemicals to illegal purposes.

MAPA, which is part of the Children's Health Act of 2000, amends the Controlled Substances Act (CSA) to reduce the retail and mail order thresholds for pseudoephedrine and phenylpropanolamine (PPA), to include certain export transactions under the mail order reporting requirement, and to provide certain exemptions from the mail order reporting requirement. This rule implements the Congressional mandate of MAPA.

**Why Is DEA Publishing a Final Rule?**

An agency may find good cause to exempt a rule from the provisions of the Administrative Procedure Act (5 U.S.C.

553), including notice of proposed rulemaking and the opportunity for public comment, if it is determined to be unnecessary, impracticable, or contrary to the public interest. Most of the requirements of MAPA were set out in such detail as to be self-implementing. Therefore the changes in this rulemaking primarily provide conforming amendments to make the language of the regulations consistent with that of the law. Hence, DEA finds it unnecessary to publish for public notice and comment.

Specifically, Title XXXVI, Methamphetamine Anti-Proliferation Act, Section 3652 of the Children's Health Act, "Mail Order Requirements," amends 21 U.S.C. 830(b)(3)(D) to exempt certain distributions and export transactions of ephedrine, pseudoephedrine, and phenylpropanolamine and drug products containing them from the monthly mail order reporting requirement as follows [emphasis added]:

(D) Except as provided in subparagraph (E), the following distributions to a nonregulated person, and the following export transactions, **shall not** be subject to the reporting requirement in subparagraph (B):

(i) Distributions of sample packages of drug products when such packages contain not more than 2 solid dosage units or the equivalent of 2 dosage units in liquid form, not to exceed 10 milliliters of liquid per package, and not more than one package is distributed to an individual or residential address in any 30-day period.

(ii) Distributions of drug products by retail distributors that may not include face-to-face transactions to the extent that such distributions are consistent with the activities authorized for a retail distributor as specified in section 102(46). [21 U.S.C. 802(46)]

(iii) Distributions of drug products to a resident of a long term care facility (as the term is defined in regulations prescribed by the Attorney General) or distributions of drug products to a long term care facility for dispensing to or for use by a resident of that facility.

(iv) Distributions of drug products pursuant to a valid prescription.

(v) Exports which have been reported to the Attorney General pursuant to section 1004 [21 U.S.C. 954] or 1018 [21 U.S.C. 971] which are subject to a waiver granted under section 1018(e)(2) [21 U.S.C. 971(e)(2)].

(vi) Any quantity, method, or type of distribution or any quantity, method, or type of distribution of a specific listed chemical (including specific formulations or drug products) or of a group of listed chemicals (including specific formulations or drug products) which the Attorney General has excluded by regulation from such reporting requirement on the basis that such reporting is not necessary for the enforcement of this title \* \* \*

**Editor's Note:** This excerpt of the amendment is published for the convenience of the reader. The official text is published at 21 U.S.C. 830(b)(3)(D).

MAPA also specifically reduces the threshold for drug products containing pseudoephedrine and phenylpropanolamine from 24 grams to 9 grams of pseudoephedrine or phenylpropanolamine as base. MAPA further establishes a new factor in determining a regulated transaction—a package size of 3 grams of pseudoephedrine base or phenylpropanolamine base. The language in Title XXXVI, Section 3622 of the Children's Health Act of 2000, "Reduction in Retail Sales Transaction Threshold for Non-Safe Harbor Products Containing Pseudoephedrine or Phenylpropanolamine," clearly establishes without opportunity for discussion the new requirements. It amends 21 U.S.C. 802(39)(a)(iv)(II) to read as follows [emphasis added]:

(II) the quantity of ephedrine, pseudoephedrine, phenylpropanolamine, or other listed chemical contained in the drug included in the transaction or multiple transactions equals or exceeds the threshold established for that chemical by the Attorney General, except that the threshold for any sale of products containing pseudoephedrine or phenylpropanolamine by retail distributors or by distributors required to submit reports by section 310(b)(3) of this title [21 U.S.C. 830(b)(3)] **shall be** 9 grams of pseudoephedrine or 9 grams of phenylpropanolamine in a single transaction and sold in package sizes of not more than 3 grams of pseudoephedrine base or 3 grams of phenylpropanolamine base; \* \* \*

**Editor's Note:** This excerpt of the amendment is published for the convenience of the reader. The official text is published at 21 U.S.C. 802(39)(a)(iv)(II).

Under the circumstances, there is no discretion for deviation from the changes made by MAPA. Therefore, DEA is implementing these conforming amendments to the regulations through a final rule.

**Do the Thresholds Apply to All Retail Distributors and All Distributors Required To Submit Mail Order Reports?**

MAPA mandated that effective October 17, 2001, both the reduction of the 24 gram transaction threshold to 9 grams and the addition of the 3 gram package size threshold for pseudoephedrine and phenylpropanolamine drug products apply to all retail distributors and all persons required to submit mail order reports under 21 U.S.C. 830(b)(3).

At the retail level, all drug products containing pseudoephedrine or phenylpropanolamine that do not meet

the definition of “ordinary over-the-counter pseudoephedrine or phenylpropanolamine product” (see 21 U.S.C. 802(45)) are subject to the threshold requirements of MAPA. This includes the single transaction threshold of 9 grams as base and the single package size of 3 grams or less of pseudoephedrine or 3 grams or less of phenylpropanolamine as base. The requirement of registration is waived for retail distributors whose activities consist solely of below-threshold distributions to an individual for a legitimate medical purpose (21 CFR 1309.24(e)). Retail distributors who engage in single transactions at or above 9 grams of pseudoephedrine or phenylpropanolamine as base or single transactions of package sizes containing more than 3 grams of pseudoephedrine base or 3 grams of phenylpropanolamine base per package will void their waiver of the registration requirement and must register with DEA. Transactions above these thresholds are regulated transactions and subject to all requirements of the Controlled Substances Act. For retail transactions, this would include customer identification, recordkeeping, and reporting.

For those required to submit mail order reports, the 9 gram transaction threshold (as base) for a single transaction and the 3 gram package size (as base) apply to every transaction involving pseudoephedrine, phenylpropanolamine or drug products containing them—regardless of the type of packaging for the products. There are no exemptions for ordinary over-the-counter pseudoephedrine and phenylpropanolamine products. All of the requirements of the CSA apply to

threshold and above transactions and to above-threshold package sizes, that is, registration, identification, recordkeeping, and reporting, as well as the monthly mail order reports submitted to DEA.

#### What Are the Changes to the Mail Order Reporting Requirement?

MAPA provides the following exemptions to the mail order reporting requirement: Transactions involving sample packages of drug products, deliveries of prescriptions to consumers by retail distributors, distributions to long-term care facilities and their residents, mail order prescription deliveries, and exports already reported to DEA on a Form 486 or granted a waiver by the Administrator. These were specifically cited in the section of this rulemaking titled, “Why is DEA publishing a final rule?”

Congress also granted the Attorney General the authority (delegated to the Administrator of DEA) to develop regulations to expand the Congressional list of exemptions.

#### What Action Is DEA Taking To Codify the MAPA Amendments in Its Regulations?

To implement the requirements of MAPA, DEA is adding the new definitions of “drug product” and “valid prescription” at 21 CFR 1300.02, and updating §§ 1310.03 and 1310.05 to reflect the revised reporting requirements for mail order distributions. Specifically, DEA is amending § 1310.05 to explicitly exempt from the reporting requirements the low-risk categories of mail order transactions previously listed.

DEA also reserves the right to exempt, by regulation, from the reporting

requirements any other quantity, method, or type of distribution of a specific listed chemical (or drug product containing it) or group of listed chemicals (or drug products containing them) determined by the Administrator to be unnecessary for the effective enforcement of the Controlled Substances Act.

#### What Is the Effect of MAPA on the Public and on Industry?

MAPA will not adversely impact the public's access to pseudoephedrine and phenylpropanolamine products. The majority of the products purchased by the public are commonly used medications most of which are available without a prescription at pharmacies, grocery stores, discount department stores, and a variety of other retail stores. Although the thresholds are being reduced, these thresholds still permit the public adequate access to these drug products for legitimate medical purposes, which include their use as decongestants for the temporary relief of nasal congestion. Each of the products is available as a single entity or in combination with antihistamines, antitussives, analgesics, and expectorants. Sale of a single package of drug product containing 3 grams or less per package of pseudoephedrine or phenylpropanolamine base is not a regulated transaction. A single transaction of less than 9 grams of pseudoephedrine or phenylpropanolamine as base is not a regulated transaction. The chart below indicates the number of tablets per package and per single transaction that constitute a regulated transaction. One tablet less would be a non-regulated transaction.

NUMBER OF TABLETS THAT CONSTITUTE A REGULATED TRANSACTION FOR DOSAGE UNITS OF MARKETING PRODUCTS \*

Product type	Number of tablets over 3-gram package size	Number of tablets per 9-gram transaction
<b>Pseudoephedrine</b>		
120-mg Hydrochloride .....	31	92
120-mg Sulfate .....	33	98
60-mg Hydrochloride .....	62	184
60-mg Sulfate .....	65	195
30-mg Hydrochloride .....	123	367
30-mg Sulfate .....	130	390
<b>Phenylpropanolamine</b>		
75-mg Hydrochloride .....	50	149
25-mg Hydrochloride .....	149	447
12.5-mg Hydrochloride .....	298	894
6.25-mg Hydrochloride .....	596	1,788

\* Calculated as base.

For example, if a member of the public purchased product containing 30-mg pseudoephedrine hydrochloride tablets in a single transaction of 366 tablets, it would not be regulated. However, if that person purchased 367 or more tablets of the same product in a single transaction, it would be a regulated transaction. The member of the public would still be permitted to make such a purchase, but would be required to provide the distributor with certain information. DEA believes that few members of the public make such large purchases for legitimate personal medical use, and thus will not be adversely impacted by this rulemaking.

Due to concerns regarding possible harmful side effects, the Food and Drug Administration initiated action in November 2000 to remove phenylpropanolamine from the market. As a result, many firms voluntarily discontinued marketing products containing it. Because MAPA specifically addresses phenylpropanolamine and there remain legitimate veterinary uses for it that will ensure some level of its continued production and availability, this action continues to apply to phenylpropanolamine.

MAPA will affect persons who sell drug products containing pseudoephedrine or phenylpropanolamine to the public. This includes retail distributors and persons required to submit mail order reports. For retail distributors, single transactions containing 9 grams or more of pseudoephedrine or phenylpropanolamine as base are regulated transactions. Single transactions in which a package contains more than 3 grams of pseudoephedrine base or more than 3 grams of phenylpropanolamine base are also regulated transactions. Above-threshold transactions will still be permitted, but will be subject to all the requirements of a regulated transaction, including registration of the distributor—as selling over-threshold amounts of these products voids the retail distributor exemption (21 CFR 1309.24(e)), identification of customers (21 CFR 1310.07), maintenance of records (21 CFR 1310.04), and the filing of reports with the Administration (21 CFR 1310.05, 1310.06). It is important to note, however, that many retail distributors have already voluntarily limited their sales in a single transaction to amounts equal to or less than those finalized in this rulemaking to help prevent diversion of these products for the illicit manufacture of methamphetamine and amphetamine.

For those required to submit mail order reports, both the 9 gram transaction threshold and the 3 gram package size for pseudoephedrine and phenylpropanolamine drug products apply to every transaction—regardless of whether the transaction is one that must be reported. Single transactions of 9 grams or more of pseudoephedrine or phenylpropanolamine as base are regulated transactions and single transactions of package sizes containing more than 3 grams of pseudoephedrine or phenylpropanolamine as base are regulated transactions. Regulated transactions subject the distributor to the following requirements—identification of the customer (21 CFR 1310.07), recordkeeping (21 CFR 1310.04), and reporting (21 CFR 1310.05 and 1310.06), in addition to the requirement to submit monthly reports of all transactions (21 U.S.C. 830(b)(3)).

MAPA added language requiring monthly mail order reports for export transactions with nonregulated persons involving ephedrine, pseudoephedrine, phenylpropanolamine, and drug products containing them which use or attempt to use the Postal Service, or any private or commercial carrier. Every export transaction for these chemicals and for drug products containing them must be reported on a monthly basis unless the export transaction is exempt. Exempt export transactions include those reported on a DEA Form 486 and those for which the Administrator has waived monthly reporting.

To reduce the burden on those who are subject to the monthly mail order reporting requirement under 21 U.S.C. 830(b)(3), MAPA added exemptions to this requirement. These exemptions include distributions of samples of drug products, deliveries of prescriptions to consumers by retail distributors, distributions of drug products to long term care facilities and their residents, mail order prescription deliveries, exports reported to DEA on a Form 486, and any quantity, method, or type of distribution of a specific listed chemical or group of listed chemicals which the Attorney General has excluded by regulation from this reporting requirement. These exemptions were previously cited in the section of this rulemaking titled, “Why is DEA publishing a final rule?” The Administrator of DEA, through the delegation of authority from the Attorney General, may exclude by regulation from the mail order reporting requirement any quantity, method, or type of distribution of listed chemicals (including specific formulations or drug products) for which such reporting is considered not necessary for the

enforcement of law. DEA will consider any suggestions submitted regarding additional exemptions to the reporting requirement under 21 U.S.C. 830(b)(3) that may be warranted.

#### Technical Amendment

The final regulations implementing the provisions of the Comprehensive Methamphetamine Control Act (MCA) amended the waiver of the retail registration activity found in 21 CFR 1309.24(e) to include a statement that the threshold for retail distributions of ephedrine, pseudoephedrine and phenylpropanolamine is 24 grams in a single transaction, regardless of whether the product meets the definition of “ordinary over-the-counter pseudoephedrine or phenylpropanolamine product.” As MAPA amends those thresholds, as previously described, a conforming technical amendment to 21 CFR 1309.24(e) is being made to remove the reference to the 24 gram threshold.

#### Regulatory Certifications

*Administrative Procedure Act (5 U.S.C. 553)*

An agency may find good cause to exempt a rule from certain provisions of the Administrative Procedure Act (5 U.S.C. 553), including notice of proposed rulemaking and the opportunity for public comment, if it is determined to be unnecessary, impracticable, or contrary to the public interest. The requirements of MAPA included in this rulemaking were set out in such detail as to be self-implementing. Therefore the changes in this rulemaking provide conforming amendments to make the language of the regulations consistent with that of the law. Hence, DEA finds it unnecessary to publish for public notice and comment.

#### Regulatory Flexibility Act

The Deputy Assistant Administrator, Office of Diversion Control, hereby certifies that this rulemaking has been drafted in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this regulation, and by approving it certifies that this regulation will not have a significant economic impact on a substantial number of small entities. This regulation will not adversely impact the public's access to drug products containing pseudoephedrine and phenylpropanolamine. At the same time, this regulation will limit the potential for diversion of these products to the clandestine manufacture of methamphetamine and amphetamine.

For mail order reporting, this action exempts from the reporting requirements a number of transactions that currently must be reported, thus reducing the overall reporting burden on many small businesses.

#### *Executive Order 12866*

The Deputy Assistant Administrator further certifies that this rulemaking has been drafted in accordance with the principles of Executive Order 12866 Section 1(b). DEA has determined that this is not a significant regulatory action. Therefore, this action has not been reviewed by the Office of Management and Budget.

#### *Executive Order 12988*

This rulemaking meets the applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988.

#### *Executive Order 13132*

This action has been analyzed in accordance with the principles and criteria in Executive Order 13132, and it has been determined that this rule does not have federalism implications and, therefore, does not warrant the preparation of a Federalism Assessment.

#### *Paperwork Reduction Act*

For those required to report under 21 U.S.C. 830(b)(3), MAPA adds the requirement of submitting a monthly report for certain export transactions with nonregulated persons involving ephedrine, pseudoephedrine, phenylpropanolamine, and drug products containing them. However, to reduce the burden on those affected, MAPA exempts monthly reporting of exports of the above list I chemicals and drug products containing them when they are reported to DEA pursuant to 21 U.S.C. 954 and 971.

MAPA further reduces the reporting burden on the regulated industry required to submit reports under 21 U.S.C. 830(b)(3) by exempting certain other transactions involving ephedrine, pseudoephedrine, phenylpropanolamine and drug products containing them from the requirement to submit reports as discussed in this rulemaking.

At this time it is not feasible for DEA to determine the extent of the impact of this rulemaking on the regulated industry. Once DEA has determined the impact, it will make the necessary filing with the Office of Management and Budget to adjust the burden of this information collection for the affected industry.

#### *Unfunded Mandates Reform Act of 1995*

This rule will not result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

#### *Small Business Regulatory Enforcement Fairness Act of 1996*

This rule is not a major rule as defined by Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This rule will not result in an annual effect on the economy of \$100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

#### **List of Subjects**

##### *21 CFR Part 1300*

Chemicals, Definitions, Drug traffic control.

##### *21 CFR Part 1309*

Administrative practice and procedure, Drug traffic control, List I and List II chemicals, Security measures.

##### *21 CFR Part 1310*

Drug traffic control, Exports, Imports, List I and List II chemicals, Reporting and recordkeeping requirements.

■ For the reasons set out above, 21 CFR parts 1300, 1309 and 1310 are amended as follows:

#### **PART 1300—DEFINITIONS [AMENDED]**

■ 1. The authority citation for Part 1300 continues to read as follows:

**Authority:** 21 U.S.C. 802, 871(b), 951, 958(f).

■ 2. Section 1300.02 is amended by revising paragraph (b)(28)(i)(D)(2) and by adding paragraphs (b)(33) and (b)(34) to read as follows:

##### **§ 1300.02 Definitions relating to listed chemicals.**

\* \* \* \* \*

(b) \* \* \*

(28) \* \* \*

(i) \* \* \*

(D) \* \* \*

(2) The quantity of ephedrine, pseudoephedrine,

phenylpropanolamine, or other listed chemical contained in the drug included in the transaction or multiple transactions equals or exceeds the threshold established for that chemical, except that the threshold for any sale of products containing pseudoephedrine or phenylpropanolamine by retail distributors or by distributors required to submit reports by § 1310.03(c) shall be 9 grams of pseudoephedrine or 9 grams of phenylpropanolamine in a single transaction and sold in package sizes of not more than 3 grams of pseudoephedrine base or 3 grams of phenylpropanolamine base. For combination ephedrine products the threshold for any sale by retail distributors or by distributors required to submit reports by § 1310.03(c) shall be 24 grams of ephedrine in a single transaction.

\* \* \* \* \*

(33) The term *drug product* means an active ingredient in dosage form that has been approved or otherwise may be lawfully marketed under the Food, Drug, and Cosmetic Act for distribution in the United States.

(34) The term *valid prescription* means a prescription that is issued for a legitimate medical purpose by an individual practitioner licensed by law to administer and prescribe the drugs concerned and acting in the usual course of the practitioner's professional practice.

#### **PART 1309—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, IMPORTERS AND EXPORTERS OF LIST I CHEMICALS [AMENDED]**

■ 1. The authority citation for Part 1309 continues to read as follows:

**Authority:** 21 U.S.C. 821, 822, 823, 824, 830, 871(b), 875, 877, 958.

■ 2. Section 1309.24 is amended by revising paragraph (e) to read as follows:

##### **§ 1309.24 Waiver of registration requirement for certain activities.**

\* \* \* \* \*

(e) The requirement of registration is waived for any retail distributor whose activities with respect to List I chemicals are limited to the distribution of below-threshold quantities of a pseudoephedrine, phenylpropanolamine, or combination ephedrine product that is regulated pursuant to § 1300.02(b)(28)(i)(D) of this chapter, in a single transaction to an individual for legitimate medical use, irrespective of whether the form of packaging of the product meets the definition of "ordinary over-the-counter pseudoephedrine or

phenylpropanolamine product" under § 1300.02(b)(31) of this chapter.

\* \* \* \* \*

**PART 1310—RECORDS AND REPORTS OF LISTED CHEMICALS AND CERTAIN MACHINES [AMENDED]**

■ 1. The authority citation for part 1310 continues to read as follows:

**Authority:** 21 U.S.C. 802, 830, 871(b).

■ 2. Section 1310.03 is amended by revising paragraph (c) to read as follows:

**§ 1310.03 Persons required to keep records and file reports.**

\* \* \* \* \*

(c) Each regulated person who engages in a transaction with a nonregulated person or who engages in an export transaction that involves ephedrine, pseudoephedrine, or phenylpropanolamine, including drug products containing these chemicals, and uses or attempts to use the Postal Service or any private or commercial carrier must file monthly reports of each

such transaction as specified in § 1310.05 of this part.

■ 3. Section 1310.04 is amended by revising paragraphs (f)(1)(ii), (c)(1) and (c)(2), (d)(2), (e)(1) and (e)(2), and (f)(2) to read as follows:

**§ 1310.04 Maintenance of records.**

\* \* \* \* \*

(f) \* \* \*

(1) \* \* \*

(ii) \* \* \*

Chemical	Threshold by weight
(C) * * *	
(1) Distributions by retail distributors .....	9 grams, and sold in package sizes of not more than 3 grams of pseudoephedrine base.
(2) Distributions by persons required to report under § 1310.03(c) of this part.	9 grams, and sold in package sizes of not more than 3 grams of pseudoephedrine base.
* * * * *	
(D) * * *	
(2) Distributions by persons required to report under § 1310.03(c) of this part.	9 grams, and sold in package sizes of not more than 3 grams of pseudoephedrine base.
* * * * *	
(E) * * *	
(1) Distributions by retail distributors .....	9 grams, and sold in package sizes of not more than 3 grams of phenylpropanolamine base.
(2) Distributions by persons required to report under § 1310.03(c) of this part.	9 grams, and sold in package sizes of not more than 3 grams of phenylpropanolamine base.
* * * * *	
(F) * * *	
(2) Distributions by persons required to report under § 1310.03(c) of this part.	9 grams, and sold in package sizes of not more than 3 grams of phenylpropanolamine base.

\* \* \* \* \*

■ 4. Section 1310.05 is amended by adding new paragraphs (f) and (g) to read as follows:

**§ 1310.05 Reports.**

\* \* \* \* \*

(f) Except as provided in paragraph (g) of this section, the following distributions to nonregulated persons, and the following export transactions, are not subject to the reporting requirements in § 1310.03(c):

(1) Distributions of sample packages of drug products when those packages contain not more than two solid dosage units or the equivalent of two dosage units in liquid form, not to exceed 10 milliliters of liquid per package, and not more than one package is distributed to an individual or residential address in any 30-day period.

(2) Distributions of drug products by retail distributors that may not include face-to-face transactions to the extent that such distributions are consistent with the activities authorized for a retail distributor as specified in § 1300.02(b)(29) of this chapter.

(3) Distributions of drug products to a resident of a long term care facility or distributions of drug products to a long term care facility for dispensing to or for use by a resident of that facility.

(4) Distributions of drug products in accordance with a valid prescription.

(5) Exports which have been reported to the Administrator under §§ 1313.31 and 1313.32 of this chapter or which are subject to a waiver granted under § 1313.21 of this chapter.

(g) The Administrator may revoke any or all of the exemptions listed in paragraph (f) of this section for an individual regulated person if the Administrator finds that drug products distributed by the regulated person are being used in violation of the regulations in this chapter or the Controlled Substances Act. The Administrator will notify the regulated person of the revocation, as provided in § 1313.41(a) of this chapter. The revocation will be effective upon receipt of the notice by the person. The regulated person has the right to an expedited hearing regarding the revocation, as provided in § 1313.56(a) of this chapter.

Dated: September 29, 2003.

**Laura M. Nagel,**

*Deputy Assistant Administrator, Office of Diversion Control.*

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**DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT**

**24 CFR Part 982**

**[Docket No. FR-4759-C-04]**

**RIN 2577-AC39**

**Housing Choice Voucher Program Homeownership Option: Eligibility of Units Owned or Controlled by a Public Housing Agency; Correction**

**AGENCY:** Office of the Assistant Secretary for Public and Indian Housing, HUD.

**ACTION:** Final rule; correction.

**SUMMARY:** On September 17, 2003, HUD published a final rule adopting without change an October 28, 2002, interim rule establishing the eligibility of units owned or substantially controlled by a