

If the Administrator determines that there is reasonable cause to believe that an existing certification must be withdrawn, DEA will notify both the Federal department or agency and the specific bidder and end-user in writing. The written notice to the specific bidder and end-user will contain a statement of the legal and factual basis for certifying that there is reasonable cause to believe the certification must be withdrawn. The bidder and end-user may, within thirty calendar days of notification, submit written comments or objections to the Administrator, providing reasons and supporting documentation to contest the decision. The Administrator will take the written comments or objections under consideration and will either (1) provide a written statement that affirms the original decision is final and that provides reasons why the written comments or objections are overruled or are not considered; or (2) confirm the written response and reinstate a certification, thereby reversing the original decision.

Regulatory Certifications

Regulatory Flexibility Act

The Acting Deputy Administrator 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 final rule only affects Federal departments or agencies which plan to sell from their stocks chemicals which could be used in the manufacture of a controlled substance. The rule provides DEA with advance notice of the sale and the opportunity to prevent sales of chemicals which could result in the illicit manufacture of controlled substances.

Executive Order 12866

The Acting Deputy Administrator further certifies that this rulemaking has been drafted in accordance with the principles in 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 regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 Civil Justice Reform.

Executive Order 13132

This rulemaking does not preempt or modify any provision of state law; nor does it impose enforcement responsibilities on any state; nor does it diminish the power of any state to enforce its own laws. Accordingly, this rulemaking does not have federalism implications warranting the application of Executive Order 13132.

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 million 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 million 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 in 21 CFR Part 1310

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

■ For the reasons set out above, 21 CFR part 1310 is amended as follows:

PART 1310—[AMENDED]

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

Authority: 21 U.S.C. 802, 830, 871(b), 890.

■ 2. Part 1310 is amended by adding § 1310.21 to read as follows:

§ 1310.21 Sale by Federal departments or agencies of chemicals which could be used to manufacture controlled substances.

(a) A Federal department or agency may not sell from the stocks of the department or agency any chemical which, as determined by the Administrator of the Drug Enforcement Administration, could be used in the manufacture of a controlled substance, unless the Administrator certifies in writing to the head of the department or

agency that there is no reasonable cause to believe that the sale of the specific chemical to a specific person would result in the illegal manufacture of a controlled substance. For purposes of this requirement, reasonable cause to believe means that the Administration has knowledge of facts which would cause a reasonable person to reasonably conclude that a chemical would be diverted to the illegal manufacture of a controlled substance.

(b) A Federal department or agency must request certification by submitting a written request to the Administrator, Drug Enforcement Administration, Washington, DC 20537, Attention: Domestic Chemical Control Unit (ODID). A request for certification may be transmitted directly to the Drug Enforcement Administration, Domestic Chemical Control Unit through electronic facsimile media. A request for certification must be submitted no later than fifteen calendar days before the proposed sale is to take place. In order to facilitate the sale of chemicals from Federal departments' or agencies' stocks, Federal departments or agencies may wish to submit requests as far in advance of the fifteen calendar days as possible. The written notification of the proposed sale must include:

- (1) The name and amount of the chemical to be sold;
- (2) The name and address of the prospective bidder;
- (3) The name and address of the prospective end-user, in cases where a sale is being brokered;
- (4) Point(s) of contact for the prospective bidder and, where appropriate, prospective end-user; and
- (5) The end use of the chemical.

(c) Within fifteen calendar days of receipt of a request for certification, the Administrator will certify in writing to the head of the Federal department or agency that there is, or is not, reasonable cause to believe that the sale of the specific chemical to the specific bidder and end-user would result in the illegal manufacture of a controlled substance. In making this determination, the following factors must be considered:

- (1) Past experience of the prospective bidder or end-user in the maintenance of effective controls against diversion of listed chemicals into other than legitimate medical, scientific, and industrial channels;
- (2) Compliance of the prospective bidder or end-user with applicable Federal, state and local law;
- (3) Prior conviction record of the prospective bidder or end-user relating to listed chemicals or controlled substances under Federal or state laws; and