

controlled under Federal or state laws; and (4) such other factors as may be relevant to and consistent with the public health and safety.

**What Recourse Is Available to a Bidder or End-user if DEA Refuses To Certify a Prospective Bidder or End-User or Withdraws an Existing Certification?**

If the Administrator determines there is reasonable cause to believe the sale of a specific chemical to a specific bidder or end-user would result in the illegal manufacture of a controlled substance and refuses to certify a prospective bidder or end-user, DEA will notify both the Federal department or agency and the prospective bidder and end-user in writing. The written notice to the prospective bidder and end-user will contain a statement of the legal and factual basis for certifying that there is reasonable cause to believe the sale of the specific chemical to that specific person would result in the illegal manufacture of a controlled substance. The prospective 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 certify the transaction, thereby reversing the original decision.

If the Administrator determines that there is reasonable cause to believe that an existing certification must be withdrawn, DEA will notify both the Federal department or agency and the specific bidder and end-user in writing.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of the legal and factual basis for certifying that there is reasonable cause to believe the certification must be withdrawn.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 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. The 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 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 rulemaking 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, Exports, Imports, Reporting and recordkeeping requirements.

For the reasons set out above, 21 CFR Part 1310 is proposed to be amended as follows:

**PART 1310—[AMENDED]**

1. The authority citation for Part 1310 is proposed to be revised to read as follows:

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

2. Part 1310 is proposed to be 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 15 calendar days before the proposed sale is to take place. In order to facilitate the sale of chemicals from