

Administration, Washington, DC 20537, Telephone: (202) 307-7297.

SUPPLEMENTARY INFORMATION:

Background

Section 520 of the National Defense Authorization Act (Pub. L. 104-201) amended the Controlled Substances Act (CSA) to prohibit a Federal department or agency from selling from its stocks any chemical which, as determined by the Administrator of the Drug Enforcement Administration (DEA), could be used in the manufacture of a controlled substance. However, the CSA as amended permits sales of such chemicals if the Administrator of DEA certifies in writing to the head of the selling Federal department or agency that there is no reasonable cause to believe that the sale of the chemical would result in the illegal manufacture of a controlled substance (21 U.S.C. 890).

On May 8, 2003, DEA published a Notice in the **Federal Register** proposing to conform its regulations to the provisions of the National Defense Authorization Act (68 FR 24689). The rule proposed requiring Federal departments or agencies to notify DEA of the names of prospective bidders and end-users prior to the sale of chemicals which could be used in the manufacture of controlled substances. This notification will allow DEA to identify whether there is reasonable cause to believe that the sale of a specific chemical to a specific bidder or end-user would result in the illegal manufacture of a controlled substance. DEA will work with Federal departments and agencies to determine which chemicals could be used in the illicit manufacture of a controlled substance.

Comments Received Regarding the May 8, 2003 Notice of Proposed Rulemaking

DEA received no written comments regarding the Notice of Proposed Rulemaking published on May 8, 2003. Accordingly, this Notice of Proposed Rulemaking is being finalized here without change.

Chemicals Affected by These Implementing Regulations

As stated in the NPRM, these implementing regulations affect any chemical which DEA determines could be used in the illicit manufacture of a controlled substance. Chemicals that can be used in the manufacture of a controlled substance include, but are not limited to, all List I and List II chemicals as provided in 21 CFR 1310.02. Further, any chemicals mentioned in the DEA "Special

Surveillance List of Chemicals, Products, Materials and Equipment Used in the Clandestine Production of Controlled Substances or Listed Chemicals" published, and updated from time to time, in the **Federal Register** (64 FR 25910, May 13, 1999; corrected at 64 FR 50541, Sept. 17, 1999) are affected by these regulations. Finally, any chemical which is neither a listed chemical nor is listed in the special surveillance list but which could be used in the illicit manufacture of a controlled substance is affected by these implementing regulations. Such chemicals could include, but are not limited to, those chemicals used in the direct illegal manufacture of a controlled substance, those chemicals used as cutting agents, and those chemicals used to process the controlled substance into a dosage form. DEA STRONGLY recommends that ANY Federal department or agency considering the sale of any chemical from its stocks contact DEA to determine whether such chemical could be used in the illicit manufacture of a controlled substance as far in advance of the sale of such chemical as possible.

Requirements of This Final Rule

By this final rule, a Federal department or agency is required to notify the Administrator of DEA in writing at least fifteen calendar days in advance of a proposed sale of chemicals covered by the Act. (DEA strongly encourages Federal departments or agencies to notify it further in advance if possible.) Written notification must be submitted on official agency letterhead to the Drug Enforcement Administration, Office of Diversion Control, Domestic Chemical Control Unit (ODID) Washington, DC 20537 and include: (1) The name and amount of the chemical to be sold; (2) the name and address of the prospective bidder(s); (3) the name and address of the potential end-user(s), in cases where a sale is being brokered; (4) point(s) of contact for the prospective bidder and end-user; and (5) the end use of the chemical.

Within fifteen calendar days from the date the written notification is received, DEA will respond in writing to the Federal department or agency certifying 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. The certification that there is no 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 will apply to future sales to the same prospective bidder and end-user for the same chemical for one calendar year unless DEA notifies the agency to the contrary in writing.

Factors Considered in Certifying a Bidder or End-User

In determining whether there is reasonable cause to believe that the sale of a specific chemical to a specific bidder or end-user would result in the illegal manufacture of a controlled substance, the Administrator will consider the following factors: (1) The prospective bidder's and end-user's past experience in the maintenance of effective controls against diversion of particular chemicals into other than legitimate medical, scientific, and industrial channels; (2) the prospective bidder's and end-user's compliance with applicable Federal, state and local law; (3) the prior conviction record of the prospective bidder and end-user relating to controlled substances or to chemicals controlled under Federal or state laws; and (4) such other factors as may be relevant to and consistent with the public health and safety.

Recourse 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.