

ephedrine products than there are pharmacies.

This reporting requirement was proposed with the intent of providing a clear standard with respect to reportable transactions involving regulated ephedrine drug products. However, the comments demonstrate that industry would prefer flexibility and discretion based on the circumstances of the transaction rather than a specific standard. Therefore, the proposed section 1310.05(a)(2) and related language in Section 1310.05(b) have been removed.

However, removal of the specific standard for reporting does not relieve regulated persons and registrants of the responsibility to report transactions involving an extraordinary quantity of a listed chemical. Registrants must review transactions involving the sale of regulated ephedrine drug products to individuals for personal use within the context of the established FDA guideline regarding the manner in which the products should be used and the appropriate dosing levels. In this regard, 375 dosage units of regulated ephedrine drug products within a calendar month for individual use provides a valid reference for registrants in determining whether additional efforts should be made to confirm the validity of a transaction.

Miscellaneous

29. Two comments were received questioning the use of the DEA Chemical Code Numbers set forth in Section 1310.02, rather than the familiar Chemical Abstract Services (CAS) or Harmonized Tariff System, (HTS) Numbers.

DEA has reviewed these numbering systems and determined that they were designed for other purposes and that their use could lead to confusion and jeopardize the accuracy of the information reported to DEA. In the HTS numbering system there are multiple chemicals that are assigned the same number and in the CAS numbering system that are chemicals that are assigned multiple codes. DEA has produced and made available a chemical reference guide that provides a cross reference to the CAS and HTS numbers, which will be updated to include the new Chemical Code Numbers.

With respect to the chemical codes, DEA discovered, following publication of the NPRM, that the Chemical Code Numbers assigned to Benzyl Chloride (8568) and Benzyl Cyanide (8570) were incorrect. The correct Chemical Code Number for Benzyl Chloride is 8570 and for Benzyl Cyanide is 8735. These

corrections have been made in this final order.

30. Three comments were submitted regarding the addition of new chemicals to List I or List II. The first comment questioned the addition of hydrochloric and sulfuric acid to List II without any justification. The second questioned the addition of benzaldehyde and nitroethane without specific justification of the addition or the thresholds. The third recommended that DEA continue to publish the proposed addition of any new chemicals for notice and comment and suggested that DEA hold public hearings on the proposed addition of new chemicals.

With respect to the hydrochloric and sulfuric acid, these chemicals were added to List II by final order published in the **Federal Register** on September 22, 1992 (57 FR 43615). The justification for the action was provided in the **Federal Register** notice regarding the addition of the two chemicals. With respect to nitroethane and benzaldehyde, Section 8 of the DCDCA amended Section 802(34) of the CSA to add the chemicals to List I; there addition to Section 1310.02 is simply a conforming amendment. Regarding the thresholds, benzaldehyde and nitroethane are diverted and used in clandestine laboratories for the illicit manufacture of controlled stimulants in a manner similar to other List I chemicals. These other chemicals, with the exception of ephedrine, have established threshold levels that were based on a review of data regarding the quantities distributed and used licitly, the quantities diverted and used illicitly, and the amount of each chemical necessary to synthesize a certain amount of controlled substance. DEA has reviewed the same type of data for benzaldehyde and nitroethane and found that the data supported the establishment of similar thresholds for the two chemicals. The specific thresholds of 4 kilograms for benzaldehyde and 2.5 kilograms for nitroethane were based on the licit and illicit uses of the two chemicals, and are consistent with the thresholds set for other List I chemicals used in the illicit production of controlled stimulants. Regarding the third comment, Section 1310.02 already clearly establishes that any proposed addition or deletion of chemicals from List I or List II must be published in the **Federal Register** with opportunity for public comment. It has been DEA's experience that the notice and comment procedure provides a satisfactory opportunity for affected persons to provide important information and advice regarding the proposed action. The comment period

also satisfies the compelling need for quick response while providing DEA the option to extend the comment period, should the need for additional comment arise.

31. Two comments argued that DEA cannot regulate "herb-containing dietary supplements and herbs containing Ephedra and its alkaloids" on the grounds that the products are dietary or nutritional supplements and not drugs.

The CDTA and DCDCA define and establish controls over List I and List II chemicals. Under these acts, the only exceptions to the application of regulatory controls over products containing listed chemicals are for certain drug products that are lawfully marketed under the Food, Drug and Cosmetic Act (21 U.S.C. 802(39)(A)(iv)) and for chemical mixtures. Within this context, DEA has reviewed the issue of ephedra, e.g., the entire plant or the overground portion the ephedra plant and determined that the unprocessed plant material ephedra and products containing the unprocessed plant material ephedra are not subject to the regulatory provisions of the CDTA and DCDCA. However, preparations of the ephedra plant, such as extracts and concentrates, that contain ephedrine, do fall within the definition of *chemical mixture* (21 C.F.R. 1310.01(g)), thus, they are subject to the regulations as they apply to chemical mixtures. Chemical mixtures are currently exempt from the regulatory provisions of the CDTA and DCDCA, pending promulgation of regulations concerning the exemption of chemical mixtures.

32. One comment requested clarification of what constitutes "unusual or excessive loss or disappearance of a listed chemical."

This term applies to circumstances that appear to be outside the framework of normal business occurrences. Regulated persons and registrants understand the nature of their chemical activities and should be able to make informed decisions as to whether the above term applies to conditions they may encounter and to be able to explain their decision sufficiently to convince a "reasonable person."

33. One comment requested clarification of the term transshipments. For purposes of DEA's regulations, a transshipment is an exportation of a listed chemical from one foreign country to another foreign country, which exportation transits the jurisdiction of the United States.

34. Two comments questioned the format of paragraphs (f)(1)(iv)(B) and (f)(1)(iv)(C) of Section 1310.01. The first noted that while the present format suggests independent subjects, the use