of ''and'' at the end of (B) implies that (C) is a subpart of (B). A second comment suggested that paragraph (f)(1)(iv)(B) should contain a reference to Section 1310.10, which sets the criteria for removal of the exemption.

DEA agrees. The two paragraphs have been redesignated as paragraphs (f)(1)(iv)(B)(*1*) and (f)(1)(iv)(B)(*2*) of Section 1310.01, and the appropriate citation to Section 1310.10 will be included. Further, in order to keep the language of the section consistent with the language of the DCDCA, the period at the end of Section 1310.01(f)(1)(iv)(A)(*4*) will be deleted and ''; or '' will be inserted in its place.

35. One comment requested clarification of the term ''imminent danger'' as used in the revocation provisions as uses in Section 1309.44.

The term ''imminent danger'', as used in Section 1309.44, refers to actions by a registrant that demonstrate a flagrant indifference to and disregard for the law and the health and safety of the public. There are no specific criteria for determining what constitutes ''imminent danger''. However, interested persons may wish to review the **Federal Register** for past notices of suspension of controlled substance registrations. In any action under this section related to the activities of a specific registrant, DEA will list the facts that are considered to present an imminent danger.

36. One comment requested clarification of Section 1310.01(f)(1)(ii), with specific emphasis on whether a common or contract carrier would be required to register with DEA for activities involving the delivery of a listed chemical either to or by the carrier.

Section 1310.01(f)(1)(ii) specifically excludes the delivery of a listed chemical by a common or contract carrier for carriage in the lawful and usual course of business from the definition of a regulated transaction. The common or contract carrier is not subject to the registration requirement when transporting chemicals on a registrant's behalf. The registrant remains responsible for the listed chemicals until they are delivered to and accepted by the consignee. In this regard, it is important that a registrant take reasonable measures to insure that any common or contract carrier used to ship listed chemicals to customers will provide adequate security against in-transit losses or thefts.

37. Two comments questioned the provisions in Sections 1310.11(b) and 1310.15(b), which establish recordkeeping and reporting requirements for regulated persons who manufacture exempted drug products, on the grounds that a person who manufactures an exempted drug product is not a regulated person.

The referenced sections as well as Section 1310.13(b), were written with respect to a regulated person who also manufactures an exempted drug product. Upon further consideration, DEA has determined that regulated persons should not be required, solely because of their status as a regulated person, to keep records and make reports of transactions that would otherwise be exempted from those requirements. Sections 1310.11(b), 1310.13(b) and 1310.15(b) have been removed.

38. One comment requested clarification of Section 1309.45 and raised questions regarding procedures to be followed if an application for registration renewal form (DEA Form 510a) is not received in a timely manner.

Section 1309.45 applies only to a registrant who is subject to action by the Administrator to revoke or suspend his or her registration. If the registrant submits a renewal application within the prescribed time period and the Administrator has not issued a final order suspending or revoking the registration, then the registration is deemed to continue in effect until the Administrator issues his final order. As to renewal in circumstances other than those set out in Section 1309.45, Section 1309.32(c) establishes the procedures. DEA will mail out renewal notices to registrants approximately 60 days prior to the date of expiration. If a registrant has not received their renewal notice within 45 days of their expiration date, then a written request for a replacement form must be provided to DEA. A properly completed renewal application and fee must be received by DEA prior to the registrant's expiration date if registration is to be continued without interruption. If a registration is allowed to expire, the registrant is no longer authorized to distribute, import or export a List I chemical. DEA will mail delinquency notices to expired registrants approximately 90 days after the expiration date.

39. One comment questioned the DEA's placing priority on the completion of pre-registration investigations of non-retail firms while DEA's **Federal Register** notice of March 17, 1994 (59 FR 12562, Elimination of Threshold for Ephedrine) focused on the diversion of ephedrine tablets at the retail level. The comment also questioned why DEA has proposed steps to lessen the impact on retail distributors and yet has not specifically proposed steps to lessen the impact on non-retail distributors.

By directing its focus at the non-retail level during the initial registration phase, DEA will identify those firms that have failed to adequately identify their customers or have been shipping to questionable retail firms. With this information, DEA can focus its initial retail investigations on the most likely sources of diversion. With respect to the second question, DEA has taken steps to limit the impact of the chemical controls on all persons. The exemption from the registration requirement in Section 1309.25 applies to any person, either retail or non-retail, registered with DEA to handle controlled substances, who also engages in activities with regulated ephedrine drug products. Further, DEA has attempted to design the chemical control requirements to be consistent with existing business practices, as noted in comment number 26 with respect to the recordkeeping requirements.

40. One comment objected to the exclusion of mail order activities from the definition of retail distribution.

As noted in the supplemental information to the NPRM, retail distributors engage in a limited activity as regulated by the DCDCA. The amounts of product distributed per transaction are generally small and sales are to individuals only. By contrast, it has been DEA's experience that mail order distributors of ephedrine drug products that are regulated deal with both individuals and businesses and the volume of sales and product can be quite large. Additionally, such firms are often less readily able to positively identify their customers. Investigations will be significantly more complex and time consuming for a mail order distributor than for a retail distributor. It is appropriate that mail order activities remain classified as distributors rather than retail distributors.

Protection of Confidential Business Information

41. Four comments expressed concern regarding the safeguarding of confidential business information (CBI) that will be collected by DEA in connection with chemical control activities. Two of the comments suggested that DEA establish specific and strong provisions regarding protection of CBI.

DEA operates national diversion control programs related to controlled substances and listed chemicals. The controlled substance program has been in effect since the early 1970's and the chemical program since the late 1980's.