possible passenger injury if emergency evacuation was needed.

Jetstream Aircraft Limited has issued Service Bulletin 52–A–JA 930901, Revision 1, dated February 11, 1994, which specifies procedures for inspecting and replacing the passenger/crew internal door handle mounting platform structure on JAL HP137 Mk1, Jetstream series 200, and Jetstream Models 3101 and 3201 airplanes. The CAA classified this service bulletin as mandatory in order to assure the continued airworthiness of these airplanes in the United Kingdom. The CAA classifying a service bulletin as mandatory in the United Kingdom is equivalent to the FAA issuing an airworthiness directive in the United States.

This airplane model is manufactured in the United Kingdom and is type certificated for operation in the United States under the provisions of § 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, the CAA has kept the FAA informed of the situation described above. The FAA has examined the findings of the CAA, reviewed all available information, and determined that AD action is necessary for products of this type design that are certificated for operation in the United States.

Since an unsafe condition has been identified that is likely to exist or develop in other JAL HP137 Mk1, Jetstream series 200, and Jetstream Models 3101 and 3201 airplanes of the same type design, the proposed AD would require repetitively inspecting the passenger/crew cabin door handle mounting platform structure for cracks, and, if found cracked, replacing with a structure of improved design as terminating action for the repetitive inspections. The proposed actions would be accomplished in accordance with the service information described above.

The FAA estimates that 165 airplanes in the U.S. registry would be affected by the proposed AD, that it would take approximately 1 workhour per airplane to accomplish the proposed modification, and that the average labor rate is approximately $55 an hour. Based on these figures, the total cost impact of the proposed AD on U.S. operators is estimated to be $8,800. This figure does not take into account any possible passenger/crew door internal handle mounting platform structure replacements nor repetitive inspections. The FAA has no way of determining how many of these structures may have cracks or the number of repetitive inspections each owner/operator may incur.

The regulations proposed herein would not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this action (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action has been placed in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. App. 1354(a), 1421 and 1423; 49 U.S.C. 106(g); and 14 CFR 11.89.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding a new AD to read as follows:

Jetstream Aircraft Limited: Docket No. 94–CE–16–AD. Applicability: HP137 Mk1, Jetstream Series 200, and Jetstream Models 3101 and 3201 airplanes (all serial numbers), certificated in any category. Compliance: Required upon the accumulation of 1,800 hours TIS or within the next 100 hours time-in-service (TIS) after the effective date of this AD, whichever occurs later, unless already accomplished, and thereafter as indicated.

To prevent the inability to open the passenger/crew door because of cracked internal handle mounting platform structure, which could result in passenger injury if emergency evacuation was needed, accomplish the following:

(a) Inspect the passenger/crew door internal handle mounting platform structure for cracks in accordance with Part 1 of the ACCOMPLISHMENT INSTRUCTIONS section of Jetstream Service Bulletin (SB) 52–A-JA 930901, Revision 1, dated February 11, 1994 .

(1) If any cracked structure is found, prior to further flight, replace the mounting platform structure with a new structure, part number 137450C23, in accordance with Part 2 of the ACCOMPLISHMENT INSTRUCTIONS section of Jetstream SB 52–A-JA 930901, Revision 1, dated February 11, 1994.

(2) If no cracks are found, reinspect the mounting platform structure at intervals not to exceed 1,800 hours TIS until a part number 137450C23 mounting platform structure is installed.

(b) The repetitive inspections required by this AD may be terminated upon installing a part number 137450C23 passenger/crew door internal handle mounting platform structure. This installation may be accomplished regardless of whether the existing structure is cracked.

(c) Special flight permits may be issued in accordance with § § 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

(d) An alternative method of compliance or adjustment of the compliance time that provides an equivalent level of safety may be approved by the Manager, Brussels Aircraft Certification Office (ACO), Europe, Africa, Middle East office, FAA, c/o American Embassy, 1000 Brussels, Belgium. The request should be forwarded through an appropriate FAA Maintenance Inspector, who may add comments and then send it to the Manager, Brussels ACO.

Note: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Brussels ACO.

(e) All persons affected by this directive may obtain copies of the documents referred to herein upon request to Jetstream Aircraft Limited, Manager Product Support, Prestwick Airport, Ayrshire, KA9 2RW Scotland; telephone (44–292) 79888; or Jetstream Aircraft Inc., Librarian, P.O. Box 16029, Dulles International Airport, Washington, DC, 20041–6029; or may examine these documents at the FAA, Central Region, Office of the Assistant Chief Counsel, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.

Issued in Kansas City, Missouri, on October 5, 1994.

John R. Colomy,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 94–25293 Filed 10–12–94; 8:45 am]

BILLING CODE 4910–13–U

Office of the Secretary

14 CFR, Parts 380, 381, 399

[Docket No. 49385; Notice 94–16]

RIN 2105–AC03

Special Event Tours

AGENCY: Office of the Secretary, DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Department seeks comment on a proposal to expand its rules on Super Bowl tours to cover air tours to other types of special events. These Super Bowl rules require that operators of Super Bowl tours that are promoted as including game tickets must have those game tickets in hand or under contract before they advertise or sell the tours, and that they must refund the entire tour price to any customer who does not receive a promised game ticket. This proposed rule would also extend the charter rule's prohibition on last-minute price increases to non-charter tours to special events. This initiative arises as a result of problems on certain tours to the 1994 Rose Bowl on which participants did not receive game tickets that were promoted as being included in the package, or were required to make additional payments in order to receive tickets.

DATES: Comments should be received by November 14, 1994. Late-filed comments will be considered to the extent practicable.

ADDRESSES: Comments should be sent to Docket Clerk/C–55, Docket No. 49385, Room 4107, Department of Transportation, 400 Seventh Street SW., Washington, DC 20590. For the convenience of persons who will be reviewing the docket, it is requested that commenters provide an original and three copies of their comments. Comments will be available for inspection at this address Monday through Friday from 9 a.m. through 5 p.m. Commenters who wish the receipt of their comments to be acknowledged should include a stamped, self-addressed postcard with their comments. The docket clerk will date-stamp the postcard and mail it to the commenter.

FOR FURTHER INFORMATION CONTACT: Tim Kelly, Consumer Affairs Division/I–25, Office of the Secretary, Room 10405, Department of Transportation, 400 Seventh Street SW., Washington, DC 20590. Telephone (202) 366–5952.

SUPPLEMENTARY INFORMATION: In conjunction with the Rose Bowl football game that was played in Pasadena, California on January 1, 1994, a large number of fans of the University of Wisconsin (one of the two teams participating in the game) purchased package tours to California. Many of those tours were promoted as including a ticket to the Rose Bowl game. However, a significant number of these individuals either did not receive the game tickets that they had been promised and did not gain admission to the game, or were required to make an additional payment after they arrived in Pasadena in order to obtain their tickets. The Department is seeking comment on a proposal to extend its rules on Super Bowl tours to include air tours to other types of special events where admission to the event is advertised as being included in the package.

The Department's rules on Super Bowl charters are contained in title 14, part 380 of the Code of Federal Regulations (14 CFR part 380):

- Section 380.2 defines a Super Bowl charter as a charter flight that is represented by its charter operator as including tickets to the National Football League's Super Bowl game as part of its ground package.
- Section 380.18a states that a Super Bowl charter may not be advertised unless the operator has submitted verification to the Department [1] that the operator (1) is in physical possession of enough Super Bowl game tickets to provide them for a substantial number of seats on the charter, or (2) has a contract with the NFL or with an NFL team for such a number of game tickets, or (3) has a contract with another person who has a contract with the NFL or an NFL team for such a number of game tickets.
- Section 380.18a also states that a Super Bowl charter may not be sold unless the operator has submitted verification to the Department that the operator has possession of, or contracts for, enough game tickets to provide one to every person who is to receive one under the terms of the operator/participant contract for the charter.
- Section 380.31(c) states that if an operator receives a booking for which he or she does not have possession of or a contract for a game ticket, the operator must return that participant's money within 3 days, unless the participant has authorized the operator in writing to retain the payment while the operator seeks additional tickets.
- Sections 380.32(s), 380.33(a)(5) and 380.33(e) state that if Super Bowl game tickets are not supplied when promised, the affected participant must be sent a refund of the price of the entire charter package within 14 days after the return flight.

These rules came about following problems with game tickets for Super Bowl tours in the late 1970's (see 45 FR 1856, January 9, 1980). The rules were limited to the Super Bowl because that was the only event where such problems had surfaced.

In addition to the Super Bowl rules in Part 380, the Department has a policy statement at 14 CFR 399.87 which states that it shall be an unfair or deceptive practice within the meaning of section 411 of the Federal Aviation Act (now 49 U.S.C. 41712) to advertise or sell an air tour that is promoted as including a ticket to the Super Bowl game unless the operator has tickets or contracts for tickets in the manner described in 14 CFR 380.18a (see above). The principal purpose of this policy statement is to reach tours operated on scheduled air service, which are not covered by the part 380 charter rules. The part 399 policy statement mirrors § 380.18a, but does not include the other part 380 provisions described above. Most importantly, it does not include the requirement that the entire tour price be refunded if a game ticket is not provided.

On January 27, 1994, the Department issued an Advance Notice of Proposed Rulemaking in this proceeding (published February 1, 1994; 59 FR 4614). In this notice, we stated that we were tentatively proposing to issue a new rule that would contain the procedures of the Super Bowl provisions of both part 380and part 399, and to extend this rule to other types of events. Like current § 399.87, the new rule would apply to tours on all forms of air transportation, not just charters. Like the existing Super Bowl charter rules in part 380, the new regulation would require the tour operator to refund the entire tour price to any participant who does not receive a promised event ticket, even if the tour were not on a charter. The proposed rule would also pick up the procedures of § 380.31(c) of the charter rule, which requires an operator to refund any money received for a booking within 3 days if the operator has no contract for an event ticket for that person, unless the person has authorized the operator in writing to retain the payment while the operator seeks a ticket.

In addition to setting out the Department's tentative rulemaking proposal, the January ANPRM asked

[1] References to "the Board" in Part 380 refers to the Civil Aeronautics Board, the Department's predecessor in aviation economic and consumer matters. The Department of Transportation now administers this rule as authorized by the Civil Aeronautics Board Sunset Act of 1984 (P.L. 98–443; 98 Stat. 1703).

commenters to address a number of questions about the types of issues that such a rule should apply to. The discussion of the comments that appears below is organized according to those questions.

Comments

The Department received comments from 11 organizations and 7 individuals. The great majority of the comments favored adoption of a rule in this area.

Q. Should the rule apply only to major sports events which would be listed in the rule (for example, the Super Bowl, college bowl games, the NCAA Final Four, the World Cup finals, the Olympics)? To any sports event? To religious events (for instance, the Passion Play in Oberammergau)? To any event?

Several of the comments discussed only sports events as the context for the rule. The National Collegiate Athletic Association (NCAA) recommended applying the rule to the Division I Final Four men's and women's basketball championships, the College World Series, and post-season college football bowl games. The Football Bowl Association (FBA), an organization representing all 19 post-season college football bowl games, also felt that all post-season football bowl games should be covered, and stated that it offered no comment on whether other events should or should not be covered. The National Hockey League (NHL) commented that the rule should apply to all major professional and amateur sports events. Ms. Sara Shea said that the Super Bowl rule should be expanded to include other special sporting events.

The Wisconsin Attorney General stated that the rule should not be limited to specifically named events, but perhaps could be limited to "competitive events" where participants and locations are determined close to the date of the event. He said that for non-competitive events such as the Passion Play in Oberammergau, the dates, locations and participants are known well in advance and existing consumer protections should be adequate.

Other commenters stated that the rule should not be limited to sports events. The American Society of Travel Agents (ASTA) said that it should apply to all events where a separately-purchased ticket is necessary for admission to the event. The RG Travel Companies, which were involved in sending 1,700 Wisconsin fans to the 1994 Rose Bowl, stated that the rule should cover any special event "where a good possibility exists that the demand for tickets will exceed the supply * * *" In a similar vein, the Pasadena Tournament of Roses commented that the rule should apply to any event with limited admission. The National Tour Association (NTA, representing motor coach tour operators) and Congressman Robert Andrews of New Jersey expressed the opinion that the rule should not be limited to sports events. Ms. Arlene Caldwell said that the rule should cover any tour that claims to include a ticket to the event, and Mr. Donald Hamilton stated that it should apply to any event for which tour packages are sold.

Q. Should the rule apply to both charter and scheduled transportation?

All of the commenters that expressed an opinion on this point felt that the rule should apply to both scheduled and charter air transportation. Those commenters were the RG Travel Companies, NACA, the NHL, ASTA, the NCAA, FBA, the Pasadena Tournament of Roses, and the Wisconsin Attorney General.

Q. Should the rule contain only the advertising and sale restrictions of §§ 380.18a and 399.87 (of the current Super Bowl rule), or should it also contain the "money back guarantee" of §§ 380.32 and 380.33 and/or the "booking rejection" and "contingent booking" procedures of § 380.31(c)?

Sections 380.18a and 399.87 prohibit advertising or sale of a "Super Bowl tour" (defined as one which is held out as including a ticket to the Super Bowl game) until the operator has physical possession of game tickets or has a contract with the National Football League, with an NFL team, or with another person who has a contract with the league or a team. Sections 380.32 and 380.33 state that any participant on a Super Bowl tour who does not receive promised game tickets must be given a refund of the entire tour price, even if a portion of the services are used. Section 380.31(c) provides that if an operator receives a booking for which he or she does not have possession of or a contract for a game ticket, the operator must return that participant's money within 3 days, unless the participant has authorized the operator in writing to retain the payment while the operator seeks additional tickets.

Except for NTA, all commenters that expressed a position on this question felt that some form of regulation along these lines was appropriate. NTA stated that the majority of its members that responded to a poll on this matter felt that regulation of special-event tours should not be a responsibility of the government, but the association said that in the event a rule is adopted it favors the "booking rejection" and "contingent booking" procedures of § 380.31(c).

ASTA and the Wisconsin Attorney General also expressed support for the "booking rejection" and "contingent booking" procedures. They favored the "money back guarantee" as well, as did the RG Travel Companies, the National Air Carrier Association (NACA, an organization of charter airlines), the NHL, NCAA, FBA, and Pasadena Tournament of Roses. The Tournament of Roses stated that this guarantee should apply "at any time prior to departure" if it is clear tickets will not be forthcoming. FBA commented "the greater the remedy available, the less likely that tour packagers will create the problem by promoting packages that may not be legitimate."

NACA said that there should be an exception to the "money back guarantee" for situations of force majeure and acts of God, such as the earthquake in San Francisco that forced postponement of the World Series. Similarly, the NHL stated that if the event is canceled or substantially altered after the tour begins, consumers should be entitled only to a refund of the face value of the event ticket, but that if such cancellation or alteration takes place before departure, the operator should be required to inform the consumers, who would have the right to cancel (presumably with a full refund).

Congressman Andrews was also in favor of the "money back guarantee," as well as a requirement for tour operators to disclose whether event tickets are guaranteed or tentative. However, he stated that any rule that would totally prohibit marketing of a special-event tour until the tour operator has event tickets in hand would not be practical. Tickets for many such events are not available until less than two weeks before the event, he pointed out, but other arrangements (e.g., air and hotel) must be made before that. NTA, the NCAA and the Wisconsin Attorney General stated that the current restrictions against marketing Super Bowl tours until the operator has game tickets in hand or under contract should be included in the new rule.

Q. If the scope of the type of event covered by the rule is broad, and the rule contains the "money back guarantee," should procedures be included that would protect the operator from having to refund the entire tour price if a participant doesn't receive promised admission to something like a welcoming cocktail party?

No commenters spoke in favor of a requirement to apply the "money back

guarantee" to events such as a welcoming cocktail party. Of those who commented on the issue, NTA, the NHL, ASTA, the Pasadena Tournament of Roses said that operators should not be required to refund the entire tour price over failure to provide something like a promised welcoming cocktail party. NACA and the Wisconsin Attorney General stated that the rule should require the value of undelivered ancillary events to be refunded, but should not require a refund of the entire tour price. FBA and the Wisconsin Attorney General both pointed out that certain events on a special event tour (e.g., the Tournament of Roses parade on a Rose Bowl tour) are integral to the experience for which the tour was organized while other events on the same tour (e.g., a side trip to Disneyland) are not. These two commenters suggest that integral events be protected by the" money back guarantee" of the total tour price, but not other events.

Q. Should the rule specifically ban last-minute or post-departure price increases for admission to the event, one of the problems that allegedly occurred on the 1994 Rose Bowl tours?

All commenters who offered an opinion on this subject felt that last-minute price increases should be regulated in some manner. The RG Travel Companies, NACA, the NCAA, ASTA, the Wisconsin Attorney General and Mr. Donald Hamilton stated that last-minute price increases should be banned. FBA and the Pasadena Tournament of Roses said that price increases at any time following purchase should be prohibited unless the consumer receives written notice that the operator reserves this right. The Pasadena Tournament of Roses also suggested that participants who cancel within a few days of notification of a price increase be entitled to a full refund. The Wisconsin Attorney General commented that on tours to special events, "last-minute or post-departure price increases are common and are tantamount to extortion" because other options may be sold out.

The NHL stated that, in general, price increases should be banned unless the face value of the ticket has been increased subsequent to departure of the tour. However, for events with short lead times such as the Stanley Cup playoffs, the NHL said that the rule should permit tours on which participants are required to agree to purchase event tickets at the yet-unknown face price plus a service fee, as long as the consumer is given prominent notice of this fact.

Q. Some tours are promoted in conjunction with a special event, but do not include, and do not represent that they include, admission to the event. For example, there have been tours to the Super Bowl host city during the Super Bowl weekend that prominently feature "Super Bowl" in the headline of advertisements and flyers, but which do not include game tickets. Should the new rule ban this practice, or require affirmative, prominent disclosure that admission to the event is not included?

All of the commenters that expressed an opinion on this issue felt that it should be regulated in some manner. The RG Travel Companies stated that they favored either banning the practice or requiring disclosure. The NCAA urged affirmative, prominent disclosure, "if such tours are to be allowed at all." All others who commented on this point (the NHL, ASTA, FBA, the Pasadena Tournament of Roses, and the Wisconsin Attorney General) recommended prominent disclosure. The NHL suggested a requirement that text disclosing the absence of event tickets from event-oriented tours should be at least 75 percent of the size of the name of the event in advertising material. The Pasadena Tournament of Roses said that such disclosures should be at least twice the size of the smallest text elsewhere in the ad or flyer, but in no case less than 12-point type, and that disclosure during verbal contacts should also be required.

Q. What would be the economic burdens of such a rule? Would the rule be impractical for events where the participants are known only a week in advance, e.g. the NCAA Final Four?

All of the parties that commented on this issue agreed that the rule can and should apply to events in which the participants are not known until shortly before the event. The RG Travel Companies commented that the rule would not be impractical because commitments centering around a particular team could be made contingent on that team qualifying for the event. NACA said the "money back guarantee" should apply regardless of the timing of the event. The NHL stated that the rule may be burdensome for organizers of short-lead-time tours, but that this is justified by the benefit to consumers. (Note also the NHL's earlier suggestion that on events where the participants become known only shortly beforehand, the rule should permit tours in which the participants must agree to purchase an event ticket whose face value is not yet known.)

ASTA, like NACA, said that the degree of advance notice is not relevant, and that an operator who markets an event-oriented tour before the participants are known should simply disclose that event tickets are not included in the advertised price. FBA commented that participating teams in college bowl games are generally known at least a month in advance, and also that any experience the Department has had with Super Bowl tours would be instructive, as the competing teams in that game are sometimes determined only a week before the game.

The Pasadena Tournament of Roses, the NCAA and the Wisconsin Attorney General all pointed out that even though the participating teams in the NCAA Final Four (the example in this question) are determined only the weekend before, the tickets are sold out months beforehand. Thus, the fact that the participants are not known until the final week has minimal impact on the availability of tickets and the feasibility of tours. The Pasadena Tournament of Roses asserted that any economic burden resulting from this rule would fall on ticket brokers and tour operators who buy event tickets from individuals in order to resell them. The Wisconsin Attorney General stated that consumer protection may be even more important in cases where event participants are determined at the last minute, because consumers have less time to investigate their options.

Other Comments

The Air Transport Association (ATA, an association of large scheduled airlines) filed a comment stating that it expressed no opinion about whether, or to what extent, the current Super Bowl rules should be made applicable to tours to other special events. However, ATA said that DOT should not make air carriers responsible for assuring that tour operators comply with the new rule. NACA echoed this view, stating that carriers should not be made the guarantors of tour operators.

Discussion

We have decided to propose a rule very similar to that described in the ANPRM, which in turn closely tracks the existing rules for Super Bowl tours.

The rule that we are proposing would apply to any tour that is organized for the purpose of attending a sporting, social, religious, educational, cultural, political or other event of a special nature and limited duration, which exists for reasons apart from the tour itself, and which is represented by the operator of the tour as including admission to that event. The Department does not wish to engage in line-drawing ofthe type that would be required were we to publish a list of

specific events that would be covered by the rule. In addition, we see no justification for limiting the applicability of the rule to sporting events. Few commenters specifically suggested such a limitation, although a number of them offered sports contests as examples of the type of event that should be covered. While the Wisconsin Attorney General is of course correct when he comments that the date and location of a non-competitive event such as the Passion Play in Oberammergau is known well in advance, this in itself does not lessen the likelihood of ticket shortages.

We agree with the comments that suggested that the rule should apply to any event where a separate ticket is required for admission to the event or where there is limited admission. The rule that we are proposing will apply to any tour to an event of the type described at the beginning of the previous paragraph in which the tour operator has represented that the tour includes admission to the event. If the event is free, or attendance is unlimited, the operator should have no trouble furnishing tickets and this rule will impose no burden. On the other hand, if tours are promoted to an unusually popular event of a non-sporting nature, those tour participants would be just as disappointed at not receiving the promised admission to the event that constituted the entire purpose of their trip as would a fan traveling to a bowl game.

We have tentatively concluded that the rule should apply to both charter and scheduled air transportation, as well as to any other form of air service meeting the statutory definition of "air transportation" that may develop in the future. Thus, we are proposing to apply it to "scheduled, charter, and other air transportation."

The proposed rule would apply to all interstate (i.e., domestic)[2] air transportation, and to foreign (i.e., international) air transportation originating at a point within the United States. Applying the rule only to outbound international flights is consistent with the approach taken in the existing Public Charter rule (see 14 CFR 380.23) and with the" country of origin" concept of regulation of international air transportation. As a policy matter, the Department has no interest in applying this rule to tours originating in foreign countries whose participants are largely or exclusively foreign citizens.

The rule that we are proposing would apply to any operator of a tour that meets the definition of a Special Event Tour, regardless of whether that operator is a direct air carrier (i.e., an airline), an indirect air carrier (e.g., a Public Charter operator), or a ticket agent (e.g., a scheduled-service tour operator, including a travel agent acting as a tour operator). The proposed rule would apply to both U.S. and foreign entities that act as operators of Special Event Tours, just as current § 399.87 does.

With regard to the comments of ATA and NACA, the ANPRM did not propose, and wedo not propose here, that this rule should include provisions that obligate direct air carriers to assure that tour operators comply with the rule. Except where an airline might choose to directly operate a Special Event Tour (i.e., to become the tour operator), a direct air carrier of a Special Event Tour will incur no greater or lesser obligations under this rule than it has in its capacity as a common carrier either certificated under 49 U.S.C. 41101 or holding a foreign air carrier permit issued under 49 U.S.C. 41301 (formerly sections 401 and 402 ofthe Federal Aviation Act).

As we suggested in the ANPRM, we are proposing to carry over the provisions from the existing Super Bowl rule that prohibit advertising or sale of such tours before game tickets are in hand or under contract. In the rule we are proposing here, these provisions will be expanded to apply to all special events. This approach was supported by the comments, and involves no novel processes since the existing procedures have been in place in the Super Bowl rule for 15 years.

In addition to the provision that prohibits advertising or sale of a Super Bowl tour until game tickets are in hand or under contract, the Super Bowl charter rule requires Super Bowl charter operators to include in the prospect us that is required to be filed with the Department for all Public Charters a certification that they have the game tickets in hand or else a copy of the contract for the game tickets. We do not propose to carry over this additional filing requirement to the new rule. The underlying requirement to have the tickets or ticket contracts before advertising or sales commence will remain and is enforceable. The Super Bowl rules that apply to scheduled-service tours have never required a filing of this type. Now that regulation of this type of tour is being consolidated in a single rule, we see no justification for having a filing requirement for charter tours but not scheduled-service tours, nor do we see a need to impose a new paperwork burden on scheduled-service tour operators. This action is consistent with the Paperwork Reduction Act and with the Department's proposal in Docket 48341 (57 FR 42864) to eliminate unnecessary paperwork burdens on charters.

Congressman Andrews expressed concern that any rule that would prohibit marketing of a tour until tickets are in hand would not be practical, since tickets for many events are not available until a couple of weeks in advance but other arrangements (e.g., air and hotel) must be made before that. However, neither the existing nor proposed rules requires that tickets be in hand before marketing is allowed; the operator must simply have a written contract for the tickets.

The proposed rule also incorporates the so-called "booking rejection" and "contingent booking" procedures currently found in § 380.31(c) of the Super Bowl charter rule, and expands them to apply to all events and to all forms of air transportation. These provisions require operators to return unsolicited bookings for which they don't have event tickets unless a tour participant authorizes the operator in writing to retain the participant's payment while the operator attempts to obtain more event tickets. We are modifying this slightly to allow for situations in which participants agree to take the tour without an event ticket; the operator would be required to obtain the participant's written acknowledgment of this understanding.

One of the key provisions of the Super Bowl charter rule is the requirement for the operator to refund the total tour price to any participant who does not receive a promised game ticket, even if the participant uses all of the other tour features. The ANPRM tentatively proposed to incorporate this provision in the new rule, but also asked for comment on whether the rule should contain only the "booking rejection" and "contingent booking" procedures without the "money back guarantee." However, the comments solidly supported the "money back guarantee," and we have incorporated it in the proposed rule. We agree with the Football Bowl Association that strong consumer remedies will also have the effect of deterring the promotion of non-legitimate tour packages.

NACA commented that there should be an exception to the "money back guarantee" for situations of force majeure and acts of God, such as the

[2] The statutory term "overseas air transportation," which referred to domestic transportation to or from U.S. territories or possessions, was abolished in a recent recodification of transportation laws. Such transportation is now included in the definition of "interstate air transportation," and consequently would be covered by this proposed rule.

earthquake in San Francisco that caused postponement of the World Series. The NHL suggested that if the event is canceled or substantially altered, participants should be entitled only to a refund of the face value of the event, not the total tour price. It was never our intent to make the tour operator the guarantor of the event itself. The "money back guarantee" in the existing Super Bowl charter rule kicks in "if game tickets are not supplied." The rule we are proposing here would require refunds ". . . if promised admission to the [event] is not furnished by the tour operator . . ." These provisions are directed toward potential problems with ticket distribution, not with the event itself. If people who *have* tickets are able to attend the event and Special Event Tour participants are shut out because they don't have tickets, the "money back guarantee" applies. On the other hand, if nobody with a ticket can use it during the period of the tour because the event itself was canceled or postponed, the "money back guarantee" does not apply.

We wish to make it clear that we are talking only about problems with the event itself, not about any or all problems that the tour operator might view as beyond its control. Failure of a ticket broker to deliver tickets to the tour operator does not invalidate the "money back guarantee."

We agree with the NHL that if the event is canceled consumers should receive a refund for the portion of their tour price that applied to the event that they paid for but did not receive. However, mandating such a partial refund in a situation where the event itself did not take place and where there were no problems with ticket distribution is beyond the scope of this proceeding. This is a matter best dealt with in the context of contract law or other applicable existing law.

The ANPRM solicited comment on whether the rule should include procedures to protect the tour operator from having to refund the total tour price to participants who don't receive promised admission to an "event" like a welcoming cocktail party. Most commenters who addressed this issue were opposed to requiring a refund of the entire tour price in these circumstances. Some suggested that participants so affected simply be entitled to a refund of the value of that ancillary event. Two commenters urged that a tour operator's failure to deliver admission to ancillary events that are integral to the experience for which the tour was organized (e.g., the Tournament of Roses parade on a Rose Bowl tour) should entitle the participant to a refund of the total tour price.

In raising this issue in the ANPRM, the Department had intended to focus on the situation of a tour that would not normally be thought of as a Special Event Tour but which held out admission to an "event" as one of its features, e.g., a welcoming cocktail party on a 5-day package to the Bahamas. If the definition of "special event" had been broad, we were concerned that the rule might have the effect of requiring refunds of the entire price on such tours after failure to deliver a relatively minor and low-value component. The comments have shed light on another issue: multiple "events" on a true Special Event Tour.

We agree with the commenters that failure to deliver a relatively minor feature should not result in a refund of the total tour price. We also feel that this rule should be limited to tours that are organized around an event, not to events that occur in the normal course of the typical vacation tour. Accordingly, we have limited the scope of the proposed rule in two ways. First, there will be a definition of "Special Event Tour" in proposed § 381.5 which is broad yet specific; it will limit the applicability of the rule to tours to sporting, social, religious, educational, cultural, political or other event of a special nature and limited duration, which exist for reasons apart from the tour itself. Second, the "money back guarantee" in proposed § 381.11 will apply only to the primary event for which a Special Event Tour is organized.

Limiting the "money back guarantee" to the primary event on the tour will solve the problem of having this guarantee cover minor events on a true Special Event Tour. However, it will also have the effect of excluding some more significant events such as the Tournament of Roses parade. Nonetheless, we have tentatively decided to move in this direction. Identifying the primary event on a Special Event Tour will seldom be a matter of debate. However, identifying secondary events that are "integral to the experience" of the tour would be a far more subjective exercise, and in any event is beyond the scope of this proceeding as set forth in the ANPRM. Tour participants who do not receive promised admission to a secondary event may have a contractual right to a refund of the value of that event, and they can pursue that with the tour operator.

In the ANPRM, the Department solicited comment on whether the rule should ban last-minute or post-departure price increases, something which occurred on certain tours to the 1994 Rose Bowl. The great majority of the comments on this subject favored banning such increases. Some commenters said no price increase should be permitted unless the tour operator has reserved this right in writing and allows participants to cancel and receive a full refund in the event of a price increase.

We have decided to incorporate into the proposed rule the price increase provisions of the Department's Public Charter rule (14 CFR § 380.33). While it is not our intent in this proceeding to address all potential sources of consumer harm on Special Event Tours, the issue of price increases is directly related to the issue of ticket availability. Almost any event ticket is procurable if the price is right; if we did not regulate price increases in the Special Event Tour rule, tour operators would always be able to acquire event tickets at greatly inflated prices and then simply increase the price to the participant to cover it. Since a ticket has been offered in this situation, the "money back guarantee" would not come into play.

The proposed provisions on price increases, modeled on similar provisions in the charter rule, state that if a given participant is assessed price increases for the tour that in the aggregate are more than 10 percent above his or her original tour price, the participant shall have the right to cancel and receive a full refund (i.e., no cancellation penalties would apply). No price increases in any amount would be permitted less than 5 days before departure (as opposed to 10 days in the charter rule, recognizing the fact that Special Event Tours often have shorter lead times than the typical charter). This would eliminate both last-minute and post-departure price hikes. Finally, proposed § 381.11 specifies that the promised event ticket must be furnished at the price agreed to before departure or else the operator is subject to the "money back guarantee" just as if he had not provided the ticket at all.

The NHL commented that for events with short lead times such as the Stanley Cup playoffs, the rule should permit tours on which participants are required to agree to purchase event tickets at the yet-unknown face price plus a service fee, as long as the consumer is given prominent notice of this fact. As an initial matter, we would point out that a tour would not be covered under this rule at all if the event ticket were simply held out as an option rather than as a mandatory feature. However, where the participant must agree to buy the event ticket, such

tours are clearly Special Event Tours since the tour operator is representing that admission to the event is included in the tour (even if the price of that admission is not yet known and consequently any price that is advertised for that tour is not the full tour price).

However, nothing in the proposed rule would explicitly prohibit a transaction of this type. The operator would still have to have the requisite number of event tickets under contract before advertising or sales could begin; in other words, the variable must be price, not availability. Beyond that, the proposed rule requires that tour participants must receive promised event tickets "at the tour price agreed to before departure" or else the participant is entitled to a refund of the total tour price. If a participant agrees to a price consisting of a known value *p* plus an unknown value *x*, and the operator delivers the tour (including the event ticket) at that price, the operator has satisfied the requirements of the rule.

The ANPRM noted that some tours are promoted in conjunction with a special event, but do not include, and do not represent that they include, admission to the event. We solicited comment on whether the new rule should ban this practice, or whether it should specify a form of required disclosure. Most of the comments favored requiring disclosure of the fact that an event ticket is not included. However, we have tentatively decided not to include such a requirement in the proposed rule. Consumers solicited for these tours are able to determine from the advertising material that an event ticket is not held out as included; this is distinguishable from the situation of a tour participant who paid for an event ticket and then did not receive it. Should any particular tour deceptively imply that event tickets are included when in reality they are not, the Department has authority to take enforcement action against deceptive practices.

The ANPRM sought comment on whether the rule would be impractical for events where the participants are known only a week in advance, such as the NCAA Final Four. All of the parties that commented on this issue thought that this should not be a problem, and that the rule should apply. As noted in the Comments section above, several commenters pointed out that the Final Four sells out months in advance even though the participating teams are not determined until the week before. Also, as FBA noted, the contestants in the Super Bowl have been determined only the week before on several occasions, and that does not appear to have either harmed the marketability of Super Bowl tours or resulted in additional consumer problems.

While the period for comment on a Notice of Proposed Rulemaking is normally 60 days, the Department is requesting comment on this notice within 30 days after it has been published in the **Federal Register**. The rule proposed in this notice has changed little from the tentative proposal that the Department discussed in detail in the Advance Notice of Proposed Rulemaking in this proceeding (59 FR 4614, February 1, 1994). The Comments on the ANPRM were largely supportive of the proposal, and we do not anticipate controversy over this NPRM. The proposed rules are drawn from existing regulations on charters and Super Bowl tours, and the industry is familiar with the procedures in those rules. If the volume or nature of the NPRM comments should warrant, the Department can extend the comment period.

Regulatory Analyses and Notices

This NPRM is considered to be a non-significant rulemaking under DOT regulatory policies and procedures, 44 FR 11034. The proposal would have minimal economic impact, and accordingly no regulatory evaluation has been prepared. The NPRM was not subject to review by the Office of Information and Regulatory Affairs pursuant to Executive Order 12866.

The NPRM has been analyzed in accordance with the principles and criteria contained in Executive Order 12612, and it has been determined that it does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

I certify that the proposal, if adopted, would not have a significant economic impact on a substantial number of small entities.

For the reasons set forth in the preamble, the Department proposes the following:

1. To amend title 14, chapter II, subchapter D by adding a new part 381, to read as follows:

PART 381—SPECIAL EVENT TOURS

Sec.

381.1 Purpose.
381.3 Applicability.
381.5 Definition.
381.7 Advertising.
381.9 Sales.
381.11 Refunds.
381.13 Price increases.

Authority: 49 U.S.C. 40113(a) and 41712 (formerly sections 204(a) and 411 of the Federal Aviation Act of 1958, as amended).

§ 381.1 Purpose.

The purpose of this part is ensure that air travelers who have purchased tours to special events will receive the promised admission to the event. This rule expands the "Super Bowl rule" (formerly contained in part 380 and §§ 399.87 of this subchapter) to other events.

§ 381.3 Applicability.

This rule applies to Special Event Tours that are (a) in interstate or overseas air transportation, or (b) in foreign air transportation originating at a point in the United States. It applies to U.S. and foreign operators of Special Event Tours, whether they be air carriers or ticket agents. It applies to scheduled, charter, and other air transportation.

§ 381.5 Definition.

Special Event Tour means a tour that is organized for the purpose of attending a sporting, social, religious, educational, cultural, political or other event of a special nature and limited duration, which exists for reasons apart from the tour itself, and which is represented by the operator of the tour as including admission to that event. Examples of such events include, but are not limited to, college and professional sporting events, the Olympics, concerts, the Passion Play in Oberammergau, etc.

§ 381.7 Advertising.

No operator of a Special Event Tour or agent of such an operator shall conduct, or cause or allow to be conducted, any advertising, solicitation or other promotion for a Special Event Tour unless:

(a) The operator is in physical possession of enough tickets for admission to the event to provide such tickets for a substantial number of seats on the tour, or

(b) The operator has entered into a written contract with an organization that is the distributor of such tickets or an organization that receives such tickets directly from the distributor (e.g., a bowl committee; football conference, league or team; concert promoter or arena; etc.), the terms of which provide for that organization to furnish the operator enough admission tickets to provide such tickets for a substantial number of seats on the tour, or

(c) The operator has entered into a written contract with another person or organization that has a written contract or series of written contracts with the distributor of such tickets or with an organization that receives such tickets directly from the distributor, the terms of which provide for that organization to

furnish the operator enough admission tickets to provide such tickets for a substantial number of seats on the tour.

§ 381.9 Sales.

(a) Except as provided in § 381.9(b):

(1) No operator of a Special Event Tour shall accept money for a seat on a Special Event Tour, or authorize an agent to accept such money, unless the operator has physical possession of, or written contracts (in the manner described in § 381.7) for, a ticket for admission to the event for that individual. To the extent that the operator receives an unsolicited booking for which the operator does not have physical possession of or written contracts for a ticket for admission to the event, any payment accompanying that booking must be returned within 3 business days.

(2) Upon acceptance of the money for a sale, the operator must reserve one event ticket for that individual. An operator may not sell more seats on the tour than it has event tickets in hand or under contract. (An operator need not continue to reserve an event ticket for an individual who withdraws from the tour by providing notice to the operator or by being notified by the operator that the individuals participation has been canceled due to failure to remit a required installment payment.)

(b) An operator of a Special Event Tour may accept a booking and payment from an individual for whom the operator does not have an event ticket in hand or under contract if that individual agrees in writing that he or she understands that no event ticket has been reserved for him or her. This agreement shall specify whether the person has agreed to participate in the tour without an event ticket and/or the operator has agreed to attempt to acquire an event ticket for this person. If the two parties agree that the operator will attempt to acquire an event ticket, the agreement shall specify any penalties that will apply if the individual later cancels because an event ticket did not become available. If the operator notifies this person that an event ticket has become available, that person shall enjoy all the other protections of this rule from that time.

§ 381.11 Refunds.

If promised admission to the primary event for which a Special Event Tour was organized is not furnished by the tour operator, at the tour price agreed to before departure (including any increases that the participant has accepted pursuant to § 381.13(a)), the operator must provide each tour participant affected in this way a refund of the total tour price. This refund is to be provided within 14 calendar days after the scheduled return date of the tour.

§ 381.13 Price increases.

(a) Should the tour operator increase a participant's tour price by more than 10 percent (aggregate of all increases to that participant), that participant shall have the option of canceling his or her participation in the tour and receiving a full refund within 14 days after the cancellation.

(b) The tour operator shall not increase the tour price to any participant less than 5 days before departure.

2. To amend Title 14, Chapter II, Subchapter D, Part 380 as follows:

A. Remove the term *Super Bowl charter* from the definitions in § 380.2.

B. Amend § 380.18, "Charters for special events," to add a new paragraph (f):

* * * * *

(d) Where the charter operator represents that the charter includes admission to the special event, the charter shall comply with part 381 of this subchapter.

C. Remove § 380.18a and its reference in the table of contents at the beginning of the part.

D. Remove § 380.28(a)(4).

E. In § 380.31(b), end the sentence after the phrase "* * * on specific alternative flights they have requested." Remove the remainder of the original sentence, which begins "* * * or, in the case of Super Bowl charters * * *."

F. In § 380.31(c), remove the phrase "* * * or in the case of Super Bowl charters, if the operator does not have either possession of or written contracts for any game tickets, * * *."

G. In § 380.31(c), remove the phrase "* * * (3 days for Super Bowl charters) * * *" in the two locations where it appears.

H. In § 380.31(c), remove the phrase "* * * or in the case of Super Bowl charters, attempts to obtain more game tickets, * * *."

I. In § 380.32(s), remove the second sentence.

J. Remove § 380.33(a)(5).

3. To amend title 14, chapter II, subchapter D by removing and reserving § 399.87.

Issued this 6th day of October, 1994 at Washington, DC.

Patrick V. Murphy,

Acting Assistant Secretary for Policy and International Affairs.

[FR Doc. 94–25318 Filed 10–12–94; 8:45 am]

BILLING CODE 4910–62–U

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1307, 1309, 1310, 1313 and 1316

Implementation of the Domestic Chemical Diversion Control Act of 1993 (Pub. L. 103–200)

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Proposed rule.

SUMMARY: DEA is proposing these regulations to implement the Domestic Chemical Diversion Control Act of 1993, which became effective on April 16, 1994, in order to provide additional safeguards against the diversion of regulated chemicals.

DATES: Written comments or objections must be received on or before December 12, 1994.

ADDRESSES: Comments and objections should be submitted in quintuplicate to the Deputy Administrator, Drug Enforcement Administration, Washington, D.C. 20537, Attention: Federal Register Representative/CCR.

FOR FURTHER INFORMATION CONTACT: G. Thomas Gitchel, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, D.C. 20537, Telephone (202) 307–4025.

SUPPLEMENTARY INFORMATION:

I. Introduction

The Chemical Diversion and Trafficking Act of 1988, (PL 100–690) (CDTA) was passed by Congress to control the diversion of certain chemicals (hereinafter referred to as listed chemicals) that are necessary for the illicit manufacture of drugs such as heroin, cocaine, methamphetamine and LSD. The CDTA and its implementing regulations, as set forth in Title 21, Code of Federal Regulations (21 CFR), parts 1310 and 1313, established a system of recordkeeping and reporting requirements through which DEA and the chemical industry could identify persons seeking to divert listed chemicals for the manufacture of illicit drugs. The CDTA allows for the tracking and, where necessary, control of domestic and international transactions involving listed chemicals.

The CDTA has had strong success. The greatest impact has been in the international arena, with a significant reduction in exports of listed chemicals from the United States to countries that are known sources of cocaine. Domestically, the volume of chemicals available to clandestine laboratories was

reduced. However, these successes also highlighted several shortcomings in the CDTA, including:

1. The CDTA provided a mechanisms for DEA, with the cooperation of the chemical industry, to identify persons engaging in suspicious transactions and, as needed, take action against those persons. However, lacking evidence that an individual knowingly supplied chemicals for the illicit manufacture of drugs, DEA's options were limited.

2. Persons engaged in the illicit manufacture of methamphetamine and methcathinone were able to obtain supplies of the listed chemicals critical to the manufacture of such drugs through the purchase of drug products that were exempted from the provisions of the CDTA.

3. Illicit drug manufacturers in foreign countries began to purchase their supplies of listed chemicals from countries other than the United States, on occasion utilizing the services of United States based brokers and traders to facilitate the transactions.

To address these and other concerns, Congress passed legislation in late 1993 to amend the CDTA.

II. The Domestic Chemical Diversion Control Act of 1993 (Pub. L. 103–200)

The Domestic Chemical Diversion Control Act of 1993 (DCDCA) was signed into law on December 17, 1993, and became effective on April 16, 1994. The DCDCA is intended to close avenues used by illicit drug manufacturers to circumvent the CDTA. The main provisions of the DCDCA are as follows:

1. Precursor and essential chemicals have been redesignated as List I and List II chemicals respectively.

2. Any person who manufactures, distributes, imports or exports a List I chemical must obtain a registration from DEA. DEA is authorized to deny an application for registration or suspend or revoke a registration to manufacture, distribute, import or export a List I chemical, if it is established that such registration would not be in the public interest.

3. Transactions involving drug products marketed under the Food, Drug, and Cosmetic Act (FDCA) which contain ephedrine, either as the sole active medicinal ingredient or in combination with therapeutically insignificant quantities of another active medicinal ingredient, are now included in the definition of regulated transaction. Subjecting these products to the registration, recordkeeping and reporting requirements eliminates a virtually unrestricted source of ephedrine for illicit manufacturers of methamphetamine and methcathinone. The DCDCA also grants DEA the authority to remove the exemption for any other drug that contains a listed chemical if DEA determines that the drug is being diverted in order to obtain the listed chemical for use in the illicit manufacture of a controlled substance.

4. Brokers and traders based in the United States who arrange international transactions involving listed chemicals will be subject to the same reporting and recordkeeping requirements as exporters of listed chemicals, thus controlling a previously unmonitored source of chemicals for clandestine laboratories in foreign countries.

5. Manufacturers of listed chemicals are required to provide DEA with annual reports regarding the manufacture of such chemicals. The reports will provide DEA with information regarding the volume of listed chemicals available in the United States.

III. Implementation of the DCDCA

To implement the DCDCA, DEA is proposing the following regulatory changes and additions:

1. A new part 1309 of Title 21, Code of Federal Regulations is to be added, setting forth the specific requirements for registration, the application forms to be used, the application fees, exemptions from the registration requirement, security provisions, and administrative procedures regarding approval or denial of an application, revocation of registration, and administrative hearings. With respect to the requirement of registration in the proposed Section 1309.21, DEA has granted a temporary exemption from the registration requirement pending implementation of the registration program, as set forth in an Interim Rule published in the **Federal Register** on March 24, 1994 (59 FR 13881).

Under the CDTA, regulated persons consist of those firms engaged in the distribution, importation or exportation of chemicals. The DCDCA regulates drug products containing ephedrine which are distributed by retail distributors such as convenience stores, liquor stores, truck stops, gas stations, nutrition centers, etc. These retail outlets do not distribute any other listed chemicals and their activities consist solely of the sale of such products directly to walk-in customers. DEA has determined that retail distributors should be categorized separately in light of the limited scope and volume of their chemical activities.

Pursuant to 21 U.S.C. 822(d), the Administrator may waive the requirement of registration. The Administrator is proposing in § 1309.25 of these regulations to exempt persons registered with DEA to manufacture, distribute, dispense, import, or export a controlled substance from the chemical registration requirement for equivalent activities involving drug products that are regulated as List I chemicals pursuant to § 1310.01(f)(1)(iv). This includes such traditional sources for these products as pharmacies, hospitals, pharmaceutical manufacturers, distributors, etc. Further, the Administrator proposes in § 1309.27 to exempt from the registration requirement those persons who manufacture a List I chemical solely for internal use, with no subsequent distribution or exportation.

With respect to the exemptions from the registration requirement, DEA has determined that persons who manufacture List I chemicals solely for internal use, without any subsequent distribution or exportation of such chemicals, should not be required to obtain a registration, since there is a low risk of diversion from such persons.

It has also been determined that persons who are registered with DEA to manufacture, distribute, or dispense controlled substances shall not be required to obtain a separate registration to distribute drug products that are regulated as List I chemicals. Further, persons who are registered with DEA to import or export controlled substances shall not be required to obtain a separate registration to engage in the same activities with drug products which are regulated as List I chemicals. Persons registered to engage in activities with controlled substances are subjected to more comprehensive investigations by Federal and state authorities relating to their controlled substance registrations than is required for a chemical registration. The Administrator reserves the right in this proposal to cancel a person's exemption from the registration requirement, if continuation of the exemption would not be in the public interest.

2. Section 1310.01 is amended to revise the definitions of "regulated transaction" and "regulated person", and to add new definitions of "broker" and "trader", and "international transaction".

3. Chemical mixtures that met the definition of "chemical mixture" set forth in § 1310.01(g) prior to the effective date of the DCDCA shall remain exempted from the definition of regulated transaction until DEA has promulgated final regulations regarding the procedures by which manufacturers may request exemption of chemical mixtures.

4. Section 1310.02 is amended to remove three chemicals from List I: d-lysergic acid, n-ethylephedrine and n-ethylpseudoephedrine; and to add to List I: nitroethane and benzaldehyde, as established by the DCDCA. In addition, the DEA chemical codes assigned to the listed chemicals have been added.

5. Section 1310.03 is amended to implement the requirement that manufacturers of listed chemicals report certain data to DEA. This requirement will only apply to bulk manufacturers of listed chemicals.

6. Section 1310.04 is amended to reflect the additions and deletions of the List I chemicals and to set forth the proposed thresholds for the new chemicals. With respect to the newly added chemicals Nitroethane and Benzaldehyde, records and reports must be kept only for those transactions, including cumulative transactions within a calendar month, which equal or exceed the proposed thresholds.

7. Sections 1310.05 and 1310.06 are amended to include a reporting requirement with respect to drug products containing ephedrine that are regulated as List I chemicals and to set forth the required format for the chemical manufacturer reports. Drug products containing ephedrine are legitimately distributed solely for human consumption. Thus, the distribution of 375 dosage units (approximately a two-month supply at the current recommended therapeutic dose) or more of such drug products in a calendar month to a person who is not registered with DEA to distribute or export a List I chemical would be considered extraordinary and therefore would have to be reported.

8. Section 1310.08 is amended to add international transactions to the types of transactions regulated.

9. Sections 1310.10 through 1310.15 are added to set forth the procedures regarding removal of the exemption from recordkeeping and reporting requirements of drugs distributed under the Food, Drug, and Cosmetic Act, the exemption from recordkeeping and reporting requirements of chemical mixtures, and the identification of drugs which contain ephedrine in combination with therapeutically significant quantities of another medicinal ingredient.

10. Section 1313.02 is amended to revise the definitions for "regulated person" and "regulated transaction"; and definitions for "regular importer", "established record as an importer", "broker" and "trader", and "international transaction"; and to remove the definition of "regular supplier".

11. Sections 1313.12, 1313.15 and 1313.21 are amended to set forth criteria regarding the waiver of the 15 day notification requirement for certain imports and exports of listed chemicals and the removal of the waiver of the 15 day notification requirement for exports of listed chemicals to specified countries.

12. Sections 1313.32, 1313.33 and 1313.34 are added to establish the notification requirements for brokers and traders engaging in international transactions.

IV. Fees

Section 1309.11 proposes the application fee for registration and reregistration of manufacturers, distributors, importers and exporters of List I chemicals, as authorized by section 3(a) of the DCDCA. The proposed fee was established pursuant to the Office of Management and Budget (OMB) Circular A–25, as revised on July 15, 1993 (58 FR 38142), which sets forth Federal policy regarding user fees.

1. Circular A–25, Section 6 provides that "[A] user charge * * * will be assessed against each identifiable recipient for special benefits derived from Federal activities beyond those received by the general public." The section further requires that the user charge be sufficient to "* * * recover the full cost to the Federal Government for providing the special benefit." A special benefit is described as a Government service which "Enables the beneficiary to obtain more immediate or substantial gains or values (which may or may not be measurable in monetary terms) than those that accrue to the general public (e.g., receiving a patent, insurance, or guarantee provision, *or a license to carry on a specific activity or business* [emphasis added] or various kinds of public land use)".

Sections 822 and 957 of Title 21, United States Code, as amended by the DCDCA, require that any person who manufactures, distributes, imports or exports a List I chemical must obtain annually a registration in accordance with DEA rules and regulations. A registration to manufacture, distribute, import or export List I chemicals is a benefit under Circular A–25, in that it allows the registrant to engage in certain activities while a member of the general public may not. Therefore, the costs associated with DEA's issuance of a registration to manufacture, distribute, import or export a List I chemical; certain costs associated with advising registrants of their responsibilities; and maintenance of the integrity of the registration system must be recovered through assessment of a user fee.

2. Section 6(d) of Circular A–25 describes the requirements for determining the full cost of a service or benefit. "Full cost" is defined as all direct and indirect costs, including, but not limited to: direct and indirect personnel costs, including salaries, fringe benefits (such as life and health insurance and retirement) and travel; physical overhead, including material and supply costs such as forms, postage, equipment, rent and utilities; management and supervisory costs; and the costs of enforcement, collection, research, establishment of standards, and regulation. Section 6(d)(1)(e) provides that the cost figures shall be established utilizing "the best available records of the agency and new cost accounting systems need not be established solely for this purpose." The cost of the services provided by DEA were determined by use of proven and accepted budget estimating techniques as outlined in the DOJ budget guidelines and OMB Circular A–11.

Considerations for the Establishment of the Original Fee

DEA has identified two distinct categories of chemical registrants: retail distributors, such as convenience stores, gas stations, truck stops, liquor stores, etc., whose regulated activities consist of the direct sale to walk-in customers of drug products that are regulated as List I chemicals; and non-retailers, such as manufacturers which distribute, distributors, importers and exporters of List I chemicals.

Based upon contacts with the chemical industry and surveys of the industry over the past three years, DEA estimates that approximately 1,500 applications for registration will be received from non-retailers.

Based on the information gathered from various sources, including association data, surveys of ephedrine manufacturers and distributors, and correspondence received from ephedrine distributors, DEA estimates that there may have been as many as 100,000 retail distributors that, prior to the April 16, 1994 effective date of the DCDCA, sold drug products that are now subject to regulation. However, estimating the number of persons who will continue to engage in activities with the regulated drug products is speculative, due to a variety of factors. Some retailers who engaged in this previously unregulated activity may decide to no longer sell items for which registration is required by law. Also, the activities of retail distributors may be affected by state laws, such as those in Wisconsin, Florida and Missouri, which require that drug products containing

ephedrine as the sole medicinal ingredient may only be dispensed pursuant to prescription. Another consideration is the availability of alternative products that are not subject to the registration, recordkeeping and reporting requirements. DEA has learned that certain distributors of single-entity ephedrine products have already advised their retail customers to switch to such alternative products to avoid the registration and recordkeeping requirements. Therefore, for purposes of establishing the initial fee, DEA estimates that 10,000 applications will be submitted by retail distributors. The number of applications is important only when considering apportionment of indirect costs associated with initial registration. For the first year of the registration program, this amount will constitute $22.00 of the total fee. Thus, a larger or smaller number of applicants would not result in any significant increase or decrease in the registration fee.

During the implementation of the DCDCA, DEA will focus on processing applications, conducting pre-registration and follow-up investigations and the creation and dissemination of information regarding the registrant's responsibilities under the DCDCA. DEA expects that the majority of its chemical control resources will be required to handle the applications which will be submitted immediately following implementation of the regulations.

Once the pre-registration process for existing businesses has been handled, the primary focus of DEA's chemical control program will be investigations of violative firms and registration denial or revocation proceedings. Such enforcement activities protect the integrity of the registration system by ensuring that registrants continue to meet the requirements of the DCDCA. DEA's activities will include, but not be limited to, extensive investigation and collection of documentation regarding violative practices by registrants; attorney review and preparation by DEA's Office of Chief Counsel; staff and attorney time to prepare for proceedings to deny or revoke a registration; Administrative Law Judge and staff to conduct registration denial hearings; and DEA budget and controller staff time for budget planning, accounting and auditing of fees collected. The benefits of these activities accrue to the over-all registrant population and the costs for such activities must be averaged across the entire registrant population. However, as described earlier, the expected registrant population and the extent of these enforcement activities are speculative at this time. Therefore, the costs associated with these activities have not been included in this initial fee, since they are indirect costs that would have to be averaged across a presently unknown population of applicants.

After the registration process is completed and the registrant population and extent of activities necessary to protect the integrity of the system has been determined, DEA will revise its fee schedule to recover the full costs of its chemical control program, as required by Circular A–25. DEA will publish in the **Federal Register** its revised fee schedule and invite comment by interested parties.

In light of the above, the initial registration fee will be based upon the cost of processing the individual application, the associated investigation of the qualifications and suitability for registration, and the creation and dissemination of information regarding the responsibilities under the DCDCA. Reregistration fees under this proposal will include enforcement and compliance costs associated with maintenance of the integrity of the registration and control system. These fees will not include enforcement costs of reviews of records and reports of fully complaint registrants exclusively to identify leads to possible illicit drug laboratories.

The Initial Registration Investigation

The fundamental purpose of the pre-registration investigation is to determine the fitness and suitability of the applicant to engage in the activities for which registration is requested and to ensure that the applicant is familiar with its responsibilities to prevent the diversion of regulated products or chemicals. This will be accomplished through an on-site visit to the applicant (following receipt and processing of the application for registration by clerical personnel) by DEA Diversion Investigators. During this on-site visit, the applicant's responsibilities with respect to security, record-keeping and reporting will be discussed; the applicant's existing provisions for security, record-keeping and reporting, if any, will be reviewed, along with previous sales and customers; and the applicant will be provided with material, such as the Chemical Handlers Manual, regarding chemical trafficking and controls. In addition, the investigator will perform background checks on the applicant, owner and employees, and prepare the necessary reports summarizing the results of the registration review.

Retail distributors engage in a limited activity as regulated by the DCDCA. By contrast, non-retail chemical firms may deal in a range of List I chemicals, in bulk lots or, pursuant to orders received by mail, telephone, facsimile or other electronic means. Consequently, the average pre-registration investigation for a retail distributor will entail less DEA investigative time than for a non-retail chemical firm.

Method for Collection of Fees

For the initial registration fee, DEA has established separate costs for processing the application, and for conducting the pre-registrant investigation. Both costs will be incurred by the applicant prior to their initial registration under the DCDCA.

As noted above, DEA anticipates receiving 1500 applications from non-retail chemical firms and approximately 10,000 applications from retail distributors. DEA will place priority on the completion of the pre-registration investigations of non-retail chemical firms. All non-retail applications will be processed and reviewed within the first year of the effective date of this regulation. Therefore, the full fee (application and pre-registration investigation costs) must be submitted with the application.

Because of the demands for resources to conduct registration reviews of non-retail applications and for other chemical control activities, DEA will be unable to process and review all of the applications submitted by retail distributors within the first year following the effective date of the final rule. As a consequence, retail distributors will be subject to a split fee schedule for their initial registration. Each retail distributor will include with their application the established fee to cover the costs of processing the application.

Based on available resources, DEA will identify and notify approximately 1500–2000 of the retail applicants that they are scheduled for pre-registration review in the first year. Each applicant so identified will be required to pay the additional established cost for the registration investigation prior to commencement of the review. Based upon the volume of applications received, DEA may conduct additional retail registration investigations in the first year. In the second year, DEA will redirect resources spent conducting non-retail pre-registration investigations to the retail level. DEA anticipates an additional 6,000 to 8,000 pre-registrant investigations to be conducted in the second year. These retail distributors will similarly be notified of the investigation fee to be paid. They will *not* be required to submit another

application fee. However, if a retail distributor fails to submit the required investigation fee within 30 days after notification by DEA, that retail distributor's application will be withdrawn.

Reregistration Fees

Following the completion of the initial registration process, DEA will dedicate ongoing resources to insuring the controls of the DCDCA are being maintained, protecting the integrity of the system, and providing assistance, guidance, and interpretation of the chemical control requirements to the registrants. These costs, along with application processing costs will establish the basis for the annual reregistration fee. Since many of these costs will be averaged across the registrant population, it is only possible to establish a reregistration fee at this time based upon estimated populations. After the full second year of the regulations implementing the DCDCA, the fee schedule will be reviewed, as required by Circular A–25, and a new fee structure proposed for public comment, based upon the actual registrant population.

As stated above, DEA will complete the registration process for all non-retail applicants in the first year. Investigative resources devoted to these pre-registration investigations (approximately 12 workyears) will be directed towards completion of the pre-registration process of retail distributor applicants in the second year. At the non-retail level, DEA will dedicate eight workyears of investigator time to conduct follow-up investigations of approximately 75 non-retail firms. Each investigation will require a comprehensive review of each registrant's records, reporting systems and security provisions to ensure that the registrant is complying with the chemical control requirements, and chemicals are not being distributed to persons seeking to divert them. Investigators will conduct a comprehensive on-site review of the registrant's records; verification of transactions and purchasers, including record checks of and visits to purchasers; travel; and report preparation. This cost, plus the reregistration processing fee and the above listed indirect costs averaged over the estimated 1500 non-retail registrants will constitute the non-retail reregistration fee.

At the retail level, due to the large volume of firms and the general lack of experience in the required record-keeping and reporting requirements, DEA will conduct a greater number of follow-up investigations. However, in light of the anticipated smaller volumes of regulated transactions of such firms, each follow-up is scheduled for a smaller amount of on-site time. DEA anticipates that two Diversion Investigator workyears will be required to conduct follow-up investigations at the retail level. This cost, plus the reregistration processing fee and above listed indirect costs averaged over the estimated 2000 retail distributors registered in the first year will constitute the reregistration fee.

As DEA completes the second year of the chemical registration program, the bulk of the retail distributor new applications will have been processed, thus freeing the resources assigned to conduct the registration investigations. In the following years, there will be a greater number of registrants submitting applications for reregistration. DEA will dedicate proportionally greater resources to these registrants. As noted earlier, following the initial two years of the registration program, DEA will conduct a review of the fee structure and, as needed, publish a notice in the **Federal Register** regarding amendment of the fee schedule.

Registration Costs.

The costs associated with the registration process are as follows. DEA estimates that 1,500 non-retail applications and approximately 10,000 retail applications will be received. As previously stated, the personnel costs listed below include all direct and indirect costs, including salaries, fringe benefits (such as life and health insurance and retirement) and travel; physical overhead, including material and supply costs such as forms, postage, equipment, rent and utilities:

COSTS FOR PROCESSING AN APPLICATION AND ISSUING A RETAIL DISTRIBUTOR REGISTRATION

Cost for processing a retail distributor application		
Clerical Time [1]	.25 hours	$6.52
Material Costs: [2]		
Application Form		0.22
Postage		0.39
Chemical Handlers Manual		0.30
Total Application Processing Cost		7.43
Cost for registration review for a retail distributor applicant		
Direct Costs:		
Investigator Time [3]	5.5 hours	219.56
Clerical Time [4]	.25 hours	6.52
Material Costs:		
Registration Certificate		0.10
Postage		0.29
Total Direct Costs		226.47
Indirect Costs:		
Management/Supervisory Time [5]		5.58
Regulatory/Policy Development [6]		1.93
Applicant/Registrant Support [7]		14.49
Total Indirect Costs		22.00
Total Direct and Indirect Costs		248.47

Notes Regarding the Costs Associated With Issuance of a Retail Distributor Registration

[1] Clerical time includes the time required for preparing and mailing out application packages, time for processing applications received, including computer data entry, encoding the application form, filing, and transmitting a copy of the application to the appropriate DEA field office for the registration review process.

[2] The printing cost for application forms of the same format as will be used for chemical registration is $4,500 for 20,000 forms or 22.5 cents per form. The cost for the last printing of the Chemical Handlers Manual was $2,250 for 7,500 copies, or 30 cents per copy.

[3] The Investigator time to conduct the registration review consists of:

2 hours time at the applicant's place of business to review with the applicant the chemical registration and control regulations; review the applicant's existing recordkeeping, reporting and security systems; and discuss customer and trafficking patterns.

.75 hours to conduct the necessary background and record checks of the applicant, owner and employees.

.75 hours to prepare the reports regarding the results of the registration review.

[4] The clerical time spent during the registration review includes the time necessary to approve the registration, initiate issuance of the registration certificate, and file copies of the report and application.

[5] Management/Supervisory time is that time spent by management and supervisory personnel in the overall development and maintenance of the registration program, including establishment of program priorities and policy, resource allocation, and administrative direction. The following positions are involved:

Deputy Assistant Administrator and Deputy Director of the Office of Diversion Control—.05 work year each—$14,619.

Chief and Deputy Chief Chemical Operations Section—.1 work year each—$27,651.

Chief, Liaison and Policy Section—.1 work year—$11,853.

Chief, Policy Unit—.1 work year—$10,045.

Total—$64,168.

Because the Management/Supervisory costs are related to the general operation of the registration program, they must be averaged across the entire applicant population. For 11,500 applicants, the average cost would be $5.58.

[6] Regulatory and policy development time consists of .25 work year of a program analyst time for drafting new/amended regulations and FEDERAL REGISTER notices, issuance of policy statements and directives related to the registration program and responding to registrant queries regarding registration matters. This time is for general chemical registration program purposes and must be spread equally across the applicant population. The cost of that time, $22,202, divided by 11,500 applicants equals $1.93.

[7] Applicant/Registrant support time will consist of 2 work years of Diversion Investigator time, which will be dedicated to providing technical assistance, advice and informational materials to the industry to assist in complying with the registration, recordkeeping and reporting requirements. The total cost for 2 work years of Diversion Investigator time is $166,616, divided by 11,500 applicants equals $14.49.

COSTS FOR PROCESSING AN APPLICATION AND ISSUING A NON-RETAIL REGISTRATION

Direct Costs:		
Clerical Time[1]	.5 hour	$13.05
Material Costs:[2]		
Application Form		0.22
Postage		0.39
Chemical Handlers Manual		0.30
Registration Certificate		0.10
Postage		0.29
Investigator Time[3]	14 hours	558.88
Total Direct Costs		573.23
Indirect Costs		
Management/Supervisory Time[4]		5.58
Regulatory/Policy Development[5]		1.93
Applicant/Registrant Support[6]		14.49
Total Indirect Costs		22.00
Total Direct and Indirect Costs		595.23

Notes Regarding the Costs Associated With Issuance of a Non-Retail Registration

[1] Clerical time includes the time required for preparing and mailing out application packages, time for processing applications received, including computer data entry, encoding the application form, filing, and transmitting a copy of the application to the appropriate DEA field office for the registration review process. Following the registration review, time is required to approve the registration, initiate issuance of the registration certificate, and file copies of the report and application.

[2] The printing cost for application forms of the same format as will be used for chemical registration is $4,500 for 20,000 forms or 22.5 cents per form. The cost for the last printing of the Chemical Handlers Manual was $2,250 for 7,500 copies, or 30 cents per copy.

[3] The investigator time to conduct the registration review consists of:

10 hours, 5 hours time each for two investigators, at the applicants place of business to review with the applicant the chemical registration and control regulations; review the applicant's existing recordkeeping, reporting and security systems; and discuss customer and trafficking patterns.

2 hours for travel to and from the applicant's location.

1 hour to conduct the necessary background and record checks of the applicant, owner and employees.

1 hour to prepare the reports regarding the results of the registration review.

[4] Management/Supervisory time is that time spent by management and supervisory personnel in the overall development and maintenance of the registration program, including establishment of program priorities and policy, resource allocation, and administrative direction. The following positions are involved:

Deputy Assistant Administrator and Deputy Director of the Office of Diversion Control—.05 work year each—$14.619.

Chief and Deputy Chief Chemical Operations Section—.1 work year each—$27,651.

Chief, Liaison and Policy Section—.1 work year—$11,853.

Chief, Policy Unit—.1 work year—$10,045.

Total Costs—$64,168.

Because the Management/Supervisory costs are related to the general operation of the registration program, they must be averaged across the entire applicant population. For 11,500 applicants, the average cost would be $5.58.

[5] Regulatory and policy development time consists of .25 work year of a program analyst time for drafting new/amended regulations and Federal Register notices, issuance of policy statements and directives related to the registration program and responding to registrant queries regarding registration matters. This time is for general chemical registration program purposes and must be spread equally across the applicant population. The cost of that time, $22,202, divided by 11,500 applicants equals $1.93.

[6] Applicant/Registrant Support time will consist of 2 work years of Diversion Investigator time, which will be dedicated to providing technical assistance, advice and informational materials to the industry to assist in complying with the registration, recordkeeping and reporting requirements. The total cost for 2 work years of Diversion Investigator time is $166,616, divided by 11,500 applicants equals $14.49.

COSTS FOR PROCESSING A RETAIL REREGISTRATION APPLICATION

Direct Costs:		
Clerical Time[1]	.25 hours	$6.52
Material Costs:[2]		
Forms		.45
Postage		.68
Total Direct Costs		7.65
Indirect Costs:		
Management/Supervisory Time[3]		18.33
Regulatory/Policy Development[4]		6.34
Follow-up Investigation Time[5]		83.30
Total Indirect Costs		107.97
Total Direct and Indirect Costs		115.62

Notes Regarding the Costs Associated With a Retail Distributor Reregistration

[1] Clerical time includes the time required for preparing and mailing out application packages, time for processing applications received, including computer data entry, encoding the application form, filing, and preparing the fee for deposit.

[2] The forms cost covers both the reregistration application form and the registration certificate. Postage is for mailing the reregistration application and the registration certificate.

[3] Management/Supervisory time is that time spent by management and supervisory personnel in the overall development and maintenance of the registration program, including establishment of program priorities and policy, resource allocation, and administrative direction. The following positions are involved:

Deputy Assistant Administrator and Deputy Director of the Office of Diversion Control—.05 work year each—$14,619.
Chief and Deputy Chief Chemical Operations Section—.1 work year each—$27,651.
Chief, Liaison and Policy Section—.1 work year—$11,853.
Chief, Policy Unit—.1 work year—$10,045.
Total Costs—$64,168.

Because the Management/Supervisory costs are related to the general operation of the registration program, they must be averaged across the entire reregistration applicant populations. For the initial reregistration year, DEA anticipates receiving 3,500 retail and non-retail reregistration applications. The average cost per application would be $18.33.

[4] Regulatory and policy development time consists of .25 work year of a program analyst time for drafting new/amended regulations and Federal Register notices, issuance of policy statements and directives related to the registration program and responding to registrant queries regarding registration matters. This time is for general chemical registration program purposes and must be spread equally across the reregistration applicant population. The cost of that time, $22,202, divided by 3,500 applicants equals $6.34.

[5] DEA will conduct follow-up investigations of retail registrants to ensure that they are complying with the chemical control requirements. The investigations will consist of a comprehensive review of each registrant's records, reporting systems and security provisions. Each investigation will require on-site record reviews; transaction follow-ups, including purchaser verification and record checks; travel; and report preparation. Based on present estimates, DEA anticipates that all such investigations combined will require 2 work years of Diversion Investigator time. The total cost for 2 work years of Diversion Investigator time is $166,616, divided by 2,000 retail reregistration applicants equals $83.30.

COSTS FOR PROCESSING A NON-RETAIL REREGISTRATION APPLICATION

Direct Costs:		
Clerical Time[1]	.25 hours	$6.52
Material Costs[2]		
Forms		.45
Postage		.68
Total Direct Costs		7.65
Indirect Costs		
Management/Supervisory Time[3]		18.33
Regulatory/Policy Development[4]		6.34
Follow-up Investigation Time[5]		444.31
Total Indirect Costs		468.98
Total Direct and Indirect Costs		476.63

Notes Regarding the Costs Associated With a Non-Retail Registration

[1] Clerical time includes the time required for preparing and mailing out application packages, time for processing applications received, including computer data entry, encoding the application form, filing, and preparing the fee for deposit.

[2] The forms cost covers both the reregistration application form and the registration certificate. Postage is for mailing the reregistration application and the registration certificate.

[3] Management/Supervisory time is that time spent by management and supervisory personnel in the overall development and maintenance of the registration program including establishment of program priorities and policy, resource allocation, and administrative direction. The following positions are involved:

Deputy Assistant Administrator and Deputy Director of the Office of Diversion Control—.05 work year each—$14,619.
Chief and Deputy Chief Chemical Operations Section—.1 work year each—$27,651.
Chief, Liaison and Policy Section—.1 work year—$11,853
Chief, Policy Unit—.1 work year—$10,045.
Total Costs—$64,168.

Because the Management/Supervisory costs are related to the general operation of the registration program, they must be averaged across the entire reregistration applicant population. For the initial renewal year, DEA anticipates receiving 3,500 retail and non-retail reregistration applications. The average cost per applicant would be $18.33.

[4] Regulatory and policy development time consists of .25 work year of a program analyst time for drafting new/amended regulations and Federal Register notices, issuance of policy statements and directives related to the registration program and responding to registrant queries regarding registration matters. This time is for general chemical registration program purposes and must be spread equally across the reregistration applicant population. The cost of that time, $22,202, divided by 3,500 reregistration applicants, 3,500, equals $6.34.

[5] DEA will conduct follow-up investigations of approximately 75 non-retail registrants to ensure that registrants are complying with the chemical control requirements and that chemicals are not being distributed to persons which wishing to divert them. The investigations will consist of a comprehensive review of each registrant's records, reporting systems and security provisions. Each investigation will require comprehensive on-site review of the registrant's records; verification of transactions and purchasers, including record checks of and visits to purchasers; travel; and report preparation. Based on current estimates, DEA anticipates that all such follow-up investigations combined will require 8 workyears of Diversion Investigator time. The total cost for 8 workyears of Diversion Investigator time is $666,464, divided by 1,500 non-retail reregistration applicants equals $444.31.

V. Regulatory Flexibility and Small Business Impact

DEA has examined the impact of the DCDCA and this proposed rule in the light of Executive Order 12866 and the Regulatory Flexibility Act (PL 96–354). DEA has identified approximately 1,500 firms or persons, other than retail distributors, who handle List I chemicals. These non-retail chemical firms are generally known to DEA because most have been subject to the recordkeeping and reporting requirements of the CDTA for a number of years. Independent retail distributors, however, are primarily small business entities.

DEA has found that in addition to the traditional sources of distribution (i.e., hospitals, pharmacies, pharmaceutical manufacturers and distributors, etc.), independently owned and operated retail outlets such as convenience stores, liquor stores, truck stops, gas stations, and nutrition centers engage in sales to the public of the single entity drug products that are not regulated. Based on information received from various distributors, the potential affected population of retail outlets that handled the single entity drug products prior to the April 1994 effective date of the DCDCA, could be as high as 100,000. How many of these will choose to continue their sales of the single entity drug products and be subject to the registration, recordkeeping and reporting requirements is unclear, due to such factors as: (1) The introduction of state laws making drug products containing ephedrine prescription drugs, (2) the availability of alternative products which are not subject to the chemical regulations at this time, and (3) the intent of the DCDCA to eliminate sales by those persons who have been supplying clandestine laboratories.

The DCDCA requires that any person wishing to distribute, import, or export a List I chemical must obtain a registration from DEA for each location at which such activities are carried out, prior to conducting such activities. The statutory basis for this requirement is found in Sections 822 and 957 of the CSA, as amended by the DCDCA. Therefore, a separate registration must be issued for each location pursuant to the factors regarding the public interest set forth in Section 823(h) of the CSA. Prior to taking final action on an application, DEA will conduct an on-site investigation at each location for which registration is requested. The guidelines set forth in the Office of management and Budget (OMB) Circular A–25 require that the costs of the registration process must be recovered through application fees charged to the applicants. As noted in the fee analysis, the preregistration investigation for retail distributor applicants will be less intensive than the investigation for other chemical applicants, due to the limited scope and volume of a retail distributor's chemical activities. As a result, the retail distributor's fees will be significantly less than those for non-retail chemical applicants. In addition to the cost of registration and reregistration, it is estimated that applicants would be required to expend one-half hour per year completing the appropriate application for registration or reregistration.

In reviewing the implementation of the registration requirement, DEA gave consideration to the specific purposes for requiring registration and the nature of the problem of diversion of List I chemicals and made the following determinations:

1. DEA will not require that persons already registered to engage in certain activities with controlled substances obtain a separate registration for similar activities with FDA approved drug products which are regulated as List I chemicals. A principal reason for requiring registration is to allow DEA to determine the fitness of the applicant to conduct a specified activity and to allow DEA, if circumstances require, to prohibit the applicant from engaging in the activity. Persons required to register with DEA to engage in activities with controlled substances are subject to Federal and State investigations of their fitness which exceed the requirements for registration for List I chemical activities. Further, the proposed regulation allows that DEA may remove any person's exemption from the registration requirement and may, if appropriate, take action against the person's controlled substance registration, if the person engages in activities in violation of the chemical laws and regulations. Accordingly, DEA is proposing in § 1309.25 to exempt persons registered with DEA to handle controlled substances from the requirement to obtain a separate chemical registration for certain similar activities with the regulated FDA approved drug products. The exemption could potentially exempt over 70,000 hospitals, pharmacies, distributors, manufacturers, importers, and exporters of controlled substances who are currently registered with DEA to handle controlled substances.

2. DEA will not require persons who manufacture a List I chemical solely for internal use, with no subsequent distribution or exportation of the chemical, to obtain a chemical registration. DEA has found that such persons have not been a source of any significant diversion of List I chemicals; the primary sources of diversion are through the distribution channels which deal directly with the public. If these manufacturers should later become a source of diversion, the exemption can be removed. DEA is proposing in Section 1309.27 that such manufacturers be exempted from the chemical registration requirement.

DEA has also determined that the requirement that manufacturers of listed chemicals report to DEA annually can be limited without compromising the intent of the requirement. DEA's primary interest in this area is determining the total quantity of each individual listed chemical that is available on the domestic market. Therefore, DEA proposes that only bulk manufacturers of the chemicals need report to DEA; other manufacturers, such as repacker/relabelers, dosage form, etc., do not need to report.

DEA has also considered the impact on small businesses of the application of the existing chemical recordkeeping and reporting requirements to those drug products containing ephedrine which are now regulated as List I chemicals. The recordkeeping and reporting provisions of the CDTA, as set forth in section 830 of the CSA and parts 1310 and 1313 of title 21 of the Code of Federal Regulations, have been in place since 1989 and form the backbone of DEA's chemical control program. The requirements were developed jointly with the chemical industry to provide the necessary information to track chemical transfers while minimizing the recordkeeping and reporting burden on the chemical industry. A retail distributor must keep records that

reflect the name and address of the purchaser, the date of the transaction, the type of chemical and amount being transferred, and the form of identification provided by the purchaser. The requirement to make reports is limited to those transactions that are unusual or suspicious and to thefts or losses of listed chemicals. It is estimated that creating and storing a record will require an average of one minute per record. These recordkeeping procedures are accepted practice in the conduct of legitimate chemical commerce in the years they have been in effect.

DEA is obligated to implement the mandate of Congress as set out in the DCDCA. The DCDCA states that persons who wish to manufacture, distribute, import or export List I chemicals must register with DEA. Further, the DCDCA makes drug products containing ephedrine as the sole medicinal ingredient subject to such registration, as well as to the existing chemical recordkeeping and reporting requirements. Consideration was given to exempting retail distributors from the registration, recordkeeping and reporting requirements. However, such an action would negate the purpose of the DCDCA by leaving a significant portion of the sales of regulated ephedrine products unregulated. Controlling the diversion of these products requires monitoring and recordkeeping by all portions of the industry. DEA has proposed steps to lessen the impact on retail distributors of the DCDCA's requirements, while simultaneously carrying out the chemical control mandate of the DCDCA.

In addition to these proposed regulations to implement the DCDCA, DEA has published two other notices that should be given consideration by parties concerned with the DCDCA. The first, published on March 17, 1994 (59 FR 12562), proposes removal of the established threshold for ephedrine to reduce the diversion of ephedrine to clandestine laboratories for the illicit manufacture of methamphetamine and methcathinone. The second, published on March 24, 1994 (59 FR 13881), establishes a temporary exemption from the registration requirements for persons who manufacture, distribute, import or export List I chemicals.

This notice proposes two new information collections: The DEA 510 and 510a application forms for registration and reregistration, and the reports required from certain manufacturers of listed chemicals. DEA is submitting a request to the Office of Management and Budget for review and approval of these new collections pursuant to the provisions of the Paperwork Reduction Act of 1980, 44 U.S.C. et seq.

This regulation has been drafted and reviewed in accordance with Executive Order 12866, section 1(b), Principals of Regulation. The DEA has determined that this rule is a significant regulatory action under Executive Order 12866, section 3(f), Regulatory Planning and Review, and accordingly this rule has been reviewed by the Office of Management and Budget.

This action has been analyzed in accordance with the principles and criteria in Executive Order 12612, and it has been determined that the proposed rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

List of Subjects

21 CFR Part 1307

Drug traffic control.

21 CFR Part 1309

Administrative practice and procedure, Drug traffic control, List I and List II chemicals, Security measures.

21 CFR Part 1310

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

21 CFR Part 1313

Drug traffic control, Exports, Imports, List I and List II chemicals, Transshipment and in-transit shipments.

21 CFR Part 1316

Administrative practice and procedure, Drug traffic control, Research, Seizures and forfeitures.

I. For the reasons set out above, it is proposed that 21 CFR part 1307 be amended as follows:

PART 1307—[AMENDED]

1. The authority citation for part 1307 continues to read as follows:

Authority: 21 U.S.C. 821, 822(d), 871(b), unless otherwise noted.

2. Section 1307.03 is proposed to be amended by revising the introductory language to read as follows:

§ 1307.03 Exceptions to regulations.

Any person may apply for an exception to the application of any provision of parts 1301–1313, or 1316 of this chapter by filing a written request stating the reasons for such exception. Requests shall be filed with the Administrator, Drug Enforcement Administration, Department of Justice, Washington, DC 20537. The Administrator may grant an exception in his discretion, but in no case shall he be required to grant an exception to any person which is not otherwise required by law or the regulations cited in this section.

II. 21 CFR part 1309 is proposed to be added to read as follows:

PART 1309—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, IMPORTERS AND EXPORTERS OF LIST I CHEMICALS

General Information

Sec.
1309.01 Scope of part 1309.
1309.02 Definitions.
1309.03 Information; special instructions.

Fees for Registration and Reregistration

1309.11 Fee Amounts.
1309.12 Time and Method of Payment; refund.

Requirements for Registration

1309.21 Persons required to register.
1309.22 Separate registration for independent activities.
1309.23 Separate registration for separate locations.
1309.24 Exemption of agents and employees.
1309.25 Exemption of certain controlled substance registrants.
1309.26 Exemption of law enforcement officials.
1309.27 Exemption of certain manufacturers.

Applications for Registration

1309.31 Time for application for registration; expiration date.
1309.32 Application forms; contents, signature.
1309.33 Filing of application; joint filings.
1309.34 Acceptance for filing; defective applications.
1309.35 Additional information.
1309.36 Amendments to and withdrawals of applications.

Action on Applications for Registration: Revocation or Suspension of Registration

1309.41 Administrative review generally.
1309.42 Certificate of registration; denial of registration.
1309.43 Suspension or revocation of registration.
1309.44 Suspension of registration pending final order.
1309.45 Extension of registration pending final order.
1309.46 Order to show cause.

Hearings

1309.51 Hearings generally.
1309.52 Purpose of hearing.
1309.53 Waiver or modification of rules.
1309.54 Request for hearing or appearance; waiver.
1309.55 Burden of proof.
1309.56 Time and place of hearing.

1309.57 Final order.

Modification, Transfer and Termination of Registration

1309.61 Modification in registration.
1309.62 Termination of registration.
1309.63 Transfer of registration.

Security Requirements

1309.71 General security requirements.
1309.72 Felony conviction; employer responsibilities.
1309.73 Employee responsibility to report diversion.

Authority: 21 U.S.C. 821, 822, 823, 824, 830, 871(b), 875, 877, 958.

General Information

§ 1309.01 Scope of part 1309.

Procedures governing the registration of manufacturers, distributors, importers and exporters of List I chemicals pursuant to sections 102, 302, 303, 1007 and 1008 of the Act (21 U.S.C. 802, 822, 823, 957 and 958) are set forth generally by those sections and specifically by the sections of this part.

§ 1309.02 Definitions.

(a) The Term *Act* means the Controlled Substances Act (84 Stat. 1242; 21 U.S.C. 801) and/or the Controlled Substances Import and Export Act (84 Stat. 1285; 21 U.S.C. 951).

(b) The term *hearing* means any hearing held pursuant to the part for the granting, denial, revocation, or suspension of a registration pursuant to sections 303 and 304 of the Act (21 U.S.C. 823–824).

(c) The term *person* includes any individual, corporation, government or governmental subdivision or agency, business trust, partnership, association, or other legal entity.

(d) The terms *register* and *registration* refer only to registration required and permitted by sections 302 and 1007 of the Act (21 U.S.C. 822 and 957).

(f) The term *registrant* means any person who is registered pursuant to either section 303 or section 1008 of the Act (21 U.S.C. 823 and 958).

(g) The term *retail distributor* means a distributor whose List I chemical activities are restricted to the sale of drug products that are regulated as List I chemicals pursuant to § 1310.01(f)(1)(iv), directly to walk-in customers for personal use.

Any term not defined in this section shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or in §§ 1310.01 and 1313.02 of this chapter.

§ 1309.03 Information; special instructions.

Information regarding procedures under these rules and instructions supplementing these rules will be furnished upon request by writing to the Drug Enforcement Administration, Chemical Operations Section, Office of Diversion Control, Washington, DC 20537.

Fees for Registration and Reregistration

§ 1309.11 Fee amounts.

(a) For each initial registration to manufacture for distribution, distribute, import, or export the applicant shall pay a fee of $595 for an annual registration.

(b) For each reregistration to manufacture for distribution, distribute, import, or export, the registrant shall pay a fee of $477 for an annual registration.

(c) For each initial registration to conduct business as a retail distributor the applicant shall pay an application processing fee of $7 and an investigation fee of $248, for an annual registration.

(d) For each reregistration to conduct business as a retail distributor the registrant shall pay a fee of $116.

§ 1309.12 Time and method of payment; refund.

(a) For each application for registration or reregistration to manufacture for distribution, distribute, import, or export the applicant shall pay the fee when the application for registration or reregistration is submitted for filing.

(b) For retail distributor initial applications, the applicant shall pay the application processing fee when the application for registration is submitted for filing. The investigation fee shall be paid within 30 days after DEA notifies the applicant that the preregistration investigation has been scheduled.

(c) For retail distributor reregistration applications, the registrant shall pay the fee when the application for reregistration is submitted for filing.

(d) Payments should be made in the form of a personal, certified, or cashier's check or money order made payable to "Drug Enforcement Administration." Payments made in the form of stamps, foreign currency, or third party endorsed checks will not be accepted. These application fees are not refundable.

Requirements for Registration

§ 1309.21 Persons required to register.

(a) Every person who distributes, imports, or exports any List I chemical, other than those List I chemicals contained in a product exempted under § 1310.01(f)(1)(iv) of this chapter, or who proposes to engage in the distribution, importation, or exportation of any List I chemical, shall obtain annually a registration specific to the List I chemicals to be handled, unless exempted by law or pursuant to §§ 1309.24–1309.27. Only persons actually engaged in such activities are required to obtain a registration; related or affiliated persons who are not engaged in such activities are not required to be registered. (For example, a stockholder or parent corporation of a corporation distributing List I chemicals is not required to obtain a registration.)

(b) Every person who distributes or exports a List I chemical they have manufactured, other than a List I chemical contained in a product exempted under § 1310.01(f)(1)(iv) of this chapter, or proposes to distribute or export a List I chemical they have manufactured, shall obtain annually a registration specific to the List I chemicals to be handled, unless exempted by law or pursuant to §§ 1309.24–1309.27.

§ 1309.22 Separate registration for independent activities.

(a) The following groups of activities are deemed to be independent of each other:

(1) Retail distributing of List I chemicals;

(2) Non-Retail distributing of List I chemicals;

(3) Importing List I chemicals; and

(4) Exporting List I chemicals.

(b) Every person who engages in more than one group of independent activities shall obtain a separate registration for each group of activities, unless otherwise exempted by the Act or §§ 1309.24–1309.26, except that a person registered to import any List I chemical shall be authorized to distribute that List I chemical, but no other chemical that the person is not registered to import.

§ 1309.23 Separate registration for separate locations.

(a) A separate registration is required for each principal place of business at one general physical location where List I chemicals are distributed, imported, or exported by a person.

(b) The following locations shall be deemed to be places not subject to the registration requirement:

(1) A warehouse where List I chemicals are stored by or on behalf of a registered person, unless such chemicals are distributed directly from such warehouse to locations other than the registered location from which the chemicals were originally delivered; and

(2) An office used by agents of a registrant where sales of List I chemicals are solicited, made, or supervised but

which neither contains such chemicals (other than chemicals for display purposes) nor serves as a distribution point for filling sales orders.

§ 1309.24 Exemption of agents and employees.

The requirement of registration is waived for any agent or employee of a person who is registered to engage in any group of independent activities, if such agent or employee is acting in the usual course of his or her business or employment.

§ 1309.25 Exemption of certain controlled substance registrants.

(a) The requirement of registration is waived for any person who distributes a product containing a List I chemical that is regulated pursuant to § 1310.01(f)(1)(iv) of this chapter, if that person is registered with the Administration to manufacture, distribute or dispense a controlled substance.

(b) The requirement of registration is waived for any person who imports or exports a product containing a List I chemical that is regulated pursuant to § 1310.01(f)(1)(iv) of this chapter, if that person is registered with the Administration to engage in the same activity with a controlled substance.

(c) The Administrator may, upon finding that continuation of the waiver would not be in the public interest, suspend or revoke a person's waiver pursuant to the procedures set forth in §§ 1309.43–1309.46 and 1309.51–1309.57. In considering the revocation or suspension of a person's waiver, the Administrator shall also consider whether action to revoke or suspend the person's controlled substance registration pursuant to 21 U.S.C. 824 is warranted.

(d) Any person exempted from the registration requirement under this section shall comply with the security requirements set forth in § 1309.71–1309.73 and the recordkeeping and reporting requirements set forth under parts 1310 and 1313 of this chapter.

§ 1309.26 Exemption of law enforcement officials.

(a) The requirement of registration is waived for the following persons in the circumstances described in this section:

(1) Any officer or employee of the Administration, any officer of the U.S. Customs Service, any officer or employee of the United States Food and Drug Administration, any other Federal officer who is lawfully engaged in the enforcement of any Federal law relating to listed chemicals, controlled substances, drugs or customs, and is duly authorized to possess and distribute List I chemicals in the course of official duties; and

(2) Any officer or employee of any State, or any political subdivision or agency thereof, who is engaged in the enforcement of any State or local law relating to listed chemicals and controlled substances and is duly authorized to possess and distribute List I chemicals in the course of his official duties.

(b) Any official exempted by this section may, when acting in the course of official duties, possess any List I chemical and distribute any such chemical to any other official who is also exempted by this section and acting in the course of official duties.

§ 1309.27 Exemption of certain manufacturers.

The requirement of registration is waived for any manufacturer of a List I chemical, if that chemical is produced solely for internal consumption by the manufacturer and there is no subsequent distribution or exportation of the List I chemical.

Application for Registration

§ 1309.31 Time for application for registration; expiration date.

(a) Any person who is required to be registered and who is not so registered may apply for registration at any time. No person required to be registered shall engage in any activity for which registration is required until the application for registration is approved and a Certificate of Registration is issued by the Administrator to such person.

(b) Any person who is registered may apply to be reregistered not more than 60 days before the expiration date of his registration.

(c) At the time a person is first registered, that person shall be assigned to one of twelve groups, which shall correspond to the months of the year. The expiration date of the registrations of all registrants within any group will be the last day of the month designated for that group. In assigning any of the above persons to a group, the Administration may select a group the expiration date of which is less than one year from the date such business activity was registered. If the person is assigned to a group which has an expiration date less than eleven months from the date of which the person is registered, the registration shall not expire until one year from that expiration date; in all other cases, the registration shall expire on the expiration date following the date on which the person is registered.

§ 1309.32 Application forms; contents; signature.

(a) Any person who is required to be registered pursuant to § 1309.21 and is not so registered, shall apply on DEA Form 510.

(b) Any person who is registered pursuant to § 1309.21, shall apply for reregistration on DEA Form 510a.

(c) DEA Form 510 may be obtained at any divisional office of the Administration or by writing to the Registration Unit, Drug Enforcement Administration, Department of Justice, Post Office Box 28083, Central Station, Washington, DC 20005. DEA Form 510a will be mailed to each List I chemical registrant approximately 60 days before the expiration date of his or her registration; if any registered person does not receive such forms within 45 days before the expiration date of the registration, notice must be promptly given of such fact and DEA Form 510a must be requested by writing to the Registration Unit of the Administration at the foregoing address.

(d) Each application for registration shall include the Administration Chemical Code Number, as set forth in § 1310.02 of this chapter, for each List I chemical to be distributed, imported, or exported.

(e) Registration shall not entitle a person to engage in any activity with any List I chemical not specified in his or her application.

(f) Each application shall include all information called for in the form, unless the item is not applicable, in which case this fact shall be indicated.

(g) Each application, attachment, or other document filed as part of an application, shall be signed by the applicant, if an individual; by a partner of the applicant, if a partnership; or by an officer of the applicant, if a corporation, corporate division, association, trust or other entity. An applicant may authorize one or more individuals, who would not otherwise be authorized to do so, to sign applications for the applicant by filing with the application or other document a power or attorney for each such individual. The power of attorney shall be signed by a person whose is authorized to sign applications under this paragraph and shall contain the signature of the individual being authorized to sign the application or other document. The power of attorney shall be valid until revoked by the applicant.

§ 1309.33 Filing of application; joint filings.

(a) All applications for registration shall be submitted for filing to the Registration Unit, Drug Enforcement

Administration, Chemical Registration/ODC, Post Office Box 2427, Arlington, Virginia 22202–2427. The appropriate registration fee and any required attachments must accompany the application.

(b) Any person required to obtain more than one registration may submit all applications in one package. Each application must be complete and must not refer to any accompanying application for required information.

§ 1309.34 Acceptance for filing; defective applications.

(a) Applications submitted for filing are dated upon receipt. If found to be complete, the application will be accepted for filing. Applications failing to comply with the requirements of this part will not generally be accepted for filing. In the case of minor defects as to completeness, the Administrator may accept the application for filing with a request to the applicant for additional information. A defective application will be returned to the applicant within 10 days of receipt with a statement of the reason for not accepting the application for filing. A defective application may be corrected and resubmitted for filing at any time.

(b) Accepting an application for filing does not preclude any subsequent request for additional information pursuant to § 1309.35 and has no bearing on whether the application will be granted.

§ 1309.35 Additional information.

The Administrator may require an applicant to submit such documents or written statements of fact relevant to the application as he deems necessary to determine whether the application should be granted. The failure of the applicant to provide such documents or statements within a reasonable time after being requested to do so shall be deemed to be a waiver by the applicant of an opportunity to present such documents or facts for consideration by the Administrator in granting or denying the application.

§ 1309.36 Amendments to and withdrawals of applications.

(a) An application may be amended or withdrawn without permission of the Administrator at any time before the date on which the applicant receives an order to show cause pursuant to § 1309.46. An application may be amended or withdrawn with permission of the Administrator at any time where good cause is shown by the applicant or where the amendment or withdrawal is in the public interest.

(b) After an application has been accepted for filing, the request by the applicant that it be returned or the failure of the applicant to respond to official correspondence regarding the application, including a request that the applicant submit the required fee, when sent by registered or certified mail, return receipt requested, shall be deemed to be a withdrawal of the application.

Action of Applications for Registration: Revocation or Suspension of Registration

§ 1309.41 Administrative review generally.

The Administrator may inspect, or cause to be inspected, the establishment of an applicant or registrant, pursuant to subpart A of part 1316 of this chapter. The Administrator shall review the application for registration and other information gathered by the Administrator regarding an applicant in order to determine whether the applicable standards of section 303 of the Act (21 U.S.C. 823) have been met by the applicant.

§ 1309.42 Certificate of registration; denial of registration.

(a) The Administrator shall issue a Certificate of Registration (DEA Form 511) to an applicant if the issuance of registration or reregistration is required under the applicable provisions of section 303 of the Act (21 U.S.C. 823). In the event that the issuance of registration or reregistration is not required, the Administrator shall deny the application. Before denying any application, the Administrator shall issue an order to show cause pursuant to § 1309.46 and, if requested by the applicant, shall hold a hearing on the application pursuant to § 1309.51.

(b) The Certificate of Registration (DEA Form 511) shall contain the name, address, and registration number of the registrant, the activity authorized by the registration, the amount of fee paid, and the expiration date of the registration. The registrant shall maintain the certificate of registration at the registered location in a readily retrievable manner and shall permit inspection of the certificate by any official, agent or employee of the Administration or of any Federal, State, or local agency engaged in enforcement of laws relating to List I chemicals or controlled substances.

§ 1309.43 Suspension or revocation of registration.

(a) The Administrator may suspend any registration pursuant to section 304(a) of the Act (21 U.S.C. 824(a)) for any period of time he determines.

(b) The Administrator may revoke any registration pursuant to section 304(a) of the Act (21 U.S.C. 824(a)).

(c) Before revoking or suspending any registration, the Administrator shall issue an order to show cause pursuant to § 1309.46 and, if requested by the registrant, shall hold a hearing pursuant to § 1309.51. Notwithstanding the requirements of this Section, however, the Administrator may suspend any registration pending a final order pursuant to § 1309.44.

(d) Upon service of the order of the Administrator suspending or revoking registration, the registrant shall immediately deliver his or her Certificate of Registration to the nearest office of the Administration.

§ 1309.44 Suspension of registration pending final order.

(a) The Administrator may suspend any registration simultaneously with or at any time subsequent to the service upon the registrant of an order to show cause why such registration should not be revoked or suspended, in any case where he finds that there is an imminent danger to the public health or safety. If the Administrator so suspends, he shall serve with the order to show cause pursuant to § 1309.46 an order of immediate suspension that shall contain a statement of his findings regarding the danger to public health or safety.

(b) Upon service of the order of immediate suspension, the registrant shall promptly return his Certificate of Registration to the nearest office of the Administration.

(c) Any suspension shall continue in effect until the conclusion of all proceedings upon the revocation or suspension, including any judicial review thereof, unless sooner withdrawn by the Administrator or dissolved by a court of competent jurisdiction. Any registrant whose registration is suspended under this section may request a hearing on the revocation or suspension of his registration at a time earlier than specified in the order to show cause pursuant to § 1309.46, which request shall be granted by the Administrator, who shall fix a date for such hearing as early as reasonably possible.

§ 1309.45 Extension of registration pending final order.

In the event that an applicant for reregistration (who is doing business under a registration previously granted and not revoked or suspended) has applied for reregistration at least 45 days before the date on which the existing registration is due to expire, and the Administrator has issued no

order on the application on the date on which the existing registration is due to expire, the existing registration of the applicant shall automatically be extended and continue in effect until the date on which the Administrator so issues his order. The Administrator may extend any other existing registration under the circumstances contemplated in this section even though the registrant failed to apply for reregistration at least 45 days before expiration of the existing registration, with or without request by the registrant, if the Administrator finds that such extension is not inconsistent with the public health and safety.

§ 1309.46 Order to show cause.

(a) If, upon examination of the application for registration from any applicant and other information gathered by the Administration regarding the applicant, the Administrator is unable to make the determinations required by the applicable provisions of section 303 of the Act (21 U.S.C. 823) to register the applicant, the Administrator shall serve upon the applicant an order to show cause why the application for registration should not be denied.

(b) If, upon information gathered by the Administration regarding any registrant, the Administrator determines that the registration of such registrant is subject to suspension or revocation pursuant to section 304 of the Act (21 U.S.C. 824), the Administrator shall serve upon the registrant an order to show cause why the registration should not be revoked or suspended.

(c) The order to show cause shall call upon the applicant or registrant to appear before the Administrator at a time and place stated in the order, which shall not be less than 30 days after the date of receipt of the order. The order to show cause shall also contain a statement of the legal basis for such hearing and for the denial, revocation, or suspension of registration and a summary of the matters of fact and law asserted.

(d) Upon receipt of an order to show cause, the applicant or registrant must, if he desires a hearing, file a request for a hearing pursuant to § 1309.54. If a hearing is requested, the Administrator shall hold a hearing at the time and place stated in the order, pursuant to § 1309.51.

(e) When authorized by the Administrator, any agent of the Administration may serve the order to show cause.

Hearings

§ 1309.51 Hearings generally.

(a) In any case where the Administrator shall hold a hearing on any registration or application therefor, the procedures for such hearing shall be governed generally by the adjudication procedures set forth in the Administrative Procedure Act (5 U.S.C. 551–559) and specifically by sections 303 and 304 of the Act (21 U.S.C. 823–824), by §§ 1309.51–1309.57, and by the procedure for administrative hearings under the Act set forth in §§ 1316.41–1316.67 of this chapter.

(b) Any hearing under this part shall be independent of, and not in lieu of, criminal prosecutions or other proceedings under the Act or any other law of the United States.

§ 1309.52 Purpose of hearing.

If requested by a person entitled to a hearing, the Administrator shall hold a hearing for the purpose of receiving factual evidence regarding the issues involved in the denial, revocation, or suspension of any registration. Extensive argument should not be offered into evidence but rather presented in opening or closing statements of counsel or in memoranda or proposed findings of fact and conclusions of law.

§ 1309.53 Waiver or modification of rules.

The Administrator or the presiding officer (with respect to matters pending before him) may modify or waive any rule in this party by notice in advance of the hearing, if he determines that no party in the hearing will be unduly prejudiced and the ends of justice will thereby be served. Such notice of modification or waiver shall be made a part of the record of the hearing.

§ 1309.54 Request for hearing or appearance; waiver.

(a) Any person entitled to a hearing pursuant to §§ 1309.42 and 1309.43 and desiring a hearing shall, within 30 days after the date of receipt of the order to show cause, file with the Administrator a written request for a hearing in the form prescribed in Section 1316.47 of this chapter.

(b) Any person entitled to a hearing pursuant to §§ 1309.42 and 1309.43, within the period permitted for filing a request for a hearing, file with the Administrator a waiver of an opportunity for a hearing, together with a written statement regarding his position on the matters of fact and law involved in such hearing. Such statement, if admissible, shall be made a part of the record and shall be considered in light of the lack of opportunity for cross-examination in determining the weight to be attached to matters of fact asserted therein.

(c) If any person entitled to a hearing pursuant to §§ 1309.42 and 1309.43 fails to file a request for a hearing, or if he so files and fails to appear at the hearing, he shall be deemed to have waived his opportunity for the hearing, unless he shows good cause for such failure.

(d) If any person entitled to a hearing waives or is deemed to waive his or her opportunity for the hearing, the Administrator may cancel the hearing, if scheduled, and issue his final order pursuant to § 1309.57 without a hearing.

§ 1309.55 Burden of proof.

(a) At any hearing for the denial of a registration, the Administrator shall have the burden of proving that the requirements for such registration pursuant to section 303 of the Act (21 U.S.C. 823) are not satisfied.

(b) At any hearing for the revocation or suspension of a registration, the Administrator shall have the burden of proving that the requirements for such revocation or suspension pursuant to section 304(a) of the Act (21 U.S.C. 824(a)) are satisfied.

§ 1309.56 Time and place of hearing.

The hearing will commence at the place and time designated in the order to show cause or notice of hearing published in the **Federal Register** (unless expedited pursuant to § 1309.44(c)) but thereafter it may be moved to a different place and may be continued from day to day or recessed to a later day without notice other than announcement thereof by the presiding officer at the hearing.

§ 1309.57 Final order.

As soon as practicable after the presiding officer has certified the record to the Administrator, the Administrator shall cause to be published in the **Federal Register** his final order in the proceeding, which shall set forth the final rule and the findings of fact and conclusions of law upon which the rule is based. This order shall specify the date on which it shall take effect, which date shall not be less than 30 days from the date of publication in the **Federal Register** unless the Administrator finds that the public interest in the matter necessitates an earlier effective date, in which case the Administrator shall specify in the order his findings as to the conditions which led him to conclude that an earlier effective date was required.

Modification, Transfer and Termination of Registration

§ 1309.61 Modification in registration.

Any registrant may apply to modify his or her registration to authorize the handling of additional List I chemicals or to change his or her name or address, by submitting a letter of request to the Drug Enforcement Administration, Chemical Registration/ODC, Post Office Box 2427, Arlington, Virginia 22202–2427. The letter shall contain the registrant's name, address, and registration number as printed on the certificate of registration, and the List I chemicals to be added to his registration or the new name or address and shall be signed in accordance with § 1309.32(g). No fee shall be required to be paid for the modification. The request for modification shall be handled in the same manner as an application for registration. If the modification in registration is approved, the Administrator shall issue a new certificate of registration (DEA Form 511) to the registrant, who shall maintain it with the old certificate of registration until expiration.

§ 1309.62 Termination of registration.

The registration of any person shall terminate if and when such person dies, ceases legal existence, or discontinues business or professional practice. Any registrant who ceases legal existence or discontinues business or professional practice shall notify the Administrator promptly of such fact.

§ 1309.63 Transfer of registration.

No registration or any authority conferred thereby shall be assigned or otherwise transferred except upon such conditions as the Administrator may specifically designate and then only pursuant to his written consent.

Security Requirements

§ 1309.71 General security requirements.

(a) All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of List I chemicals. Specific attention shall be paid to storage of and controlling access to List I chemicals as follows:

(1) Chemicals shall be stored in containers sealed in such a manner as to indicate any attempts at tampering with the container. Where chemicals cannot be stored in sealed containers, access to the chemicals should be controlled through physical means or through human or electronic monitoring.

(2) In retail settings open to the public where drugs containing List I chemicals that are regulated pursuant to § 1310.01(f)(1)(iv) of this chapter are distributed, such drugs will be stocked behind a counter where only employees have access.

(b) In evaluating the effectiveness of security controls and procedures, the Administrator shall consider the following factors:

(1) The type, form, and quantity of List I chemicals handled;

(2) The location of the premises and the relationship such location bears on the security needs;

(3) The type of building construction comprising the facility and the general characteristics of the building or buildings;

(4) The availability of electric detection and alarm systems;

(5) The extent of unsupervised public access to the facility;

(6) The adequacy of supervision over employees having access to List I chemicals;

(7) The procedures for handling business guests, visitors, maintenance personnel, and nonemployee service personnel in areas where List I chemicals are processed or stored;

(8) The adequacy of the registrant's or applicant's systems for monitoring the receipt, distribution, and disposition of List I chemicals in its operations.

(c) Any registrant or applicant desiring to determine whether a proposed system of security controls and procedures is adequate may submit materials and plans regarding the proposed security controls and procedures either to the Special Agent in Charge in the region in which the security controls and procedures will be used, or to the Chemical Operations Section Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537.

§ 1309.72 Felony conviction; employer responsibilities.

(a) The registrant shall not employ, as an agent or employee who has access to List I chemicals, any person who has been convicted of a felony offense relating to controlled substances or listed chemicals or who has, at any time, had an application for registration with the DEA denied, had a DEA registration revoked or has surrendered a DEA registration for cause. For purposes of this subsection, the term "for cause" means a surrender in lieu of, or as a consequence of, any Federal or State administrative, civil or criminal action resulting from an investigation of the individual's handling of controlled substances or listed chemicals.

(b) It is the position of DEA that employees who possess, sell, use or divert listed chemicals or controlled substances will subject themselves not only to State or Federal prosecution for any illicit activity, but shall also immediately become the subject of independent action regarding their continued employment. The employer will assess the seriousness of the employee's violation, the position of responsibility held by the employee, past record of employment, etc., in determining whether to suspend, transfer, terminate or take other action against the employee.

§ 1309.73 Employee responsibility to report diversion.

Reports of listed chemical diversion by fellow employees is not only a necessary part of an overall employee security program but also serves the public interest at large. It is, therefore, the position of DEA that an employee who has knowledge of diversion from his employer by a fellow employee has an obligation to report such information to a responsible security official of the employer. The employer shall treat such information as confidential and shall take all reasonable steps to protect the confidentiality of the information and the identity of the employee furnishing information. A failure to report information of chemical diversion will be considered in determining the feasibility of continuing to allow an employee to work in an area with access to chemicals. The employer shall inform all employees concerning this policy.

III. 21 CFR Part 1310 is proposed to be amended as follows:

PART 1310—[AMENDED]

1. The authority citation for part 1310 continues to read as follows:

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

2. Section 1310.01 is proposed to be amended by revising paragraphs (b), (c), (d), (e), (f) and (g), redesignating paragraph (k) as paragraph (m) and adding new paragraphs (k) and (l) as follows:

§ 1310.01 Definitions.

* * * * * *

(b) The term *listed chemical* means any List I chemical or List II chemical.

(c) The term *List I chemical* means a chemical specifically designated by the Administrator in Section 1310.02(a) that, in addition to legitimate uses, is used in manufacturing a controlled substance in violation of the Act and is important to the manufacture of a controlled substance.

(d) The term *List II chemical* means a chemical, other than a List I chemical, specifically designated by the

Administrator in § 1310.02(b) that, in addition to legitimate uses, is used in manufacturing a controlled substance in violation of the Act.

(e) The term *regulated person* means any individual, corporation, partnership, association, or other legal entity who manufactures, distributes, imports, or exports a listed chemical, a tableting machine, or an encapsulating machine, or who acts as a broker or trader for an international transaction involving a listed chemical, tableting machine, or encapsulating machine.

(f) The term *regulated transaction* means:

(1) A distribution, receipt, sale, or importation, or exportation of a listed chemical, or an international transaction involving shipment of a listed chemical, or if the Administrator establishes a threshold amount for a specific listed chemical, a threshold amount as determined by the Administrator, which includes a cumulative threshold amount for multiple transactions, of a listed chemical, except that such term does not include:

(i) A domestic lawful distribution in the usual course of business between agents or employees of a single regulated person; in this context, agents or employees means individuals under the direct management and control of the regulated person;

(ii) A delivery of a listed chemical to or by a common or contract carrier for carriage in the lawful and usual course of the business of the common or contract carrier, or to or by a warehouseman for storage in the lawful and usual course of the business of the warehouseman, except that if the carriage or storage is in connection with the distribution, importation, or exportation of a listed chemical to a third person, this paragraph does not relieve a distributor, importer, or exporter from compliance with this part or parts 1309 and 1313 of this chapter;

(iii) Any category of transaction or any category of transaction for a specific listed chemical or chemicals specified by regulation of the Administrator as excluded from this definition as unnecessary for enforcement of the Act;

(iv) Any transaction in a listed chemical that is contained in a drug that may be marketed or distributed lawfully in the United States under the Federal Food, Drug, and Cosmetic Act unless—

(A) The drug contain ephedrine or its salts, optical isomers, or salts of optical isomers as the only active medicinal ingredient or contains ephedrine or its salts, optical isomers or salts of optical isomers and therapeutically insignificant quantities of another active medicinal ingredient. For purposes of this paragraph, the term "therapeutically insignificant quantities" shall apply if the product formulation (i.e., the qualitative and quantitative composition of active ingredients within the product) is not listed in any of the following compendiums:

(*1*) *American Pharmaceutical Association (APhA) Handbook of Nonprescription Drugs;*

(*2*) *Drug Facts and Comparisons* (published by Wolters Kluwer Company); or

(*3*) *USP DI* (published by authority of the United States Pharmacopeial Convention, Inc.);

(*4*) Or the product is not listed in § 1310.15 as an exempt drug product. For drug products having formulations not found in the above compendiums, the Administrator shall determine, pursuant to a written request as specified in § 1310.14, whether the active medicinal ingredients are present in quantities considered therapeutically significant for purposes of this paragraph.

(B) The Administrator has determined that the drug or group of drugs is being diverted to obtain the listed chemical for use in the illicit production of a controlled substance; and

(C) The quantity of ephedrine or other listed chemical contained in the drug included in the transaction or multiple transaction equals or exceeds the threshold established for that chemical by the Administrator; or

(v) Any transaction in a chemical mixture listed in § 1310.13.

(g) The term *chemical mixture* means a combination of two or more chemical substances, at least one of which is not a listed chemical, except that such term does not include any combination of a listed chemical with another chemical that is present solely as an impurity or which has been created to evade the requirements of the act.

* * * * *

(k) The terms *broker* and *trader* mean any individual, corporation, corporate division, partnership, association, or other legal entity which assists in arranging an international transaction in a listed chemical by—

(1) Negotiating contracts;

(2) Serving as an agent or intermediary; or

(3) Bringing together a buyer and seller, a buyer and transporter, or a seller and transporter.

(l) The term *international transaction* means a transaction involving the shipment of a listed chemical across an international border (other than a United States border) in which a broker or trader located in the United States participates.

* * * * *

3. Section 1310.02 is proposed to be amended by revising paragraphs (a) and (b) to read as follows:

§ 1310.02 Substances covered.

The following chemicals have been specifically designated by the Administrator of the Drug Enforcement Administration as the listed chemicals subject to the provisions of this part and parts 1309 and 1313 of this chapter. Each chemical has been assigned the DEA Chemical Code Number set forth opposite it.

(a) List I chemicals:

(1) Anthranilic acid, its esters, and its salts	8530
(2) Benzyl cyanide	8570
(3) Ephedrine, its salts, optical isomers, and salts of optical isomers	8113
(4) Ergonovine and its salts	8675
(5) Ergotamine and its salts	8676
(6) N-Acetylanthranilic acid, its esters, and its salts	8522
(7) Norpseudoephedrine, its salts, optical isomers, and salts of optical isomers	8317
(8) Phenylacetic acid, its esters, and its salts	8791
(9) Phenylpropanolamine, its salts, optical isomers, and salts of optical isomers	1225
(10) Piperidine and its salts	2704
(11) Pseudoephedrine, its salts, optical isomers, and salts of optical isomers	8112
(12) 3,4-Methylenedioxyphenyl-2-propanone	8502
(13) Methylamine and its salts	8520
(14) Ethylamine and its salts	8678
(15) Propionic anhydride	8328
(16) Insosafrole (Isosafrole)	8704
(17) Safrole	8323
(18) Piperonal	8750
(19) N-Methylephedrine, its salts, optical isomers, and salts of optical isomers (N-Methylephedrine)	8115
(20) N-Methylpseudoephedrine, its salts, optical isomers, and salts of optical isomers	8119
(21) Hydriotic acid (Hydriodic Acid)	6695
(22) Benzaldehyde	8256
(23) Nitroethane	6724

(b) List II Chemicals:

(1) Acetic anhydride	8519
(2) Acetone	6532
(3) Benzyl chloride	8568
(4) Ethyl ether	6584
(5) Potassium permanganate	6579
(6) 2-Butanone (or Methyl Ethyl Ketone or MEK)	6714
(7) Toluene	6594
(8) Hydrochloric acid	6545
(9) Sulfuric acid	6552

* * * * *

4. Section 1310.03 is proposed to be amended by redesignating the

introductory text as paragraph (a) and adding a new paragraph (b) as follows:

§ 1310.03 Persons required to keep records and file reports.

(a) * * *

(b) Each regulated person who manufactures a listed chemical shall file reports regarding such manufacture as specified by § 1310.05. However, a manufacturer of a drug product that is exempted under § 1310.01(f)(1)(iv) shall not be required to file reports regarding such manufacture.

5. Section 1310.04 is proposed to be amended by revising paragraphs (a), (b), and (f)(1), introductory text, removing paragraphs (f)(1)(xv), (f)(1)(xxi), and (f)(1)(xxiii); redesignating paragraphs (f)(1) (xvi) through (xx) as (f)(1) (xv) through (xix), paragraph (f)(1) (xxii) as (f)(1) (xx) and paragraph (f)(1) (xxiv) as (f)(1) (xxi); and adding new paragraphs (f)(1) (xxii) and (xxiii), revising (f)(2), introductory test and (f)(2)(iv) to read as follows:

§ 1310.04 Maintenance of records.

(a) Every record required to be kept subject to Section 1310.03 for a List I chemical, a tableting machine, or an encapsulating machine shall be kept by the regulated person for four years after the date of the transaction.

(b) Every record required to be kept subject to Section 1310.03 for List II chemical shall be kept by the regulated person for two years after the date of the transaction.

* * * * *

(f) * * *

(1) List I Chemicals:

Chemical	Threshold by base weight
(i) * * *	
(xxii) Benzaldehyde	4 kilograms.
(xxiii) Nitroethane	2.5 kilograms.

(2) List II Chemicals:

(i) * * *

(iv) Exports, transshipments and international transactions to Designated Countries set forth in Section 1310.08(b).

* * * * *

6. Section 1310.05 is proposed to be amended by redesignating paragraphs (a)(2) through (a)(4) as paragraphs (a)(3) through (a)(5), adding a new paragraph (a)(2), revising paragraph (b), and adding a new paragraph (d) to read as follows:

§ 1310.05 Reports.

(a) * * *

(2) Any regulated transaction with a person not registered with DEA who is obtaining within a calendar month and quantity of 375 dosage units or more of a drug product containing ephedrine, which is regulated pursuant to § 1310.01(f)(1)(iv). The requirement to make such reports is waived if a pharmacist employed by the regulated person consults with the purchaser regarding the appropriate uses and dosing of the product for legitimate medical purposes and includes documentation of the consultation in the record of the transaction.

* * * * *

(b) Each report submitted pursuant to paragraphs (a)(1), (a)(3), (a)(4), and (a)(5) of this section shall, whenever possible, be made orally to the DEA Divisional Office for the area in which the regulated person making the report is located at the earliest practicable opportunity after the regulated person becomes aware of the circumstances involved and as much in advance of the conclusion of the transaction as possible. Written reports of transactions listed in paragraphs (a)(1), (a)(4) and (a)(5) of this section will subsequently be filed as set forth in § 1310.06 within 15 days after the regulated person becomes aware of the circumstances of the event. Written reports of transactions listed in paragraph (a)(2) of this section shall be submitted to the DEA Divisional Office for the area in which the regulated person making the report is located within 5 days following the end of the calendar month in which the transaction took place. A transaction may not be completed with a person who description or identifying characteristic has previously been furnished to the regulated person by the Administration unless the transaction is approved by the Administration.

* * * * *

(d) Each regulated bulk manufacturer of a listed chemical shall submit manufacturing, inventory, transaction and use data on an annual basis as set forth in § 1310.06 (h). For purposes of this paragraph only, the term bulk manufacturer means a person who produces a listed chemical by means of chemical synthesis or by extraction from other substances. The term bulk manufacturer does not include persons whose sole activity consists of the repackaging or relabeling of listed chemical products or the manufacture of drug products containing listed chemicals. This data shall be submitted annually to the Drug and Chemical Evaluation Section, Drug Enforcement Administration (DEA), Washington DC 20537, on or before the 31st day of January of the year immediately following the period for which submitted. This reporting requirement does not apply to drug products which are exempted under 21 U.S.c. 802 (39)(A)(iv) except as set forth in § 1310.06 (h)(5). Each report shall be submitted on company letterhead and signed by an appropriate, responsible official.

7. Section 1310.06 is amended by revising paragraphs (a), introducing text, (a)(1), (c), and (d) and by adding a new paragraph (h) to read as follows:

§ 1310.06 Content of records and reports.

(a) Each record required by § 1310.03 shall include the following:

(1) The name, address, and, if required, DEA registration number of each party to the regulated transaction.

* * * * *

(c) Each report required by § 1310.05(a) shall include the information as specified by § 1310.06(a) and, where obtainable, the registration number of the other party, if such party is registered. A report submitted pursuant to § 1310.059a)(1) or (a)(4) must also include a description of the circumstances leading the regulated person to make the report, such as the reason that the method of payment was uncommon or the loss unusual. If the report is for a loss or disappearance under § 1310.05(a)(4), the circumstances of such loss must be provided (in-transit, theft from premise, etc.)

(d) A suggested format for the reports is provided below:

Supplier:
Registration Number _____
Name _____
Business Address _____
City _____
State _____
Zip _____
Business Phone _____
Purchaser:
Registration Number _____
Name _____
Business Address _____
City _____
State _____
Zip _____
Business Phone _____
Identification _____
Shipping Address (If different than purchaser Address):
Street _____
City _____
State _____
Zip _____
Date of Shipment _____
Name of Listed Chemical(s) _____
Quantity and Form of Packaging _____
Description of Machine:
Make _____
Model _____
Serial # _____
Method of Transfer _____
If Loss or Disappearance:
Date of Loss _____
Type of Loss _____
Description of Circumstances _____

* * * * *

(h) Each annual report required by § 1310.05 (d) shall provide the following information for each listed chemical manufactured:

(1) The name and address of the listed chemical manufacturer and person to contact for information.

(2) The name and total quantity of the listed chemical manufactured during the preceding calendar year.

(3) The year end inventory of the listed chemical as of the close of business on the 31st day of December of the preceding calendar year.

(4) The total quantity of listed chemical used for internal consumption during the preceding calender year and a written description of this use.

(5) The quantity of listed chemical manufactured which has been converted to a product exempted under § § 1310.01(f)(1)(iv) or 1310.01(f)(1)(v) and a written description of the exempt products produced.

(6) The total annual quantity of the listed chemical distributed during the preceding calendar year. This data shall include an itemization of foreign versus domestic distribution.

(7) If applicable, the total annual quantity of the listed chemical purchased during the preceding calendar year.

(8) Data shall identify the specific isomer, salt or ester when applicable but quantitative data shall be reported as annydrous base or acid in kilograms.

8. Section 1310.07 is proposed to be amended by revising paragraphs (a) and (b) to read as follows:

§ 1310.07 Proof of identity.

(a) Each regulated person who engages in a regulated transaction must identify the other party to the transaction. For domestic transaction, this shall be accomplished by having the other party present documents which would verify the identity, or registration status if a registrant, of the other party to the regulated person at the time the order is placed. For export transactions, this shall be accomplished by good faith inquiry through reasonably available research documents or publicly available information which would indicate the existence of the foreign customer. No proof of identity is required for foreign suppliers.

(b) The regulated person must verify the existence and apparent validity of a business entity ordering a listed chemical, tableting machine or encapsulating machine. For domestic transactions, this may be accomplished by such methods as checking the telephone directory, the local credit bureau, the local Chamber of Commerce or the local Better Business Bureau, or, it the business entity is a registrant, by verification of the registration. For export transactions, a good faith inquiry to verify the existence and apparent validity of a foreign business entity may be accomplished by such methods as verifying the business telephone listing through international telephone information, the firm's listing in international or foreign national chemical directories or other commerce directories of trade publications, confirmation through foreign subsidiaries of the U.S. regulated person, verification through the country of destination's embassy Commercial Attache, or official documents provided by the purchaser which confirm the existence and apparent validity of the business entity.

* * * * *

9. Section 1310.08 is proposed to be amended by revising paragraph (b) to read as follows:

§ 1310.08 Excluded transactions.

* * * * *

(b) Exports, transshipments, and international transactions of hydrochloric and sulfuric acids, except for exports, transshipments and international transactions to the following countries.

* * * * *

10. Section 1310.10, 1310.11, 1310.12, 1310.13, 1310.14 and 1310.15 are proposed to be added to read as follows:

§ 1310.10 Removal of the exemption of drugs distributed under the Food, Drug and Cosmetic Act.

(a) The Administrator may remove from exemption under § 1310.01(f)(1)(iv) any drug or group of drugs that the Administrator finds is being diverted to obtain a listed chemical for use in the illicit production of a controlled substance. In removing a drug or group of drugs from the exemption the Administrator shall consider:

(1) The scope, duration, and significance of the diversion;

(2) Whether the drug or group of drugs is formulated in such a way that it cannot be easily used in the illicit production of a controlled substance; and

(3) Whether the listed chemical can be readily recovered from the drug or group of drugs.

(b) Upon determining that a drug or group of drugs should be removed from the exemption under paragraph (a) of this section, the Administrator shall issue and publish in the **Federal Register** his proposal to remove the drug or group of drugs from exemption, which shall include a reference to the legal authority under which the proposal is based. The Administrator shall permit any interested person to file written comments on or objections to the proposal. After considering any comments or objections filed, the Administrator shall publish in the **Federal Register** his final order.

(c) The Administrator shall limit the removal of a drug or group of drugs from exemption under paragraph (a) of this section to the most identifiable type of the drug or group of drugs for which evidence of diversion exists unless there is evidence, based on the pattern of diversion and other relevant factors, that the diversion will not be limited to that particular drug or group of drugs.

(d) Any manufacturer seeking reinstatement of a particular drug product that has been removed from an exemption under paragraph (a) of this section, may apply to the Administrator for reinstatement of the exemption for that particular drug product on the grounds that the particular drug product is manufactured and distributed in a manner that prevents diversion. In determining whether the exemption should be reinstated the Administrator shall consider:

(1) The package sizes manner of packaging of the drug product;

(2) The manner of distribution and advertising of the drug product;

(3) Evidence of diversion of the drug product;

(4) Any actions taken by the manufacturer to prevent diversion of the drug product; and

(5) Such other factors as are relevant to and consistent with the public health and safety, including the factors described in paragraph (a) of this section as applied to the drug product.

(e) Within a reasonable period of time after receipt of the application for reinstatement of the exemption, The Administrator shall notify the applicant of his acceptance or non-acceptance of his application, and if not accepted, the reason therefor. If the application is accepted for filing, the Administrator shall issue and publish in the **Federal Register** his order on the reinstatement of the exemption for the particular drug product, which shall include a reference to the legal authority under which the order is based. This order shall specify the date on which it shall take effect. The Administrator shall permit any interested person to file written comments on or objections to the order. If any such comments raise significant issues regarding any finding of fact or conclusion of law upon which the order is based, the Administrator shall immediately suspend the effectiveness

of the order until he may reconsider the application in light of the comments and objections filed. Thereafter, the Administrator shall reinstate, revoke, or amend his original order as he determines appropriate.

(f) Unless the Administrator has evidence that the drug product is being diverted, as determined by applying the factors set forth in paragraph (a) of this section, and the Administrator so notifies the applicant, transactions involving a specific drug product will not be considered regulated transactions during the following periods:

(1) While a bonafide application for reinstatement of exemption under paragraph (d) of this section for the specific drug product is pending resolution, provided that the application for reinstatement is filed not later than 60 days after the publication of the final order removing the exemption; and

(2) For a period of 60 days following the Administrator's denial of an application for reinstatement.

(g) An order published by the Administrator in the **Federal Register** pursuant to paragraph (e) of this section to reinstate an exemption may be modified or revoked with respect to a particular drug product upon a finding that:

(1) Applying the factors set forth in paragraph (a) to the particular drug product, the drug product is being diverted; or

(2) There is a significant change in the data that led to the issuance of the final rule.

§ 1310.11 Reinstatement of exemption for drug products distributed under the Food, Drug and Cosmetic Act.

(a) The Administrator has reinstated the exemption for the drug products listed in paragraph (e) of this section from application of sections 302, 303, 310, 1007, and 1008 of the Act (21 U.S.C. 822–823, 830, and 957–958 to the extent described in paragraphs (b), (c), and (d) of this section.

(b) Records and reports: All regulated persons who manufacture an exempted drug product must keep complete and accurate records and file all reports required under §§ 1310.05 and 1310.06 on all listed chemicals used in manufacturing the exempt drug product. Transactions involving reinstated exempt drug products contained in paragraph (e) of this section are not regulated transactions and thus records and reports are not required to be kept for listed chemicals once they become part of the reinstated exempt drug product.

(c) No reinstated exemption granted pursuant to 1310.10 affects the criminal liability for illegal possession or distribution of listed chemicals contained in the exempt drug product.

(d) Changes in exempt drug product compositions: Any change in the quantitative or qualitative composition, trade name or other designation of an exempt drug product listed in paragraph (e) of this section requires a new application for reinstatement of the exemption.

(e) The following drug products, in the form and quantity listed in the application submitted (indicated as the "date") are designated as reinstated exempt drug products for the purposes set forth in this section:

EXEMPT DRUG PRODUCTS

Supplier	Product name	Form	Date
[Reserved]			

§ 1310.12 Exemption of chemical mixtures; application.

(a) The Administrator may, by publication of a Final Rule in the **Federal Register**, exempt from the application of all or any part of the Act, a chemical mixture consisting of two or more chemical substances, at least one of which is not a List I or List II chemical, if:

(1) The mixture is formulated in such a way that it cannot be easily used in the illicit production of a controlled substance; and

(2) The listed chemical or chemicals contained in the chemical mixture cannot be readily recovered.

(b) Any person seeking an exemption for a chemical mixture from the application of all or any part of the Act, pursuant to paragraph (a) of this section, may apply to the Administrator, Drug Enforcement Administration, Department of Justice, Washington, DC 20537.

(c) An application for exemption under this section shall contain the following information:

(1) The name, address, and registration number, if any, of the applicant;

(2) The date of the application;

(3) The name, address, and registration number, if any, of the manufacturer or importer of the chemical mixture, if not the applicant;

(4) The exact trade name(s) of the applicant's chemical mixture and, if the applicant formulates or manufactures the chemical mixture for other entities, the exact trade names of the chemical mixtures and the names of the entities for which the chemical mixtures were prepared;

(5) The complete qualitative and quantitative composition of the chemical mixture (including all listed and non-listed chemicals) and its intended use;

(6) The chemical and physical properties of the mixture and how they differ from the properties of the listed chemical or chemicals;

(7) A statement which the applicant believes is justification for granting an exemption for the chemical mixture. The statement must explain how the chemical mixture meets the exemption criteria set forth in paragraph (a) of this section.

(8) The identification of any information on the application which is considered by the applicant to be a trade secret or confidential and entitled to protection under U.S. laws restricting the public disclosure of such information.

(d) The Administrator may require the applicant to submit such additional documents or written statements of fact relevant to the application which he deems necessary for determining if the application should be granted.

(e) Within a reasonable period of time after the receipt of a completed application for an exemption under this section, the Administrator shall notify the applicant of acceptance or non-acceptance of the application. If the application is not accepted, an explanation will be provided. The Administrator is not required to accept an application if any information required pursuant to paragraph (c) of this section or requested pursuant to paragraph (d) of this section is lacking or not readily understood. The applicant may, however, amend the application to meet the requirements of paragraphs (c) and (d) of this section. If the application is accepted for filing, the Administrator shall issue and publish in the **Federal Register** an order on the application, which shall include a reference to the legal authority under which the order is based. This order shall specify the date on which it shall take effect. The Administrator shall permit any interested person to file written comments on or objections to the order. If any comments or objections raise significant issues regarding any findings of fact or law upon which the order is based, the Administrator shall immediately suspend the effectiveness of the order until he may reconsider the application in light of the comments and objections filed. Thereafter, the Administrator shall reinstate, revoke, or amend the original order as deemed appropriate.

(f) The Administrator may at any time revoke or modify any exemption granted

pursuant to this section by following the procedures set forth in paragraph (e) of this section for handling an exemption application which has been accepted for filing.

§ 1310.13 Exempt chemical mixtures.

(a) The chemical mixtures listed in paragraph (e) of this section have been exempted by the Administrator from application of sections 302, 303, 310, 1007, and 1008 of the Act (21 U.S.C. 822–3, 830, and 957–8 to the extent described in paragraphs (b), (c), and (d) of this section.

(b) Records and reports: All regulated persons who manufacture an exempt chemical mixture must keep complete and accurate records and file all reports required under §§ 1310.05 and 1310.06 on all listed chemicals used in manufacturing the exempt chemical mixture. Transactions involving approved exempt chemical mixtures contained in paragraph (e) of this section are not regulated transactions and thus records and reports are not required to be kept for listed chemicals once they become part of an exempt chemical mixture.

(c) No exemption granted pursuant to § 1310.12 affects the criminal liability for illegal possession or distribution of listed chemicals contained in the exempt chemical mixture.

(d) Changes in chemical mixture compositions: Any change in the quantitative or qualitative composition, trade name or other designation of an exempt chemical mixture listed in paragraph (e) of this section requires a new application for exemption.

(e) The following chemical mixtures, in the form and quantity listed in the application submitted (indicated as the "date") are designated as exempt chemical mixtures for the purposes set forth in this section:

EXEMPT CHEMICAL MIXTURES

Supplier	Product name	Form	Date
[Reserved]			

§ 1310.14 Exemption of drug products containing ephedrine and therapeutically significant quantities of another active medicinal ingredient.

(a) Any manufacturer of a drug product containing ephedrine in combination with another active medicinal ingredient, the product formulation of which is not listed in the compendiums set forth in § 1310.01(f)(1)(iv)(A), may request that the Administrator exempt the product as one which contains ephedrine together with a therapeutically significant quantity of another active medicinal ingredient.

(b) An application for an exemption under this section shall contain the following information:

(1) The name and address of the applicant;

(2) The exact trade name of the drug product for which exemption is sought;

(3) The complete quantitative and qualitative composition of the drug product;

(4) A brief statement of the facts which the applicant believes justify the granting of an exemption under this section; and

(5) Verification from the Food and Drug Administration that the product may be lawfully marketed or distributed under the Food, Drug, and Cosmetic Act.

(6) The identification of any information on the application which is considered by the applicant to be a trade secret or confidential and entitled to protection under U.S. laws restricting the public disclosure of such information by government employees.

(c) The administrator may require the applicant to submit such additional documents or written statements of fact relevant to the application which he deems necessary for determining if the application should be granted.

(d) Within a reasonable period of time after the receipt of a completed application for an exemption under this section, the Administrator shall notify the applicant of acceptance or nonacceptance of the application. If the application is not accepted, an explanation will be provided. The Administrator is not required to accept an application if any of the information required in paragraph (b) of this section or requested pursuant to paragraph (c) of this section is lacking or not readily understood. The applicant may, however, amend the application to meet the requirements of paragraphs (b) and (c) of this section. If the application is accepted for filing, the Administrator shall issue and publish in the Federal Register an order on the application, which shall include a reference to the legal authority under which the order is based. This order shall specify the date on which it shall take effect. The Administrator shall permit any interested person to file written comments on or objections to the order. If any comments or objections raise significant issues regarding any findings of fact or law upon which the order is based, the Administrator shall immediately suspend the effectiveness of the order until he may reconsider the application in light of the comments and objections filed. Thereafter, the Administrator shall reinstate, revoke, or amend the original order as deemed appropriate.

§ 1310.15 Exempt drug products containing ephedrine and therapeutically significant quantities of another active medicinal ingredient.

(a) The drug products containing ephedrine and therapeutically significant quantities of another active medicinal ingredient listed in paragraph (e) of this section have been exempted by the Administrator from application of sections 302, 303, 310, 1007, and 1008 of the Act (21 U.S.C. 822–3, 830, and 957–8) to the extent described in paragraphs (b), (c), and (d) of this section.

(b) Records and reports: All regulated persons who manufacture an exempt drug product must keep complete and accurate records and file all reports required under §§ 1310.05 and 1310.06 on all listed chemicals used in manufacturing the exempt drug product. Transactions involving approved exempt drug products contained in paragraph (e) of this section are not regulated transactions and thus records and reports are not required to be kept for listed chemicals once they become part of an exempt drug product.

(c) No exemption granted pursuant to § 1310.14 affects the criminal liability for illegal possession or distribution of listed chemicals contained in the exempt drug product.

(d) Changes in drug product compositions: Any change in the quantitative or qualitative composition of an exempt drug product listed in paragraph (e) of this section requires a new application for exemption.

(e) In addition to the drug products listed in the compendium set forth in § 1310.01(f)(1)(iv)(A), the following drug products, in the form and quantity listed in the application submitted (indicated as the "date") are designated as exempt drug products for the purposes set forth in this section:

EXEMPT DRUG PRODUCTS CONTAINING EPHEDRINE AND THERAPEUTICALLY SIGNIFICANT QUANTITIES OF ANOTHER ACTIVE MEDICINAL INGREDIENT

Supplier	Product name	Form	Date
[Reserved]			

IV. 21 CFR Part 1313 is proposed to be amended as follows:

PART 1313—[AMENDED]

1. The authority citation for part 1313 continues to read as follows:

Authority: 21 U.S.C. 802, 830, 871(b), 971.

2. Section 1313.02 is proposed to be amended by revising paragraphs (c), (d), (h) and (i); redesignating paragraph (m) as paragraph (o) and adding new paragraphs (m) and (n) to read as follows:

§ 1313.02 Definitions.

* * * * *

(c) The term *regulated person* means any individual, corporation, partnership, association, or other legal entity who manufactures, distributes, imports, or exports a listed chemical, a tableting machine, or an encapsulating machine, or who acts as a broker or trader for an international transaction involving a listed chemical, a tableting machine, or an encapsulating machine.

(d) The term *regulated transaction* means:

(1) A distribution, receipt, sale, importation, exportation, or international transaction of a listed chemical, or if the Administrator establishes a threshold amount for a specific listed chemical, a threshold amount as determined by the Administrator, which includes a cumulative threshold amount for multiple transactions, of a listed chemical, except that such term does not include:

(i) A domestic lawful distribution in the usual course of business between agents or employees of a single regulated person; in this context, agents or employees means individuals under the direct management and control of the regulated person;

(ii) A delivery of a listed chemical to or by a common or contract carrier for carriage in the lawful and usual course of the business of the common or contract carrier, or to or by a warehouseman for storage in the lawful and usual course of the business of the warehouseman, except that if the carriage or storage is in connection with the distribution, importation, or exportation of a listed chemical to a third person, this paragraph does not relieve a distributor, importer, or exporter from compliance with this part or parts 1309 and 1310 of this chapter;

(iii) Any category of transaction or any category of transaction for a specific listed chemical or chemicals specified by regulation of the Administrator as excluded from this definition as unnecessary for enforcement of the Act;

(iv) Any transaction in a listed chemical that is contained in a drug that may be marketed or distributed lawfully in the United States under the Federal Food, Drug, and Cosmetic Act unless—

(A) The drug contains ephedrine or its salts, optical isomers, or salts of optical isomers as the only active medicinal ingredient or contains ephedrine or its salts, optical isomers or salts of optical isomers and therapeutically insignificant quantities of another active medicinal ingredient (for purposes of this paragraph, the term "therapeutically insignificant quantities" shall apply if the product formulation (i.e., the qualitative and quantitative composition of active ingredients within the product) is not listed in any of the following compendiums:

(*1*) *American Pharmaceutical Association (APhA) Handbook of Nonprescription Drugs;*

(*2*) *Drug Facts and Comparisons* (published by Wolters Kluwer Company); or

(*3*) *USP DI* (published by authority of the United States Pharmacopeial Convention, Inc.);

(*4*) Or the product is not listed in § 1310.15 as an exempt drug product. For drug products having formulations not found in the above compendiums, the Administrator shall determine, pursuant to a written request as specified in § 1310.14, whether the active medicinal ingredients are present in quantities considered therapeutically significant for purposes of this paragraph.

(B) The Administrator has determined that the drug or group of drugs is being diverted to obtain the listed chemical for use in the illicit production of a controlled substance; and

(C) The quantity of ephedrine or other listed chemical contained in the drug included in the transaction or multiple transactions equals or exceeds the threshold established for that chemical by the Administrator; or

(v) Any transaction in a chemical mixture listed in § 1310.13 of this chapter.

* * * * *

(h) The term *regular importer* means, with respect to a listed chemical, a person that has an established record as an importer of that listed chemical that is reported to the Administrator.

(i) The term *established record* as an importer means that the regulated person has imported a listed chemical at least once within the past six months, or twice within the past twelve months from a foreign supplier. The term also means that the regulated person has provided the Administration with the following information in accordance with the waiver of the 15-day advance notice requirements of § 1313.15:

(1) The name, DEA registration number (where applicable), street address, telephone number, telex number, and, where available, the facsimile number of the regulated person and of each foreign supplier; and

(2) The frequency and number of transaction occurring during the preceding 12 month period.

* * * * *

(m) The terms *broker* and *trader* means any individual, corporation, corporate division, partnership, association, or other legal entity which assists in arranging an international transaction in a listed chemical by—

(1) Negotiating contracts;

(2) Serving as an agent or intermediary; or

(3) Bringing together a buyer and seller, a buyer and transporter, or a seller and transporter.

(n) The term *international transaction* means a transaction involving the shipment of a listed chemical across an international border (other than a United States border) in which a broker or trade located in the United States participates.

* * * * *

3. Section 1313.12 is proposed to be amended by revising paragraph (c) and adding new paragraphs (d), (e) and (f) to read as follows:

§ 1313.12 Requirement of authorization to import.

* * * * *

(c) The 15-day advance notification requirement for listed chemical imports may be waived for:

(1) Any regulated person who has satisfied the requirement for reporting to the Administration as a regular importer of such listed chemicals.

(2) A specific listed chemical, as set forth in paragraph (f) of the section, for which the Administrator determines that advance notification is not necessary for effective chemical diversion control.

(d) For imports where advance notification is waived pursuant to paragraph (c)(1) of this section, the DEA Form 486 must be received by the Drug Enforcement Administration, Chemical Operations Section, on or before the date of importation through use of the mailing address listed in § 1313.12(b) or through use of electronic facsimile media.

(e) For importations where advance notification is waived pursuant to paragraph (c)(2) of this section no DEA Form 486 is required, however, the regulated person shall file quarterly reports to the Drug Enforcement

Administration, Chemical Operations Section, P.O. Box 28346, Washington, DC 20038, by no later than the 15th day of the month following the end of each quarter. The report shall contain the following information regarding each individual importation:

(1) The name of the listed chemical;

(2) The quantity and date imported;

(3) The name and full business address of the supplier;

(4) The foreign port of embarkation; and

(5) The port of entry.

(f) The 15 day advance notification requirement set forth in paragraph (a) of this section has been waived for imports of the following listed chemicals:

(1)–(2) [Reserved]

4. Section 1313.15 is proposed to be revised to read as follows:

1313.15 Waiver of 15-day advance notice for regular importers.

(a) Each regulated person seeking designation as a "regular importer" shall provide, by certified mail return receipt requested, to the Administration such information as is required under § 1313.02(i), documenting their status as a regular importer.

(b) Each regulated person making application under paragraph (a) of this section shall be considered a "regular importer" for purposes of waiving the 15-days advance notice, 30 days after receipt of the application by the Administration, as indicated on the return receipt, unless the regulated person is otherwise notified in writing by the Administration.

(c) The Administrator may, at any time, disqualify a regulated person's status as a regular importer on the grounds that the chemical being imported may be diverted to the clandestine manufacture of the chemical substance.

(d) Unless the Administration notifies the chemical importer to the contrary, the qualification of a regular importer of any one of these three chemicals, acetone, 2-Butanone (MEK), or toluene, qualifies that importer as a regular importer of all three of these chemicals.

(e) All chemical importer shall be required to file a DEA Form 486 as required by § 1313.12.

5. Section 1313.21 is proposed to be amended by revising paragraph (c), revising the text of and redesignating paragraph (d) as paragraph (g) and adding new paragraphs (d), (e), (f) to read as follows:

§ 1313.21 Requirement of authorization to export.

* * * * *

(c) The 15-day advance notification requirement for listed chemical exports may be waived for:

(1) any regulated person who has satisfied the requirements of § 1313.24 for reporting to the Administration an established business relationship with a foreign customer as defined in § 1313.02(j).

(2) A specific listed chemical to a specified country, as set forth in paragraph (f) of this section, for which the Administrator determines that advance notification is not necessary for effective chemical diversion control.

(d) For exports where advance notification is waived pursuant to paragraph (c)(1) of this section, the DEA Form 486 must be received by the Drug Enforcement Administration, Chemical Operations Section, on or before the date of exportation through use of the mailing address listed in § 1313.12(b) or through use of electronic facsimile media.

(e) For exportations where advance notification is waived pursuant to paragraph (c)(2) of this section, the regulated person shall file quarterly reports to the Drug Enforcement Administration, Chemical Operations Section, PO Box 28346, Washington, DC 20038, by no later than the 15th day of the month following the end of the each quarter. The report shall contain the following information regarding each individual importation:

(1) The name of the listed chemical;

(2) The quantity and date exported;

(3) The name and full business address of the foreign customer;

(4) The port of embarkation; and

(5) The foreign port of entry.

(f) The 15 day advance notification requirement set forth in paragraph (a) of this section has been waived for exports of the following listed chemicals to the following countries:

Name of Chemical	Country
[Reserved]	

(g) No person shall export or cause to be exported any listed chemical, knowing or having reasonable cause to believe the export is in violation of the laws of the country to which the chemical is exported or the chemical will be used to manufacture a controlled substance in violation of the Act or the laws of the country to which the chemical is exported. The Administration will publish a notice of foreign import restrictions for listed chemicals of which DEA has knowledge as provided in § 1313.25.

6. A new undesignated center heading and new §§ 1313.32, 1313.33 and 1313.34 are proposed to be added to read as follows:

Transshipments, In-Transit Shipments, and International Transactions Involving Listed Chemicals

1313.32 Requirement of Authorization for international transactions.

1313.33 Contents of an international transaction declaration.

1313.34 Distribution of the international transaction declaration.

Transshipments, In-Transit Shipments, and International Transactions Involving Listed Chemicals

§ 1313.32 Requirement of authorization for international transactions.

(a) A broker or trader shall notify the Administrator prior to an international transaction involving a listed chemical which meets or exceeds the threshold amount identified in § 1310.04 of this chapter, in which the broker or trader participates. Notification must be made no later than 15 days before the transaction is to take place. In order to facilitate an international transaction involving listed chemicals and implement the purpose of the Act, regulated persons may wish to provide advance notification to the Administration as far in advance of the 15 days as possible.

(b) A completed DEA Form 486 must be received at the following address not later than 15 days prior to the international transaction:

Drug Enforcement Administration, PO Box 28346, Washington, DC 20038.

A copy of the DEA Form 486 may be transmitted directly to the Drug Enforcement Administration, Chemical Operations Section, through electronic facsimile media not later than 15 days prior to the exportation.

(c) No person shall serve as a broker or trader for an international transaction involving a listed chemical knowing or having reasonable cause to believe that the transaction is in violation of the laws of the country to which the chemical is exported or the chemical will be used to manufacture a controlled substance in violation of the laws of the country to which the chemical is exported. The Administration will publish a notice of foreign import restrictions for listed chemicals of which DEA has knowledge as provided in § 1313.25.

§ 1313.33 Contents of an international transaction declaration.

(a) An international transaction involving a chemical listed in § 1310.02 of this chapter which meets the threshold criteria established in § 1310.04 of this chapter may be arranged by a broker or trader if the

chemical is needed for medical, commercial, scientific, or other legitimate uses.

(b) Any broker or trader who desires to arrange an international transaction involving a listed chemical which meets the criteria set forth in § 1310.04 of this chapter shall notify the Administration through the procedures outlined in § 1313.32(b).

(c) The DEA Form 486 must be executed in triplicate and must include all the following information:

(1) The name, address, telephone number, telex number, and, where available, the facsimile number of the chemical exporter; the name, address, telephone number, telex number, and, where available, the facsimile number of the chemical importer;

(2) The name and description of each listed chemical as it appears on the label or container, the name of each listed chemical as it is designated in § 1310.02 of this chapter, the size or weight of container, the number of containers, the net weight of each listed chemical given in kilograms or parts thereof, and the gross weight of the shipment given in kilograms or parts thereof;

(3) The proposed export date, the port of exportation, and the port of importation; and

(4) The name, address, telephone, telex, and where available, the facsimile number, of the consignee in the country where the chemical shipment is destined; the name(s) and address(es) of any intermediate consignee(s).

§ 1313.34 Distribution of the international transaction declaration.

The required three copies of the DEA Form 486 will be distributed as follows:

(a) Copies 1 and 3 shall be retained on file by the broker or trader as the official record of the international transaction. Declaration forms involving List I chemicals shall be retained for four years; declaration forms for List II chemicals shall be retained for two years.

(b) Copy 2 is the Drug Enforcement Administration copy used to fulfill the notification requirements of § 1313.32.

8. In addition to the amendments set forth above, DEA proposes in 21 CFR part 1313 to remove the words "Precursors and Essential Chemicals" and "Precursor and Essential Chemical" and add, in their place, the words "listed Chemicals" in the following places:

(a) The table of contents of part 1313;

(b) Section 1313.01;

(c) The center heading after Section 1313.02;

(d) Section 1313.14;

(e) The center heading after Section 1313.15;

(f) Section 1313.23.

8. In §§ 1313.13(a) and 1313.22(a) DEA proposes to remove the words "precursor or essential chemical" and add, in their place, the words "List I or List II chemical".

9. In §§ 1313.14(a) and 1313.23(a) DEA proposes to remove the words "listed precursor chemical" and "listed essential chemical" and add, in their place, the words "List I chemical" and "List II chemical" respectively.

V. 21 CFR part 1316 is proposed to be amended as follows:

PART 1316—[AMENDED]

1. The authority citation for part 1316, Subpart A is proposed to be revised to read as follows:

Authority: 21 U.S.C. 822(f), 830(a), 871(b), 880, 958(f), 965.

2. Section 1316.02 is proposed to be amended by revising paragraph (c)(2) to read as follows:

§ 1316.02 Definitions.

* * * * *

(c) * * *

(2) Places, including factories, warehouses, or other establishments and conveyances, where persons registered under the Act or exempted from registration under the Act, or regulated persons may lawfully hold, manufacture, or distribute, dispense, administer, or otherwise dispose of controlled substances or listed chemicals or where records relating to those activities are maintained.

* * * * *

3. Section 1316.03 is proposed to be amended by revising paragraphs (b), (c), (d) and (e) to read as follows:

§ 1316.03 Authority to make inspections.

* * * * *

(b) Inspecting within reasonable limits and to a reasonable manner all pertinent equipment, finished and unfinished controlled substances, listed chemicals, and other substances or materials, containers, and labeling found at the controlled premises relating to this Act;

(c) Making a physical inventory of all controlled substances and listed chemicals on-hand at the premises;

(d) Collecting samples of controlled substances or listed chemicals (in the event any samples are collected during an inspection, the inspector shall issue a receipt for such samples on DEA Form 84 to the owner, operator, or agent in charge of the premises);

(e) Checking of records and information on distribution of controlled substances or listed chemicals by the registrant or regulated person as they relate to total distribution of the registrant or regulated person (i.e., has the distribution of controlled substances or listed chemicals increased markedly within the past year, and if so why);

* * * * *

4. Section 1316.09 is proposed to be amended by revising paragraph (a)(3) to read as follows:

§ 1316.09 Application for administrative inspection warrant.

(a) * * *

(3) A statement relating to the nature and extent of the administrative inspection, including, where necessary, a request to seize specified items and/or to collect samples or finished or unfinished controlled substances or listed chemicals;

* * * * *

Dated: August 30, 1994.

Stephen H. Greene,

Deputy Administrator, Drug Enforcement Administration.

[FR Doc. 94–25071 Filed 10–12–94; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF THE INTERIOR

Indian Arts and Crafts Board

25 CFR PART 309

RIN 1090–AA45

Protection for Products of Indian Art and Craftsmanship

AGENCY: Indian Arts and Crafts Board (IACB), DOI.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This rule will establish regulations to implement Pub. L. 101–644, the Indian Arts and Crafts Act of 1990. The proposed regulations define the nature and Indian origin of products embraced by the law and specify procedures for carrying out the law. The trademark provisions of the Act are not included in this proposed rulemaking, and will be treated at a later time.

DATES: Written comments must be received on or before February 10, 1995.

ADDRESSES: Comments on the proposal should be marked "Docket No. 1090–AA45" and mailed or delivered in duplicate to: Indian Arts and Crafts Board, Room 4004–MIB, 1849 C Street, NW., Washington, DC 20240. Commenters who want the Indian Arts and Crafts Board to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which