was necessary for efficient and cost-effective delivery of services. We also do not believe that the provision of uncompensated care by community hospitals otherwise provides a reason to forego an adjustment designed to correct for excessive costs built into a rate designed for payment of Medicare beneficiaries.

Accordingly, we continue to believe that an efficiency adjustment should encourage the reduction in excess capital stock by reducing the rate over a number of years. The residual analysis would provide the basis for the reduction, although we would not necessarily remove all the residual. We would continue to study the data in order to identify the proportion of the residual that should be employed to reduce the update and the rate at which the adjustment should be applied.

We emphasize again that this approach to a capital efficiency adjustment represents only our current thinking. We believe that further development may be necessary before such an efficiency adjustment is ready for use as part of the update framework. We continue to welcome suggestions for improvement of the adjustment and we remain interested in considering suggestions for alternative approaches. In addition, we would welcome information on the possible effects of an efficiency adjustment on various segments of the hospital industry.

[FR Doc. 93–21026 Filed 8–31–93; 8:45 am]
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federal register

Wednesday
September 1, 1993

Part III

Department of Transportation

Federal Aviation Administration

14 CFR Part 121

Protective Breathing Equipment Training; Final Rule

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 121

[Docket No. 24792; Amendment No. 121–234]

RIN 2120–AD76

Protective Breathing Equipment Training

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA revises the current regulations requiring Part 121 crewmembers to perform an approved firefighting drill using protective breathing equipment (PBE). The current rule requiring training of Part 121 crewmembers in the use of protective breathing equipment (PBE) requires the use of the PBE while fighting an actual fire. This final rule will permit air carriers to use a simulated fire during PBE training if their training includes an additional firefighting drill with an actual fire. This action was prompted by a letter from the Association of Flight Attendants (AFA) and petitions for exemption from Pan American World Airways (Pan Am) and United Airlines, Inc. The objective of the amendment is to ensure that each crewmember accomplishes a firefighting drill in which the crewmember combats an actual fire in addition to, or combined with, a PBE drill.

DATES: This final rule is effective September 1, 1993.

FOR FURTHER INFORMATION CONTACT: Larry Youngblut, Project Development Branch, AFS–240, Air Transportation Division, Flight Standards Service, 304B, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591, telephone (202) 267–8096.

SUPPLEMENTARY INFORMATION:

Availability of the final rule

Any person may obtain a copy of this amendment by submitting a request to the Federal Aviation Administration, Office of Public Affairs, Attention: Public Inquiry Center, APA–430, 800 Independence Avenue SW., Washington, DC 20591, or by calling (202) 267–3484. Communications must identify the amendment number of this final rule.

Background

The requirement for Part 121 crewmembers to perform an approved firefighting drill using PBE is prescribed in § 121.417(c)(1)(i) of the Federal Aviation Regulations (FAR). The regulation requires that each crewmember perform a one-time, approved firefighting drill with an actual fire during initial training, using at least one type of installed hand fire extinguisher appropriate for the type of fire to be fought and the type of installed PBE required by § 121.337.

On May 26, 1987, the current requirement was issued in Amendment No. 121–193, Protective Breathing Equipment (52 FR 20950; June 3, 1987). The amendment was based on National Transportation Safety Board (NTSB) recommendations and on information received from investigations of accidents in which smoke and noxious fumes may have impeded crewmembers fighting cabin fires. In addressing these safety concerns, the rule included a training requirement for crewmembers to perform an approved firefighting drill, fighting an actual fire, using PBE.

On March 14, 1989, the FAA issued Advisory Circular (AC) 121–31, Training on Protective Breathing Equipment, which provided guidance for crewmember training using PBE. This AC incorrectly offered two options for meeting the firefighting drill requirements. In the first option, a carrier could require each crewmember to perform a firefighting drill by fighting an actual fire using an appropriate fire extinguisher while wearing PBE. The second option, known as a "split drill," allowed crewmembers to perform the firefighting drill by fighting a simulated fire using an appropriate fire extinguisher while wearing PBE. However, the crewmember was required to perform an additional drill, which did not have to include the use of PBE, but which had to include the fighting of an actual fire using an appropriate fire extinguisher.

The FAA received a number of inquiries about the recommended firefighting drills described in AC 121–31. Action Notice 8430.40, Training on Protective Breathing Equipment, issued on June 7, 1989, also allowed the split drill, but additionally suggested that a carrier could use simulation for both drills if the training had been approved by the Air Transportation Division. In a January 26, 1990, letter to the FAA, AFA requested enforcement of § 121.417(c)(1)(i). AFA's letter stated that some flight attendant trainees are not fighting an actual fire while wearing PBE in the firefighting drill, as required by the regulation. AFA maintained that several carriers are not in compliance with the regulation and that any deviation from the requirements should be handled through the exemption process.

The FAA, in response to AFA's letter, stated that an actual fire must be fought during the drill required by § 121.417(c)(1)(i) and that PBE must be worn while fighting an actual fire in that drill. Therefore, any carrier who is not using an actual fire during the drill required in § 121.417(c)(1)(i) is not complying with the regulation.

United Airlines, Inc., filed a petition for exemption dated September 17, 1990. The petition requested exemption from § 121.417(c)(1)(i) in order to permit the one-time firefighting drill to be accomplished using "fire simulation." The petition stated that the use of training aids was not evaluated in the preamble to Amendment No. 121–193 and that an appropriate course of action is to improve training aids and apply them to carefully developed training objectives. The petition also stated that, with the exception of the preamble language of Amendment No. 121–193, the language of the final rule appears to allow a firefighting drill using simulated fires instead of actual fires. In addition, the petitioner expressed environmental concerns about the use of actual fires, the discharge of Halon fire extinguishers during firefighting training, and possible bans or restrictions of such training imposed by political jurisdictions.

Review of Industry Practices

An FAA review of Part 121 air carrier firefighting training programs disclosed that more than one-half of all of part 121 air carrier training programs require crewmembers to fight an actual fire while wearing PBE during firefighting drills. An additional one-fourth of the air carrier training programs require crewmembers to perform two firefighting drills—one in which they fight a simulated fire while wearing PBE and another in which they fight an actual fire without using PBE. The remaining air carrier training programs use only fire simulation in their firefighting and PBE drills despite an FAA interpretation, based on the preamble to Amendment 121–193 (52 FR 20950), that an actual fire must be fought during initial training.

Notice of Proposed Rulemaking No. 92–11

On August 14, 1992, the FAA proposed in Notice No. 92–11 that air carriers be allowed to separate the training required by § 121.417 into two categories: training on PBE and training on firefighting equipment. The FAA determined that simulated training should be allowed during the training on PBE, but also maintained its longstanding position that it is essential

longstanding position that it is essential that crewmembers complete a one-time firefighting drill in which they combat an actual fire with an appropriate fire extinguisher as a part of training on firefighting equipment. Thus, the notice proposed to allow the training required under § 121.417 to be accomplished in two drills (a PBE drill using simulation and a firefighting drill using an actual fire) or one drill in which the crewmember fights an actual fire while wearing the PBE unit.

Discussion of Comments

The FAA received eight comments, including two late-filed comments, on the proposed rule.

The Association of Professional Flight Attendants (APFA) comments that it supports the action of the notice, i.e., fighting an actual fire as a part of the required drill; however, APFA also believes that the "split drill" is less effective. APFA states that flight attendants who have actually fought cabin fires have expressed a concern that the removal of the PBE from its container was much more difficult and time consuming than they anticipated. APFA recommends that a PBE drill be defined as an emergency drill in which a crewmember demonstrates the proper removal and use of the PBE, and that removal be emphasized in the training.

FAA response: The FAA has issued guidance to Principal Operations Inspectors that they should ensure that their assigned air carriers have FAA approved training courses which replicate the forces necessary to open the pouches. The FAA agrees with APFA's comment and believes that this improvement in training will have the results that the APFA wants.

The Regional Airline Association (RAA) supports the proposal, but objects to the requirement to use a fire extinguisher and PBE unit identical to that installed in the airplane instead of equivalent extinguishers and appropriate PBE training devices. The RAA is concerned that this would mean an additional training drill if a cabin crewmember is reassigned to an airplane that used a different type of fire extinguisher. The Association also urges the FAA to reword the final rule so that substitutes for HALON extinguishers may be used in order to avoid damaging the environment. RAA also proposed that the compliance date be no sooner than 1 year after the effective date.

FAA response: Simulated PBE equipment, i.e., a training hood, is acceptable if it is approved by the principal operations inspector (POI). A training hood must accurately replicate the forces necessary to open the pouch. Some airlines have installed PBE equipment in pouches which are stapled and therefore are difficult to open. When this is the case it is important that the "training" pouch simulate the forces necessary to open the actual equipment.

While it is important that each crewmember operate the fire extinguishers that are installed on the airplane, it is not necessary that installed fire extinguishers be used to actually fight the fire. The intent of the rule is that training programs accomplish the training objectives of having crewmembers know how to use the equipment and experience the psychological aspects of fighting a real fire. The training objective of knowing how to use a fire extinguisher can be met by having each crewmember remove the fire extinguisher from stowage and demonstrate the proper operation. The benefit of experiencing the psychological effect of being faced with an actual fire and having to control it can be met by the use of other extinguishing agents. To incorporate this concept in the amendatory language, definitions for simulation devices for both fire extinguishers and PBE units are added to the definitions section of the amendment.

The FAA acknowledges the comment from RAA indicating that some certificate holders may need additional time to comply with the requirement to fight an actual fire. The FAA will address the problems of those certificate holders on an individual basis.

The Air Transport Association (ATA) likewise urges the use of "training hoods" so that airlines are able to avoid higher costs associated with use of actual PBE units. ATA also notes that the FAA issued policy statements that HALON extinguishers should be avoided. ATA urges that language be added which clearly specifies the use of "other extinguishing agents" for aircraft where HALON extinguishers are used. ATA states that it continues to support United Airlines' petition for exemption to permit the use of simulation alone for the required drill. ATA states that it finds FAA inconsistent in promulgating the Advanced Qualification Program rule, which supports innovation and simulation in training, while at the same time repudiating those goals by requiring a live fire for the PBE drill.

Air Wisconsin also urges the FAA to allow training hoods and states that if carriers are required to use the approved PBE units the cost would be staggering.

An individual physician comments that the reuse of PBE units by different individuals could result in the transmission of disease, particularly hepatitis and tuberculosis. This individual urges instead that the FAA permit the use of training devices to preclude imposing an unnecessary financial burden on airlines.

FAA response: The FAA approves of the use of "training hoods" if they properly simulate the PBE equipment that is installed on the aircraft. The FAA believes that there are many "training hoods" available which do this. Most of the training problems which have been noted have concerned the opening of the pouch which houses the PBE. It is important that crewmembers receive training on the removal of the PBE from the pouch especially when the pouch is stapled and difficult to open.

This final rule allows airlines to use extinguishing materials other than HALON during the actual firefighting portion of the PBE drill. Therefore, incorporating the phrase "other extinguishing agents" is unnecessary.

The FAA does not believe that requiring crewmembers to experience the psychological effects of fighting an actual fire is in conflict with the principles of the Advanced Qualification Program rule. The training objectives of being able to use a fire extinguisher properly and to correctly use PBE are still subject to innovation and simulation. The FAA believes that by allowing the "split drill" it is encouraging the use of creativity in simulation.

The Association of Flight Attendants (AFA) opposes the proposed revision. AFA quotes one attendant who states that the PBE unit makes everything look different and particularly distorts the appearance of the fire. This crewmember found it beneficial to have experienced how the mask would feel, how the fire would look, and how the fire would respond to the extinguisher while wearing the mask. Noting that there are gradations in the sophistication of simulation, AFA urges the FAA to define the quality of the actual and simulated fires. AFA also encourages that, if the split drill is allowed, the FAA require for those carriers that elect to use it—(1) recurrent training every 24 months to reinforce the actual one-time fire experience, and (2) a drill that includes taking the PBE out of the stowed position, donning it, and learning the indications for a low or depleted oxygen supply.

FAA response: One of the reasons that the FAA has decided to allow the split drill is to provide the opportunity for airlines to use simulation and innovation during fire extinguisher training. The agency agrees that distortion occurs and believes that this training will give the flight attendant

experience in many aspects of distortion.

The FAA is aware that there are many types and grades of fires which are appropriate to the fire fighting portion of the PBE drill, and individual POI's are given the responsibility of approving the fire. The quality of fire to be used in this training is contingent on the location of the fire, the airline facilities, and local ordinances. It would be difficult for the FAA to provide guidance which would be appropriate to each situation.

The FAA will continue to monitor the PBE drills and their effectiveness, and, if it believes that further instruction should be provided during recurrent training, it will make this a requirement. The present requirement in § 121.417(b)(2), "individual instruction in the location, function, operation of emergency equipment * * *" should indicate that instruction should be given on PBE during the emergency training portion of an air carrier's approved training program.

In addition, § 121.417(c)(2) requires, "Additional emergency drill requirements to be accomplished during initial training and once each 24 calendar months during recurrent training." This additional training in § 121.417(c)(2)(i)(C) includes "Each type of emergency oxygen system to include protective breathing equipment." This means that a drill must be performed each 24 months which includes the operation of PBE. The FAA agrees with AFA that this drill should include removing the PBE from its stowed position, donning it, and demonstrating knowledge of the low oxygen indicators.

The FAA does not believe it is necessary to expose crewmembers to an actual fire every 24 months.

The Air Line Pilots Association (ALPA) opposes the proposed revision, stating that PBE training should be as realistic as possible, not given an artificial separation by a split drill that will leave crewmembers with incomplete training. ALPA states that the training is incomplete because if a crewmember had to actually fight a cabin fire, he or she would never before have used the PBE and firefighting equipment together.

FAA response: The FAA finds that the training objectives in the use of PBE can be met through either the two separate drills or one combined drill. The training benefits of the simulation are different from the psychological benefit of experiencing an actual fire. For example, locating a fire in a seat cushion, lavatory, or galley would be impracticable to duplicate with an actual fire, but such an experience has a recognized training benefit. In addition, the FAA recognizes that although not all firefighting situations require the use of PBE, they usually require the use of a fire extinguisher. Therefore, the experience of fighting an actual fire with a fire extinguisher has a separate, and intrinsic, benefit.

Finally, one comment was received from a training company, which had no substantive comments on the NPRM.

Intent of the Amendment

Based on its review of current industry practices, Pan Am and United Airlines' petitions for exemption, and letters from AFA, the FAA has reevaluated the requirements of the current regulation and hereby amends the rule. The objective of the current regulation is to train crewmembers on the use of PBE and firefighting equipment available on aircraft in which they are assigned duties. This training includes the activation of PBE and fire extinguishers in fighting an actual fire. Currently, crewmembers are required to meet these training objectives by performing an approved firefighting drill in which they fight an actual fire with an appropriate fire extinguisher while wearing PBE. The FAA has determined, however, that air carriers should be allowed to separate this training into two categories: training on PBE and training on firefighting equipment. The FAA has also determined that simulated fires should be allowed during training on PBE, but that it is essential that crewmembers complete a one-time firefighting drill in which they combat an actual fire with an approved fire extinguisher as a part of training on firefighting equipment.

Under this amendment, air carriers may continue to combine the training on PBE and firefighting equipment training into one drill if an actual fire is used during the training. However, if simulated fires are used during PBE training, each crewmember must complete a separate firefighting drill with an actual fire using a fire extinguisher. Crewmembers would still be required to have knowledge and skill relating to firefighting techniques and the operation and use of PBE, as well as first-hand knowledge of how an actual fire reacts to a fire extinguisher.

General Discussion of the Amendment

Section 121.417

Section 121.417(c)(1)(i) requires crewmembers to combat an actual or simulated fire using at least one type of installed hand fire extinguisher, or approved simulation device, appropriate for the type of fire, while wearing the appropriate type of PBE. This requirement is designated as a PBE drill, and it emphasizes the correct use of PBE in a firefighting scenario. The crewmember performs the drill by using PBE while combatting an actual or simulated fire.

The FAA acknowledges the training benefits of simulation and the various firefighting scenarios that may be enacted when using a simulated fire in combination with a mock-up of an aircraft cabin, galley, oven, lavatory, or passenger seat. In addition to demonstrating proper operation of the emergency firefighting equipment, crewmembers can be trained in proper crew coordination, communication, and decision-making. Many major air carriers currently conduct PBE training in sophisticated cabin trainers that are equipped with various types of devices that simulate smoke and fire. The FAA recognizes that training with simulated fires, in addition to a fire extinguishing drill that includes an actual fire, is beneficial because it allows various aircraft firefighting situations to be created in the environments in which they are likely to take place. The FAA also recognizes that many air carriers may choose not to use simulation. These carriers are then required to have their crewmembers perform the PBE drill using an actual fire, as prescribed by current § 121.417(c)(1)(i). In such a combined drill, crewmembers still demonstrate the proper use of PBE and fight an actual fire using an appropriate type of fire extinguisher wearing PBE.

Section 121.417(c)(1)(ii)

This new paragraph requires air carriers to conduct approved firefighting drills in which crewmembers fight an actual fire using an installed hand fire extinguisher appropriate for the type of fire. The requirement does not apply to crewmembers whose PBE drill under § 121.417(c)(1)(i) is conducted with an actual fire. The FAA acknowledges that the firefighting drill, including an actual fire, is a one-time requirement; therefore, if a crewmember fights an actual fire during the PBE drill, the crewmember need not perform another drill with an actual fire. Furthermore, crewmembers are not required to fight an actual fire in the additional initial or recurrent training drills set forth in current § 121.417(c)(2).

This added section emphasizes the importance of firefighting training that includes a drill in which a crewmember fights an actual fire. The psychological effect of facing an actual fire cannot be achieved through simulation.

The FAA's primary goal in revising these requirements is to clarify and reinforce the present requirement that crewmembers undergo a one-time training drill in which they combat an actual fire. This was stated in the preambles to Amendment No. 121–193 and Amendment 121–220. By permitting air carriers to allow crewmembers to perform the currently required PBE firefighting drill with a simulated fire, the FAA would allow air carriers additional flexibility in providing quality training for various types of situations.

One of AFA's primary concerns is that there are crewmembers working in the industry who have not fought an actual fire in training. This amendment modifies the current requirement by providing an alternative to the current regulation. However, each crewmember would still be required to fight an actual fire in initial training. The FAA recognizes that, although not all firefighting situations require the use of PBE, they usually require the use of a fire extinguisher. Therefore, the FAA believes that the change in the structure of the current regulation enhances firefighting training objectives.

Section 121.417(d)

Section 121.417(d) will require any crewmember who serves in part 121 operations to have completed the PBE drill and the firefighting drill in paragraphs (c)(1)(i) or (c)(1)(ii) by [insert effective date of final rule], the effective date of this amendment. The FAA has determined that this will allow sufficient time for carriers to determine which crewmembers have completed the training as prescribed by this amendment. If it has not been given in initial training it will be necessary for the air carrier to give that training in recurrent training sessions or in specially scheduled sessions. It will be necessary for air carriers to schedule sessions efficiently.

This section also contains a provision that would credit crewmembers who have performed the PBE and firefighting drills described in paragraphs (c)(1)(i) and (c)(1)(ii) with meeting the requirements of the regulation if the firefighting training and PBE training was performed after May 26, 1987. However, to receive credit, the carrier must present to the Director of Flight Standards Service information or documentation showing that the crewmember accomplished firefighting training in a manner that would meet the requirements of the amendment.

The May 26, 1987, date corresponds to the date of issuance of Amendment No. 121–193. The FAA believes that it is not feasible for credit to be given for firefighting drills performed prior to May 26, 1987, because requirements for firefighting drills involving an actual fire, simulated fire, or PBE training did not exist in the FAR prior to that date.

Section 121.417(f)

This final rule amends § 121.417(f) by defining the terms "actual fire," "approved fire extinguisher," "approved PBE simulation device," "observe," "perform," "simulated fire," "combats," and "PBE drill" to this section. For the purposes of this final rule, "actual fire" means an ignited combustible material, in controlled conditions, of a sufficient magnitude and duration to accomplish the training objectives outlined in paragraphs (c)(1)(i) and (c)(1)(ii) of the rule. The FAA is not requiring exact dimensions and types of materials to be used for actual fires in the firefighting drills. To do so would mean that crewmembers might have to be retrained because their previous training might not meet these specific requirements. This additional training could impose an additional cost on air carriers.

A review of current industry practice shows that air carriers frequently contact local or airport fire departments prior to conducting any type of firefighting training, and, in some cases, fire department personnel are present during training. Many local fire departments provide training course outlines on the use of small, hand fire extinguishers, and they also typically provide training on the operation of hand fire extinguishers to employees of local businesses and organizations. These employees are given the opportunity to extinguish an actual fire under fire department supervision.

Among the materials used by fire departments and air carriers in creating actual fires are kerosene or diesel fuel floating on water in a metal pan or drum. These types of fires are ignited outdoors in an open area. Some air carriers and fire departments have constructed indoor fire rooms or fire pits in which they ignite materials such as seat cushions and use exhaust fans to eliminate smoke.

The amendment defines a "simulated fire" as an artificial duplication of a fire used to create the various firefighting situations that could occur on an aircraft. Smoke simulation is a component of that fire simulation. Artificial smoke may be used to simulate smoke coming from a galley oven, under a lavatory door, or under a passenger seat.

Under the amendment, "combats," used in this context, means fighting an actual or simulated fire until such fire is extinguished. In the case of a simulated fire, extinguishment would be determined by the instructor.

The amendment defines "PBE drill" as an emergency drill in which a crewmember demonstrates the proper use of protective breathing equipment while fighting an actual or simulated fire.

The FAA plans to issue an AC or Operations Bulletin providing additional detailed guidance on the use of PBE, actual fires, and adequate simulation of a fire. The guidance will be based on industry practices that experience has shown to be adequate.

Section 121.417(c)(1)(iii)

Section 121.417(c)(1)(ii) is redesignated as § 121.417(c)(1)(iii). The emergency evacuation drill requirements listed in this section would remain unchanged.

Paperwork Reduction Act

Information collection requirements for part 121 have been previously approved by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act of 1980 (Pub. L. 96–511) and have been assigned OMB Control Numbers as follows: for Part 121, OMB Control Number 2120–0008.

Regulatory Evaluation Summary

This rule is not a major rule under Executive Order 12291 but is a significant rule under the Department of Transportation Regulatory Policies and Procedures. The rule will impose no costs on society (aviation industry, public, or government). Also, no quantifiable benefits are derived from the rule.

The rule will impose no costs because it prescribes neither additional constraints nor requirements on the airlines. The amendment simply responds to requests by the industry for clarification of PBE requirements. This rule will allow Part 121 carriers to choose between two options to meet firefighting training requirements. The rule makes clear that either of the two options is sufficient to comply with the FAR. Airlines may choose the least costly of these options.

Although the amendment will not place additional requirements on Part 121 operators, it ensures that each crewmember combats an actual fire in addition to or in combination with a PBE drill without additional requirements. Hence, the FAA considers this a cost beneficial rule.

International Trade Impact Analysis

This rule will have no effect on the sale of foreign products or services in the United States. The rule also does not affect the sale of United States products or services in foreign countries. Hence, all foreign and domestic trade will be equally unaffected by this rule.

Regulatory Flexibility Act Determination

The Regulatory Flexibility Act of 1980 (RFA) ensures that government regulations do not needlessly and disproportionately burden small businesses. The RFA requires the FAA to review each rule that may have a significant economic impact on a substantial number of small entities. This amendment will not impose additional costs at all. Hence, the rule will not impose a significant cost on a substantial number of small entities.

Objectives of and Legal Basis of the Rule

The objective of the amendment, which is discussed in detail in the preamble to this regulation, is to provide an increased margin of safety against the hazards of in-flight fires. The legal basis of the proposal comes from sections 313(a), (314)(a), 601 through 610, and 1102 of the Federal Aviation Act of 1958, as amended (49 U.S.C App 1354(a), 1355, 1356, 1357, 1401, 1421 through 1430, 1472, 1485, and 1502); 49 U.S.C. 106(g) (Revised Public Law 97–449, January 12, 1983).

Good Cause Justification for Immediate Effective Date

This amendment is being made effective immediately because delay could have an immediate impact on training of crewmembers and ultimately upon passenger service in the air carrier industry.

Accordingly, I find that good cause exists for making this final rule effective immediately.

Federalism Implications

The amendment will not have substantial direct effect 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 final rule will not have sufficient federalism implications to warrant the preparation of Federalism Assessment.

Conclusion

For the reasons discussed in the preamble, and based on findings in the Regulatory Flexibility Determination and the International Trade Impact Analysis, the FAA has determined that this regulation is not major under Executive Order 12291. In addition, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the RFA. This amendment is considered significant under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979). A final regulatory evaluation of the amendment was not prepared since it was determined that the rule will impose no costs on society.

List of Subjects in 14 CFR Part 121

Aviation safety, Air carriers, Aircraft, Transportation, Airmen, Federal Aviation Administration, Reporting and record keeping requirements, Safety.

The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends parts 121 of the Federal Aviation Regulations (14 CFR part 121) as follows:

PART 121—CERTIFICATION AND OPERATIONS: DOMESTIC, FLAG, AND AIR CARRIERS AND COMMERCIAL OPERATORS OF LARGE AIRCRAFT

1. The authority citation for part 121 continues to read as follows:

Authority: 49 U.S.C. App 1354(a), 1355, 1356, 1357, 1401, 1421–1430, 1472, 1485, and 1502; 49 U.S.C. 106(g) (Revised Pub. L. 97–449, January 12, 1983).

2. Section 121.417 is amended by revising paragraphs (c)(1)(i), (d), and (f), redesignating current paragraph (c)(1)(ii) as (c)(1)(iii) and adding a new paragraph (c)(1)(ii) to read as follows:

§ 121.417 Crewmember emergency training.

* * * * *

(c) * * *

(1) * * *

(i) At least one approved protective breathing equipment (PBE) drill in which the crewmember combats an actual or simulated fire using at least one type of installed hand fire extinguisher or approved fire extinguisher that is appropriate for the type of actual fire or simulated fire to be fought while using the type of installed PBE required by § 121.337 or approved PBE simulation device as defined by paragraph (d) of this section for combatting fires aboard airplanes;

(ii) At least one approved firefighting drill in which the crewmember combats an actual fire using at least one type of installed hand fire extinguisher or approved fire extinguisher that is appropriate for the type of fire to be fought. This firefighting drill is not required if the crewmember performs the PBE drill of paragraph (c)(1)(i) by combating an actual fire; and

* * * * *

(d) After September 1, 1993, no crewmember may serve in operations under this part unless that crewmember has performed the PBE drill and the firefighting drill described by paragraphs (c)(1)(i) and (c)(1)(ii) of this section, as part of a one-time training requirement of paragraphs (c)(1) or (c)(2) of this section as appropriate. Any crewmember who performs the PBE drill and the firefighting drill prescribed in paragraphs (c)(1)(i) and (c)(1)(ii) of this section after May 26, 1987, is deemed to be in compliance with this regulation upon presentation of information or documentation, in a form and manner acceptable to the Director, Flight Standards Service, showing that the appropriate drills have been accomplished.

* * * * *

(f) For the purposes of this section the following definitions apply:

(1) *Actual fire* means an ignited combustible material, in controlled conditions, of sufficient magnitude and duration to accomplish the training objectives outlined in paragraphs (c)(1)(i) and (c)(1)(ii) of this section.

(2) *Approved fire extinguisher* means a training device that has been approved by the Administrator for use in meeting the training requirements of § 121.417(c).

(3) *Approved PBE simulation device* means a training device that has been approved by the Administrator for use in meeting the training requirements of § 121.417(c).

(4) *Combats*, in this context, means to properly fight an actual or simulated fire using an appropriate type of fire extinguisher until that fire is extinguished.

(5) *Observe* means to watch without participating actively in the drill.

(6) *PBE drill* means an emergency drill in which a crewmember demonstrates the proper use of protective breathing equipment while fighting an actual or simulated fire.

(7) *Perform* means to satisfactorily accomplish a prescribed emergency drill using established procedures that stress the skill of the persons involved in the drill.

(8) *Simulated fire* means an artificial duplication of smoke or flame used to create various aircraft firefighting scenarios, such as lavatory, galley oven, and aircraft seat fires.

Issued in Washington, DC, on August 26, 1993.

David R. Hinson,

Administrator.

[FR Doc. 93–21280 Filed 8–27–93; 2:18 pm]

BILLING CODE 4910–13–M

federal register

Wednesday
September 1, 1993

Part IV

Environmental Protection Agency

40 CFR Part 80

Approval of South Carolina's Petition to Relax the Federal Reid Vapor Pressure Volatility Standard for South Carolina; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 80

[FRL–4702–9]

Approval of South Carolina's Petition to Relax the Federal Reid Vapor Pressure Volatility Standard for South Carolina From 7.8 psi to 9.0 psi

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: In this document EPA is approving as a direct final rule the State of South Carolina's petition to relax the Reid Vapor Pressure Standard (RVP) applicable to gasoline introduced into commerce from June 1 to September 15 in the former Cherokee County ozone nonattainment area from 7.8 pounds per square inch (psi) to 9.0 psi. South Carolina's petition is based on evidence that the Cherokee County area does not need the 7.8 psi standard to maintain ozone attainment. Cherokee County and the State of South Carolina have met the requirements for redesignation from nonattainment to attainment status contained in section 107(d)(3)(E) of the Clean Air Act as amended (the Act) and EPA has redesignated Cherokee County as a result. EPA believes that further imposition of the 7.8 psi volatility standard would impose needless costs in light of South Carolina's attainment of the National Ambient Air Quality Standard (NAAQS) for ozone and completion of an EPA approved ozone maintenance plan that demonstrates ozone attainment for the next 10 years with 9.0 psi gasoline. This action is being taken without prior proposal because EPA believes that this final rulemaking is noncontroversial, for the reasons discussed above and because of the limited scope of this rulemaking.

DATES: This action will be effective on November 1, 1993, unless notice is received by October 1, 1993, that someone wishes to submit adverse or critical comments. If notice of intention to submit adverse comments is received and the effective date is delayed, timely notice withdrawing this action will be published in the **Federal Register**. Please direct all correspondence to the addresses shown below.

ADDRESSES: Materials relevant to this rulemaking have been placed in Docket (A–93–24) by EPA. The docket is located at the Air Docket Section (LE–131), U.S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20460, in room M–1500 Waterside Mall may be inspected from 8:30 a.m. to 12:00 p.m. and from 1:30 p.m. to 3:30 p.m. Monday through Friday. A reasonable fee may be charged for copying docket material.

Comments or notice of intent to submit adverse or critical comments should be submitted (in duplicate if possible) to the Air Docket Section at the above address. A copy should also be sent to Mr. Michael Ball at the EPA address listed below: U.S. Environmental Protection Agency, Office of Air and Radiation, 401 M Street, SW. (6406–J), Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: Michael Ball of the Regional/State/Local Coordination Section (202) 233–9005 and at the above address.

SUPPLEMENTARY INFORMATION:

I. Introduction

This notice describes EPA's action to approve as a direct final rule South Carolina's request to change the federal Reid Vapor Pressure (RVP) standard of 7.8 psi to 9.0 psi in the Cherokee former ozone nonattainment area from June 1 to September 15. The remainder of this notice is divided into five parts. Section II provides the background for this action. Section III provides the Agency's policy regarding relaxation of volatility standards in nonattainment areas redesignated as attainment. Section IV reviews the South Carolina request and supporting evidence. Section V reviews EPA's redesignation of Cherokee County as attainment. Finally, Section VI presents EPA's action and rationale.

II. Background

On August 19, 1987, EPA proposed a two-phase national program to reduce summertime gasoline volatility [1]. EPA had found that gasoline had become increasingly volatile, which caused an increase in evaporative emissions from gasoline-powered sources. These emissions are referred to as volatile organic compounds (VOC), a precursor for ozone. These gasoline-related VOC emissions are currently a major contributor to the nation's serious ground level ozone problem, which harms human health and the public welfare. The Agency published a notice of final rulemaking on March 22, 1989 that promulgated Phase I of the program to require VOC reductions that were available through refining changes that could be accomplished by the beginning of the 1989 summer ozone season, when they went into effect [2]. The Phase II volatility standards were finalized on June 11, 1990 [3]. These volatility standards went into effect May 1, 1992.

The final rule for the Phase I program established a federal volatility standard in South Carolina of (10.5) psi for the month of May, and 9.5 for June through September 15. The Phase II rule required a further reduction in the volatility standard to 9.0 psi for May and 7.8 psi for June 1 through September 15 beginning in 1992. The Phase I and Phase II standards were applicable on a statewide basis.

Congress established somewhat different requirements for the fuel volatility program in the Clean Air Act Amendments of 1990. Section 211(h)(1) of the Act, as amended, required that EPA promulgate regulations making it unlawful nationwide to sell, offer for sale, dispense, supply, offer for supply, transport, or introduce into commerce, gasoline with an RVP level in excess of 9.0 psi during the high ozone season as defined by the Administrator. It further provides that EPA shall establish more stringent RVP standards in nonattainment areas if EPA finds such standards are "necessary to achieve comparable evaporative emissions reductions, on a per vehicle basis, in such areas, taking into consideration the enforceability of such standards, the need of an area for emission control, and economic factors." Section 211(h) prohibits the regulations from establishing a volatility standard more stringent than 9.0 psi in an attainment area, except that it allows EPA to impose a lower standard in any former ozone nonattainment area which is redesignated to attainment.

On May 29, 1991, EPA published a Notice of Proposed Rulemaking that proposed to modify the Phase II summer ozone volatility standards to reflect new section 211(h) of the Act.[4] In this notice, EPA proposed that the RVP standard be 9.0 psi in all attainment areas where that standard was not already in place beginning in 1992. The effect of this proposal was to prohibit the sale of gasoline with a Reid Vapor Pressure above 9.0 psi during the summer ozone season in all areas designated attainment for ozone for 1992 and beyond. For areas that have been designated as nonattainment, EPA proposed that the original Phase II standards published on June 11, 1990 should not be changed. On December 12, 1991 EPA finalized these modifications.[5]

On November 6, 1991, EPA issued its ozone nonattainment designations in

[1] 52 FR 31274 (August 16, 1987).

[2] 54 FR 11868 (March 22, 1989).

[3] 54 FR 23658 (June 11, 1990).

[4] 56 FR 24242 (May 29, 1991).

[5] 56 FR 64704 (December 12, 1991).

the **Federal Register** pursuant to section 107(d)(1)(C) of the Act, as amended. In the November 6, 1991 notice, EPA designated Cherokee County, South Carolina as a "marginal" nonattainment area. Under the original Phase II volatility rule, a statewide standard was established in South Carolina that required 7.8 psi gasoline to be provided from June 1 to September 15. The modifications to the Phase II rule finalized on December 12, 1991, pursuant to section 211(h) of the Act as amended require that areas in South Carolina that were designated as nonattainment in the November 6, 1991 notice be provided with 7.8 psi gasoline. For all other areas of South Carolina the applicable standard was revised to 9.0 psi from May 1 to September 15.

III. EPA Policy Regarding Relaxation of Volatility Standards in Nonattainment Areas Redesignated as Attainment

Under the amended Phase II regulations, any change in the volatility standard for an area must be accomplished through a separate rulemaking revising the applicable standard for that area, even for an area that was designated as nonattainment in the November 6, 1991 notice but is subsequently redesignated as being in attainment.[6] Thus, for nonattainment areas where EPA mandated a Phase II volatility standard of 7.8 psi RVP in the December 12, 1991 rulemaking, the 7.8 psi standard will remain in effect, even after such an area is redesignated as being in attainment, until a separate rulemaking is completed that revises the RVP standard in that area from 7.8 psi to 9.0 psi.[7]

The Agency believes that relaxation of any RVP standard change is best accomplished in conjunction with the redesignation process. In order for an ozone nonattainment area to be redesignated as being in attainment for ozone, revised section 107(d)(3) of the Act requires the state to make a showing, pursuant to section 175A of the Act, that the area is capable of maintaining attainment for the ozone NAAQS for ten years. This maintenance plan may demonstrate that the area is capable of maintaining attainment for ten years without the more stringent volatility standard. However, the maintenance plan could also show that the more stringent volatility standard is or may be necessary for the area to maintain its attainment with the ozone NAAQS. Therefore, in the context of a request for redesignation, the Agency will not relax the volatility standard unless the maintenance plan demonstrates to the satisfaction of the Agency that the area will maintain attainment for ten years without the need for the more stringent volatility standard.[8]

IV. South Carolina's Petition and Maintenance Plan

On July 20, 1992, Mr. R. Lewis Shaw, South Carolina Deputy Commissioner for Environmental Quality Control, acting as the representative for South Carolina Governor Carroll Campbell, petitioned EPA to redesignate Cherokee County to attainment for ozone, and permanently relax the Federal RVP standard from 7.8 psi to 9.0 psi for the months of June through September 15 for the years 1994 and beyond. This request was based on three years (1989, 1990, 1991) of quality assured monitoring data that showed that Cherokee County had not violated the NAAQS for ozone[9] and on the South Carolina Department of Health and Environmental Control's (DHEC) "Cherokee County Attainment Demonstration and Ten-Year Maintenance Plan" which was included within the petition to redesignate and relax the RVP standard for Cherokee County. This document was submitted to fulfill the requirements for both redesignation and relaxing the RVP standard.

In the petition the state cited reasons for justifying a permanent relaxation of the RVP standard. DHEC submitted air quality data for Cherokee County that demonstrated that Cherokee County had attained the ozone NAAQS for the three-year period extending from 1989–1991, during which time the RVP standard for gasoline during the summer months was 9.5 psi. During that period, there were no exceedances, and hence, no violations of the ozone standard. In addition, the maintenance plan stated that Federal Motor Vehicle Control Program (FMVCP) requirements for lower tailpipe standards have further reduced emissions in Cherokee County.

DHEC further asserted that as a small, rural county, and as South Carolina's only ozone nonattainment area, the 7.8 RVP requirement has been very disruptive in that gasoline distributors have been reluctant to stock this gasoline for such a small market. DHEC claims that distributors will not deliver the 7.8 psi RVP gasoline in quantities less than a full 7,000-gallon tank truck load. DHEC contends that this has caused gasoline marketers to be charged a higher cost for distribution. This has created a burden for small businesses without the necessary storage capacity.

The Cherokee County maintenance plan includes a requirement to assess growth factors on a triennial basis with the contingency to assess on a yearly basis if the projection inventory is exceeded by 10% or more. The projection inventory reflects both the allowable emission rate, as well as the expected emission rate and expected actual production or activity level. The plan contains a contingency to implement additional control measures such as Control Technique Guidelines (CTG) categories within nine (9) months should the area violate the ozone NAAQS. South Carolina has utilized a 9.0 psi RVP in its maintenance plan to demonstrate long-term attainment of the ozone NAAQS without the use of the 7.8 psi RVP standard required in EPA's RVP final regulations.[10]

V. EPA Approval of the Cherokee County Maintenance Plan and Redesignation

On December 15, 1992, EPA announced a direct final rule in the **Federal Register** that approved the maintenance plan and redesignation of Cherokee County, South Carolina, to attainment for ozone.[11] In this rulemaking, EPA's Regional Administrator for Region IV determined that the State has met and fulfilled the requirements for redesignation contained in section 107(d)(3)(E) of the Clean Air Act Amendments of 1990.

Included in that determination were findings that the area had attained the NAAQS for ozone, that the improvements in air quality were due to permanent and enforceable emission

[6] Relaxation of RVP standards associated with the redesignation process was discussed in the preamble to EPA's final rule modifying the Phase II volatility standards (56 FR 64706, December 12, 1991).

[7] Similarly, when an area originally designated being in attainment is redesignated nonattainment, the volatility level of the gasoline will stay at 9.0 psi RVP unless and until EPA promulgates a rulemaking changing the RVP in that area (56 FR 64706, December 12, 1991).

[8] As stated in the preamble for the Agency's initial Phase II volatility standards (see 55 FR 23609), and in the preamble in the proposal to revise those standards (56 FR 24244), EPA may also promulgate a rule to revise the volatility standard in a particular nonattainment area in order to enhance local air quality and/or increase the economic efficiency of the program. The Governor of a state, or his designee, may petition EPA for a less stringent standard if such a standard is consistent with the requirements of the Act and if the state can document: (1) Particular local economic impact that makes the less stringent standard appropriate and (2) sufficient alternative programs to achieve attainment and maintenance of the NAAQS for ozone.

[9] The Federal standard for RVP in Cherokee County from 1989–1991 was 9.5 psi. As required for nonattainment areas in the Southeast an RVP of 7.8 psi went into effect for Cherokee County on June 1, 1992.

[10] 56 FR 64706 (December 12, 1992).

[11] 57 FR 59300 (December 15, 1992).

reductions, and that the Administrator has fully approved a maintenance plan for the area as meeting the requirements of section 175A of the Act.

The finding that the area had attained the NAAQS for ozone was based on the data indicating that Cherokee County had no violations in 1989, 1990 and 1991. The finding that permanent enforceable VOC emissions reductions have been obtained was based on evidence that the FMVCP had reduced emissions in Cherokee County and that federal requirements to reduce gasoline RVP had gone into effect in 1989.

In finding that the maintenance plan meets the requirements of section 175A, EPA cited the elements of the plan discussed above. EPA noted that the plan relied on a gasoline volatility level of 9.0 psi RVP, not 7.8 psi, as is required under current regulations. However, the final rule found that Cherokee County had demonstrated that it can maintain the ozone NAAQS using the less stringent volatility level of 9.0 psi RVP. On that basis, the maintenance plan was approved. No comments were received subsequently and the redesignation of Cherokee County to attainment for ozone became effective on February 16, 1993.

VI. EPA's Final Action

Beginning on the effective date of this rule, EPA is today relaxing the RVP standard for Cherokee County, South Carolina from 7.8 psi to 9.0 psi between June 1 and September 15 for the years 1994 and beyond. South Carolina has met the criteria for relaxation of the RVP standard discussed in the December 12, 1991 notice. The State has in place a fully approved implementation plan for Cherokee County that demonstrates that the county can maintain the ozone NAAQS without the 7.8 psi standard.

South Carolina's approved implementation and maintenance plan does not require a RVP standard more stringent than 9.0 psi. EPA's approval of this plan was based on evidence that the Cherokee County area does not need the 7.8 psi standard to maintain ozone attainment. Based upon the approval of the maintenance plan, which demonstrates attainment and maintenance of the ozone NAAQS standard for 10 years with a 9.0 psi RVP standard for gasoline, EPA believes sufficient alternative programs are in place to achieve attainment and maintenance of the ozone NAAQS and that further imposition of the 7.8 psi volatility standard would impose needless costs.[12]

This action is being taken without prior proposal because EPA believes that this relaxation in the RVP regulation is noncontroversial; the effect of this rulemaking is limited to Cherokee County, South Carolina; and EPA anticipates no significant comments on this action. Today's action is based on the same information that EPA relied on in its approval of South Carolina's maintenance plan. EPA noted specifically in its December 15, 1992 **Federal Register** notice that it intended to relax the volatility standard in Cherokee County to 9.0 psi in the near future. EPA received no adverse comments regarding its approval of the maintenance plan or the redesignation of Cherokee County to attainment. Further imposition of the 7.8 psi RVP standard would impose needless costs in light of Cherokee County's attainment and maintenance of the ozone NAAQS utilizing 9.0 psi RVP gasoline.

The public should be advised that this action will be effective 60 days from the date of this **Federal Register** notice, unless notice is received within 30 days that someone wishes to submit adverse or critical comments. If such notice is received, this action will be withdrawn and two subsequent notices will be published. One notice, which will be published before the effective date, will withdraw the final action. Another notice will begin a new rulemaking by announcing a proposal of the action and establishing a comment period. Interested persons are invited to submit comments on this proposed approval. EPA will consider all comments received within thirty days of the publication of this notice.

Consequently, this procedure still allows the opportunity for public comment and opportunity for oral presentation of data that is required under CAA section 307(d). This procedure merely provides an expedited procedure for final action where a rulemaking is not expected to be controversial and no adverse comment is expected.

VII. Environmental Impact

The amendment is not expected to cause Cherokee county to violate the NAAQS for ozone. The Cherokee County nonattainment area has met the NAAQS since 1989. That is, Cherokee County, has not recorded an exceedance during the time when the RVP standard in Cherokee county was no more stringent than 9.0 psi.

VIII. Economic Impact

The relaxation of the 7.8 psi standard to 9.0 psi will result in a cost savings to consumers of approximately 1.1 cents per gallon at the pump.

IX. Administrative Requirements

Pursuant to the Regulatory Flexibility Act, 5 U.S.C. 601 through 612, whenever an agency is required to publish a general notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis which describes the impact of the rule on small entities (i.e., small businesses, small organizations and small governmental jurisdictions). The Administrator may certify, however, that the rule will not have a significant impact on a substantial number of small entities. In such circumstances, a regulatory flexibility analysis is not required.

Under Section 605 of the Regulatory Flexibility Act, I certify that these regulations will not have a significant impact on a substantial number of small entities. The regulatory revision is limited to the Cherokee County area and should have no significant economic impact on a substantial number of small entities. These regulations, therefore, do not require a regulatory flexibility analysis.

Under Executive Order 12291, EPA must judge whether a regulation is "major" and therefore subject to the requirement that a Regulatory Impact Analysis be prepared. Major regulations have an annual effect on the economy in excess of $100 million, have a significant adverse impact on competition, investment, employment or innovation, or result in a major price increase. This final action in the rulemaking package does not constitute a major rule according to the established criteria. In fact, as discussed above, this action will reduce the cost of compliance with Federal requirements in this area. Therefore, I have determined that this proposal does not constitute a "major" rule.

This regulation was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291. OMB had no comments and concurred on this rulemaking.

Under the Paperwork Reduction Act of 1980, 44 U.S.C. 3501, EPA must obtain OMB clearance for any activity that will involve collecting substantially the same information from 10 or more non-Federal respondents. This direct

[12] In the May 29, 1991 notice proposing to modify the Phase II volatility standards, EPA estimated that the 7.8 psi standard will increase the cost of gasoline by approximately 1.1 cents per gallon over the 9.0 psi standard. In addition, as noted above, South Carolina states that special circumstances in Cherokee County may create an added burden for businesses in that area.

final rule does not create any new information requirements or contain any new information collection activities.

The statutory authority for the action in this notice today is granted to EPA by Sections 114, 211, 301(a), and 307 of the Clean Air Act as amended (42 USC 7414, 7545, 7601(a), and 7607).

List of Subjects in 40 CFR Part 80

Administrative practice and procedures, Air pollution control, Environmental protection, Motor vehicle and motor vehicle engines, Fuel additives, Gasoline, Motor vehicle pollution, Penalties, Reporting and recordkeeping requirements.

Dated: August 25, 1993.

Carol M. Browner,

Administrator.

For the reasons set forth in the preamble, part 80 of title 40 of the Code of Federal Regulations is amended as follows:

PART 80—REGULATION OF FUELS AND FUEL ADDITIVES

1. The authority citation for part 80 continues to read as follows:

Authority: Sections 114, 211, and 301(a) of the Clean Air Act as amended, 42 USC 7414, 7545 and 7601(a).

2. Section 80.27 is amended by revising the entry for "South Carolina" to the table in paragraph (a)(2) and by redesignating the footnote reference following "Colorado" and the second footnote 1 at the end of the table as footnote 2 to read as follows:

§ 80.27 Controls and prohibitions on gasoline volatility.

(a) * * *

APPLICABLE STANDARDS[1] 1992 AND SUBSEQUENT YEARS

State	May	June	July	August	September
* * * *	*	*	*	*	
South Carolina[3]	9.0	9.0	9.0	9.0	9.0
* * * *	*	*	*	*	

[1] Standards are expressed in pounds per square inch (psi)

[2] * * *

[3] The standard for nonattainment areas in South Carolina from June 1 until September 15 in 1992 and 1993 was 7.8 psi.

[FR Doc. 93–21251 Filed 8–31–93; 8:45 am]

BILLING CODE 6560–01–P

federal register

Wednesday
September 1, 1993

Part V

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 804 and 807
Medical Devices; Medical Device Distributor Reporting; Final Rules

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 804 and 807

[Docket No. 91N–0295]

Medical Devices; Medical Device Distributor Reporting; Opportunity for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; opportunity for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comments on the final rule on medical device distributor reporting, which is published elsewhere in this issue of the **Federal Register**. The medical device distributor reporting tentative final rule became final on May 28, 1992, by operation of the Safe Medical Devices Act of 1990 (the SMDA), as amended by the Medical Device Amendments of 1992 (the 1992 amendments). Although not required to do so, FDA realizes that there may be issues not previously considered, such as technical issues on specific provisions, and therefore is providing this additional time for comment. If changes are warranted by comments, FDA will make further changes in the rules.

DATES: Written comments by October 1, 1993.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Joseph M. Sheehan, Center for Devices and Radiological Health (HFZ–84), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 594–4765.

SUPPLEMENTARY INFORMATION: The SMDA of 1990 (Pub. L. 101–629), which became law on November 28, 1990, included provisions requiring FDA rulemaking to implement distributor reporting requirements. The 1992 amendments (Pub. L. 102–300), which amended certain distributor reporting requirements in the SMDA, became effective on June 16, 1992. Pursuant to the provisions of the SMDA, the regulatory provision relating to distributor reporting in the November 26, 1991, tentative final rule became final by operation of the statute on May 28, 1992. These regulatory provisions were subsequently amended on June 16, 1993, by operation of certain provisions in the 1992 amendments. The final rule on distributor reporting published elsewhere in this issue of the **Federal Register** explains the distributor reporting and statutory deadline provisions in more detail.

FDA has already provided opportunities for public comment on the proposal that preceded the rule published today as required by the Administrative Procedure Act. FDA is issuing a final rule based on consideration of these comments to the November 26, 1991, proposed tentative final rule in the near future. Until that time, the rule that is published elsewhere in this issue of the **Federal Register** will govern the reporting requirements for distributors. Although FDA is allowing additional comments on this rule, this action is in no way required by the Administrative Procedure Act. FDA is not interested in receiving comments that it has already received and considered. Although the agency does not believe that any public purpose would be served by reopening for further comment at this time the issues already addressed in the final rule being published, FDA recognizes that in any rulemaking there may be technical issues involving specific provisions that have not been considered. Therefore, the agency is providing 30 days for comment on this final rule on such issues. Comments should be identified with the docket number found in brackets in the heading of this document. FDA will publish additional changes in the final rule if comments bring to FDA's attention an issue, not already considered, that warrants revision.

Under 21 CFR 10.40(e), an opportunity for comment on this final rule is being provided. Interested persons may, on or before October 1, 1993, submit to the Dockets Management Branch (address above) written comments regarding this final rule. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This document is issued under the authority of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352, 360, 360i, 360j, 371, and 374) and under authority delegated to the Commissioner of Food and Drugs.

Dated: August 25, 1993.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 93–21185 Filed 8–31–93; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 91N–0295]

21 CFR Parts 804 and 807

Medical Devices; Medical Device Distributor Reporting

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; notification of status under the Safe Medical Devices Act; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the tentative final rule on medical device distributor reporting that appeared in the **Federal Register** of November 26, 1991 (56 FR 60024), is now a final rule by operation of law. This final rule requires distributors to submit reports to FDA and to manufacturers, of deaths, serious illnesses, and serious injuries related to medical devices and to submit reports to manufacturers of certain malfunctions that may cause a death, serious illness, or serious injury, if the malfunction were to recur. The final rule also changes the reporting standard for certain distributors that are importers, and changes the definition of the term "serious injury" to conform to a recent statutory amendment. In issuing this final rule, FDA is announcing that the tentative final rule relating to adverse event reporting requirements for distributors, including importers, has the status of a final rule, as of May 28, 1992, by operation of law under the Safe Medical Devices Act of 1990 (the SMDA), as amended by the Medical Device Amendments of 1992 (the 1992 amendments), and is setting forth the regulations reflecting those requirements. FDA is also amending the regulations, based on consideration of comments on the November 26, 1991, tentative final rule, to require distributors to register their facilities and to list their devices with FDA.

DATES: Part 804 is effective May 28, 1992; the amendments to part 807 are effective October 1, 1993.

FOR FURTHER INFORMATION CONTACT: Chester T. Reynolds, Center for Devices and Radiological Health (HFZ–306), Food and Drug Administration, 1390 Piccard Dr., Rockville, MD 20850, 301–594–1156.

SUPPLEMENTARY INFORMATION:

I. Background

The current regulatory framework for medical device reporting requirements is the result of four statutes:

(1) The Federal Food, Drug, and Cosmetic Act of 1938 (21 U.S.C. 321–394) (the act);

(2) The Medical Device Amendments of 1976 (Pub. L. 94–295) (the 1976 amendments), which amended the act to establish the first comprehensive framework for the regulation of medical devices;

(3) The SMDA (Pub. L. 101–629), which amended the act to correct noted problems with the implementation and enforcement of the 1976 amendments; and

(4) The Medical Device Amendments of 1992 (Pub. L. 102–300) (the 1992 amendments), which amended certain provisions of the act relating to devices.

Section 519 of the act (21 U.S.C. 360i), as added by the 1976 amendments, authorized FDA to issue regulations to require manufacturers, importers, and distributors to maintain such records, make such reports, and provide such information to FDA as may reasonably be necessary to ensure that devices are not adulterated or misbranded and are otherwise safe and effective for human use. The legislative history of the 1976 amendments reflects clear congressional intent to permit FDA to require, under the authority of section 519 of the act, device manufacturers, importers, and distributors to report to FDA product defects and adverse effects of the firms' devices. (See H. Rept. 853, 94th Cong., 2d sess. 23 (1976).) Among other things, section 519 of the act states that any reporting requirement established under the authority of that section: (1) May not be unduly burdensome (considering the cost of compliance and the need for the requirement); (2) shall state the purpose for any required report or information and identify to the fullest extent practicable such report or information; (3) may not, except in certain circumstances, require the disclosure of a patient's identity; and (4) may not, except in certain circumstances, require the manufacturer, distributor, or importer of a class I device to maintain records, or to submit information not in its possession, unless such report or information is necessary to determine whether a device is misbranded or adulterated. The House Report cautions, however, that these limitations "should not be construed * * * as limiting the Secretary's authority to obtain information needed to insure that the public is protected from potentially hazardous devices." Id. at 24.

In discussing the notification provisions of section 518 of the act (21 U.S.C. 360h), the House Report, the principal legislative document on the amendments, states:

> The notification provision is similar to, and to some extent patterned after, comparable authority contained in the National Traffic and Motor Vehicle Safety Act of 1966, the Radiation Control for Health and Safety Act of 1968, and the Consumer Product Safety Act of 1972. These statutes also include requirements that manufacturers provide notification of defects in their products to appropriate Federal agencies. The Committee determined that a comparable provision in new section 518(a) with respect to devices would be unnecessary since the Secretary could require the reporting of such information under the recordkeeping and reporting authority provided in new section 519 of the Act.

(H. Rept. 853, supra, at 21.)

In its discussion of section 519 of the act, the House Report lists examples of reasonable reporting requirements, including reports of defects, adverse reactions, and patient injuries. That Congress intended FDA to use its authority under section 519 of the act to protect the public from potentially hazardous devices, as well as devices with confirmed hazards, is also clear from the legislative history. Id. at 24.

In the Federal Register of September 14, 1984 (49 FR 36348), FDA issued the current medical device reporting (MDR) regulations (21 CFR part 803). The regulations require manufacturers and importers of medical devices, including diagnostic devices, to report to FDA whenever the manufacturer or importer becomes aware of information that reasonably suggests that one of its marketed devices: (1) May have caused or contributed to a death or serious injury, or (2) has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Since the enactment of the 1976 amendments, Congress has focused considerable attention on FDA's implementation and enforcement of the act with respect to medical devices. During this time, the General Accounting Office (GAO), Office of Technology Assessment (OTA), and Office of Inspector General of the Department of Health and Human Services (OIG) conducted investigations and issued reports on problems associated with significant weaknesses in FDA's information gathering ability and its followup mechanisms for information that is received. S. Rept. 513, 101st Cong., 2d sess. 15 (1990). A GAO study, for example, noted that although FDA has received more than a seven-fold increase in reports associated with device-related problems since the promulgation of the MDR regulation, serious under reporting of device-related, reportable events exists. GAO also noted that many firms are unaware of their obligation to report device-related deaths, injuries, and malfunctions to FDA, and that device-related deaths in hospitals are rarely reported to either FDA or the manufacturer. A GAO followup study in 1989 concluded that despite implementation of the MDR regulations, serious shortcomings exist.

Congress concluded from its own hearings and investigations and from its review of the GAO, OTA, and OIG investigations and reports that the 1976 amendments were not always adequate to protect the public health. (H. Rept. 808, 101st Cong., 2d sess. 13–14 (1990), S. Rept. 513, 101st Cong., 2d sess. 13–16 (1990).) On November 28, 1990, to correct these problems, the SMDA was signed into law to amend the medical device provisions of the act.

The SMDA added section 519(b)(1) to the act (21 U.S.C. 360i(b)(1)) to require that certain device user facilities report deaths related to medical devices to FDA and to the manufacturer, if known. FDA may also, by regulation, include outpatient diagnostic facilities in this requirement.

Although since 1976, under section 519 of the act, FDA has had the authority to require distributors to report adverse effects and deficiencies of devices, the agency until this point had not implemented this authority. However, the legislative history of the SMDA reflects Congress' belief that FDA must require distributors to make such reports because distributors may be the first to recognize possible device problems. (See H. Rept. 808, 101st Cong., 2d sess. 22–23 (1990).) Accordingly, the SMDA added section 519(a)(6) to the act to require distributors to report to FDA adverse effects and deficiencies of devices, and to submit copies of these reports to manufacturers. Id.

The SMDA also added section 519(d) to the act requiring reporting manufacturers and distributors to certify to FDA the number of reports submitted in a year or the fact that no such reports have been submitted to the agency. This requirement was directly in response to a GAO finding that certification would increase the efficiency of the MDR. (See S. Rept. 513, 101st Cong., 2d sess. 26 (1990).)

The SMDA directed FDA to issue a proposal to implement distributor

reporting and recordkeeping requirements within 9 months of the enactment. (See section 3(c)(1)(A) of the SMDA.) The SMDA provides that the proposed rule relating to distributor reporting would become final 18 months after the enactment of the SMDA, May 28, 1992, if a final rule was not promulgated by that date.

On November 26, 1991 (56 FR 60024), under the authority of sections 502, 510, 519, 520, 701, and 704 of the act (21 U.S.C. 352, 360, 360i, 360j, 371, and 374), FDA issued a proposed rule designated as a "tentative final rule" that would implement the reporting requirements of the SMDA relating to manufacturers, distributors, and user facilities. This tentative final rule would require device user facilities and distributors, including importers, to submit reports to FDA and/or the manufacturers, of deaths, serious illnesses, and serious injuries related to medical devices. This tentative final rule also proposed to amend existing reporting requirements in 21 CFR part 803 for manufacturers to conform them with the proposed reporting requirements for user facilities and distributors. Further, it proposed to require distributors and manufacturers to report certain malfunctions that may cause a death, serious illness, or serious injury. Under the tentative final rule and pursuant to section 519(d) of the act, distributors and manufacturers would also be required to certify annually the number of reportable events submitted during the previous calendar year or the fact that no such reports were received.

The tentative final rule also proposed to amend 21 CFR part 807 to require distributors to register and list with FDA, pursuant to section 510 of the act. This exercise of authority is necessary to implement the new adverse event reporting requirements for distributors.

II. Comments

In the **Federal Register** of January 24, 1992 (57 FR 2861), FDA announced that it was extending the comment period for the tentative final rule until February 26, 1992. FDA received over 300 comments on the tentative final rule. At present, FDA is still considering the comments on the tentative final rule relating to manufacturer, distributor, and user facility adverse event reporting and has not issued a final rule that is based on consideration of those comments. Because FDA did not promulgate a final rule for distributor reporting by May 28, 1992, however, the provisions in the tentative final rule relating to distributor adverse event reporting automatically became the final rule on that date pursuant to section 3(c) of the SMDA.

On June 16, 1992, subsequent to the statutory provision making the tentative final rule with respect to distributors automatically final, additional statutory provisions further amending distributor reporting requirements became law (the 1992 amendments). Section 5(a) of the 1992 amendments adopts a single standard to determine when injuries caused by devices must be reported to FDA: A manufacturer, importer, or user facility is required to report a device-related, adverse event to FDA when information reasonably suggests that a device * * * "may have caused or contributed to * * * death or * * * serious injury."

Section 5(a) of the 1992 amendments also adopts a single definition for the types of injuries that manufacturers, importers, distributors, and user facilities must report. This definition requires reporting of an injury that is life threatening, results in permanent impairment of a body function or permanent damage to a body structure, or necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure. This definition differs from the previous statutory definition of "serious injury" that is applied to device user facilities in that it deletes the requirement that an injury must require immediate intervention to preclude permanent impairment or damage in order to qualify as a reportable injury.

The effective date of the amendments made by section 5(a) of the 1992 amendments is either 1 year from the date of the enactment of the 1992 amendments, or on the effective date of the FDA regulations implementing such amendments, whichever occurs first. Because FDA has not issued regulations implementing the 1992 amendments, the provisions of the 1992 amendments became effective by operation of law on June 16, 1993. See section 5(b) of the 1992 amendments.

FDA is issuing this rule and notifying the public pursuant to the directive of section 3(c)(2) of the SMDA that distributor adverse event reporting requirements proposed in the November 26, 1991, tentative final rule are now final. This final rule reflects certain changes from the November 26, 1991, tentative final rule that conform to the 1992 amendments that became effective on June 16, 1993. In addition, FDA is issuing this final rule, based on consideration of comments received in response to the tentative final rule, requiring distributors to register their establishments and list their devices.

At a later date, FDA intends to amend the final distributor reporting regulation and to issue final regulations governing manufacturer and user facility reporting to reflect the changes to the reporting requirements for user facilities and manufacturers made by the 1992 amendments. These future final regulations will also reflect consideration of comments relating to adverse event reporting submitted in response to the November 26, 1991, tentative final rule.

Under the provisions of this final rule that became effective by operation of law, distributors, other than importers, are required to submit a report to FDA, and a copy of such report to the manufacturer, containing the information required by new § 804.28, as soon as practicable, but not later than 10 working days after the distributor becomes aware of information from any source, that reasonably suggests that there is a probability that a device marketed by the distributor has caused or contributed to a death, serious illness, or serious injury. Distributors, other than importers, must also submit reports to the manufacturer containing the information required by new § 804.28, as soon as practicable, but not later than 10 working days after the distributor becomes aware of information, from any source, that one of the devices marketed by the distributor has malfunctioned and such information reasonably suggests there is a probability that the device or any other device marketed by the distributor would cause a death, serious illness, or serious injury, if the malfunction were to recur.

Distributors that are importers are subject to a slightly different standard as required by the 1992 amendments. Specifically, an importer must submit a report to FDA, and a copy of such report to the manufacturer, containing the information required by new § 804.28, as soon as practicable, but not later than 10 working days after the importer becomes aware of information from any source that one of the devices marketed by the importer may have caused or contributed to a death or serious injury. Importers are also required to submit reports to the manufacturer containing the information required under new § 804.28 as soon as practicable but not later than 10 working days after the importer becomes aware of information, from any source, that reasonably suggests, that one of its marketed devices has malfunctioned and such device or a similar device marketed by the importer would be likely to cause or to contribute to a death or serious injury if the malfunction were to recur.

The agency is aware that many distributors have limited capabilities to conduct followup investigations or failure analyses, or both. It is also unlikely that device user facilities are accustomed to providing patient or adverse device experience followup information to distributors. Consequently, a distributor's role in the MDR process is one of an intermediary who forwards data from user facilities, or any other source, to FDA and the manufacturer. Distributors are not required to investigate the cause of adverse device events; rather, they are required to assess whether or not a reportable event has occurred. This responsibility includes review and verification of data that they receive and supplying information that is within a distributor's control to FDA or the manufacturer, or both.

On June 3, 1993, FDA announced the availability of a new form for adverse event reports from manufacturers, user facilities, and distributors in the **Federal Register** (58 FR 31596). This single form replaces certain existing reporting forms and is to be used for reporting adverse events and product problems with devices as well as medications and other products regulated by the agency. This form will be required on the date that the final rule, based on comments to the November 26, 1991, tentative final rule, for user facility, manufacturer, and distributor reporting requirements becomes effective, or November 30, 1993, whichever occurs later. In the meantime, distributors are encouraged to submit reports on these forms. These forms may be obtained from the Division of Small Manufacturers Assistance, (HFZ–220), Center for Devices and Radiological Health, 5600 Fishers Lane, Rockville, MD 20857. Bulk copies of the form may be obtained from the Consolidated Forms and Publications Distribution Center, Washington Commerce Center, 3222 Hubbard Rd., Landover, MD 20785.

The final rule also requires that distributors certify annually to FDA either the number of MDR's during the previous annual reporting period, or that the distributor did not receive any reportable events during this period. Annual certification will follow the same schedule as registration. Distributors must also establish files of information related to MDR's and retain the files for 2 years from the date the report or information was submitted to FDA or the manufacturer or for a period of time equivalent to the design and expected life of the device, whichever is longer.

In order to implement the new adverse event reporting requirements, FDA is now issuing a final rule, based on comments on the tentative final rule, requiring distributors to register and list. The tentative final rule proposed revising current § 807.22(c) to require distributors who initiate or develop specifications for a device and distributors who repackage or relabel a device to submit a listing form and maintain an historical file (§ 807.22(c)(1) and (c)(2)). Such persons, however, are already required to list under current § 807.20(a) and (c). Therefore, in the final regulation, FDA is deleting proposed registration and listing requirements in § 807.22(c)(1) and (c)(2) for persons who initiate or develop device specifications or who repackage or relabel because these requirements would be duplicative of the existing requirements under current § 807.20(a) and (c). Accordingly, because such persons are already required to list, the new listing requirements for distributors add new requirements only for persons who do not initiate or develop the specifications for the device or repackage or relabel the device. Although these distributors are not required to submit a listing form, they must submit, for each device, listing information including the name and address of the manufacturer. Such distributors shall also be prepared to submit, when requested by FDA, the proprietary name, if any, and the common or usual name of each device for which they are distributors. The final regulations states that certain entities that manufacture devices according to another parties specifications or that sterilize devices are exempt from registration and listing requirements.

FDA received several comments relating to the distributor registration and listing requirements proposed in the tentative final rule. They are summarized below:

A. § 807.3(g)—Definitions

1. Some comments stated that clarification was needed for the difference between manufacturers and distributors.

A distributor, as defined in § 807.3(g), is any person who furthers the marketing of a device, but does not repackage, or otherwise change the container, wrapper, or labeling of the device package. A manufacturer includes any person who repackages or otherwise changes the container, wrapper, or labeling of a device in furtherance of the distribution of the device. To the extent that manufacturers are also engaged in the distribution process, they are only required to report as manufacturers.

B. § 807.20—Who Must Register and Submit a Device List

2. Two comments argued that FDA does not have authority to require distributors to register and list.

FDA does not agree with these comments. The plain language of the act provides FDA with explicit authority to require distributors to register and list. Section 510(c) of the act states that:

> "[e]very person upon first engaging in the manufacture, preparation, *propagation*, compounding, or processing of * * * a device or devices in any establishment which he owns or operates in any State shall immediately register with the Secretary his name, place of business, and such establishment."

(Emphasis added).

This language makes it clear that FDA has authority to require distributors to register because they are engaged in the "propagation" of devices. Although neither the statute nor the legislative history define the term "propagation," this term is defined in Webster's Ninth New Collegiate Dictionary as "the spreading of something abroad or into new regions." (Merriam Co. 1990). Certainly, persons who distribute medical devices in interstate commerce are "spreading * * * something * * * into new regions" and, therefore, are persons who propagate medical devices within the meaning of the statute. Moreover, the language of section 510(c) of the act demonstrates that Congress intended to provide FDA with broad authority to require persons who are engaged in a wide range of activities with respect to medical devices to register their devices. Accordingly, Congress not only authorized FDA to require persons to register who are engaged in the manufacture of devices, but also authorized FDA to require persons to register who are engaged in the "preparation, propagation, compounding, or processing" of medical devices. These words taken together, or individually, provide FDA with authority to require registration of any person who is involved with the distribution of medical devices.

The statute also provides clear authority to require distributors to list their devices. FDA's authority to require distributors to list derives directly from the agency's authority to require distributors to register. Specifically, section 510(j)(1) of the act requires that "[e]very person who registers under subsection (b), (c), or (d) shall, at the time of registration under any such subsection, file with the Secretary a list of all * * * devices * * * which are being

manufactured, prepared, propagated, compounded, or processed by him for commercial distribution." Accordingly, because FDA has authority to require distributors, as propagators of devices, to register, FDA also has authority to require distributors to list their devices pursuant to section 510(j)(1) of the act.

3. One comment stated that distributor listing information is duplicative of manufacturer listing information and that therefore, distributors should not be required to establish costly procedures to obtain and provide listing information. One comment suggested that distributors of devices be exempted from the registration and listing requirements. Another comment suggested that distributors of domestic devices be exempt form registering.

FDA does not agree with the comments that requiring distributors to list provides information that duplicates manufacturer listing information nor does FDA agree that distributors in general or distributors of domestic devices should be exempt from these requirements. Obtaining listing information from both manufacturers and distributors allows FDA to have an accurate up-to-date inventory of medical devices that is necessary to implement the agency's regulatory and enforcement authorities. Manufacturer listing information alone does not provide FDA with information about who distributes products. Distributor registration and listing information is necessary because it will provide additional information that will help FDA in enforcement of distributor medical device reporting requirements, and in implementing product recalls and notifications under section 518 of the act. Accordingly, the final rule requires distributors to provide registration and listing information.

4. Two comments requested that multisite distributors be allowed the option of decentralized registration. Another comment stated that multisite distributors should be allowed the option to choose which location would be the reporting location and FDA contact location for purposes of FDA registration and reporting.

FDA agrees that multisite distributors should have the option of registering only a central location or each location. Under the final regulation, a multisite distributor who chooses to file registration for only one central location, must register only the primary or principal place of business establishment located in the United States where the MDR complaint files are maintained.

C. § 807.21—Times for Establishment Registrationand Device Listing

5. One comment requested clarification as to when the distributor registration requirement is effective.

On June 15, 1992, FDA issued a letter notifying distributors that registration requirements were effective on July 15, 1992. FDA has reconsidered this position and is extending the deadline for submission of registration requirements to October 1, 1993. Distributors will also be required to list their devices as of October 1, 1993.

D. § 807.22—How and Where to Register and List

6. One comment suggested that this section be revised, so that there is a distinction between a repackager and a distributor.

The agency disagrees that this section should be modified because the definition does make a distinction between distributors and repackagers. Under the definition any person who changes the package or label is not a distributor. Repackagers or relabelers are considered manufacturers, and they must register and list as such.

E. § 807.65—Exemptions for Device Establishments

7. Two comments asked whether dental supply stores must register.

Under section 807.65(e) dental supply stores that dispense or sell devices in the regular course of business at the retail level are exempt from registration requirements.

The codified text below contains only those adverse event reporting requirements from the November 26, 1991, tentative final rule, as amended by the 1992 amendments, which apply to distributors, since only the distributor reporting requirements have become final. Incorporation of the distributor requirements from the tentative final rule into part 803 as it is currently written is not feasible because of organizational changes in the text. Therefore, the distributor reporting requirements are being codified separately at this time in new 21 CFR part 804. When the final rule is published in its entirety, the distributor requirements will be removed from part 804, and all of the reporting requirements for manufacturers, device user facilities and distributors, including importers, will be merged into 21 CFR part 803.

III. Paperwork Reduction Act of 1980

The recordkeeping and reporting requirements for medical device distributors, including importers, were submitted to the Office of Management and Budget (OMB) for review as part of the tentative final rule that was published in the Federal Register of November 26, 1991, that proposed the adverse event reporting requirements for manufacturers, distributors and user facilities. These recordkeeping and reporting requirements have been approved by OMB under control number 0910–0059 "Medical Devices: Medical Device Reporting, User Facility Reporting, Distributor Reporting, Manufacturer Reporting, Certification, Registration," and are in conformance with the Paperwork Reduction Act of 1980 (44 U.S.C. ch. 35).

OMB has also approved the new adverse event reporting form for use by distributors, as well as user facilities and manufacturers under control number 0910–0291 "MedWatch: FDA's Medical Products Reporting Program." The availability of the form was announced by the agency in the Federal Register of June 3, 1993 (58 FR 31596), and the form is in conformance with the requirements of the Paperwork Reduction Act of 1980 (44 U.S.C. ch. 35).

IV. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8) that this action is of a type that does not individually or cumulatively have a significant effect or the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Economic Impact

In conjunction with the agency's issuance of the tentative final rule proposing to require device user facilities and distributors, including importers, to submit reports of certain adverse events to FDA and to manufacturers (56 FR 60024, November 26, 1991), FDA placed on file at the Dockets Management Branch a copy of the agency's threshold assessment of the economic effects of this rule.FDA has carefully examined the economic impact of this action in accordance with the requirements of Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96–354). The agency concludes that the rule is not a major rule as defined in Executive Order 12291. Further, the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities, as defined in the Regulatory Flexibility Act. A copy of the document supporting this determination is on file at the Dockets Management Branch (address above) and may be seen in that office between

9 a.m. and 4 p.m., Monday through Friday.

List of Subjects

21 CFR Part 804

Imports, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 807

Confidential business information, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, new part 804 is added and part 807 is amended as follows:

1. New part 804 is added to read as follows:

PART 804—MEDICAL DEVICE DISTRIBUTOR REPORTING

Subpart A—General Provisions

Sec.

Subpart B—Reports and Records

Authority: Secs. 502, 510, 519, 520, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352, 360, 360i, 360j, 371, 374).

Subpart A—General Provisions

§ 804.1 Scope.

(a) FDA is requiring medical device distributors to report deaths, serious illnesses, and serious injuries that are attributed to medical devices. Distributors are also required to report certain device malfunctions and to submit a report to FDA annually certifying the number of medical device reports filed during the preceding year, or that no reports were filed. These reports enable FDA to protect the public health by helping to ensure that devices are not adulterated or misbranded and are otherwise safe and effective for their intended use. In addition, device distributors are required to establish and maintain complaint files or incident files as described in § 804.35, and to permit any authorized FDA employee at all reasonable times to have access to, and to copy and verify, the records contained in this file. This part supplements, and does not supersede, other provisions of this subchapter, including the provisions of part 820 of this chapter.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

§ 804.3 Definitions.

(a) Act means the Federal Food, Drug, and Cosmetic Act.

(b) and (c) [Reserved]

(d) *Distributor* means any person, including any person who imports a device into the United States, who furthers the marketing of a device from the original place of manufacture to the person who makes final delivery or sale to the ultimate user but who does not repackage or otherwise change the container, wrapper, or labeling of the device or device package. One who repackages or otherwise changes the container, wrapper, or labeling, is a manufacturer under § 804.3(k).

(e) *Distributor Report Number* means the number that uniquely identifies each report submitted by a distributor. Distributors who receive or submit reports shall use their seven digit FDA registration number, calendar year that the report is received, and a sequence number. For example, the complete number will appear as follows: 1234567–1991–0001. Distributor report numbers shall also be required on FDA form 3500A.

(f) *FDA* means the Food and Drug Administration.

(g) [Reserved]

(h) *Incident files* are those files containing documents or other information, which are related to adverse events that may have been caused by a device.

(i) *Information that reasonably suggests that there is a probability that a device has caused or contributed to a death or serious injury or serious illness* means information, including professional, scientific, or medical facts, observations, or opinions, which would cause a reasonable person to believe that a device caused or contributed to a death, serious injury, or serious illness.

(j) *Malfunction* means the failure of a device to meet any of its performance specifications or otherwise to perform as intended. Performance specifications include all claims made in the labeling for the device. The intended performance of a device refers to the objective intent of the persons legally responsible for the labeling of the device. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the device. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It also may be shown by the circumstances that the device is, with the knowledge of such persons or their representatives, offered and used to perform a function for which it is neither labeled nor advertised.

(k) *Manufacturer* means any person who manufactures, prepares, propagates, compounds, assembles, or processes a device chemically, physically, biologically, or by other procedures. The term includes any person who:

(1) Repackages or otherwise changes the container, wrapper, or labeling of a device in furtherance of the distribution of the device from the original place of manufacture, to the person who makes final delivery or sale to the ultimate user or consumer;

(2) Initiates specifications for devices that are manufactured by a second party for subsequent distribution by the person initiating the specifications; or

(3) Manufactures components or accessories which are devices that are ready to be used and are intended to be commercially distributed and are intended to be used as is, or are processed by a licensed practitioner or other qualified person to meet the needs of a particular patient.

(l) *MDR* means medical device report.

(m) *MDR reportable event* means:

(1) The event for which a distributor, other than an importer, required to report under this part has received or become aware of information that reasonably suggests that there is a probability that a device has caused or contributed to a death, serious illness, or serious injury; or

(2) The event for which an importer required to report under this part has received or become aware of information that reasonably suggests that a device may have caused or contributed to a death or serious injury; or

(3) A malfunction, for which a distributor, other than an importer, required to report under this part has received or become aware of information that reasonably suggests that there is a probability that the device, if the malfunction were to recur, would be likely to cause or contribute to a death, serious illness, or serious injury; or

(4) A malfunction, for which an importer required to report under this part has received or become aware of information that reasonably suggests that a device has malfunctioned and that such device or a similar device would be likely to cause or contribute

to a death or serious injury if the malfunction were to recur.

(n) through (p) [Reserved]

(q) *Permanent* means nonreversible impairment or damage.

(r) *Probability, probable, or probably* means, for purposes of this section, that a person would have reason to believe, based upon an analysis of the event and device, that the device has caused or contributed to an adverse event. This term does not signify statistical probability.

(s) *A remedial action* is any recall, repair, modification, adjustment, relabeling, destruction, inspection, patient monitoring, notification, or any other action relating to a device that is initiated by a distributor, in response to information that it receives or otherwise becomes aware of, that reasonably suggests that one of its marketed devices has caused or contributed to an MDR reportable event.

(t) *Serious illness* means an event that:

(1) Is life threatening;

(2) Results in permanent impairment of a body function or permanent damage to the body structure; or

(3) Necessitates immediate medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

(u) *Serious injury* means an event that:

(1) Is life threatening;

(2) Results in permanent impairment of a body function or permanent damage to a body structure, or

(3) Necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

(v) [Reserved]

(w) *Work day* means Monday through Friday excluding Federal holidays. Federal holidays include New Year's Day, Martin Luther King Jr.'s Birthday, Presidents' Day, Memorial Day, Independence Day, Labor Day, Columbus Day, Veterans Day, Thanksgiving Day, and Christmas Day.

(x) Any term defined in section 201 of the act shall have the same definition unless otherwise defined in this part.

§ 804.9 Public availability of reports.

(a) Any report, including any FDA record of a telephone report, submitted under this part is available for public disclosure in accordance with part 20 of this chapter.

(b) Before public disclosure of a report, FDA will delete from the report:

(1) Any information that constitutes trade secret or confidential commercial or financial information under § 20.61 of this chapter; and

(2) Any personnel, medical, and similar information, including the serial numbers of implanted devices, which would constitute a clearly unwarranted invasion of personal privacy under § 20.63 of this chapter; provided, that, except for the information under § 20.61 of this chapter, FDA will disclose to a patient who requests a report all the information in the report concerning that patient.

Subpart B—Reports and Records

§ 804.25 Reports by distributors.

(a)(1) A distributor, other than an importer, shall submit to FDA a report, and a copy of such report to the manufacturer, containing the information required by § 804.28 on FDA form 3500A as soon as practicable, but not later than 10 working days after the distributor receives or otherwise becomes aware of information from any source, including user facilities, individuals, or medical or scientific literature, whether published or unpublished, that reasonably suggests that there is a probability that a device marketed by the distributor has caused or contributed to a death, serious illness, or serious injury.

(2) An importer shall submit to FDA a report, and a copy of such report to the manufacturer, containing the information required by § 804.28 on FDA form 3500A as soon as practicable, but not later than 10 working days after the importer receives or otherwise becomes aware of information from any source, including user facilities, individuals, or medical or scientific literature, whether published or unpublished, that reasonably suggests that one of its marketed devices may have caused or contributed to a death or serious injury.

(b)(1) A distributor, other than an importer, shall submit to the manufacturer a report containing information required by § 804.28 on FDA form 3500A, as soon as practicable, but not later than 10 working days after the distributor receives or otherwise becomes aware of information from any source, including user facilities, individuals, or through the distributor's own research, testing, evaluation, servicing, or maintenance of one of its devices, that one of the devices marketed by the distributor has malfunctioned and such information reasonably suggests that there is a probability that the device or any other device marketed by the distributor would cause a death, serious illness, or serious injury, if the malfunction were to recur.

(2) An importer shall submit to the manufacturer a report containing information required by § 804.28 on FDA form 3500A, as soon as practicable, but not later than 10 working days after the importer receives or otherwise becomes aware of information from any source, including user facilities, individuals, or through the distributor's own research, testing, evaluation, servicing, or maintenance of one of its devices, that one of the devices marketed by the importer has malfunctioned and that such device or a similar device marketed by the importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

§ 804.27 Where to submit a report.

(a) Any telephone report required under this part shall be provided to 301–427–7500.

(b) Any facsimile report required under this part shall be provided to 301–881–6670.

(c) Any written report or additional information required under this part shall be submitted to:

Food and Drug Administration,
Center for Devices and Radiological Health,
Distributor Report,
P.O. Box 3002,
Rockville, MD 20847–3002.

§ 804.28 Reporting form.

(a) Each distributor that submits a report on an MDR reportable event shall complete and submit the applicable portions of FDA form 3500A in so far as the information is known or should be known to the distributor, and submit it to FDA, and to the manufacturer as required by § 804.25.

(b) Each distributor shall submit the information requested on FDA form 3500A, including:

(1) Identification of the source of the report.

(i) Type of source that reported the event to thedistributor (e.g., lay user owner; lay user lessee, hospital, nursing home, outpatient diagnostic facility, outpatient treatment facility, ambulatory surgical facility);

(ii) Distributor report number;

(iii) Name, address, and telephone number of the reporting distributor and the source that reported the event to the distributor; and

(iv) Name of the manufacturer of the device.

(2) Date information.

(i) The date of the occurrence of the event;

(ii) The date the source that reported the event to the distributor became aware of the event;

(iii) The date the event was reported to the manufacturer and/or FDA; and

(iv) The date of this report.

(3) The type of MDR reportable event, e.g., death, serious illness, serious

injury, or malfunction, and whether an imminent hazard was involved;

(4) Patient information including age, sex, diagnosis, and medical status immediately prior to the event and after the event;

(5) Device information including brand and labeled name, generic name, model number or catalog number or other identifying numbers, serial number or lot number, purchase date, expected shelf life/expiration date (if applicable), whether the device was labeled for single use, and date of implant (if applicable);

(6) Maintenance/service information data including the last date of service performed on the device, where service was performed, whether service documentation is available, and whether service was in accordance with the service schedule;

(7) Whether the device is available for evaluation and, if not, the disposition of the device;

(8) Description of the event.

(i) Who was operating or using the device when the eventoccurred;

(ii) Whether the device was being used as labeled or as otherwise intended;

(iii) The location of the event;

(iv) Whether there was multi-patient involvement, and if so, how many patients were involved;

(v) A list of any other devices whose performance may have contributed to the event and their manufacturers, and the results of any analysis or evaluation with respect to such device (or a statement of why no analysis or evaluation was performed); and

(vi) A complete description of the event including, but not limited to, what happened, how the device was involved, the nature of the problem, patient followup/treatment required, and any environmental conditions that may have influenced the event.

(9) The results of any analysis of the device and the event, including:

(i) The method of evaluation or an explanation of why no evaluation was necessary or possible;

(ii) The results and conclusions of the evaluation;

(iii) The corrective actions taken; and

(iv) The degree of certainty concerning whether the device caused or contributed to the reported event;

(10) The name, title, address, telephone number, and signature of the person who prepared the report.

804.30 Annual certification.

Distributors required to report under this section shall submit a certification report to FDA by the date designated for annual registration for the firm in § 807.21 of this chapter. This date will cover the period ending 1 month before the month of the scheduled date of mailing as indicated in § 807.21(a). The report will contain the following information:

(a) The name, address, telephone number, and FDA registration number of the distributor;

(b) A statement certifying that:

(1) The distributor listed in paragraph (a) of this section has filed reports under this section during the previous 12-month period and all MDR reportable events have been submitted to FDA and/or to the appropriate manufacturer. The report will also include the number of death, serious injury or serious illness reports that were submitted to FDA, and the number of malfunction reports that were submitted to manufacturers; or

(2) The distributor listed in paragraph (a) of this section did not receive any reportable events during the previous 12-month period.

(c) The name, address, title, telephone number, and signature of the individual making the certification for the firm. This person must be a responsible person designated by the firm.

§ 804.31 Additional requirements.

Requests for additional information. If FDA determines that the protection of the public health requires information in addition to that included in the medical device reports submitted to FDA under this part, the distributor shall, upon FDA's request, submit such additional information. Any request by FDA under this section shall state the reason or purpose for which the information is being requested, and specify a due date for the submission of such information.

§ 804.32 Supplemental information.

(a) Only one MDR is required under this part if the distributor becomes aware, from more than one source, of information concerning the same patient and the same event.

(b) An MDR that would otherwise be required under this section is not required by the distributor if:

(1) The distributor determines that the information received is erroneous in that a death, serious injury, serious illness, or the malfunction did not occur; or

(2) The distributor determines that the information received is erroneous in that the device that is the subject of the information was distributed by another distributor. A distributor shall forward to FDA any report that is erroneously sent to the distributor, with a cover letter explaining that the product in question is not distributed by that firm.

(c) A report or information submitted by a distributor under this part (and any release by FDA of that report or information) does not necessarily reflect a conclusion by the party submitting the report or by FDA that the report or information constitutes an admission that the device, the establishment submitting the report, or employees thereof, caused or contributed to a death, serious injury, serious illness, or malfunction. A distributor need not admit, and may deny, that the report or information submitted under this part constitutes an admission that the device, the party submitting the report, or employees thereof, caused or contributed to a death or serious injury, serious illness, or malfunction.

§ 804.33 Alternative reporting requirements.

(a) Distributors may request exemptions from any or all of the reporting requirements in this part. These requests are required to be in writing and to include both the information necessary to identify the firm and device and an explanation why the request is justified.

(b) FDA may grant a distributor, in writing, an exemption from any or all of the reporting requirements in this part and may change the frequency of reporting to quarterly, semiannually, annually, or other appropriate time periods. In granting such exemptions, FDA may impose other reporting requirements to ensure the protection of public health and safety. FDA may also authorize the use of alternative reporting media such as magnetic tape or disk, in lieu of FDA forms.

(c) FDA may revoke alternative reporting options, in writing, if FDA determines that protection of the public health justifies a return to the requirements as stated in this part.

§ 804.34 Written MDR procedures.

Device distributors shall maintain and implement written MDR procedures in the following areas:

(a) Training and education programs informing employees about obligations under this section, including how to identify and report MDR reportable events;

(b) Internal systems that provide for timely and effective identification, communication, and evaluation of events that may be subject to MDR requirements, a standardized review process/procedure for determining when an event meets the criteria for reporting under this part, and timely transmission of complete MDR's to FDA and/or manufacturers; and

(c) Documentation and recordkeeping requirements for:

(1) Information that may be the subject of an MDR;

(2) All MDR's and information submitted to FDA and manufacturers;

(3) Information that facilitates the submission of certification reports; and

(4) Systems that ensure access to information that facilitates timely followup and inspection by FDA.

§ 804.35 Files.

(a) A device distributor shall establish a device complaint file in accordance with § 820.198 of this chapter and maintain a record of any information, including any written or oral communication, received by the distributor concerning all events that were considered for possible reporting under this part. Device incident records shall be prominently identified as such and shall be filed by device. The file shall also contain a copy of any MDR along with any additional information submitted to FDA under this part. A distributor shall maintain records that document the submission of copies of MDR's to manufacturers.

(b) A device distributor shall retain copies of the records required to be maintained under this section for a period of 2 years from the date that the report or additional information is submitted to FDA under § 804.25, or for a period of time equivalent to the design and expected life of the device, whichever is greater, even if the distributor has ceased to distribute the device that is the subject of the report or the additional information.

(c) A device distributor shall maintain the device complaint files established under this section at the distributor's principal business establishment. A distributor that is also a manufacturer may maintain the file at the same location as the manufacturer maintains its complaint file under §§ 820.180 and 820.198 of this chapter. A device distributor shall permit any authorized FDA employee, during all reasonable times, to have access to, and to copy and verify, the records required by this part.

PART 807—ESTABLISHMENT REGISTRATION AND DEVICE LISTING FOR MANUFACTURERS AND DISTRIBUTORS OF DEVICES

2. The authority citation for 21 CFR part 807 is revised to read as follows:

Authority: Secs. 301, 501, 502, 510, 513, 515, 519, 520, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331, 351, 352, 360, 360c, 360e, 360i, 360j, 371, 374).

3. Part 807 is amended by revising the part heading to read as follows:

PART 807—ESTABLISHMENT REGISTRATION AND DEVICE LISTING FOR MANUFACTURERS AND DISTRIBUTORS OF DEVICES

4. Section 807.3 is amended by revising paragraphs (d)(2) and (g), by amending paragraph (e)(3) by removing the word "and" after the semicolon at the end of the paragraph, by amending paragraph (e)(4) by removing the period at the end of the paragraph and by adding in its place "; and", and by adding new paragraph (e)(5) to read as follows:

§ 807.3 Definitions.

* * * * *

(d) * * *

(2) Distribution of domestic or imported devices; or

* * * * *

(e) * * *

(5) The annual certification of medical device reports required by § 804.30 of this chapter or forwarding the certification form to the person designated by the firm as responsible for the certification.

* * * * *

(g) Distributor means any person who furthers the marketing of a device from the original place of manufacture, whether domestic or imported, to the person who makes final delivery or sale to the ultimate consumer or user, but does not repackage, or otherwise change the container, wrapper, or labeling of the device or device package.

* * * * *

5. Section 807.20 is amended by revising paragraph (a)(4) and by adding new paragraphs (c) and (d) to read as follows:

§ 807.20 Who must register and submit a device list.

(a) * * *

(4) Distributors;

* * * * *

(c) Distributors of domestic or imported devices must register and fulfill their listing obligations as described in § 807.22(c) of this part. Distributors with multiple sites may submit one registration for all sites or submit a registration for each site. If a multisite distributor chooses to file one registration, the registration must be from the principal business establishment which maintains the MDR complaint files.

(d) Registration and listing requirements shall not pertain to any person who:

(1) Manufacturers devices for another party who both initiated the specifications and commercially distributes the device;

(2) Sterilizes devices on a contract basis for other registered facilities who commercially distribute the devices.

* * * * *

6. Section 807.21 is revised to read as follows:

§ 807.21 Times for establishment registration and device listing.

(a) An owner or operator of an establishment who has not previously entered into an operation defined in § 807.20 shall register within 30 days after entering into such an operation and submit device listing information at that time. An owner or operator of an establishment shall update its registration information annually within 30 days after receiving registration forms from FDA. FDA will mail form FDA-2891a to the owners or operators of registered establishments according to a schedule based on the first letter of the name of the owner or operator. The schedule is as follows:

First letter of owner or operator name	Date FDA will mail forms
A, B, C, D, E	March.
F, G, H, I, J, K, L, M .	June.
N, O, P, Q, R	August.
S, T, U, V, W, X, Y, Z	November.

(b) Owners or operators of all registered establishments shall update their device listing information every June and December or, at their discretion, at the time the change occurs.

7. Section 807.22 is amended by revising paragraphs (a) and (c) to read as follows:

§ 807.22 How and where to register establishments and list devices.

(a) The first registration of a device establishment shall be on form FDA-2891 (Initial Registration of Device Establishment). Forms are obtainable upon request from the Center for Devices and Radiological Health (HFZ-342), Food and Drug Administration, 1390 Piccard Dr., Rockville, MD 20850, or from the Food and Drug Administration (FDA) district offices. Subsequent annual registration shall be accomplished on form FDA-2891a (Annual Registration of Device Establishment), which will be furnished by FDA to establishments whose registration for that year was validated under § 807.35(a). The forms will be mailed to the owner or operators of all establishments in accordance with the schedule as described in § 807.21(a). The completed form shall be mailed to

the above-designated address within 30 days after receipt from FDA.

* * * * *

(c) The listing obligations of the distributor are satisfied as follows:

(1) The distributor is not required to submit a form FDA-2892 for those devices for which such distributor did not initiate or develop the specifications for the device or repackage or relabel the device. However, the distributor shall submit, for each device, the name and address of the manufacturer. Distributors shall also be prepared to submit, when requested by FDA, the proprietary name, if any, and the common or usual name of each device for which they are the distributors; and

(2) The distributor shall update the information required by paragraphs (c)(1) of this section at the intervals specified in § 807.30.

8. Section 807.25 is amended by revising paragraph (b) to read as follows:

§ 807.25 Information required or requested for establishment registration and device listing.

* * * * *

(b) The owner or operator shall identify the device activities of the establishment such as manufacturing, repackaging, or distributing devices.

* * * * *

9. Section 807.65 is amended by revising paragraph (e) and by removing and reserving paragraph (g) to read as follows:

§ 807.65 Exemptions for device establishments.

* * * * *

(e) Pharmacies, surgical supply outlets, or other similar retail establishments making final delivery or sale to the ultimate user. This exemption also applies to a pharmacy or other similar retail establishment that purchases a device for subsequent distribution under its own name, e.g., a properly labeled health aid such as an elastic bandage or crutch, indicating "distributed by" or "manufactured for" followed by the name of the pharmacy.

* * * * *

Dated: August 25, 1993.

Michael R. Taylor,

Deputy Commissioner for Policy.

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