by painting the outside of the glass), and AFM supplement placement requirements of paragraphs (b), (c), and (d) of this AD, respectively, can be accomplished by:

(1) *For airplanes operated in accordance with part 91 of the Federal Aviation Regulations (14 CFR part 91):* An owner/operator who holds at least a private pilot's certificate; and

(2) *For airplanes operated in accordance with part 135 of the Federal Aviation Regulations (14 CFR part 135):* An operator who holds an operating certificate issued under part 135 of the Federal Aviation Regulations (14 CFR part 135), as authorized by sections 43.3, 43.7, and 43.9 of the Federal Aviation Regulations (14 CFR 43.3, 43.7, and 43.9).

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

(g) An alternative method of compliance or adjustment of the compliance time that provides an equivalent level of safety may be approved by the Manager, Anchorage Aircraft Certification Office (ACO), 222 West 7th Avenue, #14, Room 128, Anchorage, Alaska 99513–7587.

(1) The request shall be forwarded through an appropriate FAA Maintenance Inspector, who may add comments and then send it to the Manager, Anchorage ACO.

(2) Alternative methods of compliance approved for AD 80–10–01 are not considered approved as alternative methods of compliance for this AD.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Anchorage ACO.

(h) The modifications, placard installation, airspeed indicator re-marking, and AFM supplement placement required by this AD shall be done in accordance with AECI SB No. LW3600–3, originally issued: September 21, 1979; Amended: October 10, 1997; AECI Drawing No. LW3600–180A–1 and –2, Revision ''B'', dated September 21, 1979; AECI Drawing No. LW3600–180A–3, Revision ''A'', dated April 30, 1979; AECI Drawing No. LW3600–180, Revision ''F'', dated September 21, 1979 (for single position wheel ski installations) or AECI Drawing No. LW3600–180A, Revision ''E'', dated September 21, 1979 (for two position wheel ski installations); AECI Drawing No. LW3600–180A–11, originally issued: September 21, 1979; and AECI Document AE97–13FM, ''Supplemental Airplane Flight Manual and Airplane Flight Manual Supplement'', dated October 10, 1997. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Airglas Engineering Company, Inc., P.O. Box 190107, Anchorage, Alaska 99519–0107. Copies may be inspected at the FAA, Central Region, Office of the Regional Counsel, Room 1558, 601 E. 12th Street, Kansas City, Missouri, or at the Office of the Federal Register, 800 North Capitol Street, NW, suite 700, Washington, DC.

(i) This amendment supersedes AD 80–10–01, Amendment 39–3762.

(j) This amendment becomes effective on December 22, 1998.

Issued in Kansas City, Missouri, on October 27, 1998.

James E. Jackson,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 98–29363 Filed 11–3–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 211

[Docket No. 92N–0314]

Tamper-Evident Packaging Requirements for Over-the-Counter Human Drug Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations on tamper-resistant packaging to require that all over-the-counter (OTC) human drug products marketed in two-piece, hard gelatin capsules be sealed using a tamper-evident technology; to change the term ''tamper-resistant'' in the labeling of all OTC drug products to ''tamper-evident;'' and to specify that the required OTC drug product labeling statement must refer to all packaging features used to comply with the tamper-evident packaging requirements, including those on the secondary package, the immediate container or closure, and any capsule sealing technologies used. FDA is taking this action as a result of its continuing review of the potential public health threat posed by product tampering and to improve consumer protection by addressing specific vulnerabilities in the OTC drug market.

DATES: Effective December 4, 1998.

Compliance dates: All two-piece, hard gelatin capsules subject to the final rule that are initially introduced or initially delivered for introduction into interstate commerce by November 4, 1999, must be sealed in compliance with the requirements of the final rule.

OTC drug products that use the term ''tamper-resistant'' in their labeling must change the term to ''tamper-evident'' by November 6, 2000.

FOR FURTHER INFORMATION CONTACT: Thomas C. Kuchenberg, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5640.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 18, 1994 (59 FR 2542), FDA proposed to amend the tamper-evident packaging requirements for OTC drug products in § 211.132 (21 CFR 211.132). This regulation, which is intended to protect consumers from malicious tampering with OTC drug products, was first codified in 1982 and amended in 1989.

The 1982 regulation (47 FR 50442, November 5, 1982) was issued in response to a tampering incident in the Chicago area in which seven people died after ingesting cyanide-laced Extra-Strength Tylenol capsules. The regulation required, among other things, that any OTC drug product (except a dermatologic, dentifrice, insulin, or lozenge product) for retail sale be packaged in a ''tamper-resistant'' package, so that a breach of the package would provide visible evidence to consumers that tampering had occurred. Although the risk of tampering was reduced significantly by this rule, the two-piece, hard gelatin capsule remained vulnerable to tampering. Three deaths in 1986 were associated with this dosage form. In response to the continued susceptibility of two-piece, hard gelatin capsules, FDA amended § 211.132 (54 FR 5227, February 2, 1989) to require that OTC drug products marketed in two-piece, hard gelatin capsules must be packaged using at least two tamper-resistant packaging features, or with at least one tamper-resistant packaging feature if a tamper-resistant capsule seal was employed.

Despite these regulations, two-piece, hard gelatin capsules have continued to be a target of malicious drug tampering. This dosage form was implicated in a February 1991 tragedy, resulting in two deaths, involving Sudafed capsules contaminated with cyanide. The Sudafed package and dosage form met FDA's tamper-resistant standards, and there were visible signs of tampering that were both numerous and conspicuous. Based on investigations and discussions surrounding the 1991 tampering fatalities, as well as FDA's ongoing review of the public health threat from OTC drug product tampering, the agency initiated this rulemaking to reduce the potential for tampering with vulnerable two-piece, hard gelatin capsules. The agency invited comments from the public not only with respect to the proposed amendments, but also on effective ways to educate consumers about OTC drug product tampering issues and steps

consumers could take to reduce the threat from tampering. FDA also invited comments on consumer behavior in buying and using OTC drug products and how tamper-evident packaging and associated labeling affect their behavior. The agency also requested comments on whether additional regulatory changes, such as the establishment of performance standards for tamper-evident packaging, may be necessary.

II. Highlights of the Final Rule

The final rule amends the current tamper-resistant packaging requirements for OTC human drug products to further decrease the risks posed by product tampering by: (1) Mandating the sealing of all OTC two-piece, hard gelatin capsules; and (2) changing the terminology used throughout the agency's regulatory program from ''tamper-resistant'' to ''tamper-evident'' to characterize more accurately the role of tamper-evident packaging in protecting consumers.

The final rule requires that all OTC drug products marketed in two-piece, hard gelatin capsules be sealed using a tamper-evident technology, and that the packaging of the sealed capsules have a minimum of one tamper-evident feature. This amends the current requirement that a minimum of two tamper-resistant features be used for this dosage form if the capsule is not sealed. The capsule sealing requirement is necessary because two-piece hard gelatin capsules remain vulnerable to malicious tampering.

The final rule changes the terminology used throughout FDA's regulatory program from ''tamper-resistant'' to ''tamper-evident.'' The words ''tamper-evident'' appropriately underscore the importance of heightening consumer awareness to any evidence of tampering, rather than implying that a particular package is difficult to breach or is tamper-proof. Labeling is unacceptable if it implies that the product is tamper resistant or tamper proof.

The final rule clarifies, in § 211.132(c), that an OTC drug product's labeling statement must identify all tamper-evident packaging features used, including those on the secondary package, the immediate container or closure, and any capsule sealing technologies used. This clarification is necessary because some firms have interpreted the regulation as requiring reference to the tamper-evident features only on the outside of the package.

The final rule replaces the term ''throat lozenge'' with ''lozenge'' in § 211.132(a) and (b), thus slightly broadening the exemption from, and narrowing the scope of, the rule.

Reflecting the change from tamper-resistant to tamper-evident, and consistent with proposed § 211.132(b), the final rule eliminates the reference to ''aerosol product container.'' However, the reference to ''aerosol products'' in § 211.132(c) was inadvertently omitted in the proposed rule, and FDA has restored this language to make it clear that no tamper-evident features are required for aerosol products. FDA is also restoring the words ''materials or through commonly available'' in the explanation of the term ''distinctive by design'' in § 211.132(b). These words were inadvertently omitted in the proposed rule.

The dates for compliance with the sealing requirement and terminology change are 1 year and 2 years respectively from the date of publication of this final rule in the **Federal Register**. In response to comments, the final rule does not include a retail effective date as proposed because of the expected high rate of manufacturer compliance with the rule.

III. Comments on the Proposed Rule

A. General

FDA received 43 comments on the proposed rule, a substantial majority of which were from the general public. The remaining comments were from OTC drug manufacturers and packers, professional societies, and organizations with special interests in consumer safety and product packaging.

Many comments supported the requirement that two-piece, hard gelatin capsules be sealed. One of these comments stated:

> [U]nless two-piece, hard gelatin capsules used in OTC drug products are required to be sealed, as FDA is proposing, it is just a matter of time until another successful tampering incident involving this dosage form occurs. Each publicized tampering incident further erodes the public confidence in the safety of our OTC drug supply.

However, some comments were less supportive, including one that stated that:

> [T]he amendment requiring two-piece, hard gelatin capsules be sealed is unnecessary in light of the protections already required under the present regulation. * * * [F]urther regulation will only result in additional costs which will be borne by the consumer. Furthermore, such changes cannot completely eliminate the dangers of product tampering.

A significant majority of comments supported the change in terminology from ''tamper-resistant'' to ''tamper-evident.'' These comments concurred with the agency's position that the term ''tamper-evident'' more accurately describes the role of packaging and other features designed to decrease the risk of harm from tampering. A typical comment on this issue stated that ''such a change imparts an added degree of awareness to the consumer that no package design is 'tamper-proof'.'' Other comments were less supportive, saying that the change in language would not substantially aid consumer awareness or significantly reduce the threat of tampering harm.

B. Scope

Current § 211.132 applies to manufacturers and packers who package OTC drug products, except dermatologic, dentifrice, insulin, or throat lozenge products. The final rule maintains the current scope, except that it exempts all lozenge products rather than only throat lozenges.

1. One comment stated that the agency should expand the scope of the rule to include all OTC drug products, including dermatologics.

Dermatologic, dentifrice, and insulin products have been exempted from the OTC tampering regulations since they were issued in 1982. These product classes are exempted because of a lower probability of tampering and in the case of dermatologic and dentifrice products, a lower risk of severe consequences. Therefore the agency declines to apply the regulation to these product classes in this rulemaking.

2. One comment asserted that FDA had not considered the effect of the proposed rule on vitamins and other supplements sold in two-piece, hard gelatin capsules and stated that the economic impact on dietary supplement manufacturers and the public would be immense.

The scope of the regulation is limited to OTC drug products and is not intended to cover products that are regulated as dietary supplements.

C. Effectiveness of Sealing Requirement

Proposed § 211.132(b)(2) stated that, in addition to an acceptable tamper-evident packaging feature, any two-piece, hard gelatin capsule covered by the OTC tamper-evident packaging rule must be sealed using an acceptable tamper-evident technology.

3. Four comments asserted that if two-piece, hard gelatin capsules were sealed, consumers would have a false sense of security that such capsules are impenetrable.

The agency recognizes that an additional level of protection against tampering may make consumers feel more secure about using OTC drug products. However, the sealing requirement, along with the other

regulatory standards set forth in this final rule, will in fact add a measure of protection against malicious tampering by making it more difficult for a person to tamper with a product without leaving visible evidence that tampering has occurred. Thus the heightened sense of security may have some basis in fact. Because all packaging is penetrable and no packaging or dosage form is tamper-proof, consumers should be vigilant when buying and using OTC drug products. The change in terminology from ''tamper-resistant'' to ''tamper-evident,'' in combination with the agency's efforts to educate consumers about tamper-evident packaging, is designed to alert consumers to examine OTC drug product packaging for evidence of tampering.

4. Two comments claimed that consumers would not notice any tampering with sealed capsules and, thus, would not be protected by this requirement. Another comment stated that a breach in the tamper-evident packaging feature would more likely be noticed than a breach of a capsule seal.

The agency does not agree with the comments. However, a major benefit of the capsule-sealing feature is that sealing makes it virtually impossible for a tamperer to disturb the integrity of the product and recombine the two parts of the capsule without leaving conspicuous signs of entry. Although not all seals are visible in the unbreached state, some seals have distinctive characteristics (e.g., color scheme) that make it less likely that a substituted capsule would go unnoticed. Such signs of tampering with the product itself may be more likely to be noticed than less obvious manifestations of tampering left on certain tamper-evident packaging features such as container mouth inner seals, film wrappers, and heat shrink bands or wrappers. Some or all of these protective features could be removed by a tamperer without leaving any signs of tampering to consumers unaware of the packaging normally used. Thus, for the two-piece, hard gelatin capsule dosage form, which has been particularly vulnerable to criminal tampering, it is important to have the dual protection of a package tamper-evident feature plus the capsule-sealing feature.

5. Three comments stated that the sealing requirement would be ineffective in reducing the overall tampering risk because it only addresses the vulnerability of one OTC drug product dosage form, the two-piece, hard gelatin capsule, while other dosage forms go unprotected.

It is true that consumer products other than two-piece, hard gelatin capsules are vulnerable to tampering. For this reason, in addition to the capsule sealing requirement, current § 211.132 requires that all OTC drug products (except those specifically exempted) be packaged using a tamper-evident feature. This final rule maintains this requirement and proposes an extra measure of protection for OTC two-piece, hard gelatin capsules which, as explained in the preamble to the proposed rule, have been persistently implicated in the most serious tampering incidents (59 FR 2542 at 2543). Thus the agency believes the rule will reduce the overall tampering risk.

6. Two comments stated that the sealing requirement would not yield a significant benefit because most OTC two-piece, hard gelatin capsule drug products are already sealed.

While it is true that there are few two-piece, hard gelatin capsule drug products currently marketed without a seal, the remaining unsealed capsules may provide an attractive target for would-be tamperers. The availability of unsealed OTC drug product capsules makes it relatively easy for the tamperer to substitute them for other, sealed capsules with a similar appearance. Thus, the universal sealing of two-piece, hard gelatin capsule drug products will not only make products that are presently unsealed safer, but will also bolster the effectiveness of the sealing feature on currently sealed products by reducing opportunities for substitution.

7. Several comments proposed alternative means of reducing the threat of drug tampering. Some comments recommended that OTC drug products marketed in two-piece, hard gelatin capsules be banned or restricted to pharmacy counter sales.

FDA has considered these options and finds that a ban or restriction on the sale of two-piece, hard gelatin capsule OTC drug products is not warranted because the benefits of allowing the continued OTC marketing of the dosage form outweigh the risks posed by possible tampering. Consumers might mistakenly think that the threat of tampering has been eliminated by such an action and thus be lulled into a false sense of security. A complacent consumer may not remain vigilant to signs of tampering with other dosage forms.

In addition, capsules are a valuable dosage form option for several reasons: (1) Many consumers prefer capsules because they are easier to swallow than some other dosage forms and this factor may increase patient compliance with a drug regimen. (2) Some medicines cannot easily be put in tablet form because of the detrimental effects of tableting on the stability of the ingredients. (3) Capsules are less susceptible than other dosage forms to damage during shipping. Uncoated tablets may chip or break during shipping and, thus, may deliver less than the recommended amounts of ingredients, possibly affecting the product's efficacy. (4) Capsules contain fewer inactive ingredients than some tablet and oral liquid formulations, thus lowering the risk of allergic reactions. (5) Capsules are a preferred means of delivering sustained-release medications. Capsules containing encapsulated beads of active ingredients provide a means of delivering medications safely over prolonged periods, thus enhancing patient compliance. (6) The printing and color combinations that are possible with capsules aid consumers and health professionals in distinguishing medicines. Product distinction is important in aiding patient compliance with drug regimens and in the effective handling of overdose cases (Ref. 1).

Because of the numerous advantages of capsules, the agency believes that restricting two-piece, hard gelatin capsules to behind-the-counter sales would be a disservice to consumers. If capsules were kept behind the counter, consumers could not easily compare products. Also, because behind-the-counter space is limited, the expense and inconvenience of storing products might cause retail outlets to limit the number of OTC capsule drug products they make available.

8. Comments suggested several other alternative methods of protecting consumers against tampering, including requiring video surveillance of areas where tamper-prone products are displayed, and requiring that tamper-prone products have a holographic label to make evidence of tampering more visible.

Although these suggestions have merit insofar as they would provide an additional level of protection against tampering, FDA has determined that sealing the capsules is the preferred alternative because it will benefit the consuming public while keeping implementation costs low. FDA encourages manufacturers to continue to use innovative tamper-evident technologies to provide protection to the consumer and encourages retail outlets to play a significant role in protecting the consumer and apprehending tamperers. Retailers are encouraged, for example, to train their employees to handle products properly to avoid an accidental breach of the tamper-evident features and to play a role in inspecting products for signs of tampering when working at the cash register, placing

products on retail shelves, and otherwise handling products.

9. Two comments asserted that consumers accustomed to the use of two package tamper-evident features on their OTC drug products may be concerned if one of the familiar features is missing. As a result, manufacturers would, in effect, be compelled to use two package tamper-evident features in addition to the sealing feature.

FDA is not mandating that three tamper-evident features be used, and the agency is not convinced that consumers will be alarmed by a change in a product's tamper-evident features. Informative labeling will help allay the anxiety that consumers may feel. Retailers will also be able to explain the change in packaging to interested or concerned customers.

D. Dates

10. Two comments opposed the proposed retail level effective date for compliance with the sealing requirement. These comments characterized the effective date as extraordinary, insupportable, and unprecedented. The comments said that the retail effective date places an undue burden on retailers to examine all of their products, determine which products covered by the rule are out of compliance, and return those products to the manufacturers. According to the comments, the prospect of conducting these resource-intensive compliance checks would likely lead retailers to return all products marketed in two-piece, hard gelatin capsules rather than just those products that were, in fact, out of compliance. The comments asserted that such a marketing disruption is not justified in light of the negligible number of unsealed capsules that would be on the market 2 years after the publication of the final rule.

FDA has considered the benefits of a retail level effective date and the burden that would be placed on retailers, and agrees that such a condition is currently unwarranted. The agency expects that, because no unsealed capsules may be initially introduced into interstate commerce 1 year after publication of this final rule, a negligible quantity of noncomplying products will remain on the market 2 years after publication of the final rule. The agency bases this expectation in part on the high level of compliance with the effective date of the 1982 tamper-resistant packaging rule. The agency has, accordingly, removed the proposed retail level effective date from this final rule.

While FDA encourages manufacturers to revise OTC drug product labeling to replace the term ''tamper-resistant'' with ''tamper-evident'' as soon as possible, the agency recognizes that substantial revision of OTC labeling may be required by a final rule based on the proposed OTC labeling rule published in the **Federal Register** of February 27, 1997 (62 FR 9024). A reasonable effort has been made to coordinate implementation of the two rules and, following publication of a final OTC labeling rule, FDA will consider whether to extend the compliance date of the labeling changes provided by this regulation to coincide with the effective date of the OTC labeling final rule. The agency emphasizes that any such extension would apply only to the labeling requirements and not to the sealing requirements of this rule. All two-piece, hard gelatin capsules subject to this regulation that are initially introduced or initially delivered for introduction into interstate commerce must be sealed in compliance with this regulation by the date provided in the ''Dates'' section of this document.

E. Effectiveness of Change in Terminology from ''Tamper-Resistant'' to ''Tamper-Evident''

FDA proposed to amend § 211.132 by changing the term ''tamper-resistant'' to ''tamper-evident.''

11. Fourteen comments, while agreeing with the proposed change, stated that its effectiveness would depend on an education campaign to bolster awareness of steps consumers can take to protect themselves. The most common concerns expressed by comments opposed to the proposed change were that consumers will not notice the change or that they will not understand the distinction between ''tamper-resistant'' and ''tamper-evident.''

The agency recognizes that this change may go unnoticed by those consumers who do not regularly read labels. It is nonetheless important that labeling accurately and truthfully characterize the degree of protection afforded by tamper-evident packaging. It is particularly important that measures designed to discourage tampering do not convey a false sense of security or reduce consumer vigilance. The agency believes the term ''tamper-evident'' better indicates the need for active consumer surveillance of protective packaging features. FDA stated in the proposed rule and reiterates here that ''the term 'tamper evident' more accurately describes the role of packaging in reducing the likelihood of harm from tampering, and emphasizes the necessity of consumer involvement in the effectiveness of any packaging system designed to meet the requirements of this regulation'' (59 FR 2542 at 2544). The role of consumer education in enhancing protection against tampering is discussed in the response to comment 20 in section III.G of this document.

12. Several comments suggested a requirement that the labeling statement on tamper-evident features be printed in a more conspicuous format (e.g., in bold face, underlined type, or contrasting colors).

The agency does not believe that such a requirement is necessary at this time. While such labeling measures would no doubt attract some consumers' attention initially, the agency believes that many other factors must be weighed in a consideration of such a requirement. First, such prominence of the tamper-evident message may distract consumers from other labeling information, such as warnings and directions for use, that may be equally important. Second, in light of the crucial role of OTC drug products in our health care system, consumers must not be discouraged from using OTC medications because of an excessive emphasis on the tampering threat.

13. One comment stated that the term ''tamper-evident'' would not convey the appropriate message, but rather would give consumers a false sense that it would be ''glaringly obvious'' if a product's antitampering feature had been breached. Another comment stated that consumers are intelligent and do not interpret the term ''tamper-resistant'' to mean ''tamper-proof.''

FDA does not agree that the term ''tamper-evident'' will mislead the consumer or that the term ''tamper-resistant'' does not. While the term ''tamper-resistant'' does not technically mean that a product is tamper proof, the term focuses on the packaging technology itself and can imply that it is difficult to breach an antitampering feature. While it may not be difficult to breach some commonly used antitampering features, it is difficult to breach a feature without leaving visible signs of tampering. Such visible signs will only protect consumers from tampering harm if they are aware that an antitampering feature is breached or missing. The proposed change in the terminology appropriately shifts the emphasis from the ability of the feature itself to protect consumers to the ability of vigilant consumers to protect themselves.

14. One comment asserted that the rule improperly shifts the burden of preventing drug product tampering from the OTC industry to the ''unsuspecting sick and poor consumers.''

FDA does not agree. The proposed rule will require some manufacturers of hard capsules to take additional steps to prevent tampering by sealing two-piece, hard gelatin capsules. Nonetheless, because it is impossible to make a tamper-proof package, the success of an antitampering regulatory program necessarily depends in part on consumers' attentiveness; consumers must take some responsibility for protecting themselves. FDA-mandated tamper-evident features will allow vigilant consumers to minimize their chances of being victimized by a malicious tamperer. Ultimately, the best defense against tampering is an awareness of the tamper-evident features and a careful inspection of all products.

15. One comment stated that packages should, in fact, be required to be tamper resistant.

FDA does not believe that such a requirement is practical. The intent of tamper-evident packaging is to alert the consumer to signs of tampering without making the package more difficult to open. Otherwise, those who have difficulty opening packages, such as the elderly and disabled, are more likely to avoid using products contained in such packaging.

16. One comment requested clarification regarding the extent of the regulation's restriction on the use of certain terms in OTC drug product labeling.

It is not the intent of the regulation to mandate the use of the specific term ''tamper-evident'' in labeling. Indeed, any words that correctly characterize the role of packaging in reducing the likelihood of harm from tampering (without an implication that a package or dosage form is tamper resistant or tamper proof) and that place appropriate emphasis on the importance of consumer involvement in their own protection would be acceptable under the rule.

17. One comment recommended shortening the 2-year effective date for implementing the labeling changes.

FDA does not agree that the proposed time for implementation of the labeling change should be shortened. The agency determined that a 2-year implementation is prudent because it achieves an expeditious implementation while at the same time not unreasonably burdening industry. Any burden to industry is minimized by a 2-year compliance date because most product labels are routinely reprinted within an 18- to 24-month period.

F. Listing of All Tamper-Evident Features

Proposed § 211.132(c) clarified that the labeling statements on all OTC drug products are required to identify all packaging features used to comply with proposed § 211.132(b)(1), not just the features on the external package. These packaging features would include those on the secondary package, the immediate container or closure, and any capsule-sealing technologies used to meet the requirements of the regulation.

18. Five of the seven comments raising the issue were in favor of this proposed revision. One comment expressed reservations about the lack of a requirement that the labeling on the inner package contain information regarding tamper-evident features, stating that persons are more likely to read the information on the inner labeling. The comment suggested that the proposed rule should give manufacturers more specific direction as to what information must be provided regarding possible signs of tampering (e.g., directions to compare lot numbers of blister packs with those on the box) and more specific guidance regarding the requisite prominence with which such information must be displayed.

The role of drug labeling is to effectively communicate consequential information regarding the safe and effective use of a drug. If the amount of information is too great, consumers may miss the essential message. The agency believes that § 211.132(c)(1) provides sufficient guidance to ensure that the important safety message is conveyed to consumers and that more specific direction to manufacturers is unnecessary.

19. One comment stated that revised labeling is unwarranted because consumers do not read the labeling and, thus, the reworded rule will have no impact.

FDA is charged with protecting the public health, and package labeling is one indispensable mechanism for conveying such information as instructions for use, warnings, and signs of possible tampering. Many consumers do read package labeling, and all consumers should have the opportunity to avail themselves of such information.

G. Consumer Education Campaign

The proposal stated that consumer education and involvement are important to help prevent malicious tampering, and discussed steps that FDA has taken to inform consumers to be alert for drug product tampering.

20. Nearly all of the comments stressed the need for a consumer education campaign in conjunction with implementation of the new tamper-evident requirements. Several comments cited the Sudafed tampering incident, which resulted in two deaths despite numerous and conspicuous signs of intrusion, as evidence that consumer education is an indispensable element of an antitampering campaign. The comments generally focused on two options for educating consumers: (1) A widespread media campaign using such means of communication as public service announcements, magazine advertisements, news articles, press releases, signs placed where OTC drug products are sold, brochures, or public workshops; and (2) a requirement for additional or stronger warnings on OTC drug product labels about the risks from product tampering.

While FDA encourages the drug industry to provide consumers as much information as is feasible regarding tampering, the agency will not mandate stronger tamper-evident messages on drug product labeling at this time. As previously discussed, the agency believes that the labeling requirements in this final rule provide necessary information to consumers without the negative consequences that can result from exaggerated emphasis on a single issue. Rather, FDA will focus its efforts on disseminating information through public service announcements, journal articles, store displays, flyers sent through the mail or disseminated with the purchase of an OTC drug product, or workshops aimed at specific target audiences. Messages will be aimed at informing consumers about tamper-evident packaging, the need for vigilance, and the safety of the OTC drug supply.

The extent of educational efforts undertaken depends, in large part, on support from interested parties. FDA appreciates the willingness of some professional societies to assist in the agency's educational endeavors. The agency requests assistance from the drug industry, professional organizations, consumer groups, and other Government agencies in conveying an effective, consistent message to consumers about drug tampering. Organizations, in coordination with FDA, are encouraged to use their newsletters, magazines, or other networking capacities to notify constituencies about the signs of drug product tampering.

21. Comments advocating a media campaign emphasized the importance of reaching a vast audience (e.g., through publication in a widely circulated magazine or through prime time

television public service announcements).

FDA recognizes the importance of imparting the message about drug tampering to as great a target audience as feasible. However, the agency must conduct any educational campaign so that the increased visibility of the tampering issue does not have the unintended effects of stimulating tampering or creating undue anxiety about the threats posed by tampering. In an effort to achieve this delicate balance, FDA must carefully choose a clear and focused message and a method of delivery to ensure that the message is perceived as intended.

H. Packaging Performance Standards

In the proposed rule FDA invited discussion on the possibility of establishing performance standards for tamper-evident packaging.

Three comments urged FDA to adopt packaging performance standards and two comments opposed such standards.

22. One comment in support of packaging performance standards stated that FDA's current method of evaluating tamper evidence is not objective and does not take into consideration all factors involved in violating a package seal. Another comment expressed a different view, stating that packaging performance standards are unnecessary because packaging guidance already exists through this rule and FDA's Compliance Policy Guide (CPG) 7132a.17 entitled ''Tamper-Resistant Packaging Requirements for Certain Over-the-Counter (OTC) Human Drug Products'' (Ref. 2). One comment that supported the use of packaging performance standards stated that many aspects of packaging needed to be improved if the packages are to provide adequate evidence of tampering.

The agency has concluded that § 211.132 and CPG 7132a.17 (which the agency will amend to conform to this final rule) will provide adequate guidance for a determination of whether a package meets the tamper-evident requirement. FDA does not use a rigid checklist of criteria to determine whether a package meets the tamper-evident requirement. The agency deems a technology to be in compliance with the regulation if the feature provides visible evidence to consumers that tampering has occurred, as required by the tamper-evident packaging regulation, and complies with the other regulatory requirements of § 211.132. Additional guidance on tamper-evident packaging is found in CPG 7132a.17 that lists examples of packaging and sealing technologies that are, and are not, capable of meeting tamper-evident packaging requirements.

FDA has considered the advantages and disadvantages of implementing packaging performance standards and finds that the drawbacks of requiring tamper-evident features to meet specific performance standards outweigh the advantages of such a system. The agency's current policy allows for flexibility in packaging technology and encourages technical innovation to improve tamper evidence and enhance packaging security.

The agency believes that the way to encourage improvements in feature design is not to impose additional regulatory requirements, but rather to set forth the general standard of tamper evidence and to remain flexible with respect to use of alternative technologies. Use of measurable performance standards might result in a premature ranking of tamper-evident technologies, and FDA has concluded that the establishment of performance standards for tamper-evident packaging is not necessary at this time.

23. One comment expressed a concern that a tamper-evident feature of a package may interfere with the package's child-resistant feature.

The agency wishes to clarify that the tamper-evident packaging rule does not affect a manufacturer's responsibility to comply with other applicable regulatory requirements, including the requirement of child-resistant packaging issued by the Consumer Product Safety Commission and found at 16 CFR 1700. The agency appreciates the comment's concern and reiterates that the manufacturer must ensure that the tamper-evident features of a package do not interfere with its child-resistant features.

I. Economic Impact

As noted earlier, FDA requirements for OTC drug product packaging to protect against drug tampering have been in effect since 1982. This final rule clarifies the application of the current regulation, amends the current regulation to require sealing of products marketed in two-piece, hard gelatin capsules, and requires that the labeling of certain products be modified to substitute the term ''tamper-evident'' for ''tamper-resistant.'' FDA estimated, in the proposed rule, that the total one-time costs of the changes would be approximately $1.8 to $3 million to seal the few two-piece, hard gelatin capsule products that are currently unsealed, and for other minor costs associated with a change in the terminology used in the labeling of some products.

24. Some of the comments that specifically raised the issue of the cost of sealing considered the cost reasonable. Other comments stated that the sealing requirement is unduly burdensome and would result in unwarranted increased costs to manufacturers and higher prices to consumers.

An analysis of the costs of compliance with the new regulation is only meaningful in the context of expected benefits. While the important benefits that are expected to result from the sealing requirement have been discussed, it is impossible to predict precisely the number of lives that may be saved or injuries prevented by these new requirements. Nevertheless, in view of the public health benefits that can be reasonably expected from this added measure of consumer protection, the costs of compliance with the sealing requirement are relatively low.

25. Five comments stated that the cost of sealing all two-piece, hard gelatin capsules would be much higher than FDA's estimate. The comments questioned the premises on which the cost to industry estimate of $1.8 to $3 million was based. One of these comments said that at least 22 OTC drug products—not 12, as FDA estimated—are currently marketed as unsealed two-piece, hard gelatin capsules. Another comment said that, for companies with numerous OTC drug products offered in the capsule dosage form, compliance with the proposed rule would require the purchase of more than one hard gelatin capsule sealing machine, which, in combination with the required parts for the sealing machine and gelatin sealing solution, would total approximately $700,000. The comment asserted that the eventual cost of compliance would be substantially more because of additional costs for necessary alterations to the manufacturing facility's encapsulating area.

FDA's original cost estimate assumed that each affected product would require a separate gelatin capsule sealing and banding machine at a cost of $250,000 per machine. Consequently, this calculation is not inconsistent with the estimate of $700,000 for a company that manufactures several affected products. FDA acknowledges that its earlier estimate of 12 affected products may be too small and has accepted the estimate that 22 products are currently marketed in unsealed two-piece hard gelatin capsules. Using this higher figure, as detailed in section VIII of this document, FDA has revised its estimated compliance costs for this provision to $5.5 million.

26. Five comments expressed concern that the costs of compliance would be passed on to consumers of OTC drug products in the form of higher prices. One comment estimated that the cost passed on to the consumer would be in the range of $1 to $2 per bottle. Another comment estimated that the cost passed on to the consumer would be about 35 to 55 cents per 100-count bottle.

FDA realizes that a portion of the cost of compliance may be passed on to consumers and the agency has revised its estimate of this cost in section VIII of this document. In addition to the $250,000 cost of a gelatin capsule sealing and banding machine, the cost of labeling changes is expected to average $2,500 for each branded OTC drug and $850 for each private label OTC drug. Individual companies control product pricing and it is conceivable that the price of certain very low volume drug products might be noticeably increased. However, given the one-time impact of most of the costs of this rule, the safety benefits, and the overall costs of drug product manufacturing, the agency does not believe the price of many products will be substantially affected.

27. One comment stated that tamper-evident packaging features would be a cheaper, more effective alternative to sealing. The comment provided no support for this theory.

As explained earlier, FDA believes that packaging requirements do not effectively minimize the dangers posed by OTC drug product tampering and that the sealing requirement is necessary to address the continued vulnerability of two-piece, hard gelatin capsules.

28. Several comments stated that the cost of the labeling change to eliminate terms such as ''tamper-resistant'' was unreasonably burdensome.

In response to several comments, FDA reexamined the estimated cost of proposed labeling changes and has revised the $5 to $6 million estimate to $10 million. Even as revised, however, FDA disagrees that the cost of the labeling change is unreasonably burdensome. The use of terminology accurately characterizing the degree of protection offered by tamper-resistant packaging is a cost effective step toward educating consumers. The agency has further reduced the burden of the labeling change to industry by giving manufacturers up to 2 years to make the conversion.

IV. Legal Authority

FDA's revision of the tamper-resistant packaging requirements for OTC drug products is authorized by the Federal Food, Drug, and Cosmetic Act (the act). As discussed in the proposed rule (59 FR 2542 at 2545), the agency is authorized to establish requirements for container and package design that provide protection against intentional product adulteration by tampering and to establish requirements for labeling statements alerting consumers to tamper-evident features. (See also 47 FR 50442 at 50447, November 5, 1982, for additional discussion of the legal authority for requirements related to drug product tampering.)

V. References

The following references have been placed on display in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen between 9 a.m. and 4 p.m, Monday through Friday.

1. The Nonprescription Drug Manufacturers Association, ''The Sale of OTC Medicines in Capsule Form Should Not Be Banned or Restricted,'' position statement, March 9, 1991.

2. FDA Compliance Policy Guide 7132a.17, ''Tamper Resistant Packaging Requirements for Certain Over-the-Counter (OTC) Human Drug Products,'' May 21, 1992. This document is also available at cost from the National Technical Information Service (NTIS), U.S. Dept. of Commerce, 5285 Port Royal Rd., Springfield, VA 22161, 703–487–4650.

VI. Paperwork Reduction Act of 1995

FDA concludes that this final rule is not subject to review by the Office of Management and Budget. Requiring manufacturers to use the term ''tamper-evident'' in the labeling and to identify tamper-evident features and capsule sealing technologies in the labeling is exempt under 5 CFR 1320.3(c)(2) as a public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public.

VII. Environmental Impact

The agency has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. Analysis of Impacts

FDA has examined the impact of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612). Executive Order 12866 directs agencies to assess all cost and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). If an agency determines that a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Section 202 of the Unfunded Mandates Reform Act (Pub. L. 104–4) requires that agencies prepare an assessment of anticipated costs and benefits before proposing any rule that might result in an expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of $100 million (adjusted annually for inflation) in any year.

As discussed in this preamble, the regulatory history of measures to reduce the risk of product tampering, the agency evaluation of alternative control strategies suggested in response to comments, and the revised implementation schedule demonstrate that this rule is consistent with the principles set forth in the Executive Order and these two statutes.

A. Executive Order 12866

FDA had estimated that the January 18, 1994 (59 FR 2542) proposed rule to strengthen tamper-evident packaging requirements would impose compliance costs of $3 million for sealing the two-piece hard gelatin capsules. One comment to the proposed rule stated that at least 22 products are currently marketed in unsealed two-piece hard gelatin capsules, not 12 products as FDA had estimated. Based on this comment, FDA has revised its estimated compliance costs for this provision to $5.5 million ($250,000 per capsule sealing machine x 22 products).

Compliance costs for relabeling OTC's containing the ''tamper-resistant'' terminology with the ''tamper-evident'' terminology was estimated at $5 to $6 million in the proposed rule. Based on information from the Nonprescription Drug Manufacturers Association (NDMA) indicating that these labels were routinely reprinted within an 18 to 24 month period, the incremental cost of this provision was expected to be minimal. Several comments, however, stated that the cost of the labeling change was unreasonably burdensome. FDA has reviewed the latest data on label change costs and patterns and revised its estimate of compliance costs for this provision. The agency estimates that about 20 percent of OTC drug labels are reprinted over any 2-year period, as shown by survey data from NDMA.

Further, FDA finds that branded OTC drugs have much higher per label costs than do private label OTC drugs. Based on recent information, FDA estimates that a minor label change would cost from $2,000 to $3,000 for each branded OTC drug. Private label costs for a minor change are estimated to range from $500 to $1,200, or an average of $850 per OTC drug.

FDA has also revised its estimate of the number of products (stock keeping units or SKU's) that are subject to the labeling provisions of the tamper-evident packaging. FDA estimates this number at about 62,000 SKU's (including both branded and private label SKU's). Whereas the proposal estimated that 60 percent of the SKU's would be out of compliance with the new rule, a very limited survey of OTC drug products now shows a noncompliance rate of about 15 percent. Accounting for all of the above factors, FDA estimates the compliance cost of the labeling provision at $10 million. These costs, however, would be mitigated to the extent that companies can coordinate this effort with the forthcoming rule to standardize all OTC drug labels.

To summarize, the estimated total one-time costs of the final rule are the sum of the $5.5 million to seal the capsule products that are currently not sealed and the $10 million to change the labeling on the products that currently use the ''tamper-resistant'' terminology. Total one-time compliance costs, therefore, are estimated at $15.5 million. The rule will not impose any other annual costs on the OTC drug industry.

Because this final rule is not a significant regulatory action as defined by Executive Order 12866, an additional assessment of the rule under section 6 of the Executive Order is not necessary.

B. Regulatory Flexibility Act

According to the Regulatory Flexibility Act, the final rule should include ''a succinct statement of the need for, and objectives of, the rule.'' FDA is taking this action as a result of its continuing review of the potential public health threat posed by product tampering and to improve consumer protection by addressing specific vulnerabilities in the OTC drug market.

FDA accepts the industry estimate of 22 products currently marketed in two-piece hard gelatin capsules. FDA does not have a definitive estimate of the percentage of these companies that may be small. The Small Business Administration (SBA) defines small pharmaceutical manufacturers as those having less than 750 employees. It is likely, however, that many of these firms will not be small. FDA estimates that, at a maximum, only 2 of the original 12 products identified by FDA were made by a small manufacturer. Using the same ratio (2:12), a low-end range estimate of about 4 of the 22 affected products would be made by a small manufacturer. A high-end estimate of 12 was developed by assuming that all of the 10 products not previously accounted for (22 - 12 = 10) are made by different small manufacturers. The final estimate, therefore, is a range of 4 to 12 products from small manufacturers that are marketed in two-piece hard gelatin capsules. These small businesses are expected to incur average one-time compliance costs of $150,000 to $250,000 for purchasing the capsule sealing machinery if it is not already available. Other firms may choose to contract out the manufacturing process for these products.

Further, the proposed rule estimated that about 780 products (including different sizes and strengths) would be affected by the labeling provisions of this rule. Using more recent data, FDA revised its estimate of the number of product SKU's in need of relabeling to about 9,300. Due to the 2-year phase-in period for ''tamper-evident'' labeling, FDA expects only about 7,450 of these SKU's to be affected outside of their normal reprinting patterns. FDA does not have a good estimate of the number of small companies that would have to relabel their products. It can be assumed, however, that each small company has very few SKU's, as the large companies and a small number of large private labelers market numerous SKU's. As noted previously, each affected SKU is estimated to incur a one-time relabeling cost of either $850 or $2,500.

FDA attempted to minimize the burden of this rule on manufacturers by granting them 2 years after final publication to comply with the labeling provisions. Also, FDA has not included any new reporting or recordkeeping requirements. After review of the comments, FDA has revised the final rule even further. The proposed rule would have created a 2-year effective date at the retail level. Comments to the proposed rule claimed that it would require burdensome compliance checks by retailers in order to check for a negligible quantity of noncomplying products. In response to these comments, FDA has chosen an alternative policy that does not include a retail effective date.

Several other alternatives were considered. Comments suggested a requirement that: (1) Two-piece capsules be kept behind the counter, (2) video surveillance be provided for retail space where OTC drug products are sold, (3) holographic labels be used on OTC drugs, (4) bold print or contrasting colors be used to further illuminate the tamper-evident warning on OTC drugs and (5) packaging performance standards be developed and applied to tamper-evident OTC drug packaging. FDA considered these alternatives and determined that the additional compliance costs they would create cannot be justified by the small amount of increased awareness of tamper-evident packaging they would offer.

C. Unfunded Mandates Reform Act

FDA concludes that this regulation will not result in expenditure of $100 million by State, local or tribal governments, in the aggregate, or by the private sector, in any 1 year. Therefore, under the Unfunded Mandates Reform Act, no further analysis is required.

List of Subjects in 21 CFR Part 211

Drugs, Labeling, Laboratories, Packaging and containers, Prescription drugs, Reporting and recordkeeping requirements, Warehouses.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 211 is amended as follows:

PART 211—CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS

1. The authority citation for 21 CFR part 211 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 355, 357, 360b, 371, 374.

2. Section 211.132 is amended by revising the section heading, by removing in paragraph (a) the word ''throat'', by removing in paragraphs (a) and (d)(2) the words ''tamper-resistant'' and adding in their place the words ''tamper-evident'', and by revising paragraphs (b) and (c), and the second sentence in the introductory text of paragraph (d) to read as follows:

§ 211.132 Tamper-evident packaging requirements for over-the-counter (OTC) human drug products.

* * * * *

(b) *Requirements for tamper-evident package.* (1) Each manufacturer and packer who packages an OTC drug product (except a dermatological, dentifrice, insulin, or lozenge product) for retail sale shall package the product in a tamper-evident package, if this product is accessible to the public while held for sale. A tamper-evident package

is one having one or more indicators or barriers to entry which, if breached or missing, can reasonably be expected to provide visible evidence to consumers that tampering has occurred. To reduce the likelihood of successful tampering and to increase the likelihood that consumers will discover if a product has been tampered with, the package is required to be distinctive by design or by the use of one or more indicators or barriers to entry that employ an identifying characteristic (e.g., a pattern, name, registered trademark, logo, or picture). For purposes of this section, the term ''distinctive by design'' means the packaging cannot be duplicated with commonly available materials or through commonly available processes. A tamper-evident package may involve an immediate-container and closure system or secondary-container or carton system or any combination of systems intended to provide a visual indication of package integrity. The tamper-evident feature shall be designed to and shall remain intact when handled in a reasonable manner during manufacture, distribution, and retail display.

(2) In addition to the tamper-evident packaging feature described in paragraph (b)(1) of this section, any two-piece, hard gelatin capsule covered by this section must be sealed using an acceptable tamper-evident technology.

(c) *Labeling.* (1) In order to alert consumers to the specific tamper-evident feature(s) used, each retail package of an OTC drug product covered by this section (except ammonia inhalant in crushable glass ampules, containers of compressed medical oxygen, or aerosol products that depend upon the power of a liquefied or compressed gas to expel the contents from the container) is required to bear a statement that:

(i) Identifies all tamper-evident feature(s) and any capsule sealing technologies used to comply with paragraph (b) of this section;

(ii) Is prominently placed on the package; and

(iii) Is so placed that it will be unaffected if the tamper-evident feature of the package is breached or missing.

(2) If the tamper-evident feature chosen to meet the requirements in paragraph (b) of this section uses an identifying characteristic, that characteristic is required to be referred to in the labeling statement. For example, the labeling statement on a bottle with a shrink band could say ''For your protection, this bottle has an imprinted seal around the neck.''

(d) * * * A request for an exemption is required to be submitted in the form of a citizen petition under § 10.30 of this chapter and should be clearly identified on the envelope as a ''Request for Exemption from the Tamper-Evident Packaging Rule.'' * * *

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Dated: October 28, 1998.

William B. Schultz,

Deputy Commissioner for Policy

[FR Doc. 98–29388 Filed 11–3–98; 8:45 am]

BILLING CODE 4160–01–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[FRL–6182–9]

Technical Amendments to Approval and Promulgation of Air Quality State Implementation Plans, Texas; Recodification of, and Revisions to the State Implementation Plan; Chapter 114; Correction of Effective Date Under the Congressional Review Act (CRA)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; correction of effective date under CRA.

SUMMARY: On July 1, 1998 (63 FR 35839), EPA published in the **Federal Register** a direct final rule concerning the Approval and Promulgation of Air Quality Implementation Plans, Texas; Recodification of, and Revisions to the State Implementation Plan, Chapter 114, which established an effective date of August 31, 1998. This document corrects the effective date of the rule to November 4, 1998 to be consistent with sections 801 and 808 of the Congressional Review Act (CRA), enacted as part of the Small Business Regulatory Enforcement Fairness Act, 5 U.S.C. 801 and 808.

EFFECTIVE DATE: November 4, 1998.

FOR FURTHER INFORMATION CONTACT: Bill Deese, Air Planning Section (6PD–L), EPA Region 6, 1445 Ross Avenue, Dallas, Texas 75202–2733, telephone (214) 665–7253.

SUPPLEMENTARY INFORMATION:

I. Background

Section 801 of the CRA precludes a rule from taking effect until the agency promulgating the rule submits a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States, head of the General Accounting Office (GAO). EPA recently discovered that it had inadvertently failed to submit the above rule as required; thus, although the rule was promulgated on July 1, 1998, by operation of law, the rule did not take effect on August 31, 1998 as stated. Now that EPA has discovered its error, the rule is being submitted to both Houses of Congress and the GAO. This document amends the effective date of the rule consistent with the provisions of the CRA.

Section 553 of the Administrative Procedure Act, 5 U.S.C. 553(b)(B), provides that, when an agency for good cause finds that notice and public procedure are impracticable, unnecessary or contrary to the public interest, an agency may issue a rule without providing notice and an opportunity for public comment. EPA has determined that there is good cause for making today's rule final without prior proposal and opportunity for comment because EPA merely is correcting the effective date of the promulgated rule to be consistent with the congressional review requirements of the Congressional Review Act as a matter of law and has no discretion in this matter. Thus, notice and public procedure are unnecessary. The Agency finds that this constitutes good cause under 5 U.S.C. 553(b)(B). Moreover, since today's action does not create any new regulatory requirements and affected parties have known of the underlying rule since July 1, 1998, EPA finds that good cause exists to provide for an immediate effective date pursuant to 5 U.S.C. 553(d)(3) and 808(2).

II. Administrative Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' and is therefore not subject to review by the Office of Management and Budget. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described in the Unfunded Mandates Reform Act of 1995 (Public Law 104–4), establish any technical standards subject to the section 12(d) of the National Technology Transfer and Advancement Act, or require prior consultation with State officials as specified by Executive Order 12875 (58 FR 58093, October 28, 1993) or with officials of Indian tribal governments as specified by Executive Orders 12875 and 13084 (63 FR 27655, involve special consideration of environmental justice related issues as required by Executive Order 12898 (59 FR 7629, February 16, 1994), or involve special consideration of children's health and safety risks under Executive Order 13045 (62 FR 19885, April 23, 1997). Because this action is not subject to notice-and-comment requirements under the Administrative Procedure Act or any other statute, it is not subject to