(d) To assure safe use of the additive:

(1) In addition to the other information required by the act, the label or labeling of the additive shall bear the name of the additive.

(2) The label of the additive shall bear adequate directions to provide a final product that complies with the limitations prescribed in paragraph (c) of this section.

Dated: May 27, 1988.

**Fred R. Shank,**

*Acting Director, Center for Food Safety and Applied Nutrition.*

[FR Doc. 88-12941 Filed 6-8-88; 8:45 am]

BILLING CODE 4160-01-M

## 21 CFR Part 201

**[Docket No. 87N-0371]**

## Labeling for Oral and Rectal Over-the-Counter Aspirin and Aspirin-Containing Drug Products; Reye Syndrome Warning

**AGENCY:** Food and Drug Administration.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is making permanent the regulation that requires a Reye syndrome warning on the labeling of oral and rectal over-the-counter (OTC) human drug products containing aspirin. The current regulation expires on June 6, 1988, unless extended by FDA. In addition, the agency is revising the warning statement to state clearly that Reye syndrome is reported to be associated with aspirin. These actions are based primarily on the results of a study by the Public Health Service (PHS) Reye Syndrome Task Force and the report of the Institute of Medicine's Committee on Reye Syndrome and Medication Use. The PHS study confirms earlier reports of an association between Reye syndrome and aspirin use in children and teenagers with chicken pox or flu.

**EFFECTIVE DATES:** Continuation of the current warning statement effective June 9, 1988; revision of the warning statement effective December 9, 1988.

**FOR FURTHER INFORMATION CONTACT:** Howard P. Muller, Center for Drug Evaluation and Research (HFD-362), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8049.

**SUPPLEMENTARY INFORMATION:**

### I. Background

In the **Federal Register** of March 7, 1986 (51 FR 8180), FDA published a final regulation requiring the following labeling statement on oral and rectal OTC drug products containing aspirin: "WARNING: Children and teenagers should not use this medicine for chicken pox or flu symptoms before a doctor is consulted about Reye syndrome, a rare but serious illness." FDA took this action to aid in increasing the public's awareness of the association between the use of aspirin and Reye syndrome [1] and to bring uniformity and consistency to the labeling of aspirin and aspirin-containing drug products in the marketplace. The 1986 regulation was based, in large part, on the results of a "pilot study" conducted by PHS which showed an association between the use of aspirin and the onset of Reye syndrome.

The 1986 final rule also provided that the regulation would expire June 6, 1988, 2 years from the effective date, unless the agency acted to extend it. This 2-year period was to allow for the completion and evaluation of further research by PHS, known as the "main study," into the association between Reye syndrome and various exposure factors, including the use of aspirin.

*1. The PHS Main Study.*

The PHS main study confirmed the results of the pilot study and found a large, statistically significant association between Reye syndrome in children and teenagers and the ingestion of aspirin during previous illnesses. The PHS report, entitled "Reye Syndrome and Medications—Report of the Main Study," November 12, 1986, was prepared by the PHS Reye Syndrome Task Force (Ref. 1). The PHS report was evaluated by the Institute of Medicine (IOM) of the National Academy of Sciences in a report entitled "The PHS Study of the Reye Syndrome: Review of a Continuing Study—Report Number 6—Review of the PHS Continuing Study by the Committee on the Reye Syndrome and Medications," February 1987 (Ref. 2). A report of the main PHS study was published in the *Journal of the American Medical Association* on April 10, 1987 (Ref. 3). These reports have been placed on display with the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, under Docket No. 87N-0371. Additional background information may be found in Docket Nos. 82N-0158 and 85N-0553.

The PHS main study concluded that the association between Reye syndrome and aspirin is consistent with estimates of risk determined in earlier studies and reflects the strength of the epidemiologic association observed in those studies. The study reinforced the importance of reducing the use of aspirin in the treatment of children and teenagers with chicken pox and flu-like illnesses. FDA believes that the available evidence supports the continuing need to maintain a high level of public awareness of the association between the use of aspirin in children and teenagers with chicken pox and flu and the incidence of Reye syndrome.[2] Accordingly, based on the results of this PHS research, in the **Federal Register** of January 22, 1988 (53 FR 1796), FDA published a proposed rule to make permanent the requirement regarding the Reye syndrome warning.

*2. Public Education Program*

In its efforts to create and maintain a high level of public awareness of the association between the use of aspirin in children and teenagers and the incidence of Reye syndrome, FDA has conducted an extensive public education program in addition to the required warning information on aspirin product labeling. FDA has initiated public educational activities on Reye syndrome for several years, beginning in 1982. Earlier educational efforts were directed at raising the awareness of Reye syndrome among parents of young children. More recently, FDA has focused its educational program towards teenagers who may still be unaware of the association between Reye syndrome and aspirin use for their age group during the flu or chicken pox. Accordingly, during 1987, the agency distributed approximately 40,000 posters to high schools and colleges warning of the association between Reye syndrome and the ingestion of aspirin during illness with the flu or chicken pox. In addition, FDA distributed public service announcements to approximately 2,000 radio stations, and sent advertisements to approximately 11,000 daily and weekly newspapers across the United States, with the message consistently directed toward teenagers.

The aspirin industry, through the Aspirin Foundation of America, has also conducted an extensive public education program during the past several years. Public service announcements were distributed to television and radio stations around the

[1] Reye syndrome is a rare but serious illness affecting children and teenagers. Characteristically, its onset follows illness due to influenza B, influenza A, or chicken pox as the child or teenager appears to be getting well. Reye syndrome is a degenerative disease of the brain; the symptoms include nausea, vomiting, and behavioral changes.

[2] The preliminary results of another Reye syndrome study, conducted by Yale University, have been presented to FDA. These results support the conclusion of the PHS study. The final report from the Yale study is expected within the next several months.

country, as well as the major networks, beginning in the spring of 1985 and continuing in each of the succeeding three flu seasons. As with the FDA efforts, recent educational initiatives have sought to reach teenage audiences, by featuring teenage television and radio personalities in public service announcements. Several retail grocery and pharmacy stores and chains have also participated in a number of educational efforts regarding Reye syndrome.

*3. Decline in Incidence of Reye Syndrome*

The Centers for Disease Control has reported that the number of cases of Reye syndrome has declined significantly between 1980 (658 cases) and 1985 (93 cases). Moreover, according to a study published in *Pediatrics* in June 1987 ("National Patterns of Aspirin Use and Reye Syndrome Reporting, United States, 1980 to 1985") (Ref. 4), pediatric aspirin use during that same time also declined. These favorable trends appear to be continuing, with 101 Reye syndrome cases reported for 1986 in the *Morbidity and Mortality Weekly Report* (Ref. 5). Although the data show a decline in Reye syndrome cases over the past few years, the fact that 101 cases were reported as recently as 1986 indicates the continuing need for a clear and uniform Reye syndrome warning on aspirin-containing drug products and for a continued public education program.

## II. Highlights of the Final Rule

As described further below, all the comments received on the proposed rule expressed support for continuing the Reye syndrome warning requirement. The final rule, therefore, makes permanent the requirement that all orally and rectally administered OTC aspirin products bear an appropriate Reye syndrome warning.

The final regulation revises the warning statement to make clear that aspirin use in children and teenagers has been reported to be associated with Reye syndrome. Specifically, the final regulation amends the previous warning by adding the phrase "reported to be associated with aspirin" at the end, so that the new Reye syndrome warning reads as follows: "WARNING: Children and teenagers should not use this medicine for chicken pox or flu symptoms before a doctor is consulted about Reye syndrome, a rare but serious illness *reported to be associated with aspirin.*" FDA believes the revision is appropriate and necessary to reflect the PHS study finding of a large, statistically significant association between Reye syndrome and the ingestion of aspirin during chicken pox or flu. As with the 1986 regulation, this revised warning, once fully implemented, will provide consumers with a clear and consistent message and will continue to ensure consistency and uniformity in the marketplace.

The final rule also continues the requirement in the 1986 regulation that the Reye syndrome warning be "prominent." Such prominence is achieved, in part, by the regulation's continuing requirement that the Reye syndrome warning be the first warning on the label under the "WARNINGS" heading. In addition, in order to call consumers' attention to the revised wording of the Reye syndrome warning, FDA is interpreting the requirement for prominence as requiring, for a period of 1 year, an attention-getting statement on the principal display panel of the product.

Finally, the revised warning is required to appear on affected product packages that are initially introduced or initially delivered for introduction into interstate commerce by December 9, 1988. Until the effective date of the revised Reye syndrome warning, the current Reye syndrome warning requirement remains in effect.

## III. Comments

The proposal provided 60 days for public comment. FDA received 17 comments on the proposed rule. The comments were submitted by drug companies, pharmaceutical trade associations, consumer groups, professional medical associations, congressional representatives, individual health practitioners, and groups representing the interests of victims of Reye syndrome. All comments generally supported a continued requirement for a Reye syndrome warning. A summary of the comments received by FDA during the comment period and the agency's response to them follows:

*1. Text of Warning Statement*

Several comments expressed concern about the precise language of the warning statement. The major concern raised was that the warning should be revised to make clear the concept of an association between Reye syndrome and aspirin use. One comment also recommended that the warning's reference to "chicken pox or flu symptoms" be removed, contending that reports of Reye syndrome associated with aspirin use have not been limited to patients suffering from varicella or influenza. Another comment urged that the warning note the potential fatal consequences of Reye syndrome. This comment argued that individuals do not always appreciate the seriousness of a warning unless it discloses the consequences that can result if the warning is not heeded.

FDA agrees with the suggestion that the warning statement should be revised to make clear that aspirin use in children has been reported to be associated with Reye syndrome. Now that the PHS study has been completed and has reported a large, statistically significant association between Reye syndrome and aspirin use, FDA believes it is appropriate and necessary that the warning statement indicate this association. Accordingly, the warning statement has been revised to read: "WARNING: Children and teenagers should not use this medicine for chicken pox or flu symptoms before a doctor is consulted about Reye syndrome, a rare but serious illness reported to be associated with aspirin."

FDA does not believe that the other issues raised by the comments warrant changes in the final rule. FDA believes it appropriate at this time that the warning continue to refer to "chicken pox and flu symptoms" because these symptoms were the symptoms of most of the antecedent illnesses in the PHS study on which FDA is relying as the scientific justification for the warning requirement. In addition, FDA believes that the warning's reference to Reye syndrome as a "serious illness" is sufficient for consumers to appreciate the medical importance of the warning statement. Accordingly, based on the data available at this time, FDA does not believe that further changes to the warning statement in the final rule are now necessary.

*2. Prominence of Required Warning*

Several comments suggested that the required Reye syndrome warning be given more prominence on aspirin drug product labeling. Comments variously urged that the warning statement be made conspicuous through large type size or be set off by use of a contrasting color. One comment recommended that the entire warning statement be boxed.

FDA agrees that it is essential to bring the Reye syndrome warning to the attention of the consumer. In order to achieve this, the final rule continues the requirement in the current regulation that the Reye syndrome warning appear "prominently" on the label. This includes the requirements that the Reye syndrome warning appear as the first warning on all labeling of aspirin drug products under the heading "Warnings"; that the warning must appear on the

mediate container label and on the
ail package; and that the warning
must appear on all product labeling that contains warnings. These provisions thus help assure that the warning statement will be seen and read by the consumer.

In addition, because the text of the Reye syndrome warning is being revised, FDA interprets the "prominence" requirement in the regulations (21 CFR 201.15 and 201.315(h)(1)), in the unique circumstances presented here, as requiring that the principal display panel call consumers' attention to the new warning. Specifically, FDA interprets this as requiring manufacturers of aspirin and aspirin-containing drug products to provide an attention-getting statement, such as a "flag," alerting consumers to the revised Reye syndrome warning. A phrase using the words "new" and "warning," such as one of the following phrases, should be used: (1) "See new warning for children/teens"; (2) "Read new label warning"; or (3) "Read new warning for children/teens." To assure that consumers are alerted to the new warning, the language of the attention-getting statement must: (i) Appear on the principal display
(ii) be carried in type size which
nspicuous; and (iii) be carried for 1
ar after the revised Reye syndrome warning statement is added to the labeling. For that 1-year period, FDA will view as misbranded any aspirin or aspirin-containing OTC drug product whose principal display panel fails to contain an appropriate attention-getting statement.

FDA is not prescribing a minimum type size or use of contrasting color for the warning. However, under section 502(c) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 352(c)), a drug is misbranded if a required labeling statement is not sufficiently prominent to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use. Agency regulations state that a labeling statement may lack the prominence and conspicuousness required by section 502(c) of the act by reason, among others, of "[s]mallness or style of type in which such * * * statement * * * appears, insufficient background contrast, obscuring designs or vignettes, or crowding with other written, printed, or graphic matter." (21 CFR 201.15(a)(6).) In its surveillance of
OTC drug products FDA routinely
es the warning statements on
pirin products to be sure that these
equirements regarding prominence and conspicuousness of the warning statements have been met.

*3. Australian Study*

One comment said the proposed warning statement is acceptable as currently worded and advised against changing the language to make it more stringent. The comment was reacting to a letter referenced in the proposal which advocated a stronger warning statement. The comment contended that the association between Reye syndrome and aspirin is not supported by all studies. Specifically, the comment referred to an Australian study that found no correlation between the use of aspirin and the occurrence of Reye syndrome. The comment concluded that the current warning statement is sufficient in light of the lack of complete agreement among the studies.

FDA does not find the results of the Australian study cited by the comment to be persuasive. The Australian study, reported in *Pediatrics* (Ref. 6), is a retrospective review of medical records of patients hospitalized during a 10-year period between 1973 and 1982. Unlike the PHS study, the Australian study was not controlled. Moreover, medication histories for the period before hospitalization were based on chart reviews, a less reliable method of gathering data than that followed in the PHS study. The reported cases in the Australian study were predominantly in a very young age group, in which metabolic errors may be indistinguishable from Reye syndrome. Therefore, the identification of cases as Reye syndrome cases in the Australian study is questionable. The approach of applying new criteria to a review of older medical records is certainly not as reliable as the rigorous approach prospectively developed and applied in the PHS studies. The agency continues to believe that the evidence from research to date clearly indicates a strong association between Reye syndrome and the ingestion of aspirin.

*4. Adult-only Aspirin*

One comment suggested that FDA permit labeling for aspirin-containing drug products that are not intended for use by children or teenagers to bear this special warning statement: "Warning: This medicine is not for children or teenagers. Children and teenagers should not use this medicine because of concerns about Reye Syndrome, a rare but serious illness."

FDA does not agree with this suggestion. As stated more fully in the proposal of December 17, 1985 (50 FR 51400), FDA believes that the public interest is best served by assuring that the same warning statement is used on all products covered by the regulation. This approach eliminates the potential for consumers being confused by various forms of the warning statement.

*5. Other Salicylates*

Another comment recommended that the labeling warning statement be required not only for aspirin and aspirin-containing drug products, but for all products containing salicylates.

FDA notes that the scientific research to date, on which the Reye syndrome warning statement requirement is based, focuses on the association between Reye syndrome and aspirin, rather than on the broader category of drug products containing nonaspirin salicylates. Indeed, the PHS study reported that there were too few subjects with reported exposures to nonaspirin salicylates for a meaningful analysis. FDA believes at the present time that priority must be given to continuing the warning on aspirin and aspirin-containing products. FDA will consider extending the scope of the warning requirement to nonaspirin salicylates at some time in the future, if warranted by further research or other appropriate information.

*6. Changing the Marketing Status of Certain Aspirin Products*

Several comments suggested that FDA require that aspirin be removed as an ingredient from compounds that may be used by individuals under 21 years of age. Another comment proposed that aspirin be available for children and adolescents only under a physician's prescription.

FDA believes that continuing to require a Reye syndrome warning statement on aspirin and aspirin-containing OTC drug products is sufficient and that the more drastic measures of banning use of aspirin in products for individuals under 21 years of age or limiting such products to prescription use are unnecessary. As noted, the latest epidemiological data indicate a marked decline in the incidence of Reye syndrome among children and adolescents since 1980. FDA does not believe that removing aspirin from compounds used by individuals under 21 years of age would be justifiable because other aspirin-containing compounds would still be readily available for administration to children and teenagers. Moreover, the agency believes that OTC aspirin-containing products properly labeled with the Reye syndrome warning statement can be safely used in the proper circumstances by individuals

under 21 years of age. Therefore, FDA disagrees with the suggestion that aspirin for individuals under 21 years of age be made available only under a physician's prescription.

*7. Labeling in Spanish*

Two comments suggested that the current warning statement would be more effective if it were also required to be in Spanish.

Under FDA labeling regulations (21 CFR 201.15(c)), labeling may be written in the predominant local language when it is distributed solely in the Commonwealth of Puerto Rico or in a Territory where the predominant language is one other than English. Although in the 50 states all required labeling must appear in English, the regulations do not preclude the distribution of labeling in a language other than English, in a special format, or in Braille along with the conventional English language labeling. FDA encourages the preparation of labeling to meet the needs of non-English speaking or special user populations so long as such labeling fully complies with agency regulations.

*Effective Dates*

The agency believes it is of the utmost importance that there be no time gap in the requirement for a Reye syndrome warning statement on aspirin and aspirin-containing drug products. The available evidence supports the continuing need to maintain a high level of public awareness of the risks of use of aspirin in children and teenagers. In addition, no additional costs associated with labeling changes would result from this action, since it would simply require the continued use of labeling already prepared. Because of the importance to the public health of assuring that the labeling of all oral and rectal OTC aspirin products bears a Reye syndrome warning, the Commissioner finds good cause for making effective immediately that part of this final rule which makes a Reye syndrome warning statement a permanent requirement. Accordingly, § 201.314 is revised by deleting paragraph (h)(5) effective June 9, 1988.

This final rule also amends the warning statement to read: "WARNING: Children and teenagers should not use this medicine for chicken pox or flu symptoms before a doctor is consulted about Reye syndrome, a rare but serious illness reported to be associated with aspirin." To provide aspirin drug product manufacturers with adequate lead time to make the necessary printing changes, this provision is effective December 9, 1988. After December 9, 1988 any orally or rectally administered aspirin or aspirin-containing product that does not contain the revised warning statement and that is initially introduced or initially delivered for introduction into interstate commerce is misbranded under sections 201(n) and 502 (a) and (f) of the act (21 U.S.C. 321(n) and 352 (a) and (f)). As noted earlier, until the effective date of the revised Reye syndrome warning, the current Reye syndrome warning requirement remains in effect.

Also as noted in the response to comment number 2 above, after December 9, 1988, FDA will view as misbranded under section 502 of the act any aspirin drug product subject to this regulation that is initially introduced or initially delivered for introduction into interstate commerce and that does not contain an appropriate attention-getting statement on the principal display panel. To assure that consumers are alerted to the new warning statement for at least the equivalent of a single flu season, the attention-getting statement is to be carried on the principal display panel of each product subject to this regulation that is initially introduced or initially delivered for introduction into interstate commerce until December 11, 1989.

FDA believes that a 6-month effective date for the revised warning statement gives manufacturers sufficient time to make the required labeling changes. FDA recognizes, however, that there may be a few small manufacturers for whom, for various financial or other reasons, it is impossible to comply with the revised labeling provision of this final rule by the effective date. In these unusual circumstances, FDA will consider requests for limited extensions. Such requests should be sent to Office of Compliance, Center for Drug Evaluation and Research (HFD–300), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, and should document both the need for a extension and the duration of time requested.

## III. Economic Impact

FDA has examined the regulatory impact and regulatory flexibility implications of the final rule in accordance with Executive Order 12291 and the Regulatory Flexibility Act. This regulation requires manufacturers to incur costs for making one-time typesetting changes to the Reye syndrome warning statement in the product label. The warning statement appears on the immediate container label and, in those cases where the immediate container is not the retail package, also on the retail package label. In addition, the warning statement must appear on any labeling that contains warnings. Therefore, this action may require one-time typesetting changes for as many as three labels per product.

In addition, this regulation requires manufacturers to incur costs for making one-time typesetting changes to the principal display panel on a product's label to include an attention-getting statement or flag bringing to the consumer's attention the warning statement.

Any costs incurred by manufacturers as a result of discarding outdated label inventories would be negligible because the regulation gives 6 months of update labels before products are initially introduced or initially delivered for introduction into interstate commerce.

FDA estimates that the regulation will impose direct one-time costs associated with changing product labels that total less than $6 million. Therefore, the agency has determined that the final rule is not a major rule as defined in Executive Order 12291. Further, FDA certifies that the final rule will not have a significant impact on a substantial number of small entities as defined by the Regulatory Flexibility Act.

## IV. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(11) 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.

## V. References

The following information has been placed in the Dockets Management Branch (HFA–305), Food and Drug Administration, Room 4–62, 5600 Fishers Lane, Rockville, MD 20857, and may be seen by interested persons from 9 a.m. to 4 p.m., Monday through Friday.

(1) "Reye Syndrome and Medications—Report of the Main Study," Public Health Service Reye Syndrome Task Force, November 12, 1986.

(2) "The PHS Study of the Reye Syndrome: Review of a Continuing Study—Report Number 6—Review of the PHS Continuing Study by the Committee on the Reye Syndrome and Medications," Institute of Medicine of the National Academy of Sciences, February 1987.

(3) Hurwitz, E.S., et al., "Public Health Service Study of Reye's Syndrome and Medications, Report of the Main Study," *Journal of the American Medical Association*, 257(14): 1905–1911, 1987.

(4) Arrowsmith, J.B., et al., "National Patterns of Aspirin Use and Reye Syndrome Reporting, United States, 1980 to 1985," *Pediatrics*, 79:858–863, June 1987.

(5) *Morbidity and Mortality Weekly Report*, Vol. 36, No. 41, October 23, 1987.
(6) Orlowski, James P., et al., "A Catch in the Reye," *Pediatrics*, 80:638–642, November 1987, C0001, Docket No. 87N–0371, Dockets Management Branch.

**List of Subjects in 21 CFR Part 201**

Drug, Labeling.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, Part 201 is amended as follows:

## PART 201—LABELING

1. The authority citation for 21 CFR Part 201 continues to read as follows:

Authority: Secs. 501, 502, 701, 52 Stat. 1049–1051 as amended, 1055–1056 as amended (2 U.S.C. 351, 352, 371); 21 CFR 5.10; § 201.21 also issued under secs. 301, 505, 52 Stat. 1042–1043 as amended, 1052–1053 as amended (21 U.S.C. 331, 355).

2. Section 201.314 is amended by revising the warning statement in paragraph (h)(1) and by removing (h)(5) to read as follows:

**§ 201.314 Labeling of drug preparations containing salicylates.**

* * * * *

(h)(1) * * * "WARNING: Children and teenagers should not use this medicine for chicken pox or flu symptoms before a doctor is consulted about Reye syndrome, a rare but serious illness reported to be associated with aspirin."

* * * * *

Dated: May 25, 1988.

Frank E. Young,

*Commissioner of Food and Drugs.*

[FR Doc. 88–13058 Filed 6–7–88; 11:35 am]
BILLING CODE 4160–01–M

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## DEPARTMENT OF TRANSPORTATION

## Federal Highway Administration

## 23 CFR Part 650

**[FHWA Docket No. 82–17, Notice 3]**

## Alternate Designs for Bridges

**AGENCY:** Federal Highway Administration, (FHWA), DOT.

**ACTION:** Notice of policy statement.

**SUMMARY:** This notice provides a restatement of FHWA policy requiring the development of alternate designs for major bridges to be constructed with Federal-aid highway funds. The policy statement includes modifications which are based on an analysis of data considered over a period of 9 years concerning alternate designs.

**FOR FURTHER INFORMATION CONTACT:** Mr. Robert L. Nickerson, Review and Design Branch, Bridge Division, (202) 366–4592, or Mr. Michael J. Laska, Office of the Chief Counsel, (202) 366–1383, Federal Highway Administration, 400 Seventh Street SW., Washington, DC 20590. Office hours are from 7:45 a.m. to 4:15 p.m. ET, Monday through Friday.

**SUPPLEMENTARY INFORMATION:** On December 4, 1979, the FHWA issued a Technical Advisory [TA] entitled Alternate Bridge Designs. This Technical Advisory was intended to stimulate competition in the design of safe and economical bridge structures and, at the same time, through the competitive bidding process, to take advantage of the prevailing economic conditions which would provide a finished structure at the lowest possible cost without sacrificing safety, quality, or aesthetics.

A memorandum was issued to all Regional Federal Highway Administrators on April 22, 1981, to strengthen FHWA's effort in promoting the use of alternate bridge designs among all State and local governments, including those that have adopted Certification Acceptance. On September 23, 1981, a second memorandum to all Regional Federal Highway Administrators requested each division office to review and revise its administrative procedures to ensure that alternate bridge designs would be incorporated in all major bridge projects. Guidelines were presented in still a third memorandum on June 16, 1982, to all Regional Federal Highway Administrators, so that FHWA field offices could take appropriate measures to assure themselves that the spirit and intent of alternate bridge designs were being followed. On May 12, 1983, the FHWA published a Notice of policy statement [48 FR 21409] which replaced the existing TA with a consolidated formal FHWA policy on alternate bridge designs.

### Discussion

With over 9 years experience with the use of alternate designs for well over 100 major bridges, an in-depth review of the results of this policy was performed with the clear conclusion that the policy has resulted in more cost-effective designs and better use of the highway tax dollar.

Project specific data, including design costs, engineering estimates and low bids, were received for 128 projects during the years 1979 through 1987. These projects had an average bid cost of $16 million representing over $2 billion worth of work that were bid with alternates in 39 different States with low bids ranging from $1.5 million to $88 million. For completed projects, cost data was reviewed on construction engineering, claims and overruns. An analysis of this data was performed in numerous ways. The following summarizes the more significant results:

1. The term "saving" to be used as a measure of effectiveness of this policy, can be defined different ways:

a. As the difference between the lowest bid received for each of the two alternates.

b. As the difference between the lowest bid received and the lowest estimate.

c. As the difference between the lowest bid for one alternate and the lowest bid for the other alternate adding the design fee of the "losing" alternate to the difference.

d. Same as paragraph "c" above, but also adding the difference in construction engineering, if any, that is identifiable for different types of bridges.

Using any of the above methods, the data clearly indicates substantial savings are accruing as a result of this policy. Complete data was available on only 47 projects which allowed a determination of savings in paragraph "d" above to be made. For these projects, a 3 percent of low bid "penalty" was assessed to any bridge with a concrete low bid (data indicates construction engineering for concrete bridges is an average of 3 percent higher than for steel bridges; this can be attributable to the "state-of-the-art" type of construction being used, e.g., cable stayed and segmental). This sample of the data indicates an average savings per project of over $2 million!

There are also less quantifiable savings, such as, does the presence of an alternate result in lower bids for both types? Of the 128 projects, the lowest bid was lower than the lowest final estimate in over 75 percent of the time. This would indicate the presence of alternates in reducing bridge prices. Also, the presence of an alternate involves material suppliers and subcontractors in the pre-bid phase, allowing the contractor to further reduce his proposal amount to be more competitive with the alternate design.

2. The decision to use or not use alternate designs is made at the beginning of the design phase when estimates of bridge costs are, at best, crude. Since we have to assume that the estimates prepared at bidding time are more representative of anticipated costs, it is noteworthy that over 25 percent of the time, the type of bridge with the lowest estimate was not the bridge type