

VIII

It is further ordered, That Ashland shall, within sixty (60) days after service upon it of this Order, file with the Commission a written report setting forth in detail the manner and form in which it has complied with this Order.

Analysis of Proposed Consent Order To Aid Public Comment

The Federal Trade Commission has accepted an agreement to a proposed consent order from Ashland Oil, Inc. ("Ashland").

The proposed consent order has been placed on the public record for sixty (60) days for reception of comments by interested persons. Comments received during this period will become part of the public record. After sixty (60) days, the Commission will again review the agreement and the comments received and will decide whether it should withdraw from the agreement or make final the agreement's proposed order.

The complaint, which was issued May 8, 1984, challenges, as violations of Section 7 of the Clayton Act, 15 U.S.C. 18, and Section 5 of the Federal Trade Commission Act, 15 U.S.C. 45, the proposed acquisition by Bass Brothers Enterprises, Inc. ("Bass Brothers") and Sid Richardson Carbon & Gasoline Co. ("Sid Richardson") of Ashland's United States carbon black industry assets. The complaint alleges that both Sid Richardson and Ashland are substantial competitors in the United States carbon black market, that the United States carbon black market is highly concentrated, and that barriers to entry into the production and distribution of carbon black are substantial. The complaint alleges that the effects of the proposed acquisition would be to eliminate substantial actual competition between Sid Richardson and Ashland, and eliminate Ashland as a substantial competitor in the carbon black market; to substantially increase concentration in an already highly concentrated market and encourage additional mergers or acquisitions in that market, thus increasing the likelihood of collusion; to tend to reduce the degree of price competition and to reduce the volume of production below competitive levels; and to tend to reduce the actual competition among other companies engaged in the production and distribution of carbon black. The complaint charges that the proposed acquisition constitutes a violation of Section 5 of the Federal Trade Commission Act, and if consummated, would constitute a violation of Section 7 of the Clayton Act.

The proposed order requires Ashland for a period of four years to notify the Director of the Commission's Bureau of Competition in advance of any proposed sale or divestiture of one or more of Ashland's three U.S. carbon black plants to a competitor in the U.S. carbon black industry. In this order, "carbon black" includes both rubber carbon black and "industrial," non-rubber carbon black. No prior notice is required if only one plant is being transferred to a competitor who has less than 15 percent of U.S. production capacity, or if the transaction must be reported under the statutory premerger notification program. Ashland is required to report to the Commission within 30 days any carbon black plant sale for which prior notice is not required.

The order provides that, upon application by Ashland, the order may be terminated if the Commission dismisses the still-pending complaint against Bass Brothers and Sid Richardson, Docket No. 9178.

The agreement is for purposes of settlement only; it does not constitute an admission by Ashland that the law has been violated as alleged in the Complaint.

The purpose of this analysis is to facilitate public comments on the proposed order, and it is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.

Emily H. Rock,
Secretary.

[FR Doc. 85-29779 Filed 12-16-85; 8:45 am]

BILLING CODE 6750-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 201

[Docket No. 85N-0553]

Proposed Labeling for Oral Aspirin-Containing Drug Products

AGENCY: Food and Drug Administration.
ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to require the labeling of oral over-the-counter (OTC) aspirin and aspirin-containing drug products for human use to bear a warning that such products should not be used to treat chicken pox or flu symptoms in children and teenagers before consulting a doctor about Reye syndrome, a rare but serious illness. FDA is preparing this rule in order to bring uniformity and

consistency to the marketplace and to aid in increasing the public awareness about this disease.

DATES: Comments by January 15, 1986. These labeling requirements are proposed to become effective for products initially introduced or initially delivered for introduction into interstate commerce 90 days after the date of publication of any final rule based on this proposal, or May 30, 1986, whichever is later. Further, FDA is proposing that this rule, if promulgated, would expire in 2 years following the effective date unless extended by the agency after publication for notice and comment in the Federal Register.

ADDRESS: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Christopher Smith, Office of the Commissioner (HF-9), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5133.

SUPPLEMENTARY INFORMATION: This proposed rule would require that the labeling of oral aspirin and aspirin-containing OTC drug products for human use bear a warning that such products should not be used to treat chicken pox or flu symptoms in children and teenagers before consulting a doctor about Reye syndrome, a rare but serious illness. This rule is being proposed in order to bring uniformity and consistency to the marketplace and to aid in increasing the public awareness about this disease.

I. Background

A. Reye Syndrome

First described by the pathologist Douglas Reye of Australia in 1963, Reye syndrome is classically described as occurring in a child or teenager during the course of or while recovering from a mild respiratory tract infection, flu, chicken pox, or other viral illness. Flu and chicken pox are the mostly commonly associated viral illnesses. The disease is characterized by severe vomiting and irritability or lethargy, which may progress to delirium and coma. The illness is described clinically as having an acute onset in which the initial symptom is usually vomiting, which may be profuse and persistent, and which is often accompanied by a change in mental status. Although the cause of Reye syndrome is unknown, some scientific studies, as described below, have looked at the possible association between the use of aspirin and the onset of the disease.

B. Early Scientific Studies

The Public Health Service (PHS) first initiated nationwide surveillance for Reye syndrome in December 1973. In 1976, the Centers for Disease Control (CDC) and State health departments intensified this surveillance and four CDC-supported case-control studies were conducted by the Arizona, Ohio, and Michigan State Health Departments. These studies, however, raised as many questions as they answered and generated considerable controversy in the medical community over the conclusion to be drawn from the available information.

In the Federal Register of December 28, 1982 (47 FR 57886), FDA published an advance notice of proposed rulemaking, which discussed in great detail the disease, the State studies, the findings of a FDA working group review, and a Reye syndrome workshop cosponsored by FDA, CDC, and the National Institutes of Health (NIH). FDA concluded, in the advance notice, that the State studies did not establish a conclusive link between aspirin use and Reye syndrome and that further research was needed to provide definitive data, but, in the interim, the public and the health care community should be educated about the possibility of an association between aspirin use and Reye syndrome raised by the State studies. FDA initiated, in the fall of 1982, an educational program aimed at achieving this result. These educational efforts have been renewed in each successive fall since then.

C. The Public Health Service Study

Because FDA determined that additional research was needed to study the possible relationship between aspirin use and Reye syndrome, in 1982 and 1983, PHS developed a plan for further research into the possible association between Reye syndrome and various exposure factors, including the use of aspirin. A main study was planned and is now being conducted under the direction of the PHS Reye Syndrome Task Force. The main study was preceded by a pilot phase (methodology study) to determine the study feasibility and to establish the appropriate methodology for the full-scale main investigation.

The methodology study phase was completed in late 1984, and the data were reviewed shortly thereafter by the Institute of Medicine (IOM) of the National Academy of Sciences. HHS is committed to making these data, except for the identification of persons involved and other safeguards, available to specified scientists for further scientific

review and analysis. Final discussions are underway regarding the procedures by which these data would be made available.

In the methodology study full report, 90 percent of the identifiable Reye syndrome cases had a history of aspirin use during an antecedent respiratory illness or an episode of chicken pox, compared to 46 percent of the controls who had used aspirin but did not develop Reye syndrome. Moreover, a majority of Reye syndrome cases (73 percent) were patients between the ages of 10 and 18. The methodology study, although not conclusive, reported an association between the use of aspirin and the onset of Reye syndrome in children and teenagers. The study results also highlighted the vulnerability of teenagers to this disease. As noted above, the main study is now underway. The data generated will be reviewed, critiqued, and monitored by IOM as the study progresses.

D. Educational Activities

In January 1985, based on the data from the methodology study, FDA expanded its public education program. Agency efforts included newspaper columns, radio public service announcements (PSA's), and newspaper advertisements. Based on findings in the methodology study, FDA placed specific emphasis in its 1985 educational campaign on teenagers. These educational activities are continuing into the 1985-1986 flu season.

Separately, but in concert with FDA's educational campaign, the aspirin industry developed and implemented its own educational program, beginning in January 1985. The industry's educational efforts consisted of television and radio PSA's, store posters, and revised product labeling.

The American Pharmaceutical Association also distributed Reye syndrome warning posters to its membership. Retail establishments headed by Giant Foods, Safeway, Walgreen, Thrift, Osco, People's Drug Stores, and others initiated similar efforts.

The voluntary nature of the aspirin industry's efforts led to considerable diversity in the specific message being conveyed to consumers, particularly through product labeling. For example, the eight companies making up the Aspirin Foundation of America (Bristol-Meyers Co. (Bufferin; Excedrin); Burroughs Wellcome Co. (Empirin); E.R. Squibb & Sons (Trigesic); Glenbrook Laboratories (Bayer Aspirin); L.T. York Co. (York Aspirin); Miles Laboratories, Inc. (Alka-Seltzer, Alka-Seltzer Plus); Proctor & Gamble Co. (Nerwich

Aspirin), and Whitehall Laboratories (Anacin)) all agreed to place the following warning on their aspirin labels: "Consult a physician before giving this medicine to children, including teenagers, with chicken pox or flu." In addition, the references to flu as an indication for use on the labels of children's aspirin products were deleted.

In contrast, Plough, Inc. (St. Joseph's Aspirin), which is not a member of the Aspirin Foundation, developed its own voluntary precautionary labeling program. Its program includes labeling revisions for all its aspirin-containing products to bear the following statement: "WARNING: Reye syndrome is a rare but serious disease which can follow flu or chicken pox in children and teenagers. While the cause of Reye syndrome is unknown, some reports claim aspirin may increase the risk of developing this disease. Consult a doctor before use in children or teenagers with flu or chicken pox." In addition, Plough, Inc., has included the following statement in its patient package insert: "The symptoms of Reye syndrome can include persistent vomiting; sleepiness and lethargy; violent headaches; unusual behavior, including disorientation, combativeness, and delirium. If any of these symptoms occur, especially following chicken pox or flu, call your doctor immediately, even if your child has not taken any medication. REYE SYNDROME IS SERIOUS, SO EARLY DETECTION AND TREATMENT ARE VITAL."

Other companies used additional variations. For example, Publix Super Markets, Eckard Drug Co., and LKS Products use the following statement: "REYE SYNDROME WARNING: Children and teenagers who exhibit signs of chicken pox or flu should consult a physician before using aspirin-containing products."

Giant Foods Inc. has also used its own statement. It says: "REYE SYNDROME WARNING: Consult a doctor before giving this product to children 19 years and under with chicken pox or flu."

Still another example is the approach taken by William H. Rorer Inc., which has elected to use the following statement: "Reye's syndrome Warning: Do not use in children, including teenagers, with chicken pox or flu."

Finally, in the case of Menley and James Laboratories, that firm has elected to use two different statements on its products. In one case, the statement reads: "If under medical care, or with a history of ulcers, or for children, including teenagers, with chicken pox or flu, consult a physician before taking this product." In the other

case, the statement reads: "Individuals being treated for depression, high blood pressure, asthma, heart disease, diabetes, thyroid disease, glaucoma, or an enlarged prostate or children, including teenagers, with chicken pox, or flu, should use only as directed by a physician."

In each case, the manufacturer has chosen where the warning statement appears. In some, it is in the "Warning" section of the labels. Others have placed the statement in different labeling sections or on the package side panel, back panel, or end flap. Some firms have simply flagged the label to "See New Label Directions."

On February 28, 1985, the "Emergency Reye Syndrome Act" (S. 538 and H.R. 1381) was introduced in Congress. On October 29, 1984, H.R. 3640 was introduced to amend H.R. 1381. These bills were introduced to amend the Federal Food, Drug, and Cosmetic Act to require prominent warnings concerning the use by children and teenagers of drugs containing aspirin or another salicylate. S. 538 and H.R. 1381 would require the following labeling: "WARNING: This product should not be given to individuals under the age of 21 years who have chicken pox, influenza, or flu symptoms. This product contains aspirin or another salicylate which has been strongly associated with the development of Reye syndrome, a serious and often fatal childhood disease."

In addition, in January 1985, S. 26 was introduced into the Illinois Senate to amend that State's Food, Drug, and Cosmetic Act to require the labeling of OTC aspirin-containing drug products with a warning statement about the possible association between use of the products and Reye syndrome. Although the bill did not pass, Resolution S. 54 did pass in March 1985 urging the United States Senate and House of Representatives to require labeling on OTC aspirin-containing products with a warning statement concerning Reye syndrome.

More recently, in a letter to the Secretary of Health and Human Services dated September 25, 1985, the American Academy of Pediatrics also expressed its concerns regarding the adequacy of such labeling. The Academy said that many of these warnings were not specific enough because they do not mention the possible link with Reye syndrome, and that in most instances the warnings do not stand out prominently enough on product labels. In its letter, the Academy suggested a warning of its own to be used. It stated: "WARNING: Reye syndrome is a rare but serious illness which can follow

influenza or chicken pox in children and teenagers. While the cause of Reye syndrome is unknown, studies indicate that aspirin may increase the risk of developing this illness. Consult a doctor before use in children and teenagers with symptoms of influenza or chicken pox." The Academy's concern about the labeling language and its location was reiterated in a second letter to the Secretary on November 14, 1985.

II. Regulatory Evaluation

FDA recognizes that the available data do not establish a definitive cause-and-effect relationship between aspirin-containing products and Reye syndrome. However, the agency has concluded that the studies suggest a possible association between aspirin use and Reye syndrome, prompting a major public education campaign as discussed in the advance notice of proposed rulemaking and in this document. In addition, as also discussed above, in January 1985, the aspirin industry, in response to a request by the Secretary, began an education program of its own, including various types of product labeling as presented above.

The Secretary believes that the voluntary program has made real and substantial progress and has done much more in a relatively brief period of time to inform and caution the general public about Reye syndrome and the possible association of the disease with aspirin use than the most ambitious mandatory program alone could have done in the same time frame. The Secretary also believes that this unprecedented voluntary program has proven itself to be, even in hindsight, the most appropriate response to the possible association between aspirin and Reye syndrome based on the scientific information available from the pilot study. In fact, cases of Reye syndrome have decreased from 422 in the 1980-1981 flu season, before FDA's educational program began, to 171 cases reported during last year's flu season, a 60 percent decline.

The relabeling component of this voluntary program has also been positive. For example, all aspirin and aspirin-containing products shipped since August 31, 1985, by the Aspirin Foundation manufacturers and Plough, Inc., which together represent approximately 75 percent of the U.S. aspirin market, contained a new warning statement. Moreover, these relabeled products have worked their way through the pipeline onto retail shelves in increasing quantity with each successive month.

Despite these positive aspects, the diversity of the label messages used is

likely to be somewhat confusing. As noted above, the label statements being used now, while similar, differ in several respects. Some do not mention Reye syndrome specifically. The mere multiplicity of warning statements also may cause consumer confusion. Finally the location of the statement on the label varies from product to product. FDA believes it is in the best interest of the consumer, industry, and the marketplace to have uniformity in presentation and clarity of message.

Although the previously mentioned eight Aspirin Foundation companies and Plough, Inc., represent some 75 percent of the aspirin market, FDA is unable to ascertain with certainty whether all aspirin-containing products in the marketplace are being relabeled. Thus, to increase consumer awareness, avoid public confusion, and achieve uniformity in the marketplace, FDA is proposing to require the following statement:

"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." Further, FDA is proposing that this warning shall precede any additional warnings that may appear on the product labeling in order to assure the prominence of the message.

III. Labeling Provisions

The agency has concluded that a regulation is necessary to achieve consistency and uniformity with respect to the labeling of oral aspirin-containing products and Reye syndrome. The proposed rule would amend § 201.314 *Labeling of drug preparations containing salicylates* (21 CFR 201.314) by adding a new paragraph (h), which would specify the proposed required OTC warning statement. The warning statement would appear in the labeling, as required by the proposed rule, of all aspirin-containing OTC drugs for human use that are administered orally. The aspirin may be present either as a single ingredient or in combination with one or more other ingredients. Aspirin-containing products that are not included would be those that are administered topically, rectally, vaginally, by aerosol, or those used as a mouthwash, toothpaste, or flavoring. This proposal does not apply to prescription drug products because, by definition, physicians are to be consulted prior to their use.

The warning statement that would be required by the proposed rule would be: "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."

The proposed rule would require that all OTC drug products subject to the rule prominently bear the required warning statement on the immediate container labeling, such as the outside container or wrapper label, and on all other labeling accompanying the product. If the labeling contains other warnings, the warning statement proposed in this document would be required to appear as the first warning under the heading "Warning".

In addition to this warning statement, the proposal would amend § 201.314 to require that the labeling for OTC aspirin-containing drug products subject to this proposed rule packaged solely for use by children (pediatric products) would not be permitted to recommend the product for use in flu or chicken pox.

IV. Compliance

It is proposed that these labeling requirements shall become effective for all products initially introduced into interstate commerce 90 days after publication of any final rule based on this proposal, or May 30, 1986, whichever is later. Any aspirin-containing OTC drug product for human use that is covered by this proposed rule that is initially introduced or initially delivered for introduction into interstate commerce on or after the effective date would be required to contain the labeling required by this proposed rule or be subject to regulatory action.

In addition, FDA is proposing that this regulation, if made final, would expire 2 years following the effective date, unless the agency acts to extend it through proposed rulemaking with notice and public comment. This 2-year period should allow completion of the main study now underway that is looking at the association between these products and Reye syndrome.

V. Legal Authority

This proposed rule would provide that oral OTC drugs which contain aspirin would be misbranded under section 502(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 352(a)), if the drugs are not labeled with a warning as required by the regulation and are initially introduced or initially delivered for introduction into interstate commerce after the effective date of the regulation.

Section 701(a) of the act (21 U.S.C. 371(a)) provides authority for promulgating substantive rules for the efficient enforcement of the act. See *National Ass'n of Pharmaceutical Manufacturers v. FDA*, 637 F.2d 877, 879 (2d Cir 1981). The courts have upheld

FDA's authority to promulgate regulations requiring label warnings. See, *Cosmetic, Toiletry and Fragrance Ass'n v. Schmidt*, 409 F. Supp. 57 64 (D.D.C. 1976), *Aff'd without opinion*, No. 75-1715 (D.C. Cir., August 19, 1977).

In proposing this regulation, FDA is aware that the voluntary labeling program undertaken by the aspirin industry together with FDA has been successful and has resulted in the labeling of many of the drugs which would be covered by this proposed regulation. However, FDA is of the view that the public interest would best be served by ensuring that the same warning is used on all products covered by this regulation and that it appear in the same place on all packaging. In addition, there may be a small number of products containing aspirin which have not been relabeled to include a warning as part of the voluntary labeling program. By promulgating this regulation, FDA eliminates the potential for consumers being confused and misled by variant forms of label statements about the important subject of aspirin and Reye syndrome (21 U.S.C. 352)).

FDA has a well-established policy of promoting uniformity in the area of labeling. For example, in requiring a warning directed to pregnant and nursing women on all OTC drugs intended for systemic absorption, FDA addressed the need to have the same language appear in the same manner on all labels. (See 47 FR 54753; December 3, 1982.) This preference for uniformity is also recognized by the judiciary in its construction of the Supremacy Clause of the United States Constitution. One of the four factors used to determine if Federal preemption of State regulation in a particular area exists is whether "the nature of the subject matter regulated * * * is one which demands 'exclusive Federal regulation in order to achieve uniformity vital to national interests.'" *Cosmetic, Toiletry and Fragrance Ass'n v. State of Minnesota*, 440 F. Supp. 1216, 1220 (D. Minn. 1977), *aff'd per curiam*, 575 F.2d 1256 (10th Cir. 1978), quoting, *Northern States Power Co. v. State of Minnesota*, 447 F.2d 1143, 1146-1147 (8th Cir. 1971), *aff'd* 405 U.S. 1035 (1972).

VI. Economic Impact

FDA has examined the regulatory impact and regulatory flexibility implications of the proposed rule in accordance with Executive Order 12291 and the Regulatory Flexibility Act. The proposal would impose direct one-time costs associated with changing product labels, but that cost is estimated to total less than \$3 million.

VII. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(11) (April 26, 1985; 50 FR 16636) 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.

VII. Comments

Interested persons may, on or before January 16, 1986, submit to the Dockets Management Branch (address above) written comments regarding this proposal. FDA is proposing this rule with a 30-day comment period in order to allow the agency to publish a final rule within the time for products subject to the rule to be properly labeled prior to the 1986-1987 flu season. Accordingly, good cause exists for a comment period of less than 60 days. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 201

Drugs, Labeling.

Therefore, under the Federal Food, Drug, and Cosmetic Act, it is proposed that Part 201 be amended as follows:

PART 201—LABELING

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

Authority: Secs. 201, 502, 505, 701, 52 Stat. 1040-1042 as amended, 1050-1053 as amended, 1055-1056 as amended (21 U.S.C. 321, 352, 355, 371); 21 CFR 5.10 and 5.11.

2. In §201.314 by adding new paragraph (h), to read as follows:

§201.314 Labeling of preparations containing salicylates.

(h)(1) The labeling of an orally administered over-the-counter aspirin-containing drug products subject to this paragraph is required to prominently bear a warning. The warning shall be 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."

(2) This warning statement shall appear on the immediate container labeling and on all other labeling accompanying such drug products. It shall be the first warning statement

under the heading "Warning" if the labeling contains warnings.

(3) Over-the-counter drug products subject to this paragraph and labeled solely for use by children (pediatric products) shall not recommend the product for use in treating flu or chicken pox.

(4) Any product subject to this paragraph that is not labeled as required by this paragraph and that is initially introduced or initially delivered for introduction into interstate commerce after (effective date to be 90 days after the date of publication of any final rule based on this proposal, or May 30, 1986, whichever is later) is misbranded under sections 201(n) and 502(a) and (f) of the Federal Food, Drug, and Cosmetic Act.

(5) The requirements of this paragraph shall expire (date 2 years after the effective date of the final rule), unless extended by the Food and Drug Administration by publication for notice and comment in the Federal Register.

Dated: December 11, 1985.

Frank E. Young,

Commissioner of Food and Drugs.

Margaret M. Heckler,

Secretary of Health and Human Services.

[FR Doc. 85-29789 Filed 12-16-85; 8:45 am]

BILLING CODE 4150-01-M

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Parts 625 and 655

[FHWA Docket No. 85-27]

National Standards for Traffic Control Devices; Request for Comments on Proposed Amendments to the Manual on Uniform Traffic Control Devices

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of proposed amendments to the Manual on Uniform Traffic Control Devices; request for comments.

SUMMARY: The FHWA is inviting comments on proposed amendments to the Manual on Uniform Traffic Control Devices (MUTCD). The MUTCD is incorporated by reference in the design standards for Federal-aid Highways found in Part 625 of Title 23, Code of Federal Regulations. It is also recognized in 23 CFR Part 655 as the national standard for traffic control devices on all public roads.

The amendments affect various parts of the MUTCD and are intended to expedite traffic, improve safety, and provide a more uniform application of highway signs, signals, and markings.

DATES: Comments must be received on or before July 19, 1986.

ADDRESS: Submit written comments, preferably in triplicate, to FHWA Docket No. 85-27, Federal Highway Administration, Room 4205 HCC-10, 400 Seventh Street SW., Washington, DC 20590. All comments received will be available for examination at the above address between 8:30 a.m. and 3:30 p.m. e.t., Monday through Friday. Those desiring notification of receipt of comments must include a self-addressed, stamped postcard.

The MUTCD is available for inspection and copying as prescribed in 49 CFR Part 7, Appendix D. It may be purchased for \$30.00 from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20420, Stock No. 050-001-81001-8.

FOR FURTHER INFORMATION CONTACT: Mr. Philip O. Russell, Office of Traffic Operations, (202) 426-0411, or Mr. Michael J. Laska, Office of the Chief Counsel, (202) 426-0702, 400 Seventh Street SW., Washington, DC 20590. Office hours are from 7:45 a.m. to 4:15 p.m. e.t., Monday through Friday, except legal holidays.

SUPPLEMENTARY INFORMATION: The FHWA both receives and initiates requests for amendments to the MUTCD. Each request is assigned an identification number which indicates, by Roman numeral, the organizational part of the MUTCD affected and, by Arabic numeral, the order in which the request was received.

This notice is being issued to provide the public an opportunity to comment on the desirability of proposed amendments to the MUTCD. Based upon comments received in response to this notice and upon its own experience, the FHWA will issue a final rule concerning these requests.

Index of Requests

General Provisions (Part I)

(1) Request I-4(Chng.)—Manual Changes, Interpretations and Authority to Experiment (Section 1A-6).

Signs (Part II)

(2) Request II-106(Chng.)—Use of No Parking Symbol Sign (R8-3a) in Rural Areas.

(3) Request II-107(Chng.)—Standards for and Applications of Lane-Use Control Signs at Intersections.

(4) Request II-109(Chng.)—Cloverleaf With Collector-Distributor Roadways.

(5) Request II-110(Chng.)—Tourist Oriented Directional Signs (TODS).

Markings (Part III)

(6) Request III-30(Chng.)—Wrong Way and Lane Use Pavement Marking Arrows.

(7) Request III-38(Chng.)—Warrants for No-Passing Zones at Curves.

(8) Request III-39(Chng.)—Delineator Placement and Spacing.

Signals (Part IV)

(9) Request IV-52(Chng.)—Median Width Criteria for Pedestrian Signals.

(10) Request IV-58(Chng.)—A Required Yellow Arrow Clearance Interval and Left Turn Signal Displays.

(11) Request IV-60(Chng.)—Warrants for Traffic Signal Installation.

(12) Request IV-67(Chng.)—Accident Experience Warrant.

(13) Request IV-68(Chng.)—Effects of Right Turn On Red on Volume Warrants.

Traffic Control for Street and Highway Construction and Maintenance Operations (Part VI)

(14) Request VI-33(Chng.)—Location of Reflective Collars with Respect to Top of Cones.

(15) Request VI-34(Chng.)—Size and Location of Additional Reflective Bands on Cones.

(16) Request VI-35(Chng.)—ROAD (STREET) CLOSED Sign.

(17) Request VI-36(Chng.)—Length of Construction Sign.

Traffic Control Systems for Railroad-Highway Grade Crossings (Part VIII)

(18) Request VIII-18(Chng.)—Delete Traffic Signal Preemption Drawing, Figure 8-8.

Traffic Control for Bicycle Facilities (Part IX)

(19) Request IX-4(Chng.)—U.S. Bicycle Route Marker (M1-9).

Copies of the proposed text changes to the MUTCD will be distributed to everyone currently appearing on the FHWA mailing list for MUTCD matters.

Those wishing to be added to the mailing list or receive copies of the proposed text should write to the Federal Highway Administration, Office of Traffic Operations (HTO-21), 400 Seventh Street SW., Washington, D.C. 20590 or contact Mr. Philip O. Russell (202) 426-0411.

Discussion of Requests

The FHWA proposes to act on the requests for change to the MUTCD as noted below:

General Provisions (PART 1)

(1) Request I-4(chng.)—Manual Changes, Interpretations and Authority