submit written comments on the rule on or before December 28, 2015. The DEA received one comment in response to the publication of the interim final rule, voicing support for the action. The DEA appreciates the support for the rule.

This exclusion only applies to the finished drug product in the form of an inhaler (in the exact formulation detailed in the application for exclusion), which is lawfully sold under the FD&C Act over-the-counter without a prescription. The extraction or removal of the active ingredient (levmetamfetamine) from the inhaler shall negate this exclusion and result in the possession of a schedule II controlled substance.

Regulatory Analyses
Executive Orders 12866 and 13563

This regulation has been developed in accordance with the Executive Orders 12866, “Regulatory Planning and Review,” section 1(b) and Executive Order 13563, “Improving Regulation and Regulatory Review.” The DEA has determined that this rule is not a significant regulatory action, and accordingly this rule has not been reviewed by the Office of Management and Budget. As discussed above, this product was previously exempted under a different company name. As discussed in the interim final rule, this action will not have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities; create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in Executive Order 12866.

Regulatory Flexibility Analysis

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612) applies to rules that are subject to notice and comment. The DEA determined, as explained in the interim final rule, that public notice and comment were impracticable and contrary to the public interest. Consequently, the RFA does not apply. Although the RFA does not apply to this rulemaking, the DEA has reviewed the potential impacts of this final rule and determined that it will not have a significant economic impact on a substantial number of small entities. As discussed above and in the interim final rule, this product was previously exempted under a different company name. The Deputy Assistant Administrator, in accordance with the RFA, has reviewed this regulation and by approving it certifies that this regulation will not have a significant economic impact on a substantial number of small entities.

Executive Order 12988

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988, “Civil Justice Reform,” to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132

This rulemaking does not have federalism implications warranting the application of Executive Order 13132. The rule does not have substantial direct effects on the States, on the relationship between the Federal Government and the States, or the distribution of power and responsibilities among the various levels of government.

Executive Order 13175

This rule does not have tribal implications warranting the application of Executive Order 13175. This rule does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Unfunded Mandates Reform Act of 1995

The DEA has determined and certifies pursuant to the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1501 et seq., that this action would not result in any Federal mandate that may result “in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted for inflation) in any one year . . . .” Therefore, neither a Small Government Agency Plan nor any other action is required under provisions of the UMRA.

Paperwork Reduction Act

This rule does not impose a new collection of information requirement under the Paperwork Reduction Act, 44 U.S.C. 3501–3521. This action would not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Congressional Review Act

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act (CRA)). This rule will not result in: An annual effect on the economy of $100,000,000 or more; a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure. Drug traffic control, Reporting and recordkeeping requirements.

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

Accordingly, for the reasons stated above, the interim final rule that was published in the Federal Register on October 27, 2015 (80 FR 65632), is adopted as a final rule without change.


Louis J. Milione,
Deputy Assistant Administrator, Office of Diversion Control.

BILLING CODE 4410–09–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 571

[Docket No. NHTSA–2014–0073]

RIN 2127–AL27

Federal Motor Vehicle Safety Standards: Lamps, Reflective Devices, and Associated Equipment

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: NHTSA is amending the side marker requirements contained in the
Federal Register / Vol. 81, No. 25 / Monday, February 8, 2016 / Rules and Regulations

Federal Motor Vehicle Safety Standard (FMVSS) on lamps, reflective devices and associated equipment for vehicles 80 inches or more in width and less than 30 feet long. This final rule adopts the amendments proposed in the Notice of Proposed Rulemaking (NPRM), published on December 4, 2012. These amendments will restore the side marker photometry requirements for motor vehicles under thirty feet in length that were in place prior to the 2007 final rule that reorganized the standard. Restoration of the side marker requirements will have no negative impact on safety or function and will allow motor vehicle manufacturers to avoid unnecessary modifications to their side marker lamps with no added safety or functional benefit.

DATES: Effective Date: August 8, 2016. Compliance Date: Optional early compliance as discussed below.

Petitions for Reconsideration: Petitions for reconsideration of this final rule must be received not later than March 24, 2016.

ADDRESSES: Any petitions for reconsideration should refer to the docket number of this document and be submitted to: Administrator, National Highway Traffic Safety Administration, 1200 New Jersey Avenue SE., West Building, Ground Floor, Docket Room W12–140, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: For technical issues: Mr. Wayne McKenzie, Office of Crash Avoidance Standards, NHTSA, 1200 New Jersey Avenue SE., West Building, Washington, DC 20590. For legal issues: Mr. John Piazza, Office of the Chief Counsel, NHTSA, 1200 New Jersey Avenue SE., West Building, Washington, DC 20590.

SUPPLEMENTARY INFORMATION:

I. Background

Side marker lamps have been required by FMVSS No. 108 since it was promulgated as one of the initial Federal Motor Vehicle Safety Standards in 1967. The main purpose of side marker lamps when it was reorganized FMVSS No. 108 in 2007. Before considering the changes made by this final rule, it is useful to briefly examine the evolution of the side marker requirements before 2007. Relevant to the present rulemaking is a change that was made to the side marker requirements in 1980 in response to a petition for rulemaking from Chrysler Corporation. At the time of the Chrysler petition, FMVSS No. 108 required that the photometric requirements for side marker lamps be met at test points 45 degrees outboard and inboard of the lateral center line passing through the lamps. FMVSS No. 108, however, permitted an additional compliance option for vehicles less than 80 inches in width. This additional compliance option had the effect of relaxing the inboard photometry requirements for the side marker lamps. Chrysler—wanted to use a common side marker design for its single-wheeled (less than 80 inches wide) and dual-wheeled (greater than 80 inches wide) pickup trucks—a different compliance option available to all vehicles regardless of width. NHTSA agreed with Chrysler that eligibility for the additional compliance option should not depend on a vehicle’s width, but did not agree that it should be available to all vehicles. The agency explained that the additional compliance option would not be appropriate for vehicles that are 30 feet or longer. Accordingly, the 1980 final rule revised FMVSS No. 108 by deleting the words “80 inches in overall width” and substituting “30 feet in overall length.” The next change to the side marker requirements relevant to this final rule occurred in 2007, when NHTSA reorganized FMVSS No. 108. The reorganization was intended to streamline the regulatory text and clarify the standard’s requirements. That final rule made the standard more user-friendly by significantly reducing the number of third-party documents, such as SAE standards, incorporated by reference. Prior to the reorganization, FMVSS No. 108 would, in many instances, specify requirements by simply referencing an SAE standard (which contained the requirements), instead of explicitly specifying those requirements in the text of FMVSS No. 108. However, when the standard was reorganized in 2007, requirements contained in the referenced third-party standards were included directly in the regulatory text, instead of incorporating the requirements by referencing the standard that contained those requirements. The agency explained that the reorganization was administrative in nature and that the FMVSS No. 108 requirements were not being increased, decreased, or substantively modified.

However, the newly revised version of FMVSS No. 108 inadvertently changed the alternative compliance option for side marker lamps. Prior to the reorganization, side marker lamps were required to conform to SAE Standard J592e (July 1972) (i.e., the requirements were specified using incorporation by reference). In addition, the pre-reorganization regulatory text also explicitly specified the alternative compliance option that was the subject of the 1980 final rule. The side marker lamp requirements specified in SAE J592e (July 1972) also included (in a footnote) an alternative compliance option for vehicles less than 80 inches wide. This was the same compliance option for which the agency had deleted the words “80 inches in overall width” and added the words “30 feet in overall length” in the 1980 final rule. When NHTSA reorganized FMVSS No. 108 in 2007, the requirements contained in SAE Standard J592e (July 1972) were included directly into the regulatory text of FMVSS No. 108, thus eliminating the incorporation by reference; this included the width-based compliance option that we had deleted from FMVSS No. 108 in 1980. Accordingly, the 2007 reorganization specified the alternative compliance option that for each motor vehicle less than 30 feet in overall length and less than 2032 mm (80 inches) in overall width, the minimum photometric intensity requirements for a
side marker lamp may be met for all inboard test points at a distance of 15 feet from the vehicle and on a vertical plane that is perpendicular to the longitudinal axis of the vehicle and located midway between the front and rear side marker lamps. NHTSA stated that this enforcement policy would be effective until the rulemaking was completed. That enforcement policy will end as of the effective date of this final rule.

III. Comments on the NPRM

NHTSA received only three comments in response to the 2012 NPRM. The Alliance of Automobile Manufacturers (the “Alliance”) stated that it agrees with NHTSA’s analysis of the situation surrounding the changes to FMVSS No. 108 during the administrative reorganization process as well as the proposed revisions. The Alliance stated that the proposed changes would bring the side marker photometry requirements back in line with the original intent of the 1980 final rule and restore the requirements that were in force prior to the 2007 final rule. The Alliance also commented that the phrase “and less than 80 inches (2m) in overall width” should be deleted from footnote 1 of Table X to ensure there is no ambiguity concerning the application of side marker lamp inboard photometry requirements.

General Motors submitted a comment in support of the change to the proposal and stated that the proposed changes would restore the previous requirements and would have no overall effect on safety.

The European Commission submitted a comment requesting an extension of the comment period to February 5, 2013.

IV. Agency Comment Analysis and Agency Decision

NHTSA has carefully considered the comments submitted in this rulemaking. We have reviewed the comments received from GM and the Alliance and agree with the rationale presented. Having received no information to the contrary, we are amending S7.4.13.2 of FMVSS No. 108 to delete the phrase “and less than 2032 mm in overall width,” consistent with the proposal. This revision will restore the photometric requirements in FMVSS No. 108 for side marker lamps on vehicles less than 30 feet in length so that the requirements may be met for all inboard test points at a distance of 15 feet from the vehicle on a vertical plane that is perpendicular to the longitudinal axis of the vehicle and located midway between the front and rear side marker lamps, regardless of the width of the vehicle.

We have also decided to adopt the Alliance’s proposed revision to footnote 1 of Table X. The text in the footnote that the Alliance proposes to delete—“and less than 80 inches (2m) in overall width”—is essentially the same as the text we are deleting from S7.4.13.2. Similarly revising this footnote will make the requirements stated in the footnote consistent with the requirements stated in S7.4.13.2.

With respect to the comment from the European Commission, NHTSA chose not to extend the comment period formally because we stated in the NPRM that the agency would consider late comments to the extent practicable. Given that this final rule is being published several years after the NPRM and we did not receive any additional comments or requests to extend the comment period, we consider this comment resolved.

V. Effective Date

In the NPRM we proposed an effective date of 30 days after publication of the final rule. Under the Safety Act, a FMVSS typically is not effective before the 180th day after the standard is published. We did not receive any comments concerning the proposed effective date. Therefore, in keeping with typical practice, this final rule will be effective August 8, 2016, with optional early compliance. We believe that specifying a later effective date for this final rule will not have any adverse effects or prejudice regulated entities. Moreover, providing for optional early compliance will allow manufacturers to immediately benefit from the flexibility afforded by the revised side marker requirements the same as if the effective date were earlier. NHTSA’s compliance policy stated in the 2012 NPRM is terminated as of the effective date of this final rule.

VI. Regulatory Notices and Analyses

A. Executive Order 12866, Executive Order 13563, and DOT Regulatory Policies and Procedures

NHTSA has considered the impact of this rulemaking action under Executive Order 12866, Executive Order 13563, and the DOT’s regulatory policies and procedures. This final rule was not reviewed by the Office of Management and Budget (OMB) under E.O. 12866, “Regulatory Planning and Review.” It is not considered to be significant under E.O. 12866 or the Department’s regulatory policies and procedures.

This final rule restores requirements to the standard that were unintentionally changed during the administrative revision of the standard. Because this final rule merely restores previously existing requirements it is not expected to have any costs. This
final rule allows manufacturers to avoid the cost of redesigning the side marker lamps for dual-wheeled pickup trucks because these vehicles can now continue to meet the side marker photometry requirements for narrower vehicles. Because there are not any costs associated with this rulemaking and only minor benefits, we have not prepared a separate economic analysis for this rulemaking.

B. Executive Order 13609: Promoting International Regulatory Cooperation

The policy statement in section 1 of Executive Order 13609 provides, in part:

The regulatory approaches taken by foreign governments may differ from those taken by U.S. regulatory agencies to address similar issues. In some cases, the differences between the regulatory approaches of U.S. agencies and those of their foreign counterparts might not be necessary and might impair the ability of American businesses to export and compete internationally. In meeting shared challenges involving health, safety, labor, security, environmental, and other issues, international regulatory cooperation can identify approaches that are at least as protective as those that are or would be adopted in the absence of such cooperation. International regulatory cooperation can also reduce, eliminate, or prevent unnecessary differences in regulatory requirements.

NHTSA is not aware of any conflicting regulatory approach taken by a foreign government concerning the subject matter of this rulemaking.

C. Regulatory Flexibility Act

In compliance with the Regulatory Flexibility Act, 5 U.S.C. 601 et seq., NHTSA has evaluated the effects of this action on small entities. I hereby certify that this rule would not have a significant impact on a substantial number of small entities. The final rule would affect manufacturers of motor vehicle light equipment, but the entities that qualify as small businesses would not be significantly affected by this rulemaking because the agency is restoring requirements that previously existed in an older version of the regulation. This rulemaking is not expected to affect the cost of manufacturing motor vehicle lighting equipment.

D. Executive Order 13132

NHTSA has examined this rule pursuant to Executive Order 13132 (64 FR 43255, August 10, 1999) and concluded that no additional consultation with States, local governments or their representatives is mandated by the rulemaking process. The agency has concluded that the rulemaking would not have sufficient federalism implications to warrant consultation with State and local officials or the preparation of a federalism summary impact statement. The final rule would not have “substantial direct effects on the States, or the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.”

NHTSA rules can preempt in two ways. First, the National Traffic and Motor Vehicle Safety Act contains an express preemption provision: “When a motor vehicle safety standard is in effect under this chapter, a State or a political subdivision of a State may prescribe or continue in effect a standard applicable to the same aspect of performance of a motor vehicle or motor vehicle equipment only if the standard is identical to the standard prescribed under this chapter.” 49 U.S.C. 30103(b)(1). It is this statutory command by Congress that preempts any non-identical State legislative and administrative law addressing the same aspect of performance.

The express preemption provision set forth above is subject to a savings clause under which “[c]ompliance with a motor vehicle safety standard prescribed under this chapter does not exempt a person from liability at common law.” 49 U.S.C. 30103(e). Pursuant to this provision, State common law tort causes of action against motor vehicle manufacturers that might otherwise be preempted by the express preemption provision are generally preserved.

However, the Supreme Court has recognized the possibility, in some instances, of implied preemption of such State common law tort causes of action by virtue of NHTSA’s rules, even if not expressly preempted. This second way that NHTSA rules can preempt is dependent upon there being an actual conflict between an FMVSS and the higher standard that would effectively be imposed on motor vehicle manufacturers if someone obtained a State common law tort judgment against the manufacturer, notwithstanding the manufacturer’s compliance with the NHTSA standard. Because most NHTSA standards established by an FMVSS are minimum standards, a State common law tort cause of action that seeks to impose a higher standard on motor vehicle manufacturers will generally not be preempted. However, if and when such a conflict does exist—for example, when the standard at issue is both a minimum standard and the State common law tort cause of action is impliedly preempted. See Geier v. American Honda Motor Co., 529 U.S. 861 (2000).

Pursuant to Executive Order 13132 and 12988, NHTSA has considered whether this rule could or should preempt State common law causes of action. The agency’s ability to announce its conclusion regarding the preemptive effect of one of its rules reduces the likelihood that preemption will be an issue in any subsequent tort litigation.

To this end, the agency has examined the nature (e.g., the language and structure of the regulatory text) and objectives of this rule and finds that this rule, like many NHTSA rules, prescribes only a minimum safety standard. As such, NHTSA does not intend that this rule preempt state tort law that would effectively impose a higher standard on motor vehicle manufacturers than that established by this rule. Establishment of a higher standard by means of State tort law would not conflict with the minimum standard announced here. Without any conflict, there could not be any implied preemption of a State common law tort cause of action.

E. National Environmental Policy Act

NHTSA has analyzed this final rule for the purposes of the National Environmental Policy Act. The agency has determined that implementation of this action would not have any significant impact on the quality of the human environment.

F. Paperwork Reduction Act

Under the procedures established by the Paperwork Reduction Act of 1995, a person is not required to respond to a collection of information by a Federal agency unless the collection displays a valid OMB control number. This final rule would not establish any new information collection requirements.

G. National Technology Transfer and Advancement Act

Under the National Technology Transfer and Advancement Act of 1995 (NTTAA) (Pub. L. 104–113), “all Federal agencies and departments shall use technical standards that are developed or adopted by voluntary consensus standards bodies, using such technical standards as a means to carry out policy objectives or activities determined by the agencies and departments.” This final rule would not adopt or reference any new industry or consensus standards that were not already present in FMVSS No. 108.

H. Civil Justice Reform

With respect to the review of the promulgation of a new regulation, section 3(b) of Executive Order 12988,
“Civil Justice Reform” (61 FR 4729, February 7, 1996) requires that Executive agencies make every reasonable effort to ensure that the regulation: (1) Clearly specifies the preemptive effect; (2) clearly specifies the effect on existing Federal law or regulation; (3) provides a clear legal standard for affected conduct, while promoting simplification and burden reduction; (4) clearly specifies the retroactive effect, if any; (5) specifies whether administrative proceedings are to be required before parties file suit in court; (6) adequately defines key terms; and (7) addresses other important issues affecting clarity and general draftsmanship under any guidelines issued by the Attorney General. This document is consistent with these requirements.

Pursuant to this Order, NHTSA notes as follows. The preemptive effect of this final rule is discussed above. NHTSA notes further that there is no requirement that individuals submit a petition for reconsideration or pursue other administrative proceeding before they may file suit in court.

I. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 requires agencies to prepare a written assessment of the costs, benefits and other effects of proposed or final rules that include a Federal mandate likely to result in the expenditure by State, local or tribal governments, in the aggregate, or by the private sector in excess of $100 million annually. This final rule would not result in expenditures by State, local or tribal governments, in the aggregate, or by the private sector in excess of $100 million annually.

J. Executive Order 13211

Executive Order 13211 (66 FR 28355, May 18, 2001) applies to any rulemaking that: (1) Is determined to be economically significant as defined under E.O. 12866, and is likely to have a significantly adverse effect on the supply of, distribution of, or use of energy; or (2) that is designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action. This rulemaking is not subject to E.O. 13211.

K. Regulation Identifier Number (RIN)

The Department of Transportation assigns a regulation identifier number (RIN) to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. You may use the RIN contained in the heading at the beginning of this document to find this action in the Unified Agenda.

L. Privacy Act

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT’s complete Privacy Act Statement in the Federal Register published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78).

Regulatory Text

List of Subjects in 49 CFR Part 571

Imports, Motor vehicle safety, Motor vehicles, Tires.

In consideration of the foregoing, NHTSA is amending 49 CFR part 571 as set forth below.

PART 571—FEDERAL MOTOR VEHICLE SAFETY STANDARDS

§ 571.108 Standard No. 108; Lamps, reflective devices, and associated equipment.

S7.4.13.2 Inboard photometry. For each motor vehicle less than 30 feet in overall length, the minimum photometric intensity requirements for a side marker lamp may be met for all inboard test points at a distance of 15 feet from the vehicle and on a vertical plane that is perpendicular to the longitudinal axis of the vehicle and located midway between the front and rear side marker lamps.

Table X—Side Marker Lamp Photometry Requirements

(1) Where a side marker lamp installed on a motor vehicle less than 30 feet in overall length has the lateral angle nearest the other required side marker lamp on the same side of the vehicle reduced from 45° by design as specified by S7.4.13.2, the photometric intensity measurement may be met at the lesser angle.

Issued in Washington, DC, on February 1, 2016 under authority delegated in 49 CFR 1.95.

Mark R. Rosekind, Administrator.

[FR Doc. 2016–02268 Filed 2–5–16; 8:45 am]

BILLING CODE 4910–59–P

NATIONAL TRANSPORTATION SAFETY BOARD

49 CFR Part 830

[Docket No. NTSB–AS–2012–0001]

RIN 3147–AA11

Notification and Reporting of Aircraft Accidents or Incidents and Overdue Aircraft, and Preservation of Aircraft Wreckage, Mail, Cargo, and Records

AGENCY: National Transportation Safety Board (NTSB).

ACTION: Final rule; confirmation of effective date.

SUMMARY: The NTSB publishes confirmation of an amendment to its regulations concerning notification and reporting requirements with regard to aircraft accidents or incidents, titled, “Immediate notification.” The regulation requires reports of Airborne Collision and Avoidance System (ACAS) resolution advisories issued under certain specific circumstances. In a Direct Final Rule published December 15, 2015, the NTSB narrowed the ACAS reporting requirement, consistent with the agency’s authority to issue non-controversial amendments to rules. The NTSB also updated its contact information for notifications. This document confirms the changes and the effective date.

DATES: The final rule published December 15, 2015 (80 FR 77586) becomes effective February 16, 2016.


SUPPLEMENTARY INFORMATION: As described in the NTSB’s preamble summarizing the direct final rule, in 2010, the NTSB added a requirement for