

**DEPARTMENT OF TRANSPORTATION****Office of the Secretary****14 CFR Chapters I, II, III****23 CFR Chapters I, II, III****46 CFR Chapter II****48 CFR Chapter 12****49 CFR Chapters I, II, III and V, VI, VII, VIII, X, XI**

[Docket No. DOT-OST-2011-0025]

**Regulatory Review of Existing DOT Regulations****AGENCY:** Office of the Secretary of Transportation (OST), DOT.**ACTION:** Notice and request for comments.

**SUMMARY:** In accordance with Executive Order 13563, "Improving Regulation and Regulatory Review," the Department of Transportation (Department or DOT) is conducting a review of its existing regulations to evaluate their continued validity and determine whether they are crafted effectively to solve current problems. As part of this review, the Department invites the public to participate in a comment process designed to help the Department ensure that it has a plan for periodically analyzing existing significant rules to determine whether they should be modified, streamlined, expanded, or repealed and identify specific rules that may be outmoded, ineffective, insufficient, or excessively burdensome. The Department also will hold a public meeting to discuss and consider comments from members of the public.

**DATES:** Comments should be received on or before April 1, 2011. Late-filed comments will be considered to the extent practicable. In addition, the Department will hold a public meeting beginning at 9:30 a.m. ET on March 14, 2011, at the DOT headquarters, to discuss the regulatory review and take public comments. Commenters wishing to have time allocated to them at the public meeting should submit initial comments by March 3, 2011, and clearly indicate their desire to have time allocated at the public meeting.

**ADDRESSES:** You may submit comments to Docket DOT-OST-2011-0025 by any of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov> and follow the instructions for sending your comments electronically.

- *Mail:* Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue, SE., Washington, DC 20590-0001. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed envelope or postcard.

- *Hand Delivery or Courier:* West Building, Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC between 9 a.m. and 5 p.m. ET., Monday through Friday, except Federal holidays.

- *Fax:* 202-493-2251.

To avoid duplication, please use only one of these four methods. All comments received will be posted without change to <http://www.regulations.gov> and will include any personal information you provide.

*Docket:* To read background documents or comments received, go to <http://www.regulations.gov> and click on the "read comments" box in the upper right hand side of the screen. Then, in the "Keyword" box insert "OST-2011-0025" and click "Search." Next, click the "Open Docket Folder" in the "Actions" column. Finally, in the "Title" column, click on the document you would like to review. If you do not have access to the Internet, you may view the docket online by visiting the Docket Management Facility in Room W12-140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** Neil R. Eisner, Assistant General Counsel for Regulation and Enforcement, Department of Transportation, 1200 New Jersey Avenue, SE., Washington, DC 20590; (202) 366-4723. *E-mail:* [neil.eisner@dot.gov](mailto:neil.eisner@dot.gov).

**SUPPLEMENTARY INFORMATION:****Executive Order 13563**

On January 18, 2011, President Obama issued Executive Order 13563, which outlined a plan to improve regulation and regulatory review (76 FR 3821, 1/21/11). Executive Order 13563 reaffirms and builds upon governing principles of contemporary regulatory review, including Executive Order 12866, "Regulatory Planning and Review," (58 FR 51735, 10/4/1993), by requiring Federal agencies to design cost-effective, evidence-based regulations that are compatible with economic growth, job creation, and competitiveness. The President's plan

recognizes that these principles should not only guide the Federal government's approach to new regulation, but to existing ones as well. To that end, Executive Order 13563 requires agencies to review existing significant rules to determine if they are outmoded, ineffective, insufficient, or excessively burdensome.

To facilitate this review, Executive Order 13563 requires each agency to develop and submit to the Office of Management and Budget's Office of Information and Regulatory Affairs a preliminary plan for retrospectively analyzing existing rules. Specifically, the Department must provide a plan for periodically reviewing existing significant regulations to determine whether any such regulations should be modified, streamlined, expanded, or repealed so as to make the Department's regulatory program more effective or less burdensome in achieving the Department's regulatory objectives.

As Executive Order 13563 reaffirms, the regulatory process must be transparent and provide opportunities for public participation. The Department particularly believes, given its broad regulatory responsibility, this participation should extend to the Department's obligations under the Executive Order to conduct a retrospective review of existing regulations. This review will be more meaningful if it involves input from those affected by the Department's regulations.

**DOT's Regulatory Responsibility**

The mission of the Department is to serve the United States by ensuring a safe, fast, efficient, accessible, and convenient transportation system that meets our vital national interests and enhances the quality of life of the American people, today and into the future. The Department carries out its mission through the Office of the Secretary (OST) and the following operating administrations (OAs): Federal Aviation Administration (FAA); Federal Highway Administration (FHWA); Federal Motor Carrier Safety Administration (FMCSA); Federal Railroad Administration (FRA); Federal Transit Administration (FTA); Maritime Administration (MARAD); National Highway Traffic Safety Administration (NHTSA); Pipeline and Hazardous Materials Safety Administration

(PHMSA); Research and Innovative Technology Administration (RITA); and St. Lawrence Seaway Development Corporation (SLSDC). Although the Surface Transportation Board (STB) is a component of DOT, it is organizationally independent and, as a result, the Department does not have responsibility for the STB's regulatory agenda.

DOT has statutory responsibility for a wide range of regulations. For example, DOT regulates safety in the aviation, motor carrier, railroad, motor vehicle, commercial space, and pipeline transportation areas. DOT regulates aviation consumer and economic issues, and provides financial assistance and writes the necessary implementing rules for programs involving highways, airports, mass transit, the maritime industry, railroads, and motor transportation and vehicle safety. It writes regulations carrying out such disparate statutes as the Americans with Disabilities Act and the Uniform Time Act. Finally, DOT has responsibility for developing policies that implement a wide range of regulations that govern programs such as acquisition and grants management, access for people with disabilities, environmental protection, energy conservation, information technology, occupational safety and health, property asset management, seismic safety, security, and the use of aircraft and vehicles.

#### **DOT's Existing Process for Reviewing Rules**

The Department has long recognized that there should be no more regulations than necessary and those that are issued should be simple, comprehensible, and impose as little burden as necessary. Likewise, the Department understands that review and revision of existing regulations is essential to ensure that they continue to meet the needs for which they originally were designed and remain cost-effective and cost-justified. The Department regularly makes a conscientious effort to review its rules in accordance with the Department's 1979 Regulatory Policies and Procedures (44 FR 11034, 2/26/1979), Executive Order 12866, and section 610 of the Regulatory Flexibility Act.

The Department follows a repeating 10-year plan for the review of our existing regulations, which is set forth in our semi-annual Regulatory Agenda published in the **Federal Register** (see Appendix D to "Department Regulatory Agenda; Semiannual Summary" published on December 20, 2010 (75 FR 79812)). The reviews conducted under this plan comply with section 610 of the

Regulatory Flexibility Act. OST and most OAs have also elected to use this repeating 10-year plan to comply with the review requirements of the Department's Regulatory Policies and Procedures and Executive Order 12866. Generally, the agencies have divided their rules into 10 different groups and analyze one group each year, then start over again. We regularly invite public participation in those reviews and seek general suggestions on rules that should be revised or revoked. In the fall Regulatory Agenda, we publish information on the results of the examinations completed during the previous year. We are now engaged in our second 10-year review.

The FAA, in addition to following a 10-year review plan in accordance with section 610 of the Regulatory Flexibility Act, has established a triennial process to comply with other review requirements. The FAA's latest notice was published November 15, 2007 (72 FR 64170). NHTSA conducts an evaluation of both the costs and benefits of each of its significant rules approximately 4 years after the effective date on which 100 percent of the annual production of all types of vehicles subject to the rule must comply with the rule. This interval is necessary to ensure that sufficient crash data are available for the agency to determine whether a statistically significant reduction in crashes, injuries, and fatalities has occurred. Other OAs also conduct periodic public reviews to focus on specific issues or to obtain comments on rulemaking priorities. Moreover, under 49 CFR part 5, anyone may petition the Department for rulemaking or for an amendment or exemption to a rule.

As part of implementing Executive Order 13563, we will assess our current processes for reviewing rules and examine whether our approach should be modified going forward. While the Department may use these existing processes as significant inputs into its preliminary plan, the Department strongly encourages all parties affected by DOT regulations to comment on opportunities to improve our current review processes in a manner that best addresses the principles outlined in Executive Order 13563.

#### **Public Participation and Request for Comments**

DOT is an active regulatory agency with broad regulatory responsibilities. A robust regulatory program being essential to our mission, it is all the more important that we maintain a consistent culture of retrospective review and analysis. Thus, to implement Executive Order 13563, the

Department solicits the views of the public on the following matters.

The public is first asked to comment on how the Department should devise a preliminary plan, with a defined method and schedule, for identifying certain significant rules that may be obsolete, unnecessary, unjustified, excessively burdensome, or counterproductive. Comments might address how best to evaluate and analyze regulations in order to expand on those that work and to modify, improve, or rescind those that do not. Comments might usefully address how the Department can best obtain and consider accurate, objective information and data about the costs, burdens, and benefits of existing regulations and whether there are existing sources of data that the Department can use to evaluate the post-promulgation effects of regulations over time. The Department is particularly interested in the public's views about how well its current processes for reviewing regulations function and how those processes might be expanded or otherwise adapted to meet the objectives of Executive Order 13563. The Department is further interested in comments about factors that the Department should consider in setting priorities and selecting rules for review. Our initial selection criteria for these rules are currently based on the factors listed below, on which we seek public comment.

The Department intends for its preliminary plan to include an initial list of candidate rules for review. The Department solicits suggestions for specific rules that should be on that list. In nominating candidate rules for this list, commenters might usefully address, among other things, opportunities to use the Department's review process to achieve the following objectives: (1) Promote economic growth, innovation, competitiveness, and job creation; (2) eliminate outdated regulations; (3) lessen the burdens imposed on those directly or indirectly affected by our regulations, increase the benefits provided to the public by our regulations, and improve the cost-benefit balance of our regulations; (4) lessen burdens imposed on small entities; (5) eliminate duplicative or overlapping regulations; (6) reduce paperwork by eliminating duplication, lessening frequency, allowing electronic submission, standardizing forms, exempting small entities, or other means; (7) eliminate conflicts and inconsistencies in the Department's regulations and those of its own agencies or other Federal agencies or state, local, or tribal governmental

bodies; (8) simplify or clarify language in regulations; (9) revise regulations to address changes in technology, economic conditions, or other factors; (10) determine if matters in an existing regulation could be better handled fully by the states without Federal regulations; (11) reduce burdens by incorporating international or industry consensus standards into regulations; (12) reconsider regulations that were based on scientific or other information that has been discredited or superseded; and (13) expand regulations that are insufficient to address their intended objectives or to obtain additional benefits.

Comments should focus on regulations that have demonstrated deficiencies. Comments that rehash debates over recently issued rules will be less useful. Particularly where comments relate to a rule's costs or benefits, comments will be most useful if there are data and experience under the rule available to ascertain the rule's actual impact. For that reason, we encourage the public to emphasize those rules that have been in effect for a sufficient amount of time to warrant a fair evaluation. Furthermore, the public should focus on rule changes that will achieve a broad public impact, rather than an individual personal or corporate benefit. Where feasible, comments should reference a specific regulation, by Code of Federal Regulations (CFR) cite, and provide the Department information on what needs fixing and why. Comments do not necessarily need to address how to fix the perceived problem, though such comments are welcome. Lastly, we also want to stress that this review is for existing rules; the public should not use this process to submit comments on proposed rules.

The public meeting will begin with a discussion of and taking comments on the Department's preliminary plan for regulatory review required by Executive Order 13563. After that, we plan to allow for comments on candidate rules for review. The Department's General Counsel will preside over the meeting. Other senior officials from the Department and its OAs will also attend. It is our intent that the public meeting will provide an opportunity for these officials to interact with individuals or stakeholder representatives. To enable them to effectively participate in the public meeting, they will need some information in advance. As a result, we are establishing the following process.

#### 1. Suggestions for Discussion at Public Meeting:

a. By March 3, 2011, the Department requests that commenters submit their

suggestions for discussion at the public meeting and indicate whether they want time allocated to them at the public meeting. Commenters are welcome to indicate how much time they would like to be allocated, but the Department reserves the right to allocate time as necessary to ensure that as many commenters as possible may participate in the public meeting in a meaningful manner.

b. The initial comments from those intending to participate in the public meeting should contain enough details to permit DOT officials to sufficiently prepare and ask questions.

c. The initial comments may be augmented anytime before the end of the full comment period.

d. Anyone who needs auxiliary aids and services, such as sign language interpreters, to effectively participate in the meeting should contact the Department via the "**FOR FURTHER INFORMATION CONTACT**" information provided above.

#### 2. Public Meeting:

a. After receiving this initial round of public comment, the Department will organize those suggestions by topic and OA for discussion during the public meeting.

b. By having the public meeting after receiving initial public comment and by organizing the discussion around topics and OAs, the Department will be better positioned to discuss issues regarding a particular rule, broad category of rules, or affected group or industry, rather than merely recording public comment for later review.

c. The Department will hold its public meeting beginning at 9:30 a.m. ET on March 14, 2011 at the Department of Transportation, West Building, Ground Floor, DOT Conference Center, Oklahoma Room, 1200 New Jersey Avenue, SE., Washington, DC. We will make a meeting outline available on <http://regs.dot.gov> in advance of the meeting. Furthermore, we are exploring the use of technology to enable remote participation in the meeting. We will update <http://regs.dot.gov> with information about opportunities for the public to participate remotely.

#### 3. Other Written Comments:

The Department will continue to accept written comments through April 1, 2011. Those who do not wish to attend the public meeting may, of course, submit comments at any time during the comment period.

#### 4. Follow-up Action by DOT:

a. We will place a transcript or summary of the public meeting in our public docket (<http://www.regulations.gov>) as soon as possible after the end of the meeting.

We note that because the docket is Internet accessible, it should allow those with Internet access to review those proceedings as well as other comments. We hope this will further improve the interchange of ideas.

b. This review will provide meaningful and significant input to the Secretary, the General Counsel, OA Administrators, and other DOT senior officials. As soon as possible, depending on the number of comments we receive and the issues raised, the Department will publish a report providing at least a brief response to the comments we have received, including a description of any further action we intend to take.

#### Regulatory Notices

*Privacy Act:* Anyone may search the electronic form of 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 (65 FR 19477-78) or you may visit <http://www.gpoaccess.gov/fr/browse.html> and browse under 2000 for April 11, looking under Department of Transportation.

**Authority:** 5 U.S.C. 610; E.O. 13563, 76 FR 3821, Jan. 21 2011; E.O. 12866, 58 FR 51735, Oct. 4, 1993.

Issued on February 10, 2011, in Washington, DC.

**Robert S. Rivkin,**  
*General Counsel.*

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## CONSUMER PRODUCT SAFETY COMMISSION

### 16 CFR Part 1700

[CPSC Docket No. CPSC-2011-0007]

#### Poison Prevention Packaging Requirements; Proposed Exemption of Powder Formulations of Colesevelam Hydrochloride and Sevelamer Carbonate

**AGENCY:** Consumer Product Safety Commission.

**ACTION:** Proposed rule.

**SUMMARY:** The Consumer Product Safety Commission ("CPSC," "Commission," or "we") is proposing to amend its child-resistant packaging requirements to exempt powder formulations of two oral prescription drugs, colesevelam hydrochloride and sevelamer carbonate. Colesevelam hydrochloride, currently