proposes to amend part 43 of Title 14, Code of Federal Regulations, as follows:

PART 43—MAINTENANCE, PREVENTIVE MAINTENANCE, REBUILDING, AND ALTERATION

1. The authority citation for part 43 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701, 44703, 44705, 44707, 44711, 44713, 44717, 44725.

2. Amend § 43.3 by adding paragraph (k) to read as follows:

§ 43.3 Persons authorized to perform maintenance, preventive maintenance, rebuilding, and alterations.

* * * * *

(k) The holder of a pilot certificate issued under part 61 of this chapter may perform updating of self-contained, front-instrument panel-mounted and pedestal-mounted air traffic control (ATC) navigational system databases (excluding those of automatic flight control systems, transponders, and microwave frequency distance measuring equipment (DME), and any updates that affect system operating software) provided—

(1) No disassembly of the unit is required;

(2) The pilot has written procedures available to perform and evaluate the accomplishment of the task; and

(3) The database is contained in a field-loadable configuration and imaged on a medium, such as a Compact Disc Read-Only Memory (CD–ROM), Synchronous Dynamic Random-Access Memory (SDRAM), or other non-volatile memory that contains database files that are non-corruptible upon loading, and where integrity of the load can be assured and verified by the pilot upon completing the loading sequences.

(4) Records of when such database uploads have occurred, the revision number of the software, and who performed the upload must be maintained.

(5) The data to be uploaded must not contain system operating software revisions.

Appendix A to Part 43 [Amended]

3. Amend Appendix A to part 43 by removing paragraph (c)(32).

Issued in Washington, DC, on August 31, 2011.

John W. McGraw,

Deputy Director, Flights Standards Service.

[FR Doc. 2011–27036 Filed 10–18–11; 8:45 am]

BILLING CODE 4910–13–P

CONSUMER PRODUCT SAFETY COMMISSION

[Docket No. CPSC–2011–0078]

16 CFR Chapter II

Review of Commission's Regulations; Request for Comments and Information

AGENCY: Consumer Product Safety Commission.

ACTION: Request for comments and information.

SUMMARY: Consumer Product Safety Commission (''CPSC'' or ''we'') staff is considering the appropriate process and substance of a plan to review existing CPSC regulations. CPSC has conducted reviews of rules in the past and intends to build on that experience to develop a plan of review that also satisfies recent direction from President Obama, set forth in Executive Order 13579, ''Regulation and Independent Regulatory Agencies'' (76 FR 41587 (July 14, 2011)), which states that independent regulatory agencies should follow certain key principles when developing new regulations and should review existing significant regulations. To that end, Executive Order 13579 (''E.O. 13579'') emphasizes the importance of retrospective analysis of rules and the need to develop a plan under which the agency will conduct periodic reviews of existing regulations. We invite comments on the issues discussed in this document to help us formulate a plan that builds on our past review efforts while incorporating the principles outlined in E.O. 13579.

DATES: Comments must be submitted by December 19, 2011.

ADDRESSES: You may submit comments, identified by Docket No. CPSC–2011–0078, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

To ensure timely processing of comments, the Commission is no longer accepting comments submitted by electronic mail (e-mail), except through *http://www.regulations.gov.*

Written Submissions

Submit written submissions in the following way:

Mail/Hand delivery/Courier (for paper, disk, or CD–ROM submissions), preferably in five copies, to: Office of the Secretary, Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504–7923.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All comments received may be posted without change, including any personal identifiers, contact information, or other personal information provided to: *http://www.regulations.gov.* Do not submit confidential business information, trade secret information, or other sensitive or protected information electronically. Such information should be submitted in writing and marked as confidential.

Docket: For access to the docket to read background documents or comments received, go to: *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Robert J. Howell, Deputy Executive Director for Safety Operations, U.S. Consumer Product Safety Commission, 4330 East-West Highway, Bethesda, Maryland 20814; telephone (301) 504–7621; e-mail *rhowell@cpsc.gov.*

SUPPLEMENTARY INFORMATION:

A. Previous Review Programs

1. The Systematic Review Program (2004 to 2007)

In 2004, CPSC began a program to review existing regulations. This review resulted from an initiative by the Office of Management and Budget (''OMB''), the Program Assessment Rating Tool (''PART''), which was intended to provide a consistent approach to rating programs across the federal government. OMB recommended that the CPSC develop a plan to systematically review its regulations to ensure consistency among them in accomplishing program goals. In fiscal year (FY) 2004, we conducted a pilot review program as the initial step in implementing that recommendation. The notice announcing the pilot program appeared in the **Federal Register** on January 28, 2004 (69 FR 4095), and we continued the program for several years thereafter (see 70 FR 18338 (April 11, 2005); 71 FR 32882 (June 7, 2006); 72 FR 40265 (July 24, 2007)).

The rule review focused on determining whether the CPSC's regulations were:

- Consistent with CPSC's program goals;
- Consistent with other CPSC regulations;
- Current with respect to technology, economic, or market conditions, and other mandatory or voluntary standards; and

• Subject to revision to reduce regulatory burdens, particularly burdens on small entities.

See 69 FR 4096. When choosing which rules to review, the CPSC decided to exclude from review any rules that it considered nonsubstantive (*i.e.,* those with requirements that were: administrative or procedural; exemptions; labeling; test methods; or definitions).

The CPSC used the following criteria to select rules for the 2004 pilot program: (1) The rule had been in effect at least 10 years; (2) at least one of the rules selected for review had multiple requirements; (3) the rules addressed different hazard areas to ensure the review process was not overly burdensome to any one internal discipline; and (4) the rules were issued under different statutes. Once the rules were chosen, CPSC staff reviewed the rule to look for: Inconsistencies within the rule or with other CPSC rules; references to, or use of, obsolete standards, technology, procedures, or requirements that were no longer needed; and the potential to streamline requirements of the rule. Following that analysis, CPSC staff prepared a memo for the Commission's consideration, discussing these issues and noted areas where changes to the rule were needed. This approach was followed for the review program in 2004 through 2007.

The rules reviewed in the 2004 pilot included the safety standard for walk-behind mowers; requirements for electrically operated toys; the standard for the flammability of vinyl plastic film; and the child-resistant packaging requirements for aspirin and methyl salicylate. 69 FR 4095 (Jan. 28, 2004). In FY 2005, the CPSC reviewed the safety standard for cigarette lighters and multipurpose lighters; the requirements for bicycles; the standards for surface flammability of carpets and rugs; and the regulations requiring child-resistant packaging for oral subscription drugs subject to the Comprehensive Drug Abuse Prevention and Control Act. 70 FR 18338 (April 11, 2005). In FY 2006, the CPSC reviewed the safety standard for matchbooks; the requirements for toy rattles; and the requirements for baby bouncers, walker-jumpers, or baby walkers. 71 FR 32882 (June 7, 2006). In FY 2007, the CPSC reviewed the ban of unstable refuse bins and the requirements for pacifiers. 72 FR 40265 (July 24, 2007).

In 2008, the enactment of the Consumer Product Safety Improvement Act of 2008 (Pub. L. 110–314) required us to assign resources to implement the new law. Consequently, we have not pursued additional systematic rule reviews since 2007.

2. Periodic Review Under the Regulatory Flexibility Act

In addition to the Systematic Review Program discussed in the previous section, the CPSC conducts reviews of rules in accordance with the Regulatory Flexibility Act (''RFA''). The RFA directs agencies to publish in the **Federal Register**, a ''plan for the periodic review of the rules issued by the agency which have or will have a significant economic impact on a substantial number of small entities.'' 5 U.S.C. 610(c). The plan must ''provide for the review of all such agency rules existing on the effective date of [the RFA] within ten years'' of that date and for the review of such rules adopted after the RFA's effective date within 10 years of the publication of such rules. (The RFA took effect on January 1, 1981.)

The review is to ''determine whether such rules should be continued without change, or should be amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize any significant economic impact of the rules upon a substantial number of such small entities.'' The review must consider:

• The continued need for the rule;
• The nature of complaints or comments concerning the rule received from the public;
• The complexity of the rule;
• The extent to which the rule overlaps, duplicates or conflicts with other Federal rules, and, to the extent feasible, with state and local governmental rules; and
• The length of time since the rule has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the rule.

Furthermore, each year, an agency must publish in the **Federal Register** a list of the rules that have a significant economic impact on a substantial number of small entities. The list must include a brief description of each rule and the need for and legal basis of such rule, and public comment upon the rule must be invited.

We published both our plan for review under the RFA and the list of rules in the **Federal Register** on August 14, 1981 (46 FR 45621). The plan contemplated a two-part review process: (a) a review of CPSC regulations that were in existence on the effective date of the RFA (January 1, 1981), and (b) a second review process for regulations issued after January 1, 1981. The plan provided that the first part of the review process (for rules issued before January 1, 1981) would run from 1981 to 1987, and the second part of the process (for regulations issued after that date) would run from 1986 through 1991. In general, the plan stated that we would invite comments from all interested parties on our regulations, review the comments, and consider staff recommendations for appropriate administrative action for those regulations that have a significant economic impact on a substantial number of small entities. The plan further indicated that Commission action based on the recommendations would be consistent with the objectives of the statute(s) under which the regulations were issued.

The CPSC reviewed the rules it had issued before the RFA took effect in 1981 and found that none of them had a significant economic impact on a substantial number of small entities. After the RFA took effect, the CPSC reviewed the potential impact on small entities whenever it issued a proposed and final rule. Few of the CPSC's rules had a significant economic impact on a substantial number of small entities when they were issued. Therefore, few of CPSC's rules warrant section 610 reviews.

3. Retrospective Analysis of Existing Regulations Under Executive Orders 13563 and 13579

On January 18, 2011, President Barack Obama issued Executive Order (''E.O.'') 13563, ''Improving Regulation and Regulatory Review'' (76 FR 3821 (January 21, 2011)), which articulated certain principles of regulation and directed agencies to take certain actions to promote those principles, including a retrospective analysis of existing significant regulations. ''Agency,'' as defined in E.O 13563, does not include independent agencies.

On July 11, 2011, the President issued E.O. 13579, which applies to independent agencies such as the CPSC. Section 2 of E.O. 13579 states: ''To facilitate the periodic review of existing significant regulations, independent regulatory agencies should consider how best to promote retrospective analysis of rules.'' Further, E.O. 13579 directs that within 120 days, each independent regulatory agency should (consistent with law and reflecting the agency's resources and regulatory priorities and processes) develop and provide to the public a plan for periodic review of existing significant rules. The retrospective analysis is to identify significant rules that ''may be outmoded, ineffective, insufficient, or excessively burdensome.'' The agency is to ''modify, streamline, expand, or

repeal'' identified rules in accordance with what it learns through the review process.

Both Executive Orders call for review of ''significant regulations.'' Neither order defines that term. However, E.O. 13563 supplements E.O. 12866, ''Regulatory Planning and Review.'' Although E.O. 12866 does not define ''significant regulation,'' it does define ''significant regulatory action'' as, among other things, ''any regulatory action that is likely to result in a rule that may: 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.'' [1] 58 FR 51375, 51378 (October 4, 1993). The CPSC has issued few rules that would be considered ''significant'' under this criterion.

On July 22, 2011, OMB issued a memorandum providing guidance concerning E.O. 13579. This OMB memorandum states that the aim behind the retrospective review plans called for in E.O. 13579 is ''to create a defined method and schedule for identifying certain significant rules that are obsolete, unnecessary, redundant, unjustified, excessively burdensome, or counterproductive,'' but that ''such review should also consider strengthening, complementing, or modernizing rules where necessary or appropriate—including, if relevant, undertaking new rulemaking.'' The OMB memorandum identifies certain types of rules that would be good candidates for review, such as rules that ''new technologies or unanticipated circumstances have overtaken'' or that impose significant reporting or paperwork burdens.''

The OMB memorandum recognizes that each agency should set its own priorities for review in its plan, ''tailored to its specific mission, resources, organizational structure, and rulemaking history and volume.'' The memorandum notes some topics that all plans might address, including:

- Public participation: Solicit the public's views, preferably before the agency develops its plan;
- Prioritization: Specify factors that will be considered in choosing rules for review and include an initial list of candidate rules for review over the next two years;
- Analysis of costs and benefits and potential savings: Such analysis could be useful to identify rules where reforms could have the greatest potential for significant impact;
- Structure and staff: Responsibility for review should be vested with a high-level agency official and the plan should consider how to maintain sufficient independence from the offices that write and implement rules; and
- Coordination with other forms of review: Coordinate with other programs in place to review existing rules (e.g., review under the RFA).

B. Proceeding With Retrospective Review of Existing CPSC Rules

In accordance with E.O. 13579, the CPSC is proceeding with review of existing CPSC rules. Chairman Inez Tenenbaum directed agency staff to reinvigorate the CPSC's voluntary review process for existing rules. (See the Chairman's statement posted on the CPSC's Web site on July 11, 2011 (*http://www.cpsc.gov/pr/regreform07112011.html*).)

With this notice, we are seeking public comments and information to help us develop a plan for review of existing rules that will be appropriate to the agency, be consistent with (and not duplicate) previous and ongoing reviews, and fulfill the spirit of E.O. 13579. We intend for the CPSC's review to be broader than the reviews contemplated by the RFA and the Executive Orders because we are not limiting our evaluation to only regulations that have a significant economic impact on a substantial number of small entities, nor are we limiting it to significant regulations, as defined in E.O. 12866.

We invite comments on any aspects of the review discussed in this document and particularly concerning the following issues:

1. Selection of Rules for Review

a. Criteria

- What criteria should we use to select candidate rules for review?
- Should we use any of the criteria that were used to select rules for the 2004 pilot project for CPSC's Systematic Rule Review Program (these were: The rule has been in effect at least 10 years; at least one of the rules selected for review has multiple requirements; the rules address different hazard areas; and the rules were issued under different statutes)?
- How should we identify rules that may be obsolete, unnecessary, redundant, unjustified, excessively burdensome, or counterproductive? Are there specific rules that commenters can identify?
- How should we identify rules that may be in need of strengthening, complementing, modernizing, or, if relevant, undertaking new rulemaking?
- How should we identify rules that may have been overtaken by new technologies or unanticipated circumstances, or that impose significant reporting or paperwork burdens? Are there specific rules that commenters can identify?

b. Possible Exclusions

- Should the review exclude rules that were excluded under the CPSC's Systematic Rule Review Program (rules that are administrative or procedural; exemptions; labeling; test methods; or definitions)?
- Are there other categories of rules that should be excluded?

2. Process of Review

a. Timing

- How should we determine the number of rules to be reviewed, and possibly revised, each year and at what intervals?
- How should the number of rules reviewed, and possibly revised, each year be prioritized against other agency work?
- Should different rules be reviewed at different intervals? Please explain.
- Should the schedule for review be similar to that under section 610 of the RFA (*i.e.,* a rule should be reviewed after it has been in effect for 10 years?)

b. Public Participation

- How should we involve the public in the review?
- Should comments be requested for each rule reviewed?
- Should we hold public meetings concerning the selection of rules for review?
- Should there be public meetings related to each rule as it is reviewed?

c. Coordination

- How can we coordinate our review with reviews required by section 610 of the RFA and with reviews envisioned by E.O. 13579?
- How can we coordinate better with other agencies and with other jurisdictions (such as states, other countries, and international bodies) to harmonize regulatory requirements and eliminate redundant or inconsistent regulations?

[1] The additional criteria under E.O. 12866 that could make a regulatory action ''significant'' are: ''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 or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.'' 58 FR 51378. These are not likely to come into play in the CPSC's review of existing rules.

• How can we modify, streamline, or expand our regulatory review process?

d. Prioritization

• How should we prioritize rules that are to be reviewed (*e.g.,* chronologically; based on rules where the greatest impact could be made from potential changes; rules with potential to have greatest savings in costs or paperwork/reporting burdens; rules with most potential for changes to enhance safety)?

3. Substance of Review

• Should the review include any or all of the considerations in RFA reviews (i.e., continued need for the rule; nature of complaints or comments concerning the rule; complexity of the rule; extent of overlap or conflicts with other federal (and possibly state and local) rules; and length of time since the rule has been evaluated; or extent of change in technology, economic conditions, or other factors)?

• Should we conduct cost-benefit analyses with every rule we review or only for significant rules as anticipated by the Executive Orders? Please explain your reasoning. Do commenters have suggestions for how we might develop our analysis of costs and benefits for rules under consideration for retrospective review?

Dated: October 12, 2011.

Todd A. Stevenson,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2011–26820 Filed 10–18–11; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 316

[Docket No. FDA–2011–N–0583]

RIN 0910–AG72

Orphan Drug Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the 1992 Orphan Drug Regulations issued to implement the Orphan Drug Act. These amendments are intended to clarify regulatory provisions and make minor improvements to address issues that have arisen since those regulations were issued.

DATES: Submit either electronic or written comments on the proposed rule by January 17, 2012. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by November 18, 2011 (see the ''Paperwork Reduction Act of 1995'' section of this document).

ADDRESSES: You may submit comments, identified by Docket No. FDA–2011–N–0583 and/or RIN number 0910–AG72, by any of the following methods, except that comments on information collection issues under the Paperwork Reduction Act of 1995 must be submitted to the Office of Regulatory Affairs, Office of Management and Budget (OMB) (see the ''Paperwork Reduction Act of 1995'' section of this document).

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

• *Fax:* 301–827–6870.

• *Mail/Hand delivery/Courier (for paper, disk, or CD–ROM submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA–2011–N–0583 and Regulatory Information Number (RIN) 0910–AG72 for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Erica K. McNeilly, Office of Orphan Products Development, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5271, Silver Spring, MD 20993, 301–796–8660.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Background

Since the publication of the Orphan Drug Regulations in the **Federal Register** of December 29, 1992 (57 FR 62076), FDA has reviewed over 3,350 requests for orphan-drug designation of drugs for rare diseases and conditions. Based on these experiences, FDA believes it is useful to clarify certain regulatory language in the current orphan drug regulations and to propose areas of minor improvement. These amendments are intended to assist sponsors who are seeking and who have obtained orphan-drug designation of their drugs, as well as FDA in administering the orphan drug program. These amendments are consistent with the Orphan Drug Act (Pub. L. 97–414) and continue to provide incentives for the development of potentially promising orphan drugs that otherwise would not be developed for rare diseases and conditions.

The specific issues addressed in this proposal include: (1) Demonstration of an appropriate ''orphan subset'' of persons with a particular disease or condition that otherwise affects 200,000 or more persons in the United States, for the purpose of designating a drug for use in that subset; (2) eligibility for