80 Stat. 1304–05, 83 Stat. 187–89 (15 U.S.C. 1261, 1262); Pub. L. 107–319, 116 Stat. 2776.

2. Amend § 1512.2 by revising paragraphs (b) and (d) and adding paragraph (g) to read as follows:

§ 1512.2 Definitions.

* * * * *

(b) *Sidewalk bicycle* means a bicycle with a seat height of no more than 635 mm (25.0 in); the seat height is measured with the seat adjusted to its highest position. Recumbent bicycles are not included in this definition.

* * * * *

(d) *Track bicycle* means a bicycle designed and intended for sale as a competitive velodrome machine having single crank-to-wheel ratio, and no free-wheeling feature between the rear wheel and the crank.

* * * * *

(g) *Recumbent bicycle* means a bicycle in which the rider sits in a reclined position with the feet extended forward to the pedals.

3. Amend § 1512.4 by revising paragraphs (b) and (i) to read as follows:

§ 1512.4 Mechanical requirements.

* * * * *

(b) *Sharp edges.* There shall be no unfinished sheared metal edges or other sharp parts on assembled bicycles that are, or may be, exposed to hands or legs; sheared metal edges that are not rolled shall be finished so as to remove any feathering of edges, or any burrs or spurs caused during the shearing process.

* * * * *

(i) *Control cable ends.* Ends of all accessible control cables shall be provided with protective caps or otherwise treated to prevent unraveling. Protective caps shall be tested in accordance with the protective cap and end-mounted devices test, § 1512.18(c), and shall withstand a pull of 8.9 N (2.0 lbf).

* * * * *

4. Amend § 1512.6 by revising paragraphs (a) and (c) to read as follows:

§ 1512.6 Requirements for steering system.

(a) *Handlebar stem insertion mark.* Quill-type handlebar stems shall contain a permanent ring or mark which clearly indicates the minimum insertion depth of the handlebar stem into the fork assembly. The insertion mark shall not affect the structural integrity of the stem and shall not be less than 2½ times the stem diameter from the lowest point of the stem. The stem strength shall be maintained for at least a length of one shaft diameter below the mark.

* * * * *

(c) *Handlebar.* Handlebars shall allow comfortable and safe control of the bicycle. Handlebar ends shall be symmetrically located with respect to the longitudinal axis of the bicycle and no more than 406 mm (16 in) above the seat surface when the seat is in its lowest position and the handlebar ends are in their highest position. This requirement does not apply to recumbent bicycles.

* * * * *

5. Amend § 1512.12 by revising paragraph (b) to read as follows:

§ 1512.12 Requirements for wheel hubs.

* * * * *

(b) *Quick-release devices.* Lever-operated, quick-release devices shall be adjustable to allow setting the lever position for tightness. Quick-release levers shall be clearly visible to the rider and shall indicate whether the levers are in a locked or unlocked position. Quick-release clamp action shall emboss the frame or fork when locked, except on carbon fiber material.

* * * * *

6. Amend § 1512.15 by revising paragraphs (a) and (b) to read as follows:

§ 1512.15 Requirements for seat.

(a) *Seat limitations.* No part of the seat, seat supports, or accessories attached to the seat shall be more than 125 mm (5.0 in) above the top of the seat surface at the point where the seat surface is intersected by the seat post axis. This requirement does not apply to recumbent bicycles.

(b) *Seat post.* The seat post shall contain a permanent mark or ring that clearly indicates the minimum insertion depth (maximum seat-height adjustment); the mark shall not affect the structural integrity of the seat post. This mark shall be located no less than two seat-post diameters from the lowest point on the post shaft, and the post strength shall be maintained for at least a length of one shaft diameter below the mark. This requirement does not apply to bicycles with integrated seat masts.

* * * * *

7. Amend § 1512.18 by revising paragraphs (k)(1)(i) and (n)(2)(vii) as follows:

§ 1512.18 Tests and test procedures.

* * * * *

(k) * * *

(1) * * *

(i) *Procedure.* With the fork stem supported in a 76 mm (3.0 in) vee block and secured by the method illustrated in figure 1 of this part 1512, a load shall be applied at the axle attachment in a direction perpendicular to the centerline of the stem and against the direction of the rake. Load and deflection readings shall be recorded and plotted at the point of loading.

* * * * *

(n) * * *

(2) * * *

(vii) A recommended coordinate system for definition of color is the "Internationale de l'Eclairage (CIE 1931)" system. In the coordinate system and when illuminated by the source defined in table 4 of this part 1512, a reflector will be considered to be red if its color falls within the region bounded by the red spectrum locus and the lines $y = 0.980 - x$ and $y = 0.335$; a reflector will be considered to be amber if its color falls within the region bounded by the yellow spectrum locus and the lines $y = 0.382$, $y = 0.790 - 0.667x$, and $y = x - 0.120$.

* * * * *

Dated: October 26, 2010.

Todd A. Stevenson,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2010–27503 Filed 10–29–10; 8:45 am]

BILLING CODE 6355–01–P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1632

[CPSC Docket No. CPSC–2010–0105]

Standard for the Flammability of Mattresses and Mattress Pads

AGENCY: Consumer Product Safety Commission.

ACTION: Proposed rule.

SUMMARY: The Consumer Product Safety Commission ("CPSC" or "Commission") is proposing to amend its standard for the flammability of mattresses and mattress pads. The ignition source cigarette specified in the standard for use in the mattress standard's performance tests is no longer being produced. The Commission is proposing to amend the mattress standard to require a standard reference material cigarette, which was developed by the National Institute of Standards and Technology, as the ignition source for testing to the mattress standard.

DATES: Comments on the proposal should be submitted no later than January 18, 2011.

ADDRESSES: You may submit comments, identified by Docket No. CPSC–2010–0105, 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.

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

FOR FURTHER INFORMATION CONTACT: Patricia K. Adair, Directorate for Engineering Sciences, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814–4408; telephone (301) 504–7536; *padair@cpsc.gov.*

SUPPLEMENTARY INFORMATION:

A. Background

1. The Current Standard and the Need for Amendment

The Standard for the Flammability of Mattresses and Mattress Pads ("the Standard"), 16 CFR part 1632, was initially issued by the U.S. Department of Commerce in 1972 under the authority of the Flammable Fabrics Act ("FFA"), 15 U.S.C. 1191 *et seq.* When the Consumer Product Safety Act ("CPSA") created the Consumer Product Safety Commission, it transferred to the Commission the authority to issue flammability standards under the FFA.

The Standard sets forth a test to determine the ignition resistance of a mattress or mattress pad when exposed to a lighted cigarette. Lighted cigarettes are placed at specified locations on the surface of a mattress (or mattress pad). The Standard establishes pass/fail criteria for the tests. The Standard currently specifies the ignition source for these tests by its physical properties. These properties were originally selected to represent an unfiltered Pall Mall cigarette, which was identified as the most severe smoldering ignition source.

In January 2008, CPSC staff learned that the R.J. Reynolds Tobacco Company planned to stop producing unfiltered Pall Mall cigarettes (although it would continue to make a reduced ignition propensity or "RIP" version). The CPSC staff, mattress manufacturers, and testing organizations were concerned about testing to the Standard if the specified ignition source cigarettes were unavailable. Under an Interagency Agreement ("IAG") with the CPSC, the National Institute of Standards and Technology ("NIST") developed a standard reference material ("SRM") cigarette that could be used as the ignition source in the Standard.

2. Incident Data

Recent fire loss estimates for mattresses and bedding indicate that smoking material ignitions of mattresses or bedding lead to a large number of fire deaths and injuries. The most recently available estimates are from 2005 through 2007. For that time period, there was an estimated annual average of 2,100 fires in which smoking materials ignited mattresses or bedding. These led to an estimated annual average of 150 deaths, 350 injuries, and $57 million in property loss.

B. Statutory Provisions

The FFA sets forth the process by which the Commission can issue or amend a flammability standard. In accordance with those provisions, the Commission is proposing to amend the Standard to specify the SRM cigarette developed by NIST as the ignition source to be used for testing under the Standard. As required by the FFA, the proposed rule contains the text of the amendment, alternatives that the Commission has considered, and a preliminary regulatory analysis. 15 U.S.C. 1193(i). Before issuing a final rule, the Commission must prepare a final regulatory analysis and make certain findings concerning any relevant voluntary standard, the relationship of costs and benefits of the rule, and the burden imposed by the regulation. *Id.* 1193(j). In addition, the Commission must find that the standard: (1) Is needed to adequately protect the public against the risk of the occurrence of fire leading to death, injury, or significant property damage; (2) is reasonable, technologically practicable, and appropriate; (3) is limited to fabrics, related materials, or products which present unreasonable risks; and (4) is stated in objective terms. *Id.* 1193(b).

The Commission also must provide an opportunity for interested persons to make an oral presentation concerning the rulemaking before the Commission may issue a final rule. *Id.* 1193(d). The Commission requests that anyone who would like to make an oral presentation concerning this rulemaking please contact the Commission's Office of the Secretary (*see* the **ADDRESSES** section of this notice) within 45 days of publication of this notice. If the Commission receives requests to make oral comments, a date will be set for a public meeting for that purpose, and notice of the meeting will be provided in the **Federal Register.**

C. Description of the Proposed Amendment

1. NIST's Research

Currently, the Standard requires that the ignition source for testing mattresses "shall be cigarettes without filter tips made from natural tobacco, 85 ± 2 mm long with a tobacco packing density of 0.270 ± 0.02 g/cm^3 and a total weight of 1.1 ± 0.1 g." 16 CFR 1632.4(a)(2). This specification was intended to describe a conventional unfiltered Pall Mall cigarette that was available when the Standard was developed. This specification was chosen in order to replicate the most severe smoldering ignition source for testing mattresses and mattress pads.

When the CPSC learned in January 2008 that R.J. Reynolds would be stopping production of the unfiltered Pall Mall cigarettes, the CPSC sought to find an alternate ignition source that would have the same burning characteristics as the ignition source specified in the Standard so that mattresses could be tested in accordance with the Standard and so that the safety level of the Standard would not be changed. In August 2008, the CPSC entered into an IAG with NIST to develop a new cigarette ignition source SRM that would have the ignition strength of the test cigarette required in the Standard.

There are no cigarette ignition test data to characterize the ignition propensity of cigarettes from 1972, when the Standard was promulgated. In the absence of such data, NIST sought to identify the highest ignition strength cigarette, consistent with the intent of the original Standard. NIST evaluated Pall Mall cigarettes of different vintages (1992 through 2008) to determine the ignition strengths of the cigarettes that had been used to test soft furnishings,

such as mattresses. Although SRM cigarettes are now becoming available, sufficient quantities of previous (1992 through 2003) cigarettes no longer exist to perform any comparative studies of ignition propensity. The NIST research strongly indicated, however, that the SRM is equivalent in ignition strength to the previous highest known strength unfiltered Pall Mall cigarette. After developing a standard procedure for determining the ignition strength of cigarettes and assessing different vintage cigarettes, NIST recommended to CPSC staff that the new SRM cigarette meet the following specification:

- Nominal length: 83 mm ± 2 mm
- Tobacco packing density: 0.270 g/cm3 ± 0.020g/cm3
- Mass: 1.1 g ± 0.1 g
- Ignition Strength: 70 Percent Full Length Burn (PFLB) to 95 PFLB using ASTM E 2187, as modified in Section 4.2 of NIST Technical Note 1627
- Non "Fire Safe Cigarette" (FSC)

The first three descriptors restate the physical requirements listed in the Standard for the ignition source. The recommended ignition strength range reflects the three oldest vintages of the Pall Mall cigarette tested by NIST and represents a worst-case ignition source.

In June 2009, NIST provided CPSC staff with a report on its research, "*NIST Technical Note 1627: Modification of ASTM E 2187 for Measuring the Ignition Propensity of Conventional Cigarettes*" (Ref. 1). The CPSC used NIST's research described in this report as the basis to establish specific parameters for a new ignition source specified in the Standard. Therefore, the proposed rule would amend 16 CFR 1632.4(a)(2) to specify the use of an SRM cigarette, developed in 2010 based on NIST's research. The new SRM cigarette would be designated SRM 1196, and the proposed amendment also would state that SRM 1196 is available for purchase from the National Institute of Standards and Technology, 100 Bureau Drive, Gaithersburg, MD, 20899

2. Issues Raised by Comments on NIST's Report

The Commission posted *NIST Technical Note 1627* on its Web site in July 2009. The Commission received three comments, all from industry trade associations. The principal issues raised by the comments that are relevant to this rulemaking and the Commission's responses are discussed below.

Comment: Some comments stated that the cigarette specified in the Standard does not reflect real-world conditions and argued that the CPSC should not try to replicate it in establishing a new ignition source.

Response: The intent of the Standard was not to represent the typical cigarette of that time, but to specify a cigarette with the highest potential to ignite soft furnishings in order to provide a high level of safety. The Commission intends to specify an ignition source that is close to the original specification, to maintain the level of safety established by the Standard.

Comment: Some comments noted that many States are requiring RIP cigarettes, and, because these will be widely in use, the ignition source in the Standard should be a RIP cigarette.

Response: The CPSC has no data indicating a correlation between the use of RIP cigarettes and reduction in fire losses where soft furnishings, such as mattresses, are the first item to ignite. The National Fire Protection Association's ("NFPA's") model State legislation calls for testing RIP cigarettes in accordance with ASTM standard E 2187–04, "*Standard Test Method for Measuring the Ignition Strength of Cigarettes*." This model legislation requires that no more than 25 percent of cigarettes tested in a trial test burn their full length. This means that even with full compliance, some RIP cigarettes may be expected to burn like non-RIP cigarettes. Moreover, only 8 of the 50 States that have enacted (or soon will enact) legislation mandating RIP cigarettes require auditing to confirm compliance with ASTM E 2187–04. Thus, the extent of fire safety gains due to RIP cigarettes is uncertain. Under these circumstances, specifying a RIP cigarette as the ignition source in the Standard could reduce the level of fire safety provided by the Standard.

Comment: One comment expressed concern about the cost of SRM cigarettes for small manufacturers, such as upholstery fabric manufacturers.

Response: As discussed in greater detail in the preliminary regulatory analysis summarized in section D of this preamble, the Commission does not anticipate that the cost of SRM cigarettes will add significantly to testing costs for mattresses. The CPSC estimates that using SRM cigarettes at up to $245 per carton would increase total annual testing costs for mattresses by about $70,000 or approximately 10 percent. The CPSC notes that, for mattresses, individual ticking fabrics generally are not tested; instead, testing of the assembled mattress is usually performed by a third party laboratory. Also, existing qualified designs and constructions of mattresses would not have to be retested.

As for the impact on upholstered furniture fabric makers, the cost of SRM cigarettes would be one aspect of testing costs that the Commission would consider in evaluating the costs and benefits of an upholstered furniture flammability standard in the context of that rulemaking. (In the **Federal Register** of March 4, 2008, the Commission published a proposed rule that would establish flammability standards for residential upholstered furniture under the FFA (73 FR 11702), and CPSC staff is in the process of testing and evaluation to support a possible final upholstered furniture flammability rule.)

Comment: One comment stated that a surrogate equivalent to the discontinued non-RIP cigarette is needed quickly, given that those materials are no longer being produced. The commenter opined that to specify a nonequivalent SRM as NIST recommends would require the CPSC to conduct a lengthy rulemaking procedure to amend 16 CFR part 1632.

Response: The new SRM cigarette is designed to be equivalent to the original test cigarette. In its report, NIST recommended a replacement cigarette that is as close as possible to the original test cigarette specified in the Standard. The purpose of developing the SRM cigarette is to enhance repeatability of test results without changing the level of fire safety provided by the Standard.

D. Preliminary Regulatory Analysis

Section 4(i) of the FFA requires that the Commission prepare a preliminary regulatory analysis when it proposes to issue or amend a flammability standard under the FFA and that the analysis be published with the proposed rule. 15 U.S.C. 1193(i). The following discussion extracted from the staff's memorandum entitled "Preliminary Regulatory Analysis: Smoldering Ignition Source Proposed Technical Amendment to the Flammability Standard for Mattresses and Mattress Pads (16 CFR Part 1632)" (Ref. 2) addresses this requirement.

1. Market/Industry Information

Domestic manufacturers of mattresses and related sleep products (for example, mattress pads, box springs, innerspring cushions, and air-flotation sleep systems) are classified under the 2002 North American Industry Classification System (NAICS) in sector code 337910, Mattress Manufacturing. This group includes firms classified under the 1997 Standard Industry Classification (SIC) category 2515. Available U.S. Economic Census data show an estimated total value of shipments for this category of about $5 billion in recent years. Domestic employment is estimated at about 20,000 workers. Industry estimates indicate that the number of mattresses (including unconventional

items such as futons, crib and juvenile mattresses, and sleep sofa inserts) shipped in the United States residential market is roughly 25 million units annually. About 5 to 10 percent of this total is comprised of imported products, including some imports marketed by the domestic manufacturers. The proportion of imports for mattress pads is higher.

An estimated 150 to 200 domestic firms produce new mattresses or mattress pads in manufacturing facilities in the United States. An unknown but potentially similar number of firms in the United States sell renovated mattresses, which may account for 2.5 to 5 million units, or between 10 and 20 percent of mattresses sold. Thus, there may be as many as approximately 400 manufacturing firms subject to 16 CFR part 1632. These firms comprise more than 600 production establishments. Larger manufacturers may offer dozens of models (not counting different size designations, *e.g.,* twin, full, queen, king) at any given time; new models may be introduced once or twice per year. Many smaller firms market only a few models and make few, if any, construction changes in a year.

2. The Mattress Standard

The mattress standard at 16 CFR part 1632 requires premarket, full-scale prototype testing for each new mattress design. Prototype testing also must be performed for each change in materials of an existing design that may affect cigarette ignition resistance. Under the Standard, a minimum of 18 cigarettes (*i.e.,* about one pack) are consumed per mattress surface. Under the CPSC's 2006 interim enforcement policy, two mattress surfaces must be tested (the Standard specifies that six surfaces must be tested; however, current reported practice is to test two surfaces). For two-sided, traditional mattresses, one mattress is consumed per prototype. With the market trend in recent years toward single-sided mattresses (*i.e.,* those designed not to be flipped), it is much more common that two mattresses are consumed per prototype. In either case, at least 36 cigarettes (*i.e.,* about two packs) are consumed per prototype.

No post-prototype, periodic testing is required under 16 CFR part 1632. However, the Standard allows the use of "subordinate" prototypes (*i.e.,* a mattress that differs from the prototype in certain acceptable ways and therefore does not need to be tested) based on a confirmatory test of a complying model, such that multiple producers can market that same complying product in different production facilities or under different brand names. This practice is common in the industry among licensees, and especially among smaller firms that manufacture models based on qualified prototypes developed and tested for certification of compliance with both 16 CFR part 1633 and part 1632 by larger firms or "prototype developers." Further, 16 CFR part 1632 allows substitutions of cover or "ticking" materials, based on a set of small scale classification tests in lieu of new prototypes for each ticking. In this test, 9 to 18 cigarettes (approximately one half to one full pack) are consumed. Equivalency of performance for a majority of new mattress models is demonstrated using this optional ticking substitution test.

Some manufacturers perform tests pursuant to 16 CFR part 1632 in their production facilities. Most, however, use third party testing laboratories since the advent of 16 CFR part 1633 in 2006.

3. Potential Benefits and Costs

The SRM cigarette described in the proposal would have approximately the same ignition strength characteristics as originally intended by the Standard. The use of SRM cigarettes would not alter the stringency of the flammability performance tests in the Standard, so the proposal would not amend the test method itself.

i. Potential Benefits

Because the proposed amendment is "safety-neutral," mattresses that passed or failed under the existing Standard would be expected to generate similar results when the NIST-developed SRM is used. The level of protection provided by the Standard would neither increase nor decrease as a result. Thus, there would be no impact on the level or value of fire safety benefits derived from the 16 CFR part 1632 Standard.

There would, however, be potential benefits associated with the proposed amendment that are not readily quantifiable. Currently, manufacturers and testing laboratories do not have access to continued supplies of test cigarettes other than RIP Pall Mall cigarettes. Existing inventories of conventional Pall Mall cigarettes have been depleted or exhausted. Many industry representatives have requested guidance on the issue of which cigarette to use in testing.

Even if continuing supplies of conventional test cigarettes were available, the variability in cigarette performance described in the NIST research may lead to an unacceptably low level of test outcome reproducibility. This is causing uncertainty among testing firms and manufacturers and importers certifying compliance with the Standard; these firms have expressed concern that tests conducted by the CPSC and by industry may not be comparable. This inconsistency could lead to unnecessary additional testing. The proposed amendment specifying an SRM cigarette would reduce inconsistency and uncertainty for industry, testing laboratories, and the CPSC.

ii. Potential Costs

Currently, manufacturers incur testing costs related to 16 CFR part 1632 whenever new mattress models are introduced that either: (1) Are of new construction, or (2) have new tickings that may influence cigarette ignition resistance. Larger manufacturers may introduce 20 or more new constructions or ticking substitutions each year. Smaller producers and renovators probably introduce fewer items or rely on prototype developers for multiple models. Assuming that qualified prototypes are developed for all new constructions and ticking substitutions to demonstrate compliance, a range of estimates for annual prototypes and ticking substitutions can be used to project potential costs associated with the proposed amendment to incorporate SRM cigarettes into the Standard.

Pre-Amendment Testing Costs. For most mattress models that require some kind of testing, the testing cost per model to manufacturers is comprised chiefly of: (1) The resource costs of producing the mattresses used for destructive testing, including shipping to a test laboratory; and (2) the laboratory's fee for the testing service, which includes photographic and other records prepared by the test laboratory as well as the cigarettes consumed in testing.

The cost of mattresses consumed in prototype testing may amount to approximately $400 for a typical two-mattress test series (although the range can go much higher, to more than $1,000 per mattress for low-volume, specialty items). Prototype test charges reported by third party testing laboratories can vary widely, especially by location. For example, charges for tests performed in China tend to be significantly lower than charges for tests performed in the United States. Overall, these charges, which include the cost of the test cigarettes, may average about $250 per prototype (labor and material costs for manufacturers to perform their own tests may be similar). Thus, the current average total cost per mattress prototype may be roughly $400 + $250 = $650. A ticking substitution test is simpler and much less expensive, requiring only small samples of ticking

material, a reusable small-scale test apparatus, and a smaller number of cigarettes; the average total cost may be around $50.

Testing costs incurred for prototypes and ticking substitutions can be allocated over a production run of mattresses. The cost per unit may vary with production volume, the mix of tests performed, and other factors. The examples below incorporate assumptions based on discussions with industry representatives. These examples illustrate some possible baseline cost differences for larger versus smaller firms:

Typical example for a medium-to-large producer:

- 20 new models: 5 new constructions + 15 new tickings
- 5 prototype tests @ $650 each = $3,250
- 15 ticking substitution classification tests @ $50 each = $750
- Total base year cost = $3,250 + $750 = $4,000
- Baseline testing cost for production run of 50,000 units = $0.08 per unit

Typical example for a smaller producer:

- 5 new models: 2 new constructions + 3 new tickings
- 2 prototype tests @ $650 each = $1,300
- 3 ticking substitution classification tests @ $50 each = $150
- Total base year cost = $1,300 + $150 = $1,450
- Baseline testing cost for production run of 5,000 units = $0.29 per unit

These examples reflect the likely average annual testing costs to industry, assuming reasonably full compliance with 16 CFR part 1632. Thus, approximate baseline testing costs for the largest 50 mattress manufacturers would be about $50 \times \$4,000 = \$200,000$ annually; testing costs for the remaining 350 firms would be about $350 \times \$1,450 = \$507,500$. Thus, total estimated baseline testing costs may be about $200,000 + $507,500 = $707,500 per year.

Costs per Firm Associated With the Proposed Amendment. The only cost increase associated with the proposed amendment is related to the SRM cigarettes. The anticipated price of SRM cigarettes from NIST is about $245 per carton, including estimated typical shipping (a carton contains 200 cigarettes, *i.e.,* 10 packs of 20). Testing laboratories and others can obtain (RIP) Pall Mall cigarettes currently on the market for prices ranging from $60 to $100 per carton, depending on the geographic region. Thus, the cost of cigarettes for parties performing tests may increase from as little as approximately $6 to $10 per pack, to as much as approximately $25 per pack, representing an increase of $15 to $19 per pack.

Under the protocol in 16 CFR part 1632, new packs of cigarettes are opened for each test sequence. A new prototype or confirmatory test consumes about two packs, and a ticking substitution test consumes about one pack. Assuming an increase in price per pack of $19, the average cost of performing the tests could increase by $2 \times 19 = \$38$ per prototype and $19 per ticking substitution. This represents a 6 percent increase ($38/$650) in average total resource costs per prototype, and a 38 percent increase ($19/$50) in average resource costs per ticking substitution.

In the above "typical producer" examples, the larger firm with 20 new models would incur increased prototype costs of $5 \times \$38 = \$190$ plus increased ticking substitution costs of $15 \times \$19 = \$285$, for a total annual increase of $190 + $285 = $475 (about 12 percent of the firm's overall $4,000 annual testing cost). Over a 50,000 unit production run, the cost would be $0.0095 (*i.e.,* less than one cent) per unit. The smaller firm with five new models would incur increased prototype costs of $2 \times \$38 = \$76$ and increased ticking substitution costs of $3 \times 19 = \$57$, for a total annual increase of $76 + $57 = $133 (*i.e.,* about 9 percent of the firm's overall $1,450 annual testing cost). Over a 5,000 unit production run, the increased testing cost would be $0.027 (*i.e.,* less than three cents) per mattress.

In summary, the expected additional cost of testing related to the proposal may range from about $133 to $475 per firm, or about one to three cents per mattress produced. The distribution of this projected cost among manufacturers and testing laboratories is uncertain because some test laboratories may choose to pass their increased costs—in the form of higher test fees—on to manufacturers, while others may not. Even if all such costs were passed on to manufacturers, it is unlikely that there would be a noticeable effect on wholesale or retail mattress prices.

Aggregate Costs Associated With the Proposed Amendment. There may be as many as 200 new product manufacturers and 200 renovators, for a total of about 400 firms. The largest 50 firms are assumed to have 20 new models ($50 \times 20 = 1,000$ models to be tested), and the remaining 350 firms to have five new models ($350 \times 5 = 1,750$ models to be tested), for a total of 1,000 + 1,750 = 2,750 models to be tested. The aggregate annual cost of the proposed amendment will vary with the number of new prototypes and ticking substitutions. A point estimate can be developed using the pre amendment baseline examples above and the best available information on these variables.

Using the baseline assumptions for new prototypes versus ticking substitutions, the 50 largest firms would have an average of five prototypes each (for a total of $5 \times 50 = 250$) and the remaining 350 smaller firms would have two prototypes each (for a total of $2 \times 350 = 700$); thus, the overall number of prototypes to be performed would be 250 + 700 = 950. The number of ticking substitutions would be 15 each for the larger firms (for a total of $15 \times 50 = 750$) and three each for the smaller firms (for a total of $3 \times 350 = 1,050$); the overall number of ticking substitutions would be 750 + 1,050 = 1,800.

At two packs of cigarettes per prototype and one pack per ticking substitution, the estimated quantity consumed in testing would be $2 \times 950 = 1,900$ for prototypes and 1,800 for ticking substitutions, for a total of 1,900 + 1,800 = 3,700 packs. At an increase of $19 per pack, the estimated total resource cost would be $3,700 \times 19 = \$70,300$. This point estimate represents an unweighted average increase of about 10 percent of the estimated $707,500 aggregate annual industry testing costs related to 16 CFR part 1632.

In addition to the projected costs to industry, the CPSC and other government agencies (for example, the California Bureau of Home Furnishings & Thermal Insulation and the Canadian Ministry of Health) would likely purchase small quantities of SRM cigarettes from NIST for compliance testing and related research. Thus, the proposal also would have minor costs to Federal and other government agencies, depending on the numbers of tests these organizations may perform in any given year.

The proposed effective date of the amendment is one year from the date of publication of a final rule in the **Federal Register**. New mattress models are typically introduced once or twice per year. The proposed effective date would allow this product cycle to proceed without potential disruption or additional testing costs. It would also help ensure continuing availability of an adequate supply of SRM cigarettes to testing laboratories and manufacturers from NIST.

In summary, the proposed amendment to specify the SRM cigarette is not expected to have a significant impact on expected benefits or costs of the Standard in 16 CFR part 1632. Resource costs may amount to roughly $70,000 per year. The amendment would, however, reduce test variability

and uncertainty among manufacturers subject to the Standard and among testing organizations. Both the expected benefits and likely economic costs of the amendment are small, and the likely effect on testing costs per new prototype mattress or ticking substitution would be minor, especially when the projected cost is allocated over a production run of complying mattresses.

4. Regulatory Alternatives

The Commission could consider two basic alternatives to the proposed amendment: (1) Base the standard test cigarette on a different SRM, with the approximate lower ignition strength of an RIP cigarette; or (2) take no action on the smoldering ignition source issue.

Neither the proposed amendment nor either of these two alternatives would likely have a substantial economic impact. There would, however, be some relative differences in terms of resource costs and potential effects on the level of benefits the Standard affords. The advantages and disadvantages of these two basic alternatives are discussed immediately below.

a. Alternate SRM

Under this first alternative, the Commission could amend the Standard to specify a different, lower ignition propensity SRM cigarette. Such an SRM would presumably be closer in ignition strength to the "worst-case" RIP cigarettes currently on the market.

There are three possible advantages to specifying an alternative SRM: (1) The problem of test repeatability and reproducibility would be addressed, as it is under the proposed amendment; (2) an alternative SRM would, in theory, better approximate the fire risk associated with cigarettes currently available to consumers in the United States; and (3) currently, there is a low ignition propensity SRM (SRM 1082) developed by NIST for use by state regulators in assessing the compliance of RIP cigarettes. These SRM cigarettes are currently available at a price, including estimated typical shipping, of $195 per carton (compared to the projected price for the proposed SRM 1196 cigarette of $245 per carton). Thus, resource costs to manufacturers and testing laboratories (including the CPSC) to adopt a readily-available alternative SRM could be somewhat lower than under the proposed amendment; although it is likely that any new alternate SRM would be priced at least comparably to the proposed SRM 1196.

There are three possible disadvantages to specifying an alternative SRM. First, in comparison to the proposed SRM, a low ignition propensity SRM would not be considered equivalent or "safety neutral," under the presumption that the use of such cigarettes would result in a less stringent flammability test. While no data are available to describe the extent of this potential difference, it is quite possible that more mattress construction prototypes would pass a test using a lower ignition propensity SRM than do currently with commercially available cigarettes. This may result in an unknown, but potentially adverse, impact on the level of safety benefits provided by the Standard.

The second disadvantage is that the two known technical approaches to developing a lower ignition propensity SRM appear to be incompatible with the test in 16 CFR part 1632. First, under existing state regulations, all known commercial RIP cigarettes incorporate banded paper designed to impede full length burns. The current test measures mattress ignitions resulting from full length cigarette burns and allows up to three relights per cigarette to achieve a full length burn. It is likely that either: (1) Many low ignition propensity cigarettes would be wasted in completing the test; or (2) the test could not be reliably completed using banded-paper, self-extinguishing cigarettes. Second, while the existing SRM 1082 does not use banded-paper technology, it would have the same impracticalities as the banded-paper cigarette under the current Standard. The low ignition propensity design of the existing SRM 1082 is intended to yield a 12 to 15 percent full length burn rate (*i.e.,* the cigarettes are made to self-extinguish 85 to 88 percent of the time). Because this SRM is intended to be used as a calibration tool for cigarette manufacturers subject to state regulations, it is purposely designed to represent a minimal ignition propensity target, rather than a typical or representative RIP ignition propensity. It would clearly not represent a "worst-case" RIP cigarette. Further, SRM 1082 does not meet the specified physical criteria for cigarette length and density; so these cigarettes are physically unlike the current test cigarette or current RIP cigarettes.

The third disadvantage is that the properties of a new SRM that would mimic the ignition behavior of "worst case" RIP cigarettes have not been characterized. The "worst case" RIP cigarette would be one that burns its full length and may, therefore, be similar to its non-RIP counterpart. Insufficient research exists to support a new and different, low ignition propensity SRM; and a variety of as-yet-unknown modifications to the test method in 16 CFR part 1632 would likely be needed to incorporate such an SRM. The time and cost to develop a new SRM is undetermined, but the existing concern about the short-term availability of a consistent ignition source would not be resolved.

Thus, while a lower ignition strength SRM cigarette may be technically feasible, there is no readily available SRM alternative that would address the need for a consistent, "safety-neutral" ignition source.

b. No Action

Under the second alternative, the test cigarette specifications in the Standard would remain unchanged. Manufacturers and testers would remain free to conduct tests with any available cigarettes, including RIP Pall Malls, which meet the existing physical parameters.

The possible advantage of the Commission taking no action is that the projected minor increase in resource costs of testing would not be incurred.

The possible disadvantage of the Commission taking no action would be that the basic issue of test result variability due to differences in cigarettes would not be addressed, and the uncertainty and confusion surrounding the reliability of tests for compliance with 16 CFR part 1632 would not be reduced. Manufacturers and testing firms may continue to conduct tests that are either wasteful (in terms of extra RIP cigarettes required to complete a test) or have irreproducible results.

In summary, there are no readily available and/or, technically feasible alternatives to the proposed amendment that would have lower estimated costs and still address the need for a consistent ignition source that retains the "safety-neutral" approach of the proposed amendment.

E. Regulatory Flexibility Act Certification

Under the Regulatory Flexibility Act ("RFA"), 5 U.S.C. 601 *et seq.,* an agency that engages in rulemaking generally must prepare initial and final regulatory flexibility analyses describing the impact of the rule on small businesses and other small entities. Section 605 of the RFA provides that an agency is not required to prepare a regulatory flexibility analysis if the head of an agency certifies that the rule will not have a significant economic impact on a substantial number of small entities.

The proposed rule would retain the current mattress test procedure, but require that entities performing cigarette

ignition tests (including the CPSC, other state agencies, and industry testing organizations) purchase and use SRM cigarettes at a higher cost than commercial, non-SRM cigarettes. No additional actions would be required of small entities. The costs associated with the proposed rule would essentially be borne by mattress manufacturers and importers that perform (or pay fees for) compliance testing.

The latest available (2002) U.S. Census Bureau Statistics of U.S. Businesses and (2003) Economic Census data on this industry sector reported over 500 firms and more than 600 manufacturing establishments in NAICS sector code 337910, Mattress Manufacturing. More recent industry estimates suggest that the number of firms, including renovators, is closer to 400. The few industry-leading manufacturers are large firms with annual gross revenues of more than $1 billion and 3,000–5,000 employees each. However, the vast majority of producers—including all renovators—are much smaller, with annual gross revenues of under $20 million and fewer than 100 employees each. Many manufacturers serve regional markets and do not have nationwide distribution. The Economic Census reported that all but the largest 12 mattress producing firms—more than 95 percent—had fewer than 500 employees. These would be considered small businesses under the definition used by the Small Business Administration for this industry.

The larger firms are often comprised of multiple small manufacturing establishments. The average gross revenue of the 585 small manufacturing establishments identified in 2002 was about $8.1 million. Excluding small establishments with more than 100 employees from this average provides a reasonable approximation of small firms that are independent of the major producers. This approach reduces the average gross revenue to about $4 million. This $4 million average can be used to illustrate the potential effect of the proposed rule on small firms.

As discussed in the cost analysis section above, added testing and certification costs related to the proposed rule may average about $133 per small firm, or less than three cents per unit. This represents about $133/$4 million = .0033 percent (*i.e.,* less than one percent) of small firms' average gross revenues. Even using the $475 increased cost estimate presented in the analysis for larger firms, the impact on small firms' average gross revenue would be only $475/$4 million = .012 percent.

Based on this information, the proposal would have little or no effect on small producers because the design and construction of existing, compliant mattress products would remain unchanged and because the resource cost increase of using SRM cigarettes would represent a minimal increase in total testing costs. Thus, the Commission preliminarily concludes that the proposed rule would not have a significant impact on a substantial number of small businesses or other small entities.

F. Environmental Considerations

Pursuant to the National Environmental Policy Act, and in accordance with the Council on Environmental Quality regulations and CPSC procedures for environmental review, the Commission has assessed the possible environmental effects associated with the proposed rule.

The Commission's regulations state that amendments to rules providing performance requirements for consumer products normally have little or no potential for affecting the human environment. 16 CFR 1021.5(c)(1). Nothing in this proposed rule alters that expectation. Therefore, because the proposed amendment would have no adverse effect on the environment, neither an environmental assessment nor an environmental impact statement is required.

G. Executive Orders

According to Executive Order 12988 (February 5, 1996), agencies must state in clear language the preemptive effect, if any, of new regulations. The proposed rule, if finalized, would modify a flammability standard issued under the FFA. With certain exceptions that are not applicable in this instance, no state or political subdivision of a state may enact or continue in effect "a flammability standard or other regulation" applicable to the same fabric or product covered by an FFA standard if the state or local flammability standard or other regulations is "designed to protect against the same risk of the occurrence fire" unless the state or local flammability standard or regulation "is identical" to the FFA standard. *See* 15 U.S.C. 1476(a). The proposed rule would not alter the preemptive effect of the existing mattress standard.

Thus, the proposed rule would preempt nonidentical state or local flammability standards for mattresses or mattress pads designed to protect against the same risk of the occurrence of fire.

H. Effective Date

Section 4(b) of the FFA (15 U.S.C. 1193(b)) provides that an amendment of a flammability standard shall become effective one year from the date it is promulgated, unless the Commission finds for good cause than an earlier or later effective date is in the public interest, and the Commission publishes the reason for that finding. Section 4(b) of the FFA also requires that an amendment of a flammability standard shall exempt products "in inventory or with the trade" on the date the amendment becomes effective, unless the Commission limits or withdraws that exemption because those products are so highly flammable that they are dangerous when used by consumers for the purpose for which they are intended. The Commission concludes that a one-year effective date is appropriate to ensure ample time for the product cycle and continuing availability of SRM cigarettes from NIST. Therefore, the Commission proposes that the amendment to the ignition source provision of the standard would become effective one year after publication of a final amendment in the **Federal Register.**

I. Proposed Findings

Section 4(a) and (j)(2) of the FFA require the Commission to make certain findings when it issues or amends a flammability standard. The Commission must find that the standard or amendment: (1) Is needed to adequately protect the public against the risk of the occurrence of fire leading to death, injury, or significant property damage; (2) is reasonable, technologically practicable, and appropriate; (3) is limited to fabrics, related materials, or products which present unreasonable risks; and (4) is stated in objective terms. 15 U.S.C. 1193(b). In addition, the Commission must find that: (1) If an applicable voluntary standard has been adopted and implemented, that compliance with the voluntary standard is not likely to adequately reduce the risk of injury, or compliance with the voluntary standard is not likely to be substantial; (2) that benefits expected from the regulation bear a reasonable relationship to its costs; and (3) that the regulation imposes the least burdensome alternative that would adequately reduce the risk of injury. Because section 4(a) of the FFA refers to proceedings for the determination of an appropriate flammability standard "or other regulation or amendment," and because this proposed rule would be a technical amendment rather than a new flammability standard, for purposes of

this section of the preamble, we will refer to the proposed rule as a "proposed amendment." These findings are discussed below.

The amendment to the Standard is needed to adequately protect the public against unreasonable risk of the occurrence of fire. The current Standard specifies as the ignition source cigarettes that are no longer being produced. In order for the Standard to continue to be effective (and for labs to test mattresses and mattress pads to determine whether they comply with the Standard), it is necessary to change the ignition source specification. The proposed amendment is necessary to ensure that the testing is reliable and that results will not vary from one lab or manufacturer to another. Such variation would be likely if labs or manufacturers were able to use different ignition sources that have similar physical properties but different burning characteristics.

The amendment to the Standard is reasonable, technologically practicable, and appropriate. The proposed amendment is based on technical research conducted by NIST, which established that the SRM cigarette is capable of providing reliable and reproducible results in flammability testing of mattresses and mattress pads. The proposed SRM represents an equivalent, safety-neutral ignition source for use in testing to establish compliance with the Standard.

The amendment to the Standard is limited to fabrics, related materials, and products that present an unreasonable risk. The proposed amendment would continue to apply to the same products as the existing Standard.

Voluntary standards. There is no applicable voluntary standard for mattresses. The proposal would amend an existing Federal mandatory standard.

Relationship of benefits to costs. Amending the Standard to specify SRM cigarettes as the ignition source would allow testing to the Standard to continue without interruption, would maintain the effectiveness of the Standard, and would not significantly increase testing costs to manufacturers and importers of mattresses and mattress pads. Thus, there is a reasonable relationship between benefits and costs of the proposed amendment. Both expected benefits and costs of the proposed amendment are likely to be small. The likely effect on testing costs would be minor.

Least burdensome requirement. No other alternative would allow the Standard's level of safety and effectiveness to continue. Thus, the proposed amendment imposes the least burdensome requirement that would adequately address the risk of injury.

J. Conclusion

For the reasons discussed above, the Commission preliminarily finds that amending the mattress flammability standard (16 CFR part 1632) to specify SRM cigarettes as the ignition source is needed to adequately protect the public against the unreasonable risk of the occurrence of fire leading to death, injury, and significant property damage. The Commission also preliminarily finds that the amendment to the Standard is reasonable, technologically practicable, and appropriate. The Commission further finds that the amendment is limited to the fabrics, related materials, and products that present such unreasonable risks.

K. References

1. Gann, R.G., and Hnetkovsky E.J., *Modification of ASTM E 2187 for Measuring the Ignition Propensity of Conventional Cigarettes,* Technical Note 1627, National Institute of Standards and Technology, Gaithersburg, MD 20899, 2009.

2. Directorate for Economic Analysis Report, *Preliminary Regulatory Analysis: Smoldering Ignition Source Draft Proposed Technical Amendment to the Flammability Standard for Mattresses and Mattress Pads* (16 CFR part 1632).

List of Subjects in 16 CFR Part 1632

Consumer protection, Flammable materials, Labeling, Mattresses and mattress pads, Records, Textiles, Warranties.

For the reasons given above, the Commission proposes to amend 16 CFR part 1632 as follows:

PART 1632—STANDARD FOR THE FLAMMABILITY OF MATTRESSES AND MATTRESS PADS (FF 4–72, AMENDED)

1. The authority citation for part 1632 continues to read as follows:

Authority: 15 U.S.C. 1193, 1194; 15 U.S.C. 2079(b).

2. Section 1632.4 is amended by revising paragraph (a)(2) to read as follows:

§ 1632.4 Mattress test procedure.

(a) * * *

(2) *Ignition source.* The ignition source shall be National Institute of Standards and Technology ("NIST") Standard Reference Material ("SRM") 1196, available for purchase from the National Institute for Standards and Technology, 100 Bureau Drive, Gaithersburg, MD 20899.

* * * * *

Dated: October 26, 2010.

Todd A. Stevenson,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2010–27504 Filed 10–29–10; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–344P]

Listing of Approved Drug Products Containing Dronabinol in Schedule III

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: This proposed rule is issued by the Deputy Administrator of the Drug Enforcement Administration (DEA) to modify the listing of the Marinol® formulation in schedule III so that certain generic drug products are also included in that listing.

Several products are currently the subject of Abbreviated New Drug Applications (ANDAs) under review by the U.S. Food and Drug Administration (FDA). Each product is a generic formulation of Marinol® and contains dronabinol, the (-) isomer of delta-9-(trans)-tetrahydrocannabinol (THC), which is a schedule I controlled substance. Due to variations in formulation, these generic Marinol® products do not meet the specific conditions specified in the current schedule III listing.

This proposed action expands the schedule III listing to include formulations having naturally-derived dronabinol and products encapsulated in hard gelatin capsules. This would have the effect of transferring the FDA-approved versions of such generic Marinol® products from schedule I to schedule III.

DATES: Written comments must be postmarked and electronic comments must be submitted on or before January 3, 2011. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after midnight Eastern Time on the last day of the comment period.

ADDRESSES: To ensure proper handling of comments, please reference "Docket No. DEA–344" on all written and electronic correspondence. Written comments sent via regular or express