United States
CONSUMER PRODUCT SAFETY COMMISSION
Washington, D C 20207

2000 JUL 28 P 1 C8

BALLOT VOTE

DATE: JUL 28 2000

TO : The Commission
Sadye E Dunn, Secretary

THROUGH: Thomas Murr, Acting Executive Director TM

FROM : Michael S. Solender, General Counsel MSS
Stephen Lemberg, Assistant General Counsel SL

SUBJECT: Fiscal Year 2001 Regulatory Plan

BALLOT VOTE due: AUG 4 2000

Executive Order 12866 directs each agency of the Federal government, including independent regulatory agencies, to prepare a Regulatory Plan. A draft of the FY 2001 Regulatory Plan, as recommended by the Office of Hazard Identification and Reduction, for approval by the Commission and transmittal to the Office of Management and Budget, is contained in the attached Federal Register notice. The FY 2001 Regulatory Plan includes a statement of the Commission's regulatory priorities, and covers the most important significant regulatory actions the agency reasonably expects to issue in proposed or final form in the upcoming fiscal year (2001).

The information in the attached draft is current through July 27, 2000. If the Commission approves publication of the attached draft, the draft will be revised to reflect any changes in the status of any activity described in the plan that occurs between July 27, 2000, and the closing date for submission of changes to OMB.

Please indicate your vote on the following options.

I Approve the draft Regulatory Plan without change.

_____ _____
Signature Date

OPSA 6 (b)(1) Cleared
7/28/00
No Mfrs/PvtLblrs or Products Identified
__ Excepted by
__ Firms Notified.
Comments Processed.

NOTE This document has not been reviewed or accepted by the Commission
Initial SD Date 7/28/00

II Approve the draft Regulatory Plan with the following changes (please specify):

_____

_____

_____

_____ _____

Signature Date

III Do not approve the draft Regulatory Plan.

_____ _____

Signature Date

CONSUMER PRODUCT SAFETY COMMISSION (CPSC)

Statement of Regulatory Priorities

The U.S. Consumer Product Safety Commission is charged with protecting the public from unreasonable risks of death and injury associated with consumer products. To achieve this goal, the Commission.

- participates in the development or revision of voluntary product safety standards,
- develops mandatory product safety standards or banning rules when other, less restrictive, efforts are inadequate to address a safety hazard,
- obtains repair, replacement, or refund of the purchase price for defective products that present a substantial product hazard; and
- develops information and education campaigns about the safety of consumer products.

When deciding which of these approaches to take in any specific case, the Commission gathers the best available data about the nature and extent of the hazard presented by the product. The Commission then analyzes this information to determine the best way to reduce the hazard in each case. The Commission's rules require the Commission to consider, among other factors, the following criteria when deciding the level of priority for any particular project.

- frequency and severity of injury,
- causality of injury,
- chronic illness and future injuries,
- costs and benefits of Commission action;
- unforeseen nature of the risk;
- vulnerability of the population at risk;

• probability of exposure to the hazard

Additionally, if the Commission proposes a mandatory safety standard for a particular product, the Commission is generally required to make statutory cost/benefit findings and adopt the least burdensome requirements that adequately protect the public.

The Commission's statutory authority requires it to rely on voluntary standards rather than mandatory standards whenever a voluntary standard is likely to result in the elimination or adequate reduction of the risk of injury and it is likely that there will be substantial compliance with the voluntary standard. As a result, much of the Commission's work involves cooperative efforts with other participants in the voluntary standard-setting process rather than promulgating mandatory standards.

In fiscal year 2001, the Commission's significant rulemaking activities will involve (1) addressing risks of fire associated with ignition of upholstered furniture by small open flames, and (2) a requirement that drugs, when switched by the Food and Drug Administration from prescription to over-the-counter (OTC) status, remain in child-resistant packaging to protect children from being poisoned by gaining access to the drugs.

The emphasis on these rulemaking activities in the Commission's FY 2001 regulatory plan is consistent with the Commission's statutory mandate and its criteria for setting priorities

TITLE:
Flammability Standard for Upholstered Furniture

RIN: 3041-AB35 (No Stage)

REGULATORY PLAN: Yes

PRIORITY: Economically Significant Major status under 5 USC 801 is undetermined

UNFUNDED MANDATES: No

REINVENTING GOVERNMENT:
No

LEGAL AUTHORITY:
15 USC 1193 Flammable Fabrics Act

CFR CITATION:
16 CFR 1640

LEGAL DEADLINE:
None

ABSTRACT:
On June 15, 1994, the Commission published an advance notice of proposed rulemaking (ANPRM) to begin a proceeding for development of a flammability standard to address risks of death, injury, and property damage from fires associated with ignition of upholstered furniture by small open-flame sources such as matches, lighters, or candles This ANPRM was issued after the Commission granted part of a petition requesting development of a mandatory flammability standard to address risks of injury from ignition of upholstered furniture by (1) small open-flame sources, (2) large open-flame sources, and (3) cigarettes The Commission voted to deny that part of the petition requesting development of a mandatory standard to address hazards associated with ignition of upholstered furniture by large open-flame sources The Commission also voted to defer a decision on that part of the petition requesting development of a standard to address cigarette ignition, and directed the staff to report to the Commission on the effectiveness of, and the extent of industry compliance with, a voluntary program to reduce risks of ignition of upholstered furniture by cigarettes The Commission staff developed a draft standard to address ignition of upholstered furniture by small open-flame sources

On March 2, 1998, the Commission voted to defer action on small open-flame sources and gather additional information on the potential toxicity of flame-retardant chemicals that might be used to meet a standard A public hearing on this subject was held on May 5-6, 1998 The staff is analyzing data from the hearing and

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Flammability Standard for Upholstered Furniture

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completing other technical studies In CPSC's 1999 appropriations legislation Congress directed the Commission to contract with the National Academy of Sciences (NAS) for an independent study of potential health hazards associated with the use of flame retardant chemicals that might be used in upholstered furniture fabrics to meet a CPSC standard The draft NAS report was completed and forwarded to Congress in April 2000, the final NAS report was published in July 2000 The report concluded that of 16 flame-retardant chemicals reviewed, 8 could be used in upholstered furniture fabrics without presenting health hazards to consumers Additional exposure studies were recommended for the remaining 8 chemicals The report indicates that a number of suitable flame-retardant treatments are available, these include treatments already in use in various textile products, including upholstered furniture sold in the United Kingdom to meet existing U.K flammability regulations

CPSC is also considering possible impacts of flame retardant chemical use on worker safety and the environment At the CPSC staff's request, the National Institute of Occupational Safety and Health is assessing potential worker exposure to and risks from certain flame retardant chemicals that may be used by textile and furniture producers to comply with an upholstered furniture flammability standard The CPSC staff is also working with the Environmental Protection Agency to consider possible controls on flame retardant compounds used in residential upholstered furniture fabrics, under that agency's Toxic Substances Control Act Authority Upon completion of its chemical risk assessment and other technical activities, the CPSC staff will present alternatives for future action by the Commission

STATEMENT OF NEED:
In 1997, approximately 650 deaths, more than 1,500 injuries, and about $225 million in property damage resulted from 11,500 residential fires in the United States in which upholstered furniture was the first item to ignite The total societal cost attributable to upholstered furniture fires was approximately $3 75 billion in 1997 This total includes fires ignited by small open-flame sources, large open-flame sources, and cigarettes Of these, open-flame fires accounted for approximately 80 deaths, 500 injuries and $64 million in property losses

SUMMARY OF THE LEGAL BASIS:
Section 4 of the Flammable Fabrics Act (FFA) (15 USC 1193) authorizes the Commission to issue a flammability standard or other regulation for a product of interior furnishing if the Commission determines that such a standard is "needed to adequately protect the public against unreasonable risk of the

TITLE:
Flammability Standard for Upholstered Furniture

RIN: 3041-AB35 (No Stage)

occurrence of fire leading to death or personal injury, or significant property damage "

The Commission's regulatory proceeding could result in several actions, one of which could be the development of a mandatory standard requiring that upholstered furniture sold in the United States meet mandatory labeling requirements, resist ignition, or meet other performance criteria under test conditions specified in the standard

ALTERNATIVES:
The ANPRM stated that the Commission was considering the following alternatives

(1) The Commission could issue a mandatory flammability standard if the Commission finds that such a standard is needed to address an unreasonable risk of the occurrence of fire from ignition of upholstered furniture by small open-flame sources,

(2) The Commission could issue mandatory requirements for labeling of upholstered furniture, in addition to, or as an alternative to, the requirements of a mandatory flammability standard,

(3) The Commission could terminate the proceeding for development of a flammability standard and rely on a voluntary standard if a voluntary standard would adequately address the risk of fire and substantial compliance with such a standard is likely to result, and

(4) The Commission could terminate the proceeding and withdraw the ANPRM

ANTICIPATED COSTS AND BENEFITS:
The estimated annual cost of imposing a mandatory standard to address ignition of upholstered furniture by small open-flame sources will depend upon the test requirements imposed by the standard and the steps manufacturers take to meet those requirements Again, depending upon the test requirements, a small open-flame standard could also reduce cigarette-ignited fire losses, the societal cost of which was over $2 billion in 1997 For this reason, the potential benefits of a mandatory standard to address the risk of ignition of upholstered furniture by small open-flame sources could be significant, even if the standard did not prevent all such fires started by open-flame sources

RISKS:
The estimated total cost to society from all residential fires

TITLE:
Flammability Standard for Upholstered Furniture

RIN: 3041-AB35 (No Stage)

associated with upholstered furniture was $3 75 billion in 1997

Societal costs associated with upholstered furniture fires are among the highest associated with any product subject to the Commission's authority. A standard has the potential to reduce these societal costs

TIMETABLE:

ACTION	DATE	FR CITE
ANPRM	06/15/1994	59 FR 30735
ANPRM Comment Period End	08/15/1994	59 FR 30735
Staff Briefing of Commission on NPRM	12/18/1997	
Commission Voted To Defer Action Pending Results of Toxicity Hearing	03/02/1998	
Commission Hearing May 5 & 6, 1998 on Possible Toxicity of Flame Retardant Chemicals	03/17/1998	63 FR 13017
NAS Study Completed (Required by Congress)	07/10/2000	

REGULATORY FLEXIBILITY ANALYSIS REQUIRED: Undetermined

SMALL ENTITIES AFFECTED:

GOVERNMENT LEVELS AFFECTED: Undetermined

FEDERALISM: Undetermined

PROCUREMENT:
Not procurement-related

ADDITIONAL INFORMATION:

AGENCY CONTACT:

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- WILL NOT PRINT IN AGENDA
* - MISSING DATA ELEMENT

TITLE:
+ Requirement for Special Packaging of Oral Prescription Drugs That are Granted Over-The-Counter Status by the Food and Drug Administration

RIN: 3041-AB92 (Final Rule)

REGULATORY PLAN: Yes

PRIORITY: Other Significant Major status under 5 USC 801 is undetermined

UNFUNDED MANDATES: Undetermined

REINVENTING GOVERNMENT:
No

LEGAL AUTHORITY:
15 USC 1471 Poison Prevention Packaging Act

CFR CITATION:
Not Yet Determined

LEGAL DEADLINE:

ABSTRACT:
On June 23, 2000, the Commission directed the CPSC staff to draft a notice of proposed rulemaking to require that the child-resistant packaging requirements for oral prescription drugs continue when the active chemicals are granted over-the-counter (OTC) status by the Food and Drug Administration (FDA) The current regulations under the Poison Prevention Packaging Act (PPPA) require child-resistant packaging of most oral prescription drugs However, when the FDA allows an oral prescription drug to be sold over-the-counter, child-resistant packaging of that drug is no longer required. When the Commission finds that a particular switched OTC drug requires child-resistant packaging because it may cause serious injury or serious illness, it must issue an individual rule, which may not take effect for several years after the switch

On August __, 2000, the Commission issued a proposed rule that would automatically require drugs that have been switched to be in child-resistant packaging This proposed rule provides that those companies that believe their drug product does not need to be in child-resistant packaging can provide information to the Commission, as they do currently under the PPPA oral prescription drug rule, to demonstrate that the drug product will not injure children if it is marketed in non-child-resistant packaging If the Commission agrees, it will by rule exempt the drug product from the PPPA requirements The Federal Register notice also

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proposes to revoke 16 CFR 1702.16(b) to allow petitions for exemptions from child-resistant packaging requirements to be submitted and considered by the Commission before the new drug applications (NDA) are approved by the FDA. This would decrease the potential financial and regulatory burdens to the drug company associated with a post-marketing package change

The notice issued by the Commission includes proposed findings that child-resistant packaging for these products is technically feasible, practicable, and appropriate, as well as necessary to protect children from serious personal injury and illness resulting from handling, using, or ingesting the drug products It is anticipated that this proposed rule would not create a financial burden on small companies

STATEMENT OF NEED:

Currently CPSC must issue a separate child-resistant packaging requirement for each oral prescription drug that the FDA allows to be sold OTC in order to maintain child-resistant packaging for that drug. This proposed rule would require that children have the same protection when the drugs are more widely available as OTC products as they had when the drugs were available only by prescription

SUMMARY OF THE LEGAL BASIS:

Section 3 of the PPPA, 15 USC 1472, authorizes the Commission to issue special packaging standards for household substances if it finds tnat special packaging is necessary to protect children from serious injury or illness and that special packaging is technically feasible, practicable, and appropriate

ALTERNATIVES:

The Commission can either (1) issue a final rule requiring that oral prescription drugs continue to require child-resistant packaging when they are granted OTC status by the FDA, or (2) continue to issue regulations on a case-by-case basis after the status of the drug products has been switched to OTC

ANTICIPATED COSTS AND BENEFITS:

This project supports the Commission's strategic goal of keeping children safe from poisoning hazards Children would have the same protection when drugs are more widely available as OTC preparations as they had when the drugs were available only by prescription In general, the incremental cost of child-resistant packaging is mimimal ($0 005 - $0 02)

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+ Requirement for Special Packaging of Oral Prescription Drugs That are Granted Over-The-Counter Status by the Food and Drug Administration

RIN: 3041-AB92 (Final Rule)

RISKS:

For prescription medicines and aspirin alone, CPSC estimates that about 800 children's lives have been saved by the requirement for child-resistant packaging However, there continues to be about 30 deaths and one million calls to poison control centers about poisonings to young children each year Without this rule, there is the potential for certain oral drugs to be sold without child-resistant packaging when they are available as OTC drugs, even though they required special packaging as prescription drugs Children are at risk for serious injury from ingesting these products if child-resistant packaging is not required

TIMETABLE:

ACTION	DATE	FR CITE
Staff Briefing of Commission on Whether to Issue an NPRM	06/07/2000	
Commission Decision to Prepare a Draft NPRM	06/23/2000	
Notice of Proposed Rulemaking Issued	08/15/2000	
Comment Period End	10/00/2000	
Staff Sends Briefing Package to Commission	12/00/2000	

REGULATORY FLEXIBILITY ANALYSIS REQUIRED: No

SMALL ENTITIES AFFECTED:

GOVERNMENT LEVELS AFFECTED: None

FEDERALISM: No

PROCUREMENT:

Not procurement-related

ADDITIONAL INFORMATION:

AGENCY CONTACT:

Suzanne Barone Ph D ,

TITLE:

+Requirement for Special Packaging of Oral Prescription Drugs That are Granted Over-The-Counter Status by the Food and Drug Administration

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