



UNITED STATES
 CONSUMER PRODUCT SAFETY COMMISSION
 4330 EAST WEST HIGHWAY
 BETHESDA, MD 20814

BALLOT VOTE SHEET

DATE: NOV 25 2008

TO: The Commission
 Todd A. Stevenson, Secretary

THROUGH: Cheryl A. Falvey, General Counsel *CAF*
for Patricia Semple, Executive Director *pc*

FROM: Hyun S. Kim, Attorney, OGC *HSK*

SUBJECT: Final Rule exempting Boston Billow Nursing Pillow and substantially similar nursing pillows.

Ballot Vote Due: DEC 3, 2008

Attached is a staff memorandum on a final rule exempting the Boston Billow Nursing Pillow and substantially similar nursing pillows from the Commission's regulations at 16 CFR § 1500.18(a)(16)(i).

Please indicate your vote on the following options.

- I. Issue the exemption and publish the draft *Federal Register* notice without change.

 (Signature) (Date)

- II. Do not issue the exemption and do not publish the draft *Federal Register* notice.

 (Signature) (Date)

CPSA 8(b)(1) CLEARED for PUBLIC

NO MFPS/PRVTBLRS OR PRODUCTS IDENTIFIED

EXCEPTED BY: PETITION RULEMAKING ADMIN. PRCD

WITH PORTIONS REMOVED: _____

11/25/08

CPSC Hotline: 1-800-638-CPSC(2772) ★ CPSC's Web Site: <http://www.cpsc.gov>

Note: This document has not been reviewed or accepted by the Commission.
 Initials rk Date 11-25-08

III. Publish the draft *Federal Register* notice with changes. (Please specify.)

(Signature)

(Date)

Attachment: Staff Memorandum on the final rule for Boston Billow Nursing Pillow and substantially similar nursing pillows.



United States
CONSUMER PRODUCT SAFETY COMMISSION

MEMORANDUM

NOV 25 2008

To : The Commission
Todd A. Stevenson, Secretary

Through : Cheryl A. Falvey, General Counsel *CAF*
for Patricia Semple, Executive Director *jc*

From : Jay Howell, Acting Assistant Executive Director *JH*
Office of Hazard Identification and Reduction
Suad Wanna-Nakamura, PhD., Project Manager, *SW*
Infant Cushions and Pillows, Directorate for Health Sciences

Subject : Final rule for Boston Billow Nursing Pillow and substantially similar nursing pillows.

Background:

In 1992, pursuant to the Commission's authority under the Federal Hazardous Substances Act (FHSA), the Commission banned infant cushions or infant pillows following the death of 35 infants. In all incidents where the infant's position could be determined, the infant was found sleeping in a prone position. The ban applies to any article designated as an "infant cushion" or "infant pillow" having the following characteristics: (1) a flexible fabric covering, (2) loosely filled with granular material, including but not limited to polystyrene beads or pellets, (3) easily flattened, (4) capable of conforming to the body or face of an infant, and (5) intended for use by children under one year of age (57 FR 27912).

On September 15, 2005, the Commission docketed a petition from, Boston Billows, Inc. requesting exemption to the ban (petition HP05-1). On July 13, 2006, the Commission voted to grant the petition and initiate rulemaking.

On September 27, 2006, the Commission issued an advance notice of proposed rulemaking (ANPR) to determine whether a rulemaking was necessary to address any unreasonable risk of injury or death which may be associated with infant cushions/pillows, including the Boston Billow Nursing Pillow which met the ban criteria (71 FR 56418). After review of the comments, incident reports and other available information, the Commission determined that there was insufficient data or product information on infant cushions/pillows, or pillow-like products other than the Boston Billow nursing pillow and substantially similar nursing pillows, to proceed with further rulemaking on those products. Accordingly, the Commission voted on February 1, 2008

CPSA 6(b)(1) CLEARED for PUBLIC

NO MFRS/PRVT. BLRS OR
PRODUCTS IDENTIFIED

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RULEMAKING ADMIN. PRCDG

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reviewed or accepted by the Commission.
Initials *rh* Date *11-25-08*

to terminate the rulemaking on infant cushions or pillow-like products, other than the Boston Billow Nursing Pillow and substantially similar nursing pillows. A notice to terminate rulemaking was published on September 3, 2008 (73 FR 51386).

However, the Commission also determined that an exemption for the Boston Billow Nursing Pillow and substantially similar nursing pillows from classification as banned hazardous substances should be considered because nursing pillows perform a related but different function. The purpose of nursing pillows is to provide a place for the mother to rest her arms while breastfeeding. A nursing pillow may also serve to give moldable but firm support to enhance comfort during extended periods when changing position during breastfeeding is difficult.

Accordingly on September 3, 2008, a notice of proposed rulemaking was published in the Federal Register soliciting comments on the proposed exemption (73 FR 51386).

Comments:

The comment period closed on October 3, 2008. Seven comments were received. All the comments were in support of the proposed exemption. Copies of the comments are available from the Office of the Secretary and on the CPSC website at <http://www.cpsc.gov/library/foia/foia09/pubcom/infcuscmt.pdf>

The seven comments were letters of support from board certified lactation consultants (BCLC), six of whom are registered nurses (RN). The letters emphasized their opinions on the benefits of the Boston Billow Nursing Pillow for nursing mothers, particularly those mothers who delivered by Caesarian-section, had post-delivery surgery, or were nursing premature infants. Unlike other nursing pillows, the BCLC claim that due to its unique design and filling the Boston Billow Nursing Pillow can adjust to a wide range of waistlines. The BCLC further claim that the product is used as a nursing aid for breastfeeding mothers, and is not intended for use as a sleeping surface. These comments are similar to the comments submitted by the BCLC to CPSC previously.

Response to comments:

CPSC staff agrees that there are beneficial uses for the Boston Billow Nursing Pillow. The purpose of nursing pillows is to provide a place for the mother to rest her arms while breastfeeding. The nursing pillow may also serve to give moldable support to enhance comfort during extended periods when changing position during breastfeeding or after surgery is difficult.

Small Business Impact Analysis (Tab A)

Section 605 of the Regulatory Flexibility Act (RFA) requires the Commission to consider the impact of its actions on small entities, including small businesses. Commission staff has estimated that there are approximately 15 firms that either manufacture or import

nursing pillows.¹ Manufacturers of nursing pillows are considered to be a small business if they have fewer than 500 employees, while importers of nursing pillows are considered to be a small business if they have fewer than 100 employees.² Based on the definitions, most, if not all, firms are considered to be small businesses.

The proposed rule is deregulatory in nature and exempts the Boston Billow Nursing Pillow and substantially similar nursing pillows from classification as banned hazardous substances. The proposed rule will not increase production costs. The primary effect of the rule will be to increase competition and give consumers greater choice in nursing pillows. Due to the reduction in regulatory burden, the Commission could certify that this action will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Staff recommendation:

No new comments were submitted or issues raised that would change the staff's previous recommendation. Based on the available data and comments received, staff recommends that the Commission issue a final rule for an exemption from the ban on infant cushions/pillows for the Boston Billow Nursing Pillow and substantially similar nursing pillows.

¹ "Preliminary Economic Analysis: Nursing Pillows". John Peternel. Consumer Product Safety Commission. (January 21, 2008) (<http://www.cpsc.gov/LIBRARY/FOIA/FOIA08/brief/infant.pdf>) Table A

² Small Business Administration, Summary of Size Standards (visited November 12, 2008) (<http://www.sba.gov/services/contractingopportunities/sizestandardsttopics/summarywhatis/index.html>)

A



**UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207**

Memorandum

Date: November 17, 2008

TO : Suad Wanna-Nakamura, PhD., Project Manager,
Infant Cushions and Pillows, Directorate for Health Sciences

THROUGH : Gregory B. Rodgers, Ph.D., Associate Executive Director, Directorate for *GBR*
Economic Analysis
Deborah V. Aiken, Ph.D., Senior Staff Coordinator,
Directorate for Economic Analysis *DVA*

FROM : John W. Peternel, Economist, Directorate for Economic Analysis *JWP*

SUBJECT: Final Rule for Boston Billow Nursing Pillow and Substantially Similar Nursing Pillows:
Small Business Impact Analysis

On September 3, 2008, the Commission issued a notice of proposed rulemaking to exempt Boston Billows and substantially similar nursing pillows from classification as a banned hazardous substance under the Federal Hazardous Substances Act (73 FR 51386). The purpose of this memo is to examine potential impacts on small businesses as required under the Regulatory Flexibility Act.

Section 605 of the Regulatory Flexibility Act (RFA) requires the Commission to consider the impact of its actions on small entities, including small businesses. Commission staff has estimated that there are approximately 15 firms that either manufacture or import nursing pillows.¹ Manufacturers of nursing pillows are considered to be a small business if they have fewer than 500 employees, while importers of nursing pillows are considered to be a small business if they have fewer than 100 employees.² Based on the definitions, most, if not all, firms are considered to be small businesses.

The proposed rule is deregulatory in nature and exempts the Boston Billow Nursing Pillow and substantially similar nursing pillows from classification as banned hazardous substances. The proposed rule will not increase production costs. The primary effect of the rule will be to increase competition and give consumers greater choice in nursing pillows. Due to the reduction in regulatory burden, the Commission could certify that this action will not have a significant

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economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.