

CLOSURE
MANUFACTURERS
ASSOCIATION



2478 03 OCT 22 P5:13

Darla J. Williamson
President

October 22, 2003

VIA FACSIMILE

Dockets Management Branch
Food and Drug Administration, HFA-305
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket # 2003N-0361: FDA Counterfeit Drug Task Force Interim Report

Dear Sir or Madam:

The Closure Manufacturers Association ("CMA") submits these comments in response to the Food and Drug Administration's ("FDA's" or "the Agency's") Counterfeit Drug Task Force's ("the Task Force") Interim Report on measures to combat the introduction of counterfeit drugs into the United States drug distribution system.

Founded in 1984, the CMA is a national non-profit organization dedicated to improving and promoting the manufacture and use of closures. In that capacity, the CMA has developed a strong expertise in and promoted the development of closures that effectively prevent child mortality and injuries that result from the accidental ingestion of harmful or hazardous substances.

CMA's members have actively participated in the development of the FDA's Counterfeit Drug Task Force Interim Report, through the Healthcare Distribution Management Association's Product Safety Task Force. Thus, the views of CMA are already reflected in the Task Force's Interim Report. Nonetheless, the CMA is providing, for the Task Force's consideration, a copy of its comments to the U.S. Consumer Product Safety Commission ("CPSC") on a recent petition

P.O. Box 1358
Kilmarnock, VA 22482
804-435-9580
804.435.2203 (Fax)
cmadc@rivnet.net
www.cmadc.org

2003N-0361

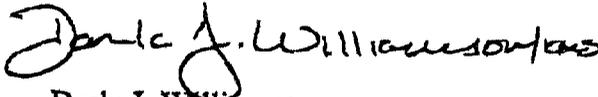
C4

Dockets Management Branch
October 22, 2003
Page 2

seeking to amend the CPSC's test failure protocol for unit-dose packaging. These comments are relevant to the Task Force's inquiry regarding the advantages and disadvantages of unit dose packaging and request for additional information regarding the economic impact of unit dose packaging. As you will see from the attached comments, the CMA objects to the proposed amendment for four reasons: (1) the CPSC does not have the authority under the Poison Prevention Packaging Act ("PPPA") to amend the test failure criteria as requested; (2) amending the test failure criteria to an objective standard as requested will not eliminate the need to conduct a toxicological analysis under the PPPA; (3) unit dose packaging is not, as contended, safer than child-resistant closures; and (4) the PPPA does not authorize consideration of economic or competitive factors in determining toxicity or child-resistant packaging standards.

The CMA appreciates the opportunity to comment on the FDA's Counterfeit Drug Task Force Interim Report. Please contact me if you have any questions or comments regarding the CMA's views on these issues.

Sincerely,



Darla J. Williamson
President

Attachment

c: Mark Fricke
Closure Technical Committee
Closure Manufacturers Association

Kathleen M. Sanzo, Esq.
Morgan, Lewis & Bockius, LLP

CLOSURE
MANUFACTURERS
ASSOCIATION

CMA

2 4 3 7 7 0 3 OCT 22 9 5 13

August 15, 2003

VIA FACSIMILE

Office of the Secretary
U.S. Consumer Product Safety Commission
4330 East West Highway
Suite 501
Bethesda, Maryland 20814

Re: Petition PP03-1, Petition for Amendment of the Child-Resistance
Testing Requirements for Unit Dose Packaging

Dear Sir or Madam:

The Closure Manufacturers Association ("CMA") submits these comments in response to the Consumer Product Safety Commission's ("CPSC's" or "the Commission's") notice of petition filed by the Healthcare Compliance Packaging Council ("HCPC") to amend the CPSC's test failure protocol for child-resistant ("CR") packaging in 16 C.F.R. § 1700.20(a)(2)(ii), as it relates to unit dose packaging.^{1/}

Founded in 1984, the CMA is a national non-profit organization dedicated to improving and promoting the manufacture and use of closures. In that capacity, the CMA has developed a strong expertise in and promoted the development of closures that effectively prevent child mortality and injuries that result from the accidental ingestion of harmful or hazardous substances. CMA has actively participated with CPSC in the development of voluntary industry standards for CR closures.

^{1/} 68 Fed. Reg. 35614 (June 16, 2003).

Office of the Secretary
 August 15, 2003
 Page 2

Based on a statutory mandate, the current CR packaging test protocol in CPSC's regulations specifies that a test failure for unit dose packaging is the lesser of either: (1) any child who opens or accesses the number of individual units which constitute the amount that may produce serious personal injury or illness; or (2) a child who opens or gains access to more than 8 individual units in 10 minutes.^{2/} The HCPC petition, if granted, proposes to eliminate the first prong of the test failure criteria above, such that a test failure for unit dose packaging would be defined only as a child who opens or gains access to more than 8 individual units in 10 minutes.

The CMA opposes the HCPC petition for four reasons and urges the Commission to maintain the CR test failure protocol as it currently appears in the CPSC's regulations. First, under the Poison Prevention Packaging Act ("PPPA" or "the Act"), the Commission does not have the authority to disregard product toxicity to amend the test failure criteria as HCPC has requested. Second, amending the CR test protocol to an objective test criteria of a child who opens or gains access to 8 unit dose packages will not eliminate the need for toxicological analysis because many products are toxic to children at fewer than 8 units. Third, unit dose packaging is not, as HCPC contends, inherently safer than CR closures. Lastly, the PPPA does not authorize consideration of economic or competitive factors in determining toxicity or CR standards. For all of these reasons, the HCPC's petition to CPSC should be denied. Each of these topics will be discussed in detail below.

I. The Commission Does Not Have the Statutory Authority to Disregard Product Toxicity in Establishing Standards for CR Packaging

The PPPA requires special packaging for any particular household substance if:

- (1) the degree or nature of the hazard to children in the availability of such substance, by reason of its packaging, is such that special packaging is required to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting such substance; and (2) the special packaging to be required by such standard is technologically feasible, practicable, and appropriate for such substance.^{3/}

"Special packaging" is defined as:

[P]ackaging that is designed or constructed to be significantly difficult for children under five years of age to open or obtain a toxic or harmful amount of the substance contained therein within a reasonable time and not difficult for normal adults to use properly, but

^{2/} 16 C.F.R. § 1700.20(a)(2)(ii).

^{3/} PPPA, §§ 3(a)(1-2); 15 U.S.C. §§ 1472(a)(1-2) (emphasis added).

Office of the Secretary
August 15, 2003
Page 3

does not mean packaging which all such children cannot open or obtain a toxic or harmful amount within a reasonable time.^{4/}

As the statute clearly mandates, CPSC first must identify poisonous or toxic substances which require special packaging and then evaluate special packaging by whether it is able to keep children from accessing a toxic or harmful amount of the particular substance contained inside the special packaging. Therefore, under the PPPA, a substance's toxicity is paramount to the analysis of the need for and acceptability of special packaging.

The legislative history supports this interpretation. For example, the report of the House of Representatives' Interstate and Foreign Commerce Committee states that:

[M]ere reference to the hazards of a particular product will not necessarily mean that its packaging will be regulated under this legislation. Regulation under this legislation must be preceded by a finding that as a result of the degree or nature of the hazard to children in the availability of the product, by reason of its packaging, special packaging is required to prevent serious injury or illness. . . .^{5/}

Further, as the CPSC has already pointed out to HCPC, the Senate Commerce Committee Report stated:

In order to establish standards for the special packaging of a substance, the [CPSC] must find that the substance is responsible for serious personal injury to, or illness of, children and that such illness or injury arises because children are enabled by its packaging to obtain access to the substance. . . . Having found that a substance should be maintained in special packaging, the [CPSC] is authorized to establish standards for special packaging of that substance.^{6/}

Moreover, in comments to the legislation submitted by the Department of Health, Education and Welfare ("HEW"), which originally had authority over the administration and implementation of the PPPA through the Food and Drug Administration ("FDA"), HEW stated:

[w]e feel that the degree or nature of the hazard *presented by a substance* should be stated as the controlling factor in making findings of the need for special packaging. The degree or nature of the hazard of a substance is evidenced in statistics and data on involvement of products in child ingestions, morbidity, and mortality. Certainly 'the

^{4/} PPPA, § 2(4); 15 U.S.C. § 1471(4).

^{5/} H.R. Rep. No. 91-1642, reprinted in 1970 U.S.C.C.A.N. 5326, 5327.

^{6/} S. Rep. No. 91-845, at 10.

Office of the Secretary
 August 15, 2003
 Page 4

availability of a substance, by reason of its packaging' is a factor in the hazards presented by a substance implicated in poisoning episodes.^{7/}

These references from the legislative history clearly illustrate that it is the hazard presented by a particular substance that drives the determination regarding the need for special packaging. Therefore, the issue of a substance's toxicity or hazardous properties cannot be eliminated from consideration in determining the need for special packaging.

The regulatory history implementing the PPPA's provisions confirms this conclusion, stating that the purpose of the test protocol is "to determine the ability of the special packaging to thwart the efforts of children under 5 years of age to open and obtain a toxic or harmful amount of the contents."^{8/} As the FDA, which originally maintained jurisdiction over CR packaging, acknowledged in the preamble to a 1973 final rule amending the test protocol, "[t]he ultimate controlling factor in determining the test failure level in the case of unit packaging remains the number of individual units which constitute the amount that may produce serious personal injury or serious illness."^{9/} Therefore, the relevant regulatory history confirms that product toxicity, including the amount of toxic substance accessible, is the key factor to be considered in evaluating the need for special packaging and, thus, the Commission does not have the authority under the PPPA to eliminate product toxicity from the test failure criteria for unit-dose packaging in 16 C.F.R. § 1700.20(a)(2)(ii).

The HCPC acknowledges that "the PPPA requires the Commission to consider toxicity in determining whether a particular substance requires special packaging."^{10/} Nonetheless, the HCPC argues that, "the PPPA does not require the subjective, zero-tolerance standard that 16

^{7/} H.R. Rep. No. 91-1642, reprinted in 1970 U.S.C.C.A.N. 5326, 5341 (emphasis in original). Another federal agency that evaluated this legislation at the time of its implementation concurred with this analysis. As the Federal Trade Commission ("FTC") noted, the purpose of the Act is to reduce injuries to, and illnesses of, young children arising from ingestion of toxic or harmful substances customarily produced or distributed for sale for consumption, use, or storage by individuals in or about the household. Child-Resistant Packaging of Household Substances: Hearing on H.R. 6179, H.R. 6180, H.R. 16541, H.R. 16884, and S. 2162 Before the Subcomm. on Commerce and Finance of the House Comm. on Interstate and Foreign Commerce, 91st Cong. 38 (1970) (statement of Caspar W. Weinberger, Chairman, FTC). Again, the toxicity of the substance in the amount accessible drives the analysis.

^{8/} "Part 295 -- Regulations Under the Poison Prevention Packaging Act," 36 Fed. Reg. 22151, 22152 (Nov. 20, 1971).

^{9/} "Modification of the Testing Procedure for Special Packaging," 38 Fed. Reg. 12738, 12738 - 12739 (May 15, 1973).

^{10/} Letter to Stephen Lemberg, Assistant General Counsel, CPSC, from Peter G. Mayberry, Executive Director, HCPC, at 2 (May 5, 2003).

Office of the Secretary
August 15, 2003
Page 5

C.F.R. § 1700.20 applies solely to unit-dose packaging.^{11/} However, the current test protocol in 16 C.F.R. § 1700.20(a)(2)(ii) does not constitute a zero-tolerance standard. Instead, the test protocol permits the lesser of eight individual units or the number of units that constitute the amount that would cause serious personal injury or illness to a child to trigger the need for special packaging. This is not a zero-tolerance standard. By contrast, for traditional cap-and-vial closures, a test failure is any child who opens the special packaging or gains access to the contents of the package. This is a more stringent standard that does not allow for the flexibility afforded unit dose packaging.^{12/}

As illustrated above, the Commission must consider the toxicity of a substance in determining the need for special packaging and the evaluation of special packaging. Consequently, the Commission must deny the HCPC's petition.

II. Product Toxicity Must Remain A Factor in the CR Test Failure Criteria Because, For Some Products, Less Than Eight Units Are Toxic to Children Under Age 5

The CMA believes that an objective test criteria for unit dose packages which defines a test failure as opening or gaining access to more than 8 individual units may, in fact, not be sufficiently stringent for some substances. Pursuant to HCPC's petition, any products packaged in unit dose packaging would be considered CR if packaged in less than 8 individual units. This result would be untenable, because many products pose a risk of serious injury or illness to small children at much lower amounts than 8 units. For example, as many commenters have pointed out, calcium channel blockers, tricyclic antidepressants, opioids, isoniazid, digoxin, and

^{11/} Id.

^{12/} Comments from Michigan State University support the argument that cap-and-vial closures are actually subject to a stricter standard than that currently imposed on unit dose packaging. "When a cap closure system is breached, it is considered an automatic failure under the current test protocol. CPSC has actually given the manufacturers of unit dose [packaging] a second chance at passing once a breach has occurred by allowing for the fact that a toxic dose has not been accessed. If the subjectivity of toxicity levels is truly the driving force behind this petition, the HCPC should err on the side of safety and make the failure Level 1, not 8. This will take the subjectivity that is uncomfortable for the manufacturers away and not allow a potentially toxic dose to be considered acceptable under the test protocol, and this would be parity with cap and vial; a single opening is failure." Comments of Laura Bix and Hugh Lockhart, Michigan State University, at 1 (Aug. 7, 2003).

Office of the Secretary
 August 15, 2003
 Page 6

clonidine are all potentially toxic to children in dosage amounts of fewer than 8 units.^{13/} As one pharmaceutical industry official noted, "[t]oday there are more once-a-day products with higher concentrations and higher potencies. So there are a lot of products where accessing just one or two tablets may be a problem."^{14/} In addition, because there is an increasing trend to make previously prescription drugs available over-the-counter ("OTC"), and such drugs can be toxic in smaller amounts, CPSC must be more vigilant, not less. Therefore, if CPSC decides to grant the HCPC petition to amend the regulation, CPSC should consider either lowering the test failure number to less than 8 units or removing the reference to 8 or less units, since it is an arbitrary number.

Consequently, because some drugs are toxic to children in fewer than 8 dosages or units, toxicological analysis of particular products is necessary unless a 1 unit access failure rule is adopted. For some substances, CPSC regulations at 16 C.F.R. § 1700.14 specifically set forth the amount or volume of a particular substance that is toxic and requires special packaging.^{15/}

As pharmaceutical industry officials have acknowledged, the current CPSC CR test protocol has worked effectively for 30 years and has achieved its objective of reducing the number of

- ^{13/} See Comments of ANEC to HCPC Petition (June 24, 2003); Comments of Steven M. Marcus, M.D., Executive Director, New Jersey Poison Information & Education System, to HCPC Petition (July 30, 2003); Comments of Anthony S. Manoguerra, Pharm.D., DABAT, FAACT, Director, San Diego Division, California Poison Control System, to HCPC Petition (July 30, 2003); Comments of Suzanne Doyon, M.D., Medical Director, Maryland Poison Center, to HCPC Petition (July 30, 2003); and Comments of James B. Mowry, Pharm.D., DABAT, FAACT, Director, Indiana Poison Control Center, to HCPC Petition (Aug. 1, 2003).
- ^{14/} "Pharmaceutical Packaging Roundtable: Devising Child-Resistant, Senior-Friendly Packaging," Pharmaceutical and Medical Packaging News, at 62 (June 2001) (statement of Arthur Jaeger, Director of Packaging Development, Merck & Co., Inc.).
- ^{15/} For example, acetaminophen must be packaged in special packaging only when a single package contains more than one gram of acetaminophen, which would equate to two 500 mg acetaminophen tablets. By contrast, a single tablet of aspirin is hazardous, and thus, requires special packaging. 16 C.F.R. §§ 1700.14(a)(1) & (16). Therefore, the alleged burden on drug manufacturers to calculate hazardous amounts is alleviated for some substances by the CPSC's regulations. The HCPC attempts to point to a recent journal article from a CPSC staff member analyzing the effectiveness of CR packaging for aspirin as one factor supporting the timeliness of its petition, however, the author's conclusions are incorrectly stated by HCPC. See HCPC Petition, at 2 (Mar. 17, 2003). The author concludes that "additional strategies designed to prevent unintentional drug poisonings need to be developed and evaluated," however, the use of unit dose packaging is not suggested as one such strategy. Gregory B. Rodgers, Ph.D., "The Effectiveness of Child-Resistant Packaging for Aspirin," Arch. Pediatr. Adolesc. Med., 2002; 156: 929, 932. Instead, the CPSC staffer points to CPSC efforts to increase consumer acceptance of CR packaging as one such strategy. Id.

Office of the Secretary
August 15, 2003
Page 7

pharmaceutical-related deaths to one or two per year.^{16/} Therefore, for public health reasons, the CPSC should not amend the CR test failure protocol for unit dose packaging as requested by HCPC.

III. Unit Dose Packaging is Not Inherently Safer Than Cap-and-Vial Closures

The HCPC petition is replete with unsubstantiated assertions that unit dose packaging is inherently safer than traditional cap-and-vial closures in preventing accidental ingestions to children. HCPC references only unvalidated CPSC incident data, and provides no evidence of the source of any other data, the sample size, statistical significance or other information to allow CPSC to determine if the analysis is reliable or merely junk science. HCPC acknowledged that the CPSC data it relied upon in its petition are not comprehensive.^{17/}

Additionally, the data relied upon by HCPC reveals that the number of incidents occurring with unit dose packaging were actually higher in recent years than cap-and-vial closures. For example, the chart on page 4 of HCPC's petition, summarizing data from November 2000 to January 2003, states that with unit dose packaging, no more than five drug units were ingested at one time, compared to a maximum of 33 units ingested at one time from products packaged with cap-and-vial closures.^{18/} What the chart also shows, however, is that during that time, there were only 15 incidents involving cap-and-vial closures, compared to 31 incidents involving unit dose packaging. As one commenter also pointed out, this table only analyzes incidents in which more than 10 dosage units were ingested. There is no corresponding reference to or mention of incidents in which less than 10 units were ingested and no indication of the seriousness of these ingestions.^{19/} Therefore, the total number of children exposed to toxic pharmaceuticals from

^{16/} "Pharmaceutical Packaging Roundtable: Devising Child-Resistant, Senior-Friendly Packaging," Pharmaceutical and Medical Packaging News, at 62 (June 2001) (statement of John Bitner, Manager of Package Design and Development, Pharmacia Corp.). The HCPC also argues that because the Second Circuit recently struck down an FDA rule requiring unit dose packaging for all dietary supplements containing 30 milligrams or more of iron per dosage unit, the CPSC must act to amend the test failure criteria for unit dose packaging. See HCPC Petition at 11. However, this argument misses the mark. The Second Circuit struck down the FDA's rulemaking on the basis that the CPSC, not the FDA, has the authority to prescribe poison prevention packaging, concluding that the FDA had exceeded its statutory authority in prescribing packaging type. See Nutritional Health Alliance v. FDA, 318 F.3d 92 (2d Cir. 2003). Thus, the Court did not address the legitimacy of mandating special packaging for iron-containing dietary supplements. As discussed above, under the PPPA, the need for special packaging for such products can and should be addressed by the CPSC.

^{17/} HCPC Petition to CPSC, at 4 (Mar. 17, 2003).

^{18/} See Comments of James B. Mowry, Pharm.D., DABAT, FAACT, Director, Indiana Poison Center (Aug. 1, 2003).

^{19/} Id.

Office of the Secretary
August 15, 2003
Page 8

accidental ingestions involving unit dose packaging is actually higher than the number of such incidents with cap-and-vial closures.

Moreover, the actual percentage of incidents involving unit dose packaging is much higher than the number involving cap and vial closures in view of the much larger number of cap-and-vial systems sold in the United States.^{20/} As other comments submitted to this petition have noted, HCPC's presentation of its analysis of the data should be "normalized to reflect the prevalence of cap-and-vial systems in order to compare performance fairly."^{21/} Therefore, HCPC's claims that unit dose packaging is inherently safer than cap-and-vial closures is unsupported by HCPC's and market data. If CPSC were to make the requirements for unit dose packaging less stringent by removing the need for a toxicological analysis, not only would the number of incidents likely increase, but the number of serious injuries or death of children would likely increase as well.

IV. The PPPA Does Not Authorize the Consideration of Competitive Factors

The PPPA does not authorize the consideration of competitive factors associated with its standards. Nonetheless, the HCPC argues that the current CR test protocol sets forth a standard for blister packaging that requires a drug product manufacturer to conduct a toxicological analysis of its product to use unit dose packaging and to submit these data to CPSC.^{22/} According to HCPC's unsubstantiated assertions, this creates a disincentive for pharmaceutical manufacturers and packagers to use unit dose packaging, and economically disadvantages unit dose packaging manufacturers compared to cap-and-vial manufacturers.^{23/} HCPC contends that these testing and data submission steps require "considerable investments of time and money [that] cannot be recovered."^{24/}

^{20/} Blister packages are estimated to occupy less than 20% market share. "Pill Blisterpacks Face New BSI Test Regime," Packaging Magazine, at 8 (Jan. 24, 2002).

^{21/} Comments of Laura Bix and Hugh Lockhart, Michigan State University, to HCPC Petition, at 1 (Aug. 7, 2003).

^{22/} The HCPC also improperly contends that under CPSC's regulations, a manufacturer that uses unit dose packaging must submit to CPSC toxicological data to support its conclusions regarding the number of units that would cause serious injury or illness and must wait for CPSC's confirmation of the manufacturer's conclusions, and following CPSC review and confirmation of a manufacturer's toxicological data, test the package again. Id. at 6.

^{23/} HCPC Petition to CPSC, at 5 (Mar. 17, 2003).

^{24/} Id.

Office of the Secretary
August 15, 2003
Page 9

However, HCPC misunderstands the CPSC's regulations in this regard. Manufacturers are requested, not required to submit their toxicological data to CPSC.^{25/} Manufacturers are permitted to market products without submission of such data, and to CMA's knowledge, there has never been an enforcement or other action based on failure to provide such data. The CPSC recently confirmed that the submission of such toxicological data is not required. "The current CPSC regulation does not require a company to test, or preclude a company from relying on test data generated by the package manufacturer or from testing of similar packaging."^{26/} Thus, product manufacturers and marketers are not required to follow the steps outlined by HCPC above with respect to the submission and review of toxicological data.

Notwithstanding the CPSC rules, product manufacturers and marketers may choose to test products anyway, because, as some product manufacturers have noted, the ultimate responsibility for ensuring package performance lies with the drug product manufacturer. Therefore, even if the package manufacturer has conducted testing, many manufacturers will still conduct their own testing. "When a vendor comes to us with a child-resistant package that's passed with a given tablet, test protocol, and regimen, we still have to test it."^{27/} Product manufacturers will still likely test product packaging rather than rely on vendor test results, regardless of the type of packaging, unit dose or cap-and-vial closures. Any such testing is voluntary, however, and is certainly not mandated by CPSC regulations as HCPC erroneously claims.

In addition, even if unit dose packaging manufacturers were economically disadvantaged, the PPPA does not require, and the CPSC is not authorized to consider, market competition factors in its rulemaking. Moreover, even if the CPSC were authorized to consider competition factors, it would likely conclude that manufacturers of cap-and-vial closures, which must meet a more stringent pass/fail product standard than unit dose package manufacturers, represent the industry segment that is economically disadvantaged. To be a truly level playing field, the test failure criteria for unit dose packaging would be the same as the criteria for cap-and-vial closures, *i.e.*, one child who opens or gains access to the contents of one package would constitute a test failure. Rather, it is not the pass/fail standard, as HCPC alleges, but other economic aspects of using unit dose packaging that drive up the cost of the product (*e.g.*, cost of materials, application, etc.). Nonetheless, CPSC does not have the statutory authority to sacrifice child

^{25/} "Manufacturers or packagers intending to use unit dose packaging for a substance requiring special packaging are *requested* to submit such toxicological data to the Commission's Office of Compliance." 16 C.F.R. § 1700.20(a)(2)(ii) (*emphasis added*).

^{26/} Letter to Peter G. Mayberry, Executive Director, HCPC, from Stephen Lemberg, Assistant General Counsel, CPSC, at 3 (Apr. 25, 2003).

^{27/} "Pharmaceutical Packaging Roundtable: Devising Child-Resistant, Senior-Friendly Packaging," Pharmaceutical and Medical Packaging News, at 63 (June 2001) (statement of John Bitner, Manager of Package Design and Development, Pharmacia Corp.).

Office of the Secretary
August 15, 2003
Page 10

safety by lowering the pass/fail standard to mitigate the additional costs arising from the use of unit dose packaging.

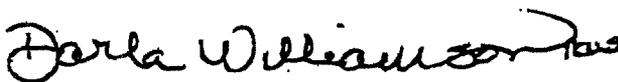
Finally, at the time that the PPPA was passed, some interested parties contemplated that the law would foster competition in the marketplace, and such competition was regarded as a positive effect of the legislation. In fact, in congressional hearings on this issue, the Federal Trade Commission expressed hope that the enactment of the PPPA would "promote competition among manufacturers to develop and promote the safest possible containers for household substances."^{28/} As predicted by FTC, there have been considerable advances in both cap-and-vial and unit dose packaging. Rather than focusing on perceived competitive disadvantages, unit dose package manufacturers should be motivated by competitive forces to continue to develop innovative technologies. For the foregoing reasons, the HCPC's claim that unit dose packaging manufacturers are competitively disadvantaged by the CPSC's test failure criteria misses the mark, and cannot be considered by CPSC as a basis to amend the current CR test failure protocol as HCPC has requested.

V. Conclusion

The CPSC does not have the statutory authority under the PPPA to amend the CR test protocol as requested by HCPC because, as discussed above, under the PPPA, the toxicity of a particular substance cannot be disregarded in determining the need for special packaging. Further, the HCPC's other arguments in support of its petition are without merit. Therefore, the petition should be denied.

The CMA appreciates the opportunity to comment on these issues. Please contact me if you have any questions or comments regarding these issues.

Sincerely,



Darla J. Williamson

c: Kathleen M. Sanzo, Esq.
Morgan, Lewis & Bockius, LLP

^{28/} Child-Resistant Packaging of Household Substances: Hearing on H.R. 6179, H.R. 6180, H.R. 16541, H.R. 16884, and S. 2162 Before the Subcomm. on Commerce and Finance of the House Comm. on Interstate and Foreign Commerce, 91st Cong. 38 (1970) (Memorandum to Accompany Report by the Department of HEW on S. 2162).

Morgan, Lewis & Bockius LLP
1111 Pennsylvania Avenue NW
Washington, D.C. 20004
TEL: 202.739.3000
FAX: 202.739.3001
www.morganlewis.com

Morgan Lewis
COUNSELORS AT LAW

SEND TO

Name: **Dockets Management** Firm: **FDA**
FAX #: **301-827-6870** Telephone #: **301-827-6860**

FROM

Name: **Kendra A. Martello** Floor: **11**
Operator Sending: Telephone #: **202-739-5809**
FAX #: **202-739-3001** Date Sent: **10/22/2003** Number of Pages: **13**
(including cover page)

FAX MESSAGE

THE INFORMATION CONTAINED IN THIS FAX MESSAGE IS INTENDED ONLY FOR THE PERSONAL AND CONFIDENTIAL USE OF THE RECIPIENTS NAMED HERE. THIS MESSAGE MAY BE AN ATTORNEY-CLIENT COMMUNICATION AND AS SUCH IS PRIVILEGED AND CONFIDENTIAL. IF THE READER OF THIS MESSAGE IS NOT THE INTENDED RECIPIENT OR AN AGENT RESPONSIBLE FOR DELIVERING IT TO THE INTENDED RECIPIENT, YOU ARE HEREBY NOTIFIED THAT YOU HAVE RECEIVED THIS DOCUMENT IN ERROR AND THAT ANY REVIEW, DISSEMINATION, DISTRIBUTION, OR COPYING OF THIS MESSAGE IS STRICTLY PROHIBITED. IF YOU HAVE RECEIVED THIS COMMUNICATION IN ERROR, PLEASE NOTIFY US IMMEDIATELY BY TELEPHONE, AND RETURN THE ORIGINAL MESSAGE TO US BY MAIL, THANK YOU.

COMMENTS