CHPA

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

CITIZEN PETITION

Dear Sir/Madam:

The undersigned submits this petition to request the Commissioner of Food and Drugs to issue a statement of enforcement policy that expressly permits manufacturers of acetaminophen over-the-counter ("OTC") drugs to label their products with dosage information for children aged six months to two years.

I. Action Requested

The Consumer Healthcare Products Association ("CHPA"), author of this petition, requests that the Food and Drug Administration ("FDA") publish a statement of enforcement policy expressly permitting manufacturers of single-ingredient acetaminophen OTC drugs subject to the ongoing internal analgesic, antipyretic, and antirheumatic monograph proceedings to include labeling on products that provides instructions for use in children aged six months to two years. CHPA requests that this statement of policy recommend use of a single, standardized dosing chart, as provided below in section II.D.

II. Statement of Grounds

A. Introduction

Use of OTC acetaminophen products is widely recognized as safe and effective when used as directed for children aged six months to two years. Parents can get dosing information for this age group from many sources—on web sites, in physicians' offices, and from respected associations of healthcare providers. But this information does not appear in the most important place of all—on the products' labels. Lack of dosing information on product labels may lead to medication errors and adverse events.

Consumer Healthcare Products Association
900 19th Street, NW, Suite 700
Washington, DC 20006
T 202.429.9260 F 202.223.6835
www.chpa-info.org • OTCsafety.org

More than fifteen years ago, an FDA advisory committee recommended that acetaminophen-containing OTC products for children be labeled for children under two years of age. Two years ago, another advisory committee recommended unanimously that OTC acetaminophen products should be labeled for ages six months to two years. CHPA believes that the agency should issue a simple statement of enforcement discretion, permitting manufacturers of such products to include this important dosing information, which is widely recognized as helpful for parents and caregivers in caring for their children. Once pediatric dosing information is permitted via the FDA OTC monograph rulemaking process, enforcement discretion no longer will be needed.

CHPA is the not-for-profit association representing the makers of OTC medicines and nutritional supplements and the consumers who rely on these healthcare products. CHPA is one of the oldest trade associations in the United States. It has more than 80 active members that manufacture or market OTC medicines and dietary supplements, as well more than 130 associate members that provide goods and services to the active members. CHPA is committed to promoting the increasingly vital role of OTC medicines and dietary supplements in America's healthcare system through science, education, and advocacy.

The goal of this Citizen Petition is to ensure that parents and caregivers administering medicine to their infants and young children can rely on an accurate and convenient source of dosing information. Children are given OTC acetaminophen more frequently than any other active ingredient, yet the labels of acetaminophen products lack specific dosing instructions for a key segment of this population: children aged six months to two years. Since the tentative final monograph for internal analgesic drugs was published in 1988, numerous studies have demonstrated the safety and efficacy of properly dosed acetaminophen in populations under two years of age, and an FDA-convened advisory committee has unanimously recommended the addition of dosing instructions for children aged six months to two years. Even in advance of issuing a final monograph covering these products, FDA has discretion to allow manufacturers to label OTC acetaminophen products in accordance with the advisory committee's recommendations. In light of these strong scientific and policy considerations, FDA should expressly permit—and encourage—dosing information on single-ingredient acetaminophen products for children aged six months to two years.

B. Use of Acetaminophen in Children

Acetaminophen, an antipyretic and analgesic, is the most commonly used active ingredient taken by children. In a 2005-2006 telephone survey conducted by the Slone Epidemiology Center at Boston University, 12% of children up to the age of 11 years had taken

acetaminophen in the previous week. The peak of acetaminophen use was among children six to 23 months of age.[1]

Acetaminophen has been available as an OTC medicine for more than 50 years, and its use as a first-line treatment of febrile children is endorsed by leading medical associations in the U.S. and other countries. The American Academy of Pediatrics ("AAP") published in March 2011 a clinical report which summarizes recommendations related to the use of antipyretics in children. In this report, AAP's Section on Clinical Pharmacology and Therapeutics and the Committee on Drugs concludes that acetaminophen doses of 10 to 15 mg/kg given every four to six hours orally was generally regarded as safe and effective. On the basis of a review of recent efficacy studies, the report further stated that approximately 80% of children experience a decreased body temperature within 30 to 60 minutes after acetaminophen administration.[2] The AAP and American Pain Society also endorse the use of acetaminophen for treating acute pain associated with conditions including pharyngitis, headache, and the common ailment of otitis media.[3]

Other leading medical associations endorse the use of acetaminophen for infants and young children:

- The American Academy of Family Physicians ("AAFP") recommends acetaminophen for treatment of fever in infants and children. On its website for consumers, FamilyDoctor.org, the American Academy of Family Physicians instructs parents to follow the label instructions or ask their doctor about the correct dosage for their child, which depends on the child's weight and age.[4]

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[1] Vernacchio L, Kelly JP, Kaufman DW, Mitchell AA. Medication Use Among Children <12 Years of Age in the United States: Results From the Slone Survey. Pediatrics. 2009; 124:446-454.

[2] Sullivan JE, Farrar HC, and the Section on Clinical Pharmacology and Therapeutics, and Committee on Drugs (American Academy of Pediatrics). Clinical Report—Fever and Antipyretic Use in Children. Pediatrics. 2011; 127:580-587.

[3] AAP & APS American Academy of Pediatrics and American Pain Society. The assessment and management of acute pain in infants, children, and adolescents. Pediatrics. 2001; 108:793-797.

[4] FamilyDoctor.org, Fever in Infants and Children | Treatment (Sept. 2010), http://familydoctor.org/familydoctor/en/diseases-conditions/fever-in-infants-and-children/treatment.html.

- The Canadian Pediatric Society recommends acetaminophen as a first-line treatment for managing fever and mild to moderate pain.[5]

- In the United Kingdom, the National Institute for Health and Clinical Excellence published a guideline in 2007 on the assessment and initial management of feverish illness in children younger than five years of age. The guideline concluded that both acetaminophen and ibuprofen are recommended for use in febrile children who appear distressed and unwell.[6]

In addition to supporting the use of acetaminophen for managing pain and fever in young children, many leading medical and healthcare professional associations support labeling that provides dosing information for children less than two years of age:

- AAP has stated that "[c]hild safety will be further enhanced by clear labeling and the development of simplified dosing methods, standardized drug concentrations, and standardized dosing devices."[7] In addition, Dr. Daniel Frattarelli, Chair of the AAP Committee on Drugs, testified at a 2011 advisory committee hearing that "pediatric labeling should be included for all children ages 6 months through 12 years."[8]

- The AAFP stated in a May 2007 submission to a monograph rulemaking that it "urges that FDA expand OTC labeling of pediatric acetaminophen products to include dosing for children less than 2 years of age. AAFP believes that providing care givers with complete dosing information will decrease the cases of

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[5] McCullough HN; Canadian Paediatric Society, Drug Therapy and Hazardous Substances Committee, Acetaminophen and ibuprofen in the management of fever and mild to moderate pain in children. Paediatric Child Health 1998;3(4):273-4; *see also* CPS / Canadian Pediatric Society. Caring for Kids, When Your Child is Sick. Fever and Temperature Taking, http://www.caringforkids.cps.ca/whensick/Fever.htm.

[6] NICE / National Institute for Health and Clinical Excellence. National Collaborating Centre for Women's and Children's Health. Feverish Illness in Children: Assessment and Initial Management in Children Younger Than 5 Years. London (UK): May 2007.

[7] Sullivan JE, Farrar HC, and the Section on Clinical Pharmacology and Therapeutics, and Committee on Drugs. American Academy of Pediatrics. Clinical Report – Fever and antipyretic use in children. Pediatrics 2011;127:580-587.

[8] Transcript of May 17, 2011 Joint Meeting of the Nonprescription Drugs Advisory Committee and the Pediatric Advisory Committee, at 357, http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/NonprescriptionDrugsAdvisoryCommittee/UCM264148.pdf.

misadministration and potentially decrease situations of overdose in young children."[9]

- In a presentation during the 2002 FDA Nonprescription Drugs Advisory Committee ("NDAC") meeting, the American Pharmacists Association encouraged "FDA to recognize the industry's efforts in this area and to further advance their efforts by allowing important dosing information for patients under the age of two to be added to the product label. The inclusion of this dosing information may prevent overdoses caused by inaccurate dose estimates."[10]

- The American Association of Poison Control Centers stated during a 1997 NDAC meeting that "[d]osing instructions on the label of OTC products could provide parents and caretakers with a readily available reference to help remind them of the proper dose to administer. Without these important data on the label, dosing instructions would be neither standardized nor controlled."[11]

C. Regulatory Background

1. The OTC Monograph Process

This petition concerns the labeling of acetaminophen products subject to the OTC monograph process. The OTC monograph system is the primary method through which OTC drugs come to market in the United States. The system has its origins in the 1962 amendments to the FDCA, which required, for the first time, that FDA determine whether drugs were effective for their intended uses.[12] Under amended section 201(p) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), all drug products were considered "new drugs"—required to be the

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[9] Comments of American Academy of Family Physicians, FDA Docket No. 1977N-0094L (May 22, 2007), *available at* http://www.fda.gov/ohrms/dockets/dockets/77n0094l/77n-0094L-c000002-vol1.pdf.

[10] Transcript of September 19, 2002 Meeting of Nonprescription Drugs Advisory Committee, at 192-93, *available at* http://www.fda.gov/ohrms/dockets/ac/02/transcripts/3882T1.pdf.

[11] Transcript of September 18, 1997 Meeting of Nonprescription Drugs Advisory Committee, at 158, *available at* http://www.fda.gov/ohrms/dockets/ac/97/transcpt/3324t1.pdf.

[12] Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780 (1962).

subject of a New Drug Application ("NDA")—unless they were considered generally recognized as safe and effective ("GRAS/GRAE") or met the criteria of one of two grandfather clauses.[13]

After the 1962 amendments, FDA began the process of taking products off the market that it considered to be unapproved new drugs. By 1972, however, FDA concluded that it would be unrealistic to apply the 1962 amendments' efficacy standard to OTC drugs on a case-by-case basis because there were between 100,000 and 500,000 OTC drug products on the market.[14] Thus, on May 11, 1972 FDA adopted the monograph process for determining whether particular OTC products not covered by NDAs are safe products, not ineffective, and not misbranded.[15]

FDA's procedures for its monograph process are now codified in 21 C.F.R. Part 330. This process begins by convening an advisory panel for each therapeutic class to review data relating to claims and active ingredients. These panel reports are then published in the Federal Register.[16] After review of the proposal, comments, and any new information submitted, FDA publishes tentative final monographs ("TFMs") that set forth FDA's proposals for the allowable claims, labeling, dosages, and active ingredients for OTC drugs in the class.[17] The final step is the publication of a final monograph for each class.[18] Drugs marketed in accordance with a final monograph are considered to be GRAS/GRAE and do not require FDA approval of a marketing application.[19]

Many OTC drugs, including internal analgesics and antipyretics, are marketed under TFMs that have not yet been finalized. As described above, the TFM is the penultimate step in finalization of a monograph, representing FDA's proposal for the conditions under which an OTC product will be considered GRAS/GRAE and not misbranded. As a result, TFMs, like the internal analgesic, antipyretic, and antirheumatic ("IAAA") TFM, serve as guidance for

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[13] § 102(a)(2), 76 Stat. at 781; § 107(c), 76 Stat. at 788. Section 201(p) also defined a new drug to be a drug that was considered GRAS/GRAE but was not in use for a "material extent or for a material time under such conditions." 21 U.S.C. § 321(p)(2).

[14] 37 Fed. Reg. 85, 85 (Jan. 5, 1972).

[15] 37 Fed. Reg. 9464, 9473 (May 11, 1972).

[16] 21 C.F.R. § 330.10(a)(1)-(6).

[17] *Id.* § 330.10(a)(7).

[18] *Id.* § 330.10(a)(9).

[19] 21 C.F.R. §§ 330.1, 330.10(a)(9); *see also* FDA, Compliance Policy Guide § 440.110 app. (2011).

industry as to the conditions FDA currently believes are necessary for a drug product to be considered GRAS/GRAE.[20]

Although FDA has a general policy of not enforcing the Act's new drug provisions against products covered by ongoing monograph proceedings,[21] FDA will take action when it deems such products to present a health risk.[22] In light of this framework, the OTC industry generally labels products subject to a TFM in substantial conformance with conditions proposed in the TFM. Although manufacturers occasionally may deviate from the proposed labeling conditions of a TFM, they generally do not do so unless they receive an affirmative indication from FDA that it does not object. The purpose of this petition is to obtain FDA's express agreement that a single-ingredient OTC acetaminophen drug covered by the pending IAAA monograph proceeding may be labeled with dosing information for children aged six months to two years.

2. Relevant Regulatory History

The rulemaking process for the IAAA monograph is ongoing. At several points during this process, however, FDA has addressed the merits of labeling on OTC acetaminophen products for children under two years of age, with FDA-convened advisory committees twice recommending that dosing information be added for this population.

On July 8, 1977, FDA published an advanced notice of proposed rulemaking ("ANPR") entitled, "Internal Analgesic, Antipyretic, and Antirheumatic (IAAA) Products for Over-the-Counter Human Use."[23] The ANPR presented the recommendations of the Panel on the acceptability of acetaminophen in OTC drug products. The Panel classified acetaminophen as a Category I (GRAS/GRAE) analgesic and a Category I antipyretic when used under specified conditions.[24] The recommended pediatric dosage schedule included six pediatric age subgroups: under two years (consult a physician), two to under four years, four to under six years, six to

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[20] *See* 21 C.F.R. § 10.85(d)(1), (e), (f) (explaining that a "statement of policy" made in "any portion of a Federal Register notice other than the text of a proposed or final regulation" is considered an "advisory opinion" that is "the formal position of FDA on a matter" that except in instances of "immediate and significant danger to health" obligates the agency "to follow it until it is amended or revoked").

[21] FDA, Compliance Policy Guide § 440.110 app. (2011).

[22] FDA, Compliance Policy Guide § 450.200 (1995).

[23] 42 Fed. Reg. 35,346 (July 8, 1977).

[24] *Id.* at 35,489-92.

under nine years, nine to under 11 years, and 11 to under 12 years.[25] Children aged 12 and over were included in the adult age group.

On June 20, 1988, FDA published a Notice of Intent requesting comments on pediatric dosing of all OTC drug products.[26] In this publication, FDA sought input on standardizing the approach to pediatric dosing and labeling because the Advisory Review Panels for the various therapeutic categories had used different approaches in recommending pediatric dosing. Later that year, on November 16, 1988, FDA published a TFM for IAAA Drug Products for Over-the-Counter Human Use.[27] The TFM proposed inclusion of acetaminophen as a Category I analgesic and antipyretic active ingredient, with labeling and directions for use based on the Panel's recommendations and comments on the ANPR.[28] FDA agreed with the Panel's recommendation to base pediatric dosing on age rather than weight, but the agency noted that it had invited industry to submit data on pediatric dosing and would consider the issue in future Federal Register publications.[29]

Since publishing the TFM, FDA has held five advisory committee hearings that addressed pediatric labeling of acetaminophen in some respect. Two of these hearings specifically addressed the merits of labeling for children under two years of age, with advisory committees recommending in both cases that such labeling be added.

On September 18, 1997, the NDAC discussed dosing and labeling of OTC pediatric analgesic/antipyretic drugs. The Committee recommended labeling products with dosages for infants two months of age and older, with some members advocating for a warning that any child under six months of age who has a fever needs to see a doctor.[30] Following this

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[25] *Id.* at 35,490-92.

[26] 53 Fed. Reg. 23,180 (June 20, 1988).

[27] 53 Fed. Reg. 46,204 (Nov. 16, 1988).

[28] *Id.* at 46,255-58.

[29] *Id.* at 46,235.

[30] Transcript of September 18, 1997 Meeting of the Nonprescription Drugs Advisory Committee, at 192-205, http://www.fda.gov/ohrms/dockets/ac/97/transcpt/3324t1.pdf. Additional advisory committee meetings addressed other dosing issues relevant to the pediatric population. On January 13, 1995, the NDAC discussed pediatric dosing for OTC drugs generally and concluded that dosing should be labeled by age and weight with a preference for weight-based dosing if the child's weight is known. On September 19, 2002, the same committee was convened by FDA to discuss unintentional acetaminophen overdose. On June 29-30, 2009, the Drug Safety and Risk Management, Nonprescription Drugs, and Anesthetic and Life Support Drugs Advisory Committees held a joint meeting to discuss possible interventions to reduce the occurrence of
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meeting, McNeil Consumer Healthcare submitted a Citizen Petition seeking to amend the IAAA TFM to label OTC acetaminophen products with dosing for children aged two months and older.[31] In April 2010, McNeil amended the petition to seek dosing for children aged six months and older.

More recently, the NDAC and the Pediatric Advisory Committee held a joint meeting on May 17-18, 2011, to discuss whether new dosing information for oral OTC drug products containing acetaminophen should be added to the label for children less than two years of age.[32] Before the committees was an extensive collection of studies regarding the safety and efficacy of acetaminophen in children. These studies are summarized in FDA's briefing package for the committees.[33]

The committees unanimously concluded (21-0) that the pharmacokinetic, safety, and efficacy data supported the addition of new labeled dosing directions corresponding to a 10-

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acetaminophen-related liver injury. The committees recommended by a vote of 36-1 that only one concentration of nonprescription acetaminophen liquid should be available. For a more detailed summary of these meetings, see FDA, Briefing Information for the May 17-18, 2011 Joint Meeting of the Nonprescription Drugs Advisory Committee and the Pediatric Advisory Committee, at 3-5 (2011), http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/NonprescriptionDrugsAdvisoryCommittee/UCM255307.pdf (hereinafter, "FDA Briefing Information").

[31] McNeil Consumer Healthcare, Citizen Petition to Amend the Tentative Final Monograph for Internal Analgesic, Antipyretic and Antirheumatic Drug Products for Over-the-Counter Use -- Expanded Age Groups for OTC Consumer Dosing Instructions Covering Acetaminophen, Docket No. FDA-77-N-0094 (Feb. 1, 1999).

[32] The committees additionally considered whether a weight-based dosing regimen should be added for children aged two to 12 years of age and ways administration by caregivers can be improved to minimize medication errors.

[33] FDA Briefing Information, *supra* note 30.

15 mg/kg dose for children aged six months to two years.[34] The committees also voted 21-0 that the labeling should include an antipyretic claim.[35]

D. FDA Should Publish a Statement of Enforcement Policy Permitting Labeling for Children Aged Six Months to Two Years in Advance of Publishing the Final Monograph

FDA should take immediate action to ensure that the millions of caretakers who use acetaminophen products in young children have access to convenient and accurate dosing information.

The agency need not wait until the final monograph is published to permit manufacturers to use such labeling. As described above, the monograph process is intended to determine the conditions under which drugs subject to the 1962 Drug Efficacy Amendment are considered GRAS/GRAE for OTC use. The process culminates in a final monograph, which specifies the conditions under which FDA will consider an OTC drug to be GRAS/GRAE. The TFM, published one step before the final monograph, represents FDA's proposal for these conditions, and FDA generally allows drugs subject to a pending monograph proceeding to be marketed under the conditions of a TFM. FDA thus has discretion to reevaluate the conditions under which it allows products subject to an ongoing monograph proceeding to be marketed, including, when appropriate, providing for labeling that departs from the labeling proposed in the TFM.[36]

Nearly 25 years have passed since FDA published the IAAA TFM, and the data and weight of scientific opinion weigh firmly in support of use of acetaminophen for children

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[34] FDA, Summary Minutes of the Joint Meeting of the May 17-18, 2011 Nonprescription Drugs Advisory Committee and the Pediatric Advisory Committee, http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/NonprescriptionDrugsAdvisoryCommittee/UCM264147.pdf.

[35] The vote split on the issue of whether to include analgesic claims for this population, with 16 members voting not to include analgesic claims, and five members voting to include such claims. *See id.* Even beyond single-ingredient acetaminophen products, pediatric dosing appears to be an issue of importance for FDA. For example, a proposed rule on pediatric dosing for cough/cold products appeared on the Department of Health and Human Services' 2012 unified regulatory agenda.

[36] Even if the monograph were finalized, FDA would have discretion not to enforce its requirements. *See, e.g.*, *Heckler v. Chaney*, 470 U.S. 821, 837-38 (1985). Additionally, 21 C.F.R. § 201.66(e) provides a process for FDA to exempt products from the requirements of that section pertaining to the content of the Drug Facts section of the label.

aged six months to two years. For the scientific and policy reasons stated below, FDA should expressly permit and encourage manufacturers to include dosing information on product labels for this population.

First, the medical community agrees that acetaminophen is a safe and effective treatment for children aged six months and older, and leading medical associations have recommended its use in these populations. These associations include, for example, the AAP, which endorses the use of acetaminophen in this population and offers a weight-based dosage table on its website, www.healthychildren.org.[37]

Moreover, two FDA-convened advisory committees have recommended that the agency allow labeling for these populations. Most recently, the NDAC and the Pediatric Advisory Committee unanimously concluded (21-0) in a 2011 meeting that the pharmacokinetic, safety, and efficacy data supported the addition of new labeled dosing directions corresponding to a 10-15 mg/kg dose for children aged six months to two years. The committee recommended 21-0 that FDA allow an antipyretic claim for this population.

Second, a key benefit of labeling for children aged six months to two years would be to provide a convenient source of safe and clear directions for caretakers. The peak of acetaminophen usage in children is for those aged six to 23 months, yet the labeling of these products lack instructions for this population. Under the current labeling system, caretakers seek out information from a variety of sources to ascertain the proper dose for a child under two years of age. Dosing instructions—ranging from charts found online to photocopied materials distributed by family physicians—may not be consistent in substance or format, leading to potential confusion regarding the proper dosage. Providing clear, reliable instructions on the label will help ensure that caretakers appropriately dose children under two years of age, potentially reducing the likelihood of medication errors. Notably, for antipyretic/analgesic ibuprofen products that are not subject to the monograph and must be approved through NDAs

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[37] HealthyChildren.org, Acetaminophen (Tylenol, etc.) Dosage Table, http://www.healthychildren.org/English/tips-tools/Symptom-Checker/Pages/Acetaminophen-Dosage-Table.aspx. In addition, Dr. Daniel Frattarelli, Chair of the American Academy of Pediatrics Committee on Drugs, testified at the 2011 advisory committee hearing that "pediatric labeling should be included for all children ages 6 months through 12 years." Transcript of May 17, 2011 Joint Meeting of the Nonprescription Drugs Advisory Committee and the Pediatric Advisory Committee, at 357, http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/NonprescriptionDrugsAdvisoryCommittee/UCM264148.pdf.

or ANDAs, FDA has approved labels with dosing information for children under two years of age.[38]

Third, FDA's decision to permit labeling for children under two years of age can help standardize dosage recommendations provided outside of the product's labeling. Because dosing information is available from a variety of sources, caretakers may find varying recommendations presented in varying formats. Although the medical community generally agrees that the safe and efficacious acetaminophen dose for antipyretic activity is 10-15 mg/kg body weight, an FDA-recommended dosing chart would help ensure consistency in substance and format.

To this end, CHPA recommends that the FDA encourage use of the following dosage chart:

Dosing Chart (for products containing acetaminophen at 160 mg/5mL)[39]

Weight (lbs.)	Age (mos.)	Dose (mL)
	Under 6 mos.	Ask a doctor
12-17 lbs.	6-11 mos.	2.5 mL
18-23 lbs.	12-23 mos.	3.75 mL

Recommending use of this chart will encourage physicians' offices, hospitals, medical associations, and others to use a single, standardized chart.

III. Conclusion

For the foregoing reasons, FDA should publish a statement of enforcement policy expressly permitting manufacturers of single-ingredient acetaminophen over-the-counter drugs subject to the ongoing IAAA monograph proceedings to include labeling on products that

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[38] *See, e.g.*, Motrin Concentrated Drops Label (Jan. 16, 2002), http://www.accessdata.fda.gov/drugsatfda_docs/label/2002/20603s5lbl.pdf.

[39] As of 2011, industry has voluntarily standardized single-ingredient liquid acetaminophen products to a concentration of 160 mg/5 mL, further simplifying potential labeling for children under two years of age.

provides instructions for use in children aged six months to two years. CHPA requests that this statement of policy recommend use of a single, standardized dosing chart, as provided above in section II.D.

IV. Environmental Impact

This petition is categorically exempt from the requirement for an environmental assessment or an environmental impact statement pursuant to 21 C.F.R. §§ 25.30(h), (k) and 25.31(a).

V. Economic Impact

Information on the economic impact of the petition will be provided upon request.

VI. Certification

The undersigned, on behalf of CHPA, certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioners which are unfavorable to the petition.

Barbara A. Kochanowski

Barbara A. Kochanowski, Ph.D.
Vice President, Regulatory & Scientific Affairs
Consume Healthcare Products Association
900 19th St, NW, Suite 700
Washington, D.C. 20009
202-429-9260