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U.S. CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MD 20814

Cheryl A. Falvey
General Counsel

Office of the General Counsel

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November 5, 2008

Mr. David T. Caroll RDH, BSM
President
Preventive Dental Specialties
2115 Edgewood Drive
Schofield, Wisconsin 54476

Dear Mr. Caroll:

I am writing in response to your request for a formal advisory opinion with regard to your toothbrushes and other patented early intervention medical devices for the prevention of dental caries. You have informed us that these products are medical devices within the meaning of the FDA regulations and asked whether these products are subject to the certification and testing requirements under the CPSIA.

The Consumer Product Safety Improvement Act (the "Act" or "CPSIA") requires third-party testing of "children's products" as that term is defined by the Act. Children's product means a consumer product designed or intended primarily for children 12 years of age or younger. Your toothbrushes and other patented early intervention dental products are designed or intended primarily for children 12 years of age or younger. However, because these products are not "consumer products," they do not fall within the definition of children's products that require third-party testing. The term "consumer products" (defined at 15 U.S.C. § 2052(a)) excludes "drugs, devices, or cosmetics (as such terms are defined in section 201 (g), (h), and (i) of the federal Food, Drug and Cosmetic Act)." Products that are medical devices do not fall within the definition of "consumer product" and, therefore, the definition of "children's product" does not include medical devices.

Likewise, certain new standards in the CPSIA would not apply to *your products* by definition. The new limits on lead in the CPSIA apply only to "children's products" and, as stated above, *your products* do not fall within that definition. Likewise, the new limits on phthalates in the Act apply only to "children's toys" and "child care articles" and both of those terms are defined to include only "consumer products" as defined by 15 U.S.C. 2052(a). For this reason, your products do not fall within the scope of the phthalates provision by definition.

ADVISORY OPINION

66 Closed 11/10/08 TRS

I hope this letter proves helpful in providing you with an understanding of the products covered under the CPSIA. I am providing you with this advisory opinion as permitted under our regulations at 16 C.F.R. § 1000.7 based upon the factual information you have provided as summarized above. The views expressed in this letter are those of the General Counsel and have not been reviewed or approved by the Commission. They are based on the best available information at the time they were written. They may be superseded at any time by the Commission or by operation of law.

Sincerely,

Cheryl A. Falvey

Falvey, Cheryl

From: Prevdentsp@aol.com
Sent: Tuesday, October 28, 2008 3:32 PM
To: Falvey, Cheryl
Cc: gene@teamtechinc.net; bradedlefsen@prevdentsp.com
Subject: CPSIA HR4040 from Preventive Dental General Mills

Dear Cheryl:
I left a brief message on your voice mail in regards to the consumer products safety commissions new HR 4040 rules. As promised I am following up with an email. My question relates to toothbrushes for children. We have recently licensed our products under the Cheerios brand and are very close to launching the products, and the General Mills team brought this to my attention. Our products are meant to be used in the mouth and we manufacture in the United States buying raw goods from Dupont. All of our materials do have MSDS sheets and do not contain lead or any other dangerous material. Do our products fall under this rule for bar coding lot codes and all the other testing required by HR 4040. I would appreciate a email addressing my questions so we can finish this project and bring our products to market.

Thank You,
In Dental health,
David T. Carroll RDH, BSM
President
Preventive Dental specialties
1 800 352 9669

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