



Resp *Archvie*
cc: Sopko
Kyle C
Joann Royce
P Jung

February 8, 2008

The Honorable John D. Dingell
Chairman
Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, D.C. 20515

VIA FEDERAL EXPRESS

The Honorable Bart Stupak
Chairman
Subcommittee on Oversight and Investigations
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, D.C. 20515

VIA FEDERAL EXPRESS

Re: BPA in Infant Formula

Dear Congressman Dingell and Congressman Stupak:

Please accept this response to your letter dated January 17, 2008, regarding the use of the chemical Bisphenol A (BPA) to line cans that contain infant formula manufactured by PBM Products. We are pleased that the Committee shares PBM's goal of providing the safest and most advanced formulas to the best of our ability.

All of PBM's infant formulas and their various packagings are specifically provided to the FDA through a premarket registration system called 'Notification' and 'Verification' wherein we provide detailed information for our infant formulas to the FDA in advance of manufacturing. Part of this information includes certifications from the can suppliers that the cans and components, including chemical liners, comply with each of the requirements of the Food Drug and Cosmetic Act.

The Honorable John D. Dingell
The Honorable Bart Stupak
February 8, 2008
Page Two

Can companies often use proprietary systems in the production of the cans supplied to PBM (and other infant formula manufacturers). As such, approval or assurance of compliance is directly between the FDA and the can company. Like other infant formula manufacturers, PBM does not manufacture its own cans, nor do we have expertise in the can manufacturing processes. We rely upon the FDA standards and the FDA-can company approvals and/or compliance with those standards. PBM uses only FDA approved packaging and provides the FDA with written guarantees from the can companies for the FDA's confirmation of compliance.

We respectfully submit our responses to each of the questions in your letter of January 17th as follows:

1. Does your company use BPA in the lining of metal cans used to hold liquid infant formula? Please provide the specific names of which brands do or do not use BPA in their can lining.

PBM's liquid infant formula is sold in two forms, ready-to-use and liquid concentrate. The ready-to-feed liquid form is sold in a 32 ounce can manufactured and supplied by Silgan Container Manufacturing. The liquid concentrate is sold in a 13 ounce can manufactured by Ball Corporation. Both Silgan and Ball have confirmed that Silgan and Ball use BPA in the epoxy lining of the cans which they supply to PBM.

On March 11, 2005, the 13 oz. concentrate infant formula can supplied by Ball Corporation was filed with the Center for Food Safety and Applied Nutrition of the Food and Drug Administration (the "FDA"). On March 29, 2005, the 32 oz. ready-to-feed can supplied by Silgan Container was filed with the FDA.

PBM included both Silgan's 32 ounce and Ball's 13 ounce cans (which are used by PBM only to contain liquid infant formula forms and not powder forms) as part of PBM's omnibus submission to the FDA of (1) its Infant Formula Notification; new soy-based infant formula supplemented with ARA (Arachidonic acid) and DHA (Docosahexaenoic acid) in powder, concentrate and

The Honorable John D. Dingell
The Honorable Bart Stupak
February 8, 2008
Page Three

ready-to-feed forms, dated September 22, 2005; and (2) its Infant Formula Notification; new milk-based infant formula supplemented with ARA (Arachidonic acid) and DHA (Docosahexaenoic acid) in powder, concentrate and ready-to-feed forms, dated February 19, 2005. PBM's powder forms constitute greater than 95% of its infant formula sales. Its liquid forms constitute less than 5% of its sales.

Each of the above referenced filings with the FDA included a Letter of Regulatory Compliance and guarantee from the manufacturer of each of the respective cans, certifying that the materials utilized in the interior lining meet all of the FDA's requirements for direct food contact.

PBM's liquid concentrate infant formula and ready-to-feed infant formula are currently distributed in the United States under the Parent's Choice brand, exclusively distributed by Wal-Mart. PBM's liquid infant formula products are not distributed under any other brands in the United States.

2. Have you ever tested your infant formula for BPA?

Yes. PBM has tested its powder infant formula for BPA. The powder infant formula was tested through an independent testing laboratory, Bodycote Testing Group.

3. If you did test your infant formula for BPA, what was the specific methodology used (e.g., gas chromatography-mass spectrometry, liquid chromatography-mass spectrometry, high performance liquid chromatography, or enzyme-linked immunosorbent assay, etc.) and what was the detection limit for the assay used?

The methodology used for the test by Bodycote of the powder infant formula was gas chromatography-mass spectrometry. The detection limit of the assay was 0.02%.

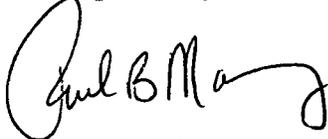
4. If you tested your infant formula for BPA, what were the specific results for each test given the methodology used?

The Honorable John D. Dingell
The Honorable Bart Stupak
February 8, 2008
Page Four

The powder infant formula test on December 14, 2007 by Bodycote Group indicated that BPA was not detectable (ND) in the infant formula.

Please be assured that PBM has registered the packaging materials it utilizes for the manufacture of infant formula with the FDA and only uses packaging deemed safe by the FDA. Please advise if you have any questions or comments regarding our responses to your inquiries.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Paul B. Manning". The signature is written in a cursive style with a large initial "P" and a long horizontal stroke extending to the right.

Paul B. Manning
President and CEO
PBM Products, LLC