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November 14, 2013

Walter J. Ellenberg, Ph.D., Designated Federal Official
Pediatric Advisory Committee
Office of the Commissioner, Office of Pediatric Therapeutics
Food and Drug Administration
10903 New Hampshire Avenue, WO32, Room 5154
Silver Spring, MD 20993

Re: Request for Notification From Industry Organizations Interested in Participating in Selection Process for Nonvoting Industry Representatives on Public Advisory Committees and Request for Nominations for Nonvoting Industry Representatives on Public Advisory Committees. 77 Fed. Reg. 47853-47854 (August 10, 2012); Docket No. FDA-2012-N-0781

Dear Dr. Ellenberg:

The U.S. Food and Drug Administration (FDA) published a *Federal Register (FR)* notice on August 10, 2012, requesting notification from industry organizations interested in participating in the selection process for nonvoting industry representatives on the FDA Pediatric Advisory Committee (PAC) (77 Fed. Reg. 47853-47854). A reference is also made to a memorandum from Dr. W. J. Ellenberg dated September 4, 2013, regarding the same. The Consumer Healthcare Products Association (CHPA) submits this letter on behalf of the following representatives of the stakeholder selection committee¹ for the FDA PAC (*listed alphabetically*).

- **Marcia D. Howard**, Ph.D., Senior Director, Regulatory & Scientific Affairs, Consumer Healthcare Products Association (CHPA)
- **Mardi K. Mountford**, MPH, Executive Vice President, International Formula Council (IFC)
- **Michelle Rohrer**, Ph.D., Vice President, US Regulatory, Genentech, Inc.
- **Lucy Vereshchagina**, Ph.D., Senior Director, Scientific & Regulatory Affairs, the Pharmaceutical Research and Manufacturers of America (PhRMA)
- **Andrew W. Womack**, Ph.D., Director, Science and Regulatory Affairs, Biotechnology Industry Organization (BIO)

The selection committee has identified the following nominees to serve as the representative and alternate (if needed). The alternate, chosen from the original pool of industry candidates,

¹ Kevin Daryl White, Head, Regulatory Affairs, Americas, Medical Diagnostics, GE Healthcare, participated in the selection process. However attempts to obtain his signature on this nomination letter were unsuccessful.

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was selected in the event the first choice nominee is unable to serve or is recused for a particular advisory committee meeting.

Stakeholder Selection Committee FDA Non-voting Industry Pediatric Advisory Committee (PAC) Nominees

- **Candidate: Samuel D. Maldonado**, M.D., M.P.H., FAAP, Janssen Research and Development

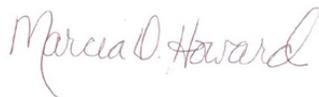
Justification: Dr. Samuel Maldonado is currently the vice president and head of the Pediatric Drug Development Center of Excellence at Janssen/Johnson & Johnson Pharmaceutical Research and Development. He is a pediatric infectious diseases physician by training. Prior to working in the private sector, Dr. Maldonado served as a medical officer in the Division of Anti-Infective Drug Products and subsequently in the Division of Antiviral Drug Products at the U.S. Food and Drug Administration (FDA). In addition to his expertise in pediatric drug development, he also has experience in pediatric pharmacokinetics (PK), and anti-infective, antibacterial, anti-fungal, and antiviral drugs. Dr. Maldonado is well-respected in the field of pediatric research. He previously served as the chair of the Pharmaceutical Research and Manufacturers of America (PhRMA) Pediatric Sub-committee. From 2003-2007, Dr. Maldonado was the industry representative to the FDA Anti-infective Drugs Advisory Committee and FDA Pediatric Advisory Sub-Committee (2003-2004).

- **Alternate:** Ronald J. Portman, M.D., FAAP, FASN, Bristol-Myers Squibb

Justification: Dr. Ronald Portman is the development lead at Bristol-Myers Squibb's Pediatric Center of Excellence. He has medical expertise in pediatrics and pediatric drug development. Previously serving on the FDA Cardiovascular and Renal Drugs Advisory Committee (2003-2007), Dr. Portman is the current chair of the Biotechnology Industry Organization (BIO) Pediatric Committee.

The members of the stakeholder selection committee respectfully submit these candidates to serve as the non-voting industry representative and alternate (as needed) for the FDA Pediatric Advisory Committee. Please don't hesitate to contact us should you have any questions.

Sincerely,



Marcia D. Howard, Ph.D.
Senior Director, Regulatory & Scientific Affairs
Consumer Healthcare Products Association (CHPA)



Mardi K. Mountford, MPH
Executive Vice President
International Formula Council (IFC)



Michelle Rohrer, Ph.D.,
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