



FDA UPDATE

Pediatricians respond to FDA call for input

by **Joshua Sharfstein, M.D., FAAP**

In the July 2009 issue of *AAP News*, I introduced myself and asked for your input regarding Food and Drug Administration (FDA) actions that would benefit children. I have received many thoughtful and informative responses reflecting critical and timely pediatric issues.

Concerns were raised over additives in infant formula, tobacco use in minors and pregnant/lactating mothers, the off-label use of drugs in

the pediatric population and issues with over-the-counter products. Pediatricians also suggested better product labeling and research on childhood obesity (see table).

We have responded to everyone who provided input. For many of the topics, we provided in-depth responses after internal agency discussion. Some of your comments reinforced our commitment to ongoing FDA projects.

Your interest and input is a critical part of understanding how to serve the community better. We routinely solicit input from pediatricians outside the agency. For example, we conducted several focus group sessions with clinicians to better understand their knowledge of and access to FDA pediatric information. A future *AAP News* article will outline some of our surprising findings.

Please continue to share your concerns or recommendations by e-mailing OPT@fda.hhs.gov.

We also invite you to visit our Web site to view new pediatric information on dosing, safety and effectiveness of products recently studied in children. Go to www.fda.gov and click on Pediatrics under Science & Research.



Dr. Sharfstein is the Food and Drug Administration's principal deputy commissioner.

Topic	Input from pediatricians to the FDA
Breastfeeding/infant formula	Concern regarding misleading ads for infant formula compared to breast milk Concern regarding safety and efficacy of new ingredients added to infant formula
Food	Recommendation to require restaurants to provide an allergen-free menu for children Concern about the use of high-fructose corn syrup in foods and beverages
Labeling	Recommendation for additional pediatric safety data in labels
Migraine	Recommendation for research on treatment of migraines in children
Obesity	Concern regarding childhood addiction to pleasurable foods
Over-the-counter (OTC) products	Recommendation for regulations related to supplements, OTC products and homeopathic remedies Concern over labeling of low-dose aspirin products: baby picture on label Recommendation for warnings for nonsteroidal anti-inflammatory drugs when used in hypovolemic children
Pacifiers	Recommendation to label pacifiers for use in children younger than 6 months of age to avoid malocclusions
Pre-market testing	Recommendation for pre-market testing of children's products
Psychotropic drugs	Concern for overuse of psychotropic drugs in children
Tobacco	Concern regarding use of tobacco in pregnant/lactating mothers and minors