Headline: Frestedt Inc. Helps with Pregnancy Warning for NSAIDs

Subheader: Frestedt Inc. Supports New NSAID Labeling

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October 19, 2020 St. Louis Park, MN

The Food and Drug Administration (FDA) recently published a Drug Safety Communication about nonsteroidal anti-inflammatory drugs (NSAIDs). This communication warns: NSAIDs used during the second half (20 weeks or later) of pregnancy may cause "rare but serious" kidney problems in the unborn baby. The FDA reviews this well-known problem and states: "After around 20 weeks of pregnancy, the unborn babies' kidneys produce most of the amniotic fluid, so kidney problems can lead to low levels of this fluid. Amniotic fluid provides a protective cushion and helps the unborn babies' lungs, digestive system, and muscles develop." (https://www.fda.gov/drugs/drug-safety-and-availability/fda-recommends-avoiding-use-nsaids-pregnancy-20-weeks-or-later-because-they-can-result-low-amniotic). NSAIDs such as ibuprofen, diclofenac, naproxen and celecoxib are often used to treat pain and fever.

The FDA is requiring labeling changes to both prescription NSAID labels and over-the-counter (OTC) NSAID Drug Facts Panel labels. These labels must now state NSAID use should be limited between 20-30 weeks of pregnancy due to the risk of fetal kidney problems and low amniotic fluid which may need to be monitored by ultrasound. This change is in addition to past warnings to avoid NSAID use after 30 weeks due to potential fetal heart problems. Also, this warning does not apply to low dose (81mg) aspirin used as directed by a healthcare professional.

Frestedt Incorporated specializes in updates to drug labeling including the pregnancy section of prescription drug labels in accordance with the Pregnancy and Lactation Labeling Rule (PLLR). If your company manufactures NSAID drug products, Frestedt Inc. would be happy to help you navigate and comply with these new label requirements.

About Frestedt Inc.

Frestedt Incorporated (www.frestedt.com) is a consulting service organization founded on February 26, 2008 to provide exquisitely targeted clinical, regulatory and quality system solutions for the pharmaceutical, medical device, biotechnology and food-related industries. We provide expertise to our clients in all stages of product development from bench, preclinical, and clinical trial services to post market research and the integration of new safety, efficacy and performance data into the developing risk management portfolio. We provide design and development leadership to research centers conducting clinical trials and regulatory submissions in order to improve the quality and cost effectiveness of the research service provided. As a result of this broad-based service approach to the industry, our clients have included some of the largest and smallest manufacturers of drugs, devices and foods in the world, as well as academic centers, Clinical Research Organizations, and clinical trial sites.

About Alimentix

Alimentix (www.Alimentix.com) is a comprehensive clinical investigation center (clinical trial site) dedicated to conducting clinical trials for foods, food ingredients, dietary supplements, natural

products, over the counter pharmaceuticals and non-significant risk medical device products. We have conducted trials as diverse as weight loss and OA, for products including calcium derived from Irish seaweed, and meal replacement beverages and we have published and presented our work both privately and within public reviewed settings.

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