

Advisory To Our Customers, Medical Professionals and Medical and Healthcare Facilities

SimplyThick is notifying our customers and medical professionals to follow the FDA's warning that SimplyThick® brand thickener not be used with or given to babies who were born before 37 weeks pending the results of our and the FDA's investigation.

Date: May 20, 2011

SimplyThick is aware of communications from certain neonatal intensive care unit physicians and staff members questioning a potential relationship between the use of Simply Thick with infants born before 37 weeks and late onset necrotizing enterocolitis. Simply Thick is currently conducting our own investigation into those issues in cooperation with the FDA.

For your information, we have attached a copy of the FDA advisory notice.

SimplyThick is notifying our customers and medical professionals to follow the FDA's warning that *SimplyThick® brand thickener not be used with or given to babies who were born before 37 weeks* pending the results of our and the FDA's investigation.

As you are aware, **possible necrotizing enterocolitis is NOT a medical concern in any other population group** (such as children, adults, or older adults) and our warning and the FDA's advisory warning is limited to babies who were born before 37 weeks.

Simply Thick is aware of no other toxicity complaints in regard to any other population group (such as children, adults, or older adults) and again our warning and the FDA's advisory warning is limited to babies who were born before 37 weeks.

The President of Simply Thick, John Holahan, is personally spearheading the company's investigation team and is in close communication with the FDA's investigation team.

Please also be aware that the FDA has not issued a recall notice regarding Simply Thick; it has issued a targeted advisory warning for infants born before 37 weeks.

We hope that this notice does **not** cause any inconvenience to medical professionals or our customers but, as you can understand, Simply Thick wants to proceed with all due caution until the investigations are concluded.

SimplyThick will strive to keep you advised as developments occur. If you would like additional information or have any questions in the meantime, please call 800-205-7115 or email latestinfo@simplythick.com.

Download a copy of the original FDA advisory by [clicking here](#).

