Kingston Pharma, LLC Issues Voluntary Recall of All Lots of DG™ Baby Gripe Water Due to Undissolved Ingredient, Citrus Flavonoid

Kingston Pharma, LLC is voluntarily recalling all lots of “DG™ Baby Gripe Water herbal supplement with organic ginger and fennel extracts” to the consumer level due to the presence of an undissolved ingredient, citrus flavonoid.

Use of the product should not be considered hazardous but could result in difficulty when swallowing the product for sensitive individuals. To date, Kingston Pharma LLC has received one report of a one-week old infant having difficulty when swallowing the product and three complaints attributed to the undissolved citrus flavonoid.

The product is administered orally to infants and adults. The recall is for all lots. The product is packaged in 4-ounce amber bottles, white plastic caps with safety seals and provided with an oral syringe, with UPC Code 8 5495400246 3. The product was distributed throughout the United States by Dollar General Corporation.

Kingston Pharma, LLC is notifying its customers by press release of the recalled product. Consumers that have product which is being recalled should stop using and discard.

To report adverse reactions or quality problems experienced with the use of this product or to ask questions regarding this recall, contact Christina Condon or C. Jeanne Taborsky by phone toll free at 844-724-7347 or by e-mail Christina.Condon@SciRegs.com. Consumers should contact their physician or healthcare provider if they or their child have experienced any problems that may be related to taking or using this product.

Adverse reactions or quality problems associated with the use of this product may be reported to FDA's MedWatch Adverse Event Reporting program either by phone, on line, by regular mail or by fax.

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.