



Michael R. Pence
Governor

Jerome M. Adams, MD, MPH
State Health Commissioner

DATE: October 27, 2014
TO: All Local Health Departments
Attn: Chief Food Inspection Officer
FROM: Laurie Kidwell, RRT Supervisor
Food Protection Program
SUBJECT: Nutek Disposables, Inc. - Recall [Medical Device]

AFFECTED PRODUCT: Baby Wipes

SUMMARY: Unclassified Recall; This recall has been initiated because some packages may contain bacteria.

The recalled products are all lots of baby wipes that it manufactured under the brand names Cuties, Diapers.com, Femtex, Fred's, Kidgets, Member's Mark, Simply Right, Sunny Smiles, Tender Touch, and Well Beginnings, because some packages may contain bacteria.

Brand Name	Retailer	Lot Numbers of Product Manufactured by Nutek
<i>Cuties</i>	Internet and various retailers	All Lots
<i>Diapers.com</i>	Diapers.com	All Lots
<i>Femtex</i>	Family Dollar	All Lots
<i>Fred's</i>	Fred's	All Lots
<i>Kidgets</i>	Family Dollar	All Lots
<i>Member's Mark</i>	Sam's Club	All Lots
<i>Simply Right</i>	Sam's Club	All Lots
<i>Sunny Smiles</i>	Walgreens	All Lots
<i>Tender Touch</i>	Various retailers	All Lots
<i>Well Beginnings*</i>	Walgreens	Certain Lots±

These wipes were distributed by Nutek prior to October 21, 2014 to the following retail stores nationwide: Walgreens, Sam's Club, Family Dollar, Fred's, and Diapers.com.

SUGGESTED ACTION: Recommend notification of affected parties via phone, fax, or e-mail. Consumers who have purchased this product can return it to the place of purchase for a full refund. Consumers with questions may contact the company at 1-855-646-4351, Monday through Friday, 10 AM – 4 PM EDT. Furthermore, if any recalled products are found, notify this office at 317-233-3213.

Recall -- Firm Press Release



2 North Meridian Street • Indianapolis, IN 46204
317.233.1325 tdd 317.233.5577
www.statehealth.in.gov

To promote and provide
essential public health services.

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Nutek Disposables, Inc. Issues Alert Due to Potential Bacteria in Baby Wipes

Contact:

Consumer:
1-855-646-4351

Media:
Sean Wood
1-212-445-8310
swood@webershandwick.com

Hallie Bozzi
1-212-445-8276
hbozzi@webershandwick.com

FOR IMMEDIATE RELEASE — Oct. 25, 2014 — MCELHATTAN, PA — Nutek Disposables, Inc. of McElhattan, PA has initiated a nationwide voluntary product recall at the retail level of all lots of baby wipes that it manufactured under the brand names Cuties, Diapers.com, Femtex, Fred's, Kidgits, Member's Mark, Simply Right, Sunny Smiles, Tender Touch, and Well Beginnings, because some packages may contain bacteria. These wipes were distributed by Nutek prior to October 21, 2014 to the following retail stores: Walgreens, Sam's Club, Family Dollar, Fred's, and Diapers.com.

After receiving a small number of complaints of odor and discoloration, Nutek conducted microbial testing that showed the presence of a bacteria, called *Burkholderia cepacia* (*B. cepacia*), in some of these products. Soon after, on October 3, 2014 the company initiated a voluntary withdrawal of lots that had tested positive for the bacteria, as well as other baby wipes in the surrounding time frame. After some additional lots were tested, as a precautionary measure, Nutek believed it was a prudent decision to withdraw all its baby wipe products.

B. cepacia poses little medical risk to healthy people. However, people who have certain health problems like weakened immune systems or chronic lung diseases, particularly cystic fibrosis, may be more susceptible to infections with *B. cepacia*. If you believe you have a weakened immune system or chronic lung disease and you have used one of the affected wipe products, you should call your doctor promptly for medical advice.

As of October 3, 2014, the date of the original withdrawal, the company had received only one report of irritation. Numerous reports of complaints have since been received by the company that include rash, irritation, infections, fever, gastro-intestinal issues, and respiratory issues, though these reports have not been confirmed to be related to the use of these products.

The company has not identified the cause of the problem, but is continuing to investigate. In the interim, Nutek has stopped shipping baby wipes manufactured at the facility.

Nutek takes the safety of consumers and the quality of its products very seriously and is taking all appropriate steps to address the issue and ensure this does not happen again.

The company is working with the U.S. Food & Drug Administration and the affected retailers and distributors throughout this process to address the issue.

Consumers who have purchased this product can return it to the place of purchase for a full refund. Consumers with questions may contact the company at 1-855-646-4351, Monday through Friday, 10 AM – 4 PM EDT.

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**These lot numbers represent all lots manufactured by Nutek. There may be other lots that are made by manufacturers other than Nutek and that are not subject to this recall.*

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