

## Foshan Flying Medical Products - Product safety alert

- On September 1, 2017, the <u>FDA alerted</u> health care professionals and patients not to use alcohol
  pads or benzalkonium chloride antiseptic towelettes made by Foshan Flying Medical Products due
  to the lack of sterility assurance and other quality issues.
- These products are distributed by Total Resources International and Simple Diagnostics.

| Product Name                             | NDC #   |
|--|---|
| Alcohol Prep Pad                         | 54429-0101-1, 54429-0101-2, 54429-0101-3, 54429-0101-6, 98302-0001-05 |
| Pharmacist Choice Alcohol Prep Pad       | 54429-0102-1  |
| Benzalkonium Chloride Antiseptic<br>Swab | 54429-0103-3, 54429-0103-4, 54429-0103-5                              |

- Alcohol pads and antiseptic towelettes are used by health care professionals and patients for preparation of the skin prior to injection, as well as in first aid to decrease germs in minor cuts, scrapes and burns.
  - The use of these alcohol pads and antiseptic towelettes could cause infections.
  - To date, the FDA has not received any adverse event reports related to the use of these alcohol pads or antiseptic towelettes.
- Patients, health care facilities, and pharmacies that have alcohol pads and antiseptic towelettes labeled by Total Resource or Simple Diagnostics should immediately stop using them and discard the products.
- Patients should contact a doctor if they experienced any adverse reactions after using these products.
- The FDA initially contacted Foshan on May 25, 2017, regarding a recall, and had several follow-up
  meetings with the company. However, Foshan has not taken action to remove its alcohol pads or
  antiseptic towelettes from the market.
- The FDA placed all drug products made by Foshan on <u>import alert</u> on May 23, 2107, to stop these
  products from entering the U.S. However, the FDA is concerned these products might still be in U.S.
  distribution. The FDA also sent Foshan a <u>warning letter</u> on August 1, 2017, for violations of current
  good manufacturing practice regulations.



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