

## QUESTIONS AND ANSWERS

**1. Why has Fleet recalled its bowel prep products?**

The FDA has just decided that oral sodium phosphate (OSP) products – such as Fleet® Phospho-soda® Oral Saline Laxative and Fleet® Phospho-soda® EZ-Prep® Bowel Cleansing System – should only be available with a prescription when taken as a bowel cleanser prior to medical procedures. As Fleet’s products are labeled for over-the-counter use, not prescription use, we believe the appropriate action is to cease distribution of the product and remove them from wholesale and retail distribution as quickly as possible.

**2. What is wrong with these products?**

Nothing. We are voluntarily taking them off the shelves to address the FDA’s decision that these products should be available by prescription only and not be available over the counter for use as bowel cleanser prior to medical procedures.

**3. Why is FDA requiring the change from over-the-counter to prescription?**

According to the letter Fleet received from the FDA and the FDA Safety Alert, the FDA has determined that, in light of the risk of acute phosphate nephropathy from use of the products at bowel cleansing dosages, OSP products should not be sold over-the-counter for bowel cleansing use, and that consumers should only use OSPs for bowel cleansing pursuant to a prescription from a healthcare professional.

**4. I have used the product as a laxative. Has FDA raised any issue with use of Phospho-soda® as a laxative?**

The FDA has stated that OSP products have a long history of safe use as a laxative and will continue to be available over-the-counter for laxative use.

**5. Does Fleet plan to continue to sell these OSP products in the future?**

Fleet has ceased distribution of all over-the-counter OSP products at this time.

**6. Has Fleet been ordered to initiate the recall?**

No, Fleet is voluntarily recalling these products based on our understanding of the FDA’s findings.

**7. What does the recall entail?**

We are recalling the product from our wholesalers and retailers to ensure these products are no longer available over-the-counter.

**8. Is the FDA aware of these actions?**

Yes, we have notified the FDA of the voluntary recall and all actions we intend to take to address their concerns about the over-the-counter availability of OSP products for bowel cleansing use.

**9. Where can I find out more information about the recall:**

You can contact our recall coordinator:

Tammie Bradley  
C.B. Fleet Commercial Representative  
434-316-1081 (phone)  
bradleyt@cbfleet.com

**10. What about Fleet® Enema? Doesn't it contain sodium phosphates?**

While our enema products do contain sodium phosphates, the FDA's actions relate only to **oral** forms of sodium phosphates, not rectal. Fleet® Enema is not part of this voluntary recall initiative.

**11. My doctor recommended that I use Fleet® Phospho-soda®/Fleet® Phospho-soda® EZ-Prep® for a colonoscopy I have scheduled. What should I do?**

You should contact your doctor and ask which alternative bowel cleansing product you should use. Based on the FDA's actions we can no longer recommend use of our over-the-counter products for bowel cleansing.

**12. I used your product last week. What should I do?**

You should contact your physician if you are concerned or if you notice any unusual symptoms such as malaise, lethargy, drowsiness, decreased urine output or swelling.

**13. I already used your product. Can I get a refund?**

We cannot provide refunds for product already used.

**14. Where can I get additional information?**

Information is available on the main page of FDA's Web site at [www.fda.gov](http://www.fda.gov).