

Smith Drug

5/28/18

Urgent Drug Recall

Dear Sandy Lawson,

On May 21, Church and Dwight received a letter from FDA, in which they requested that manufacturers of benzocaine containing products with indications for the relief of pain associated with teething, or for children under two years of age discontinue their sale and distribution. This is due to the relationship of benzocaine usage to the incidence of methemoglobinemia, a rare but serious condition.

Methemoglobinemia is the result of elevated levels of methemoglobin in the blood and it can potentially be fatal. It causes the amount of oxygen carried through the blood to be greatly reduced. The safety of our consumers and their children is our highest priority, and as a result we are fully complying with FDA's request.

This recall is to the retail level. If you have further distributed this product, you should notify your customers to the retail level. The list of affected products and their UPCs are attached to this letter. Please have them return the effected product to your warehouse so that it can be handled appropriately. We ask you to reconcile the product delivered to you with the product you have quarantined. The quarantined product may be dispositioned by:


- Contact Church & Dwight Customer Service for a return authorization and shipping instructions, DispositionRequests@churchdwight.com
- Moving the product through your recall service provider (i.e. Inmar, Stericycle) and attesting to the destruction on the attached form
- Destroying the product and verifying the destruction on the attached reconciliation form

We are informing FDA of this recall.

Sincerely,

Jeffrey Shaul
Director, Global Regulatory Affairs

Orajel Package Images and SKUs:

Product Name	Orajel™ Medicated Daytime Teething Gel - 0.125oz	Orajel™ Medicated Daytime Teething Gel - 0.33oz	Orajel™ Medicated Nighttime Teething Gel - 0.18oz
Product UPC	3-10310-32456-8	3-10310-03313-2	3-10310-33940-1
Packaging			
Material Numbers/ Case UPC	20018466/20310310324562	20018457/20310310033136 20018465/20310310323893 20018462/20310310320588	20018467/20310310339405 20018459/20310310319872
Product Name	Orajel™ Medicated Daytime & Nighttime Teething Gel - 0.18oz Each (Vertical)	Orajel™ Medicated Daytime & Nighttime Teething Gel - 0.18oz Each (Horizontal)	Orajel™ Medicated Teething Swabs
Product UPC	3-10310-00018-9	3-10310-31955-7	3-10310-34038-4
Packaging			
Material Numbers/ Case UPC	20504552/20310310000183	20018470/50310310380002	20501310/20310310340388 20501311/20310310340388



CHURCH & DWIGHT CO., INC.

Recalled Inventory Disposition

Please check all appropriate boxes.

- I have read and understand the recall instructions provided in the [date] letter.
- Please provide details for the following material numbers/case UPCs:

Product	Material Number/Case UPCs	Number of Units Sold/Shipped	Number of Units in inventory
Orajel™ Medicated Daytime Teething Gel - 0.125oz	20018466/20310310324562		
Orajel™ Medicated Daytime Teething Gel - 0.33oz	20018457/20310310033136 20018465/20310310323893 20018462/20310310320588		
Orajel™ Medicated Nighttime Teething Gel - 0.18oz	20018467/20310310339405 20018459/20310310319872		
Orajel™ Medicated Daytime & Nighttime Teething Gel - 0.18oz Each (Vertical)	20504552/20310310000183		
Orajel™ Medicated Daytime & Nighttime Teething Gel - 0.18oz Each (Horizontal)	20018470/50310310380002		
Orajel™ Medicated Teething Swabs	20501310/20310310340388 20501311/20310310340388		

- Attached is a list of customers who received/may have received this product. Please notify these customers.
- I attest to returning the quarantined product to Church & Dwight, destruction of the product, or use of my recall services.

Please circle the descriptions that best fit your business. Circle more than one if necessary.

Wholesaler/Distributor
Retailer

Other (please fill in): _____

Please provide us with your information:

Name: _____

Title: _____

Tel Number: _____

Signature: _____

Please e-mail completed response form to Jeffrey.Shaul@churchdwight.com;

fax to 609-403-7403; or mail to:

Church & Dwight Co., Inc.; Attn: Jeffrey Shaul; 469 N. Harrison Street, Princeton, NJ 08543-5297