



McNeil Consumer Healthcare, 7050 Camp Hill Road, Fort Washington, PA 19034

## **URGENT - DRUG RECALL**

September 11, 2009

Dear OTC Warehouse:

In consultation with the U.S. Food and Drug Administration (FDA), we initiated a voluntary recall of certain lots of Children's and Infants' Tylenol Suspensions at wholesalers on August 21, 2009. We are now taking the additional step of expanding this voluntary recall to include impacted product on the Retail shelves (Full List Below). The company is initiating this recall as a precaution due to the failure of one inactive raw material to meet internal testing requirements. The finished product met all specifications and there have been no adverse events reported to date. This additional action is being conducted with the knowledge of the Food and Drug Administration.

To minimize the impact to your business and help ensure uninterrupted access to medicines not impacted by this action, please consult the list of products below prior to removal from the shelf.

Please return **ALL** warehouse and retail quantities of the below listed lot codes. No product other than the ones specified should be returned.

### **Action Requested:**

1. Identify all warehouse inventory of products listed below, and return immediately as per the "Return Authorization Form". If you have any questions regarding the forms please call 800-821-5293 or email [sarah.joyner@inmar.com](mailto:sarah.joyner@inmar.com). You can also fax your questions to fax # 336-499-8601, Attn: Sarah Joyner.
2. Communicate this product recall to your retail outlets that received these products and request they return ALL identified products to your warehouse. Please place all inventory and returns of these products into quarantine in your warehouse until returned to McNeil Consumer Healthcare. A suggested communication is attached for your use.
3. Once you have all retail returns, send back immediately per enclosed instructions.
4. Please complete the enclosed Business Reply Form and return as soon as possible. This form needs to be completed even if you do not have affected product in order for McNeil to verify that you have received this communication.

We appreciate your cooperation in helping us successfully execute this voluntary recall. If you have any questions related to the product, please contact your McNeil Consumer Healthcare Division of McNEIL-PPC, Inc. Sales Representative or call 908-904-3313.

McNeil Consumer Healthcare Division of McNEIL-PPC, Inc.

| <u>UPC #</u> | <u>Product Code #</u> | <u>Lot #</u>                           | <u>Product Description</u>                                |
|--------------|-----------------------|--|---|
| 300450391049 | 3910400               | SBM041, SBM067, SCM037, SDM027, SEM109 | Children's Tylenol Plus Cold MS Suspension 4 oz. Grape    |
| 300450296047 | 2960400               | SBM042, SCM015, SCM036, SDM034         | Children's Tylenol Suspension 4oz. Grape                  |
| 300450407047 | 4070400               | SBM043, SBM044, SCM029                 | Children's Tylenol Suspension 4oz. Bubble Gum             |
| 300450493040 | 4930400               | SBM045, SCM011, SCM030, SDM035         | Children's Tylenol Suspension 4oz. Strawberry             |
| 300450122407 | 1224000               | SBM064, SCM033, SDM020                 | Infant's Tylenol Grape Suspension Drops 1/4oz.            |
| 300450186157 | 1861500               | SBM065, SCM005, SCM006, SDM032         | Infant's Tylenol Suspension 1/2oz. Cherry                 |
| 300450166043 | 1660400               | SBM066, SCM068                         | Children's Dye Free Suspension 4oz. Cherry                |
| 300450123046 | 1230400               | SBM068, SCM035, SCM070, SCM080, SDM005 | Children's Tylenol Suspension 4oz. Cherry                 |
| 300450249043 | 2490400               | SBM069, SBM070, SCM081, SDM006         | Children's Tylenol Plus Cough & Runny Nose 4oz. Cherry    |
| 300450122155 | 1221500               | SCM012, SCM067, SDM007, SDM068         | Infant's Tylenol Suspension Drops 1/2oz. Grape            |
| 300450386045 | 3860400               | SCM013, SCM014, SCM069                 | Children's Tylenol Plus Flu 4oz. Bubble Gum               |
| 300450387042 | 3870400               | SCM016, SFM024                         | Children's Tylenol Plus Cold Suspension 4oz. Grape        |
| 300450247049 | 2470400               | SCM017                                 | Children's Tylenol Plus Cough/ST Suspension 4oz. Cherry   |
| 300450122018 | 1220100               | SCM082, SDM039, SDM040                 | Infant's Tylenol Suspension Drops 1oz. Grape              |
| 300450167019 | 1670100               | SCM083, SCM084, SDM008                 | Infant's Tylenol Dye Free Suspension 1oz. Cherry          |
| 300450123015 | 1230100               | SDM064                                 | Children's Tylenol Pediatric Suspension 1oz. Cherry       |
| 300450186300 | 1863000               | SDM038, SDM009                         | Infant's Tylenol Suspension Drops 1oz. Cherry             |
| 300450390042 | 3900400               | SDM033                                 | Children's Tylenol Plus Cold/Allergy 4oz. Bubble Gum      |
| 300450122100 | 1221000               | SDM078                                 | Infant's Tylenol Drops 1oz. Grape                         |
| 350580144183 | 1221800               | SCM034                                 | Infant's Tylenol Grape Suspension Drops H/G 1/2oz.        |
| 350580123034 | 1230300               | SDM028                                 | Children's Tylenol Suspension 4oz. Cherry, Hospital Govt. |