McNeil Consumer Healthcare Announces Voluntary Nationwide Recall of Infants’ TYLENOL® Oral Suspension, 1 oz. Grape Due to Dosing System Complaints

Recall Limited to Wholesale and Retail Levels

Fort Washington, PA (February 17, 2012) – McNeil Consumer Healthcare, Division of McNEIL-PPC, Inc. ("McNeil"), is voluntarily recalling, at the wholesale and retail levels, seven lots, approximately 574,000 bottles, of Infants’ TYLENOL® Oral Suspension, 1 oz. Grape distributed nationwide in the United States (see full product list below). Infants’ TYLENOL® is an over-the-counter (OTC) product indicated as a pain reliever/fever reducer.

McNeil is initiating this voluntary recall as a precaution after receiving a small number of complaints from consumers who reported difficulty using the Infants’ TYLENOL® SimpleMeasure™ dosing system. SimpleMeasure™ includes a dosing syringe, which a parent or caregiver inserts into a protective cover, or “flow restrictor,” at the top of the bottle to measure the proper dose. In some cases, the flow restrictor was pushed into the bottle when inserting the syringe. Children's TYLENOL® products are intended for children two years of age and older and remain available.

No adverse events associated with this action have been reported to date and the risk of a serious adverse medical event is remote. Consumers can continue to use Infants’ TYLENOL® provided the flow restrictor at the top of the bottle remains in place. The company discussed how to use the product’s dosing system in a separate message to consumers also issued today.

If the flow restrictor is pushed into the bottle, the parent or caregiver should not use the product. Consumers can request a refund by visiting www.tylenol.com or contacting McNeil at 1-888-222-6036 (Monday-Friday 8 a.m. to 8 p.m. Eastern Time; Saturday-Sunday 9 a.m. to 5 p.m. Eastern Time). Parents and caregivers with any health questions or concerns should contact their healthcare provider and visit www.tylenol.com for additional information.
FULL RECALLED PRODUCT LIST:

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Lot Numbers</th>
<th>UPC Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infants’ TYLENOL® Oral Suspension 1oz. Grape</td>
<td>BIL0U00, BIL0V00, BIL3500, BJL2D00, BJL2E00, BJL2T00, BJL2U00</td>
<td>300450122308</td>
</tr>
</tbody>
</table>

Adverse events that may be related to the use of this product may be reported to U.S. Food and Drug Administration’s (FDA) MedWatch Adverse Event Reporting Program either online, by regular mail or by fax:

- Online: [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm)
- Regular mail: Use postage-paid, pre-addressed Form FDA 3500 available at: [www.fda.gov/MedWatch/getforms.htm](http://www.fda.gov/MedWatch/getforms.htm). Mail to address on the pre-addressed form.
- Fax: 1-800-FDA-0178.

This voluntary recall is being conducted with the knowledge of the FDA.

###
BUSINESS REPLY FORM

McNeil Consumer Healthcare Division of McNEIL-PPC, Inc. is recalling certain lots of the following product:

INFANTS’ TYLENOL® ORAL SUSPENSION 1 OZ. GRAPE
(full detailed list below)

We have requested our accounts to return all their warehouse, retail shelf, and backroom stocks of the products listed below. Please check your status below:

☐ We purchased our product directly from Johnson & Johnson Sales & Logistics Company, LLC.

☐ We purchased our product directly from a Wholesaler or Third Party
  ☐ Provide Name of Wholesaler or Third Party: _________________________________

☐ We have checked for stocks of the below affected product in our warehouses.

☐ We do not have any of the below affected product.

☐ We are returning _______ cases or _______ packages of the below affected product.

Please note that as a direct customer of McNeil Consumer Healthcare, reimbursement for the returned product will be reflected on your account with the J&J Sales & Logistics Co. using the RA#. All indirect (sub-distributed) customers must be reimbursed from the company from whom the product was purchased.

Customer ______________________________________________________________
Address ______________________________________________________________
City ___________________________ State ______________ Zip Code ___________
Signature: _____________________________________

Please complete and mail to:

Stericycle Recall Coordinator
Event # 2606
4350 Sam Jones Expressway
Indianapolis, IN 46241

Or fax to Stericycle at:
Fax – 888-912-7350

SHIPPING INSTRUCTIONS:

1-15 cases
One to 15 cases of impacted product should be returned to the following address via the UPS prepaid return labels enclosed in this notification, if more labels are required please contact 877-492-4794.

Stericycle Recall Coordinator
Event # 2606
4350 Sam Jones Expressway
Indianapolis, IN 46241

Phone: 877-492-4794
Fax: 888-912-7350

16 cases – 28 Pallets
Shipments greater than 16 cases up to 28 pallets, should be palletized, and shipped via ABF Freight System by calling 800-435-2213. Please mention this is a McNeil recall pickup. See return address in red above.

Over 28 pallets
Shipments over 28 pallets in size will be moved as full truckloads, and should be called or e-mailed into Schneider Transportation as below. See return address in red above.

TLCSJJ@schneider.com
Cindy Dax Pagel
800-558-6767 ext 5927248
<table>
<thead>
<tr>
<th>Product Name</th>
<th>Lot #</th>
<th>Product UPC #</th>
<th>Case UPC#</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infants’ TYLENOL® Oral Suspension 1oz. Grape</td>
<td>BIL0U00</td>
<td>300450122308</td>
<td>30300450122309</td>
</tr>
<tr>
<td></td>
<td>BIL0V00</td>
<td>300450122308</td>
<td>30300450122309</td>
</tr>
<tr>
<td></td>
<td>BIL3500</td>
<td>300450122308</td>
<td>30300450122309</td>
</tr>
<tr>
<td></td>
<td>BJL2D00</td>
<td>300450122308</td>
<td>30300450122309</td>
</tr>
<tr>
<td></td>
<td>BJL2E00</td>
<td>300450122308</td>
<td>30300450122309</td>
</tr>
<tr>
<td></td>
<td>BJL2T00</td>
<td>300450122308</td>
<td>30300450122309</td>
</tr>
<tr>
<td></td>
<td>BJL2U00</td>
<td>300450122308</td>
<td>30300450122309</td>
</tr>
</tbody>
</table>
McNeil Consumer Healthcare, Division of McNEIL-PPC, Inc. ("McNeil"), is voluntarily recalling, at the wholesale and retail levels, seven lots, approximately 574,000 bottles, of Infants' TYLENOL® Oral Suspension, 1 oz. Grape distributed nationwide in the United States (see full product list below). Infants' TYLENOL® is an over-the-counter (OTC) product indicated as a pain reliever/fever reducer.

McNeil is initiating this voluntary recall as a precaution after receiving a small number of complaints from consumers who reported difficulty using the Infants' TYLENOL® SimpleMeasure™ dosing system. SimpleMeasure™ includes a dosing syringe, which a parent or caregiver inserts into a protective cover, or “flow restrictor,” at the top of the bottle to measure the proper dose. In some cases, the flow restrictor was pushed into the bottle when inserting the syringe. Children's TYLENOL® products are intended for children two years of age and older and remain available.

No adverse events associated with this action have been reported to date and the risk of a serious adverse medical event is remote. Consumers can continue to use Infants' TYLENOL® provided the flow restrictor at the top of the bottle remains in place. The company discussed how to use the product's dosing system in a separate message to consumers also issued today.

If the flow restrictor is pushed into the bottle, the parent or caregiver should not use the product. Consumers can request a refund by visiting www.tylenol.com or contacting McNeil at 1-888-222-6036 (Monday-Friday 8 a.m. to 8 p.m. Eastern Time; Saturday-Sunday 9 a.m. to 5 p.m. Eastern Time). Parents and caregivers with any health questions or concerns should contact their healthcare provider and visit www.tylenol.com for additional information.

Adverse events that may be related to the use of this product may be reported to U.S. Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting Program either online, by regular mail or by fax:

- Online: www.fda.gov/medwatch/report.htm
- Regular mail: Use postage-paid, pre-addressed Form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm. Mail to address on the pre-addressed form.
- Fax: 1-800-FDA-0178.

This voluntary recall is being conducted with the knowledge of the FDA.

The lot numbers (a full list is attached below) for the recalled product can be found on the side of the carton label.

**Action Requested:**

1. Identify all retail inventory of products listed below, remove from your shelves and return immediately as per the “Return Authorization Form” or send to your wholesaler supplier or to your headquarter warehouse. If you have any questions regarding the form please call Stericycle at 877-492-4794 or fax to 888-912-7350.
2. If you are a Wholesaler or if you have sub-distributed any of the below product to any other locations, please take the necessary steps to have your customers return this product to you for consolidation of inventory and return to Stericycle using the attached documents. Utilize a copy of the enclosed information to facilitate and document this action with each of your sub-accounts.
Please note that as a direct customer of McNeil Consumer Healthcare, reimbursement for the returned products will be reflected on your account with the J&J Sales & Logistics Co. using the Return Authorization number. All indirect (sub-distributed) customers must be reimbursed from the company from whom the products were purchased.

We appreciate your cooperation in helping us successfully execute this voluntary recall. If you have any questions related to the return of these products, please contact Stericycle at 877-492-4794. If you have any questions about the products, please contact your McNeil Consumer Healthcare Sales Representative.

McNeil Consumer Healthcare Division of McNEIL-PPC, Inc.

FULL RECALLED PRODUCT LIST:

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Lot #</th>
<th>Product UPC #</th>
<th>Case UPC #</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infants’ TYLENOL® Oral Suspension 1oz. Grape</td>
<td>BIL0U00</td>
<td>300450122308</td>
<td>30300450122309</td>
</tr>
<tr>
<td></td>
<td>BIL0V00</td>
<td>300450122308</td>
<td>30300450122309</td>
</tr>
<tr>
<td></td>
<td>BIL3500</td>
<td>300450122308</td>
<td>30300450122309</td>
</tr>
<tr>
<td></td>
<td>BJL2D00</td>
<td>300450122308</td>
<td>30300450122309</td>
</tr>
<tr>
<td></td>
<td>BJL2E00</td>
<td>300450122308</td>
<td>30300450122309</td>
</tr>
<tr>
<td></td>
<td>BJL2T00</td>
<td>300450122308</td>
<td>30300450122309</td>
</tr>
<tr>
<td></td>
<td>BJL2U00</td>
<td>300450122308</td>
<td>30300450122309</td>
</tr>
</tbody>
</table>
URGENT VOLUNTARY DRUG RECALL

February 17, 2012

Dear OTC Warehouse or Wholesale Distributor Customer:

McNeil Consumer Healthcare Announces Voluntary Nationwide Recall of Infants’ TYLENOL® Oral Suspension, 1 oz. Grape
Due to Dosing System Complaints

Recall Limited to Wholesale and Retail Levels

Please return ALL retail and warehouse inventory of the identified product lots below. No products other than the one specified should be returned.

McNeil Consumer Healthcare, Division of McNEIL-PPC, Inc. (“McNeil”), is voluntarily recalling, at the wholesale and retail levels, seven lots, approximately 574,000 bottles, of Infants’ TYLENOL® Oral Suspension, 1 oz. Grape distributed nationwide in the United States (see full product list below). Infants’ TYLENOL® is an over-the-counter (OTC) product indicated as a pain reliever/fever reducer.

McNeil is initiating this voluntary recall as a precaution after receiving a small number of complaints from consumers who reported difficulty using the Infants’ TYLENOL® SimpleMeasure™ dosing system. SimpleMeasure™ includes a dosing syringe, which a parent or caregiver inserts into a protective cover, or “flow restrictor,” at the top of the bottle to measure the proper dose. In some cases, the flow restrictor was pushed into the bottle when inserting the syringe. Children’s TYLENOL® products are intended for children two years of age and older and remain available.

No adverse events associated with this action have been reported to date and the risk of a serious adverse medical event is remote. Consumers can continue to use Infants’ TYLENOL® provided the flow restrictor at the top of the bottle remains in place. The company discussed how to use the product’s dosing system in a separate message to consumers also issued today.

If the flow restrictor is pushed into the bottle, the parent or caregiver should not use the product. Consumers can request a refund by visiting www.tylenol.com or contacting McNeil at 1-888-222-6036 (Monday-Friday 8 a.m. to 8 p.m. Eastern Time; Saturday-Sunday 9 a.m. to 5 p.m. Eastern Time). Parents and caregivers with any health questions or concerns should contact their healthcare provider and visit www.tylenol.com for additional information.

Adverse events that may be related to the use of this product may be reported to U.S. Food and Drug Administration’s (FDA) MedWatch Adverse Event Reporting Program either online, by regular mail or by fax:

- Online: www.fda.gov/medwatch/report.htm
- Regular mail: Use postage-paid, pre-addressed Form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm.
- Fax: 1-800-FDA-0178.

This voluntary recall is being conducted with the knowledge of the FDA.

The lot numbers (a full list is attached below) for the recalled product can be found on the side of the carton label.

Action Requested:
1. Please complete the enclosed Business Reply Form and return immediately.
2. Identify all warehouse/wholesale inventory of products listed below and return immediately as per the attached “Return Authorization Form”. If you have any questions regarding the form, please call Stericycle at 877-492-4794. You can also fax your questions to 888-912-7350.
3. Communicate this product recall to your retail outlets or wholesale accounts 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 Stericycle. A suggested communication is attached for your use (Dear Retailer Customer).
4. Once you have all retail returns, send back immediately per enclosed instructions.
Please note that as a direct customer of McNeil Consumer Healthcare, reimbursement for the returned products will be reflected on your account with the J&J Sales & Logistics Co. using the Return Authorization number. All indirect (sub-distributed) customers must be reimbursed from the company from whom the products were purchased.

We appreciate your cooperation in helping us successfully execute this voluntary recall. If you have any questions related to the return of these products, please contact Stericycle at 877-492-4794. If you have any questions about the products, please contact your McNeil Consumer Healthcare Sales Representative.

McNeil Consumer Healthcare Division of McNEIL-PPC, Inc.

**FULL RECALLED PRODUCT LIST:**

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Lot #</th>
<th>Product UPC #</th>
<th>Case UPC #</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infants’ TYLENOL® Oral Suspension 1oz. Grape</td>
<td>BIL0U00</td>
<td>300450122308</td>
<td>30300450122309</td>
</tr>
<tr>
<td></td>
<td>BIL0V00</td>
<td>300450122308</td>
<td>30300450122309</td>
</tr>
<tr>
<td></td>
<td>BIL3500</td>
<td>300450122308</td>
<td>30300450122309</td>
</tr>
<tr>
<td></td>
<td>BJL2D00</td>
<td>300450122308</td>
<td>30300450122309</td>
</tr>
<tr>
<td></td>
<td>BJL2E00</td>
<td>300450122308</td>
<td>30300450122309</td>
</tr>
<tr>
<td></td>
<td>BJL2T00</td>
<td>300450122308</td>
<td>30300450122309</td>
</tr>
<tr>
<td></td>
<td>BJL2U00</td>
<td>300450122308</td>
<td>30300450122309</td>
</tr>
</tbody>
</table>
RETURN AUTHORIZATION FORM

Note: Reimbursement for product returned by direct customers of McNeil Consumer Healthcare will be reflected on their account with the J&J Sales & Logistics Co. using the RA# below. All indirect (sub-distributed) customers must be reimbursed by the company from whom the product was purchased.

Credit To: RA#: RAINFTY022012

Account: _______________________________________________________________________
Address: _______________________________________________________________________

City: ___________________________ State: ________ Zip Code: __________
Ship to Account #: ___________________________________________________________________
Customer Debit #: ___________________________________________________________________
Comments: _______________________________________________________________________
____________________________________________________________________________________
____________________________________________________________________________________
Signature: ___________________________ Date: ___________________________

SHIPPING INSTRUCTIONS:

1-15 cases
The affected lots of up to 1 to 15 cases should be returned to the following address via the UPS prepaid return labels enclosed in this notification, if more labels are required please contact 877-492-4794.

Stericycle Recall Coordinator
Event # 2606
4350 Sam Jones Expressway
Indianapolis, IN 46241
Phone: 877-492-4794
Fax: 888-912-7350

16 cases – 28 Pallets
Shipments greater than 16 cases up to 28 pallets, should be palletized, and shipped via ABF Freight System by calling 800-435-2213. Please mention this is a McNeil recall pickup. See return address in red above.

Over 28 pallets
Shipments over 28 pallets in size will be moved as full truckloads, and should be called or e-mailed into Schneider Transportation as below:

TLCSJJ@schneider.com
Cindy Dax Pagel
800-558-6767 ext 5927248

PLEASE RETAIN A COPY OF THIS RETURN AUTHORIZATION FORM FOR YOUR RECORDS PRIOR TO INCLUDING ORIGINAL WITH YOUR SHIPMENT.
**FULL RECALLED PRODUCT LIST:**

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Lot #</th>
<th>Product UPC #</th>
<th>Case</th>
<th>Each</th>
<th>Case</th>
<th>Each</th>
<th>Total Credit</th>
<th>For Office Use Only</th>
</tr>
</thead>
<tbody>
<tr>
<td>INFANTS’ TYLENOL® ORAL SUSPENSION 1 OZ. GRAPE (Case UPC 30300450122309)</td>
<td>BIL0U00</td>
<td>300450122308</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>BIL0V00</td>
<td>300450122308</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>BIL3500</td>
<td>300450122308</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>BJL2D00</td>
<td>300450122308</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>BJL2E00</td>
<td>300450122308</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>BJL2T00</td>
<td>300450122308</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>BJL2U00</td>
<td>300450122308</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Please remove the following lot codes of Infants’ TYLENOL® ORAL SUSPENSION 1 OZ GRAPE from your warehouse and retail inventory immediately.

No other products are impacted. Please do not return any other products.

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Lot Number</th>
<th>Product UPC</th>
<th>Case UPC</th>
<th>NDC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infants’ TYLENOL®</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Infants’ TYLENOL® Oral Suspension 1 oz Grape</td>
<td>BILOU00, BILOV00, BIL3500, BJL2D00, BJL2E00, BJL2T00, BJL2U00</td>
<td>300450122308</td>
<td>30300450122309</td>
<td>50580-191-01</td>
</tr>
</tbody>
</table>

###