



## McNeil Consumer Healthcare Supports Voluntary Initiatives To Help Encourage Safe, Effective Use Of Children's Cough And Cold Medicines

Fort Washington, PA (October 7, 2008) - As part of the industry's continuing dialogue with the U.S. Food and Drug Administration (FDA), McNeil Consumer Healthcare, a division of McNeil-PPC, Inc., announced today new voluntary actions that will help further encourage safe and appropriate use of children's cough and cold medicines.

After consulting with the FDA, McNeil Consumer Healthcare and other manufacturers will transition the labeling on children's cough and cold medicines to state "do not use" in children under age 4 years; and the labels on children's medicines containing a monograph antihistamine will also feature a warning, "do not use to make a child sleepy." Pediatric cough and cold medicines remain safe and effective when used as directed; and because reports of adverse events are very rare, and mostly associated with misuse or accidental ingestion in younger children, the FDA supports the continued use of these medicines for symptom relief in children age 4 years and older.

As with other OTC labeling changes in the past, FDA has indicated it does not believe this labeling change warrants the removal of products with the old labeling from store shelves during this time of transition. The transition of re-labeled McNeil Consumer Healthcare medicines should be complete before the end of the year. (Please see a complete list of affected McNeil Consumer Healthcare medicines below)

"Over-the-counter pediatric cough and cold medicines have helped families provide comfort for their children for more than 30 years," said Ashley McEvoy, President, McNeil Consumer Healthcare. "McNeil Consumer Healthcare has always encouraged the appropriate use of these medicines. Our actions today include label changes, educational initiatives for parents, caregivers and healthcare professionals as well as science and surveillance commitments."

McNeil Consumer Healthcare's pediatric cough and cold medicines will continue to include dosing information for children age 4 years and older. The label changes do not apply to single-ingredient pain reliever/fever reducers such as INFANTS' and CHILDREN'S TYLENOL® (acetaminophen) and INFANTS' and CHILDREN'S MOTRIN® (ibuprofen) and also do not apply to single-ingredient allergy medicines such as CHILDREN'S ZYRTEC® (cetirizine) and CHILDREN'S BENADRYL® (diphenhydramine).

The following cough and cold medicines should no longer be used in children under age 4 years:

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| 1. Children's TYLENOL® Plus Multi-Symptom Cold  | 9. Children's SUDAFED® PE Cold & Cough      |
| 2. Children's TYLENOL® Plus Cold                | 10. PEDIACARE® Multi-Symptom Cold           |
| 3. Children's TYLENOL® Plus Cough & Sore Throat | 11. PEDIACARE® Long-Acting Cough            |
| 4. Children's TYLENOL® Plus Cough & Runny Nose  | 12. PEDIACARE® Decongestant                 |
| 5. Children's TYLENOL® Plus Flu                 | 13. PEDIACARE® NightRest Multi-Symptom Cold |
| 6. Children's TYLENOL® Plus Cold & Allergy      | 14. PEDIACARE® NightTime Cough              |
| 7. Children's SUDAFED® Nasal Decongestant       | 15. Children's BENADRYL® D Allergy & Sinus  |
| 8. Children's SUDAFED® PE Nasal Decongestant    |   |

The following children's medicines that contain an antihistamine will be re-labeled to feature a warning; "do not use to make a child sleepy":

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| 1. Children's BENADRYL® Allergy Liquid          | 6. Children's TYLENOL® Plus Cold               |
| 2. Children's BENADRYL® Allergy Dye-Free Liquid | 7. Children's TYLENOL® Plus Cough & Runny Nose |
| 3. Children's BENADRYL® Allergy Perfect Measure | 8. Children's TYLENOL® Plus Flu                |
| 4. Children's BENADRYL® D Allergy & Sinus       | 9. Children's TYLENOL® Plus Cold & Allergy     |
| 5. Children's TYLENOL® Plus Multi-Symptom Cold  |  |

### For More Information:

Consumers or retailers who have questions or concerns about the medicines described in this communication should contact the Johnson & Johnson Consumer Care Center at 1-888-222-0082 (English and Spanish) or visit [www.tylenol.com](http://www.tylenol.com).

The American Academy of Family Physicians offers the following recommendations for caring for a child with a cough or cold:

- Talk to your doctor about your child's symptoms.
- Make sure that your child rests and drinks plenty of fluids.
- Use a humidifier to help moisten the air in your child's bedroom. This may help with nasal congestion.

- Use a saline nasal spray to thin nasal mucus, and a bulb syringe to suction mucus out of your baby or child's nose.
- Pain relievers such as acetaminophen can help ease the pain of headaches, muscle aches and sore throats as well as treat fevers. Be sure you are giving your child the correct dose according to his or her age and weight.

McNeil Consumer Healthcare Division of McNeil-PPC, Inc. markets a broad range of well-known and trusted over-the-counter (OTC) products around the globe. McNeil Consumer Healthcare is most widely recognized for the complete line of TYLENOL® (acetaminophen) products, the leading pain reliever brand in the adult and pediatric categories. The TYLENOL® product line consists of hundreds of products across a variety of pain categories including: arthritis pain, pain with accompanying sleeplessness and pain with cough, colds and allergies. Other McNeil Consumer Healthcare brands include BENADRYL® allergy medicines; IMODIUM® A-D anti-diarrheal; MOTRIN® IB; PediaCare® upper respiratory medicines for children; ROLAIDS® antacid products; ST. JOSEPH® Adult Regimen Aspirin; SUDAFED® and SUDAFED PE® nasal decongestants; and ZYRTEC® over-the-counter antihistamines for adults and children.