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Makers of OTC Cough and Cold Medicines Announce Voluntary Withdrawal of Oral Infant Medicines

- **Potential misuse of these infant medicines, not product safety, is driving the voluntary withdrawal**
- **This withdrawal does not affect cough and cold medicines for children age 2 and older**
- **Further evaluation of these oral cough and cold medicines for infants and children will occur at the October 18 and 19 FDA advisory committee meeting**

Washington, D.C., October 11, 2007 – The Consumer Healthcare Products Association (CHPA) on behalf of the leading makers of over-the-counter cough and cold medicines today announced voluntary market withdrawals of oral cough and cold medicines that refer to “infants.” The voluntary withdrawal affects only these “infant” oral medicines, not those intended and labeled for use in children age two and older.

“It’s important to point out that these medicines are safe and effective when used as directed, and most parents are using them appropriately,” said **Linda A. Suydam**, D.P.A, president of CHPA. “The reason the makers of over-the-counter, oral cough and cold medicines for infants are voluntarily withdrawing these medicines is that there have been rare patterns of misuse leading to overdose recently identified, particularly in infants, and safety is our top priority.”

The branded cough and cold medicines that are being voluntarily withdrawn are:

- Dimetapp® Decongestant Plus Cough Infant Drops
- Dimetapp® Decongestant Infant Drops
- Little Colds® Decongestant Plus Cough
- Little Colds® Multi-Symptom Cold Formula
- PEDIACARE® Infant Drops Decongestant (containing pseudoephedrine)
- PEDIACARE® Infant Drops Decongestant & Cough (containing pseudoephedrine)
- PEDIACARE® Infant Dropper Decongestant (containing phenylephrine)
- PEDIACARE® Infant Dropper Long-Acting Cough
- PEDIACARE® Infant Dropper Decongestant & Cough (containing phenylephrine)
- Robitussin® Infant Cough DM Drops
- Triaminic® Infant & Toddler Thin Strips® Decongestant

- Triaminic® Infant & Toddler Thin Strips® Decongestant Plus Cough
- TYLENOL® Concentrated Infants' Drops Plus Cold
- TYLENOL® Concentrated Infants' Drops Plus Cold & Cough

This voluntary withdrawal does not affect medicines intended for children age two and older. CHPA and its member companies have put forth recommendations to the U.S. Food and Drug Administration (FDA) to strengthen the labels on all oral OTC children's cough and cold medicines from "ask a doctor" before using to "do not use" in children under two years.

CHPA made these recommendations to the FDA in preparation for a joint FDA advisory committee meeting on October 18 and 19. These recommendations, as well as several additional recommendations, including those proposed by FDA review staff, will be explored further at this meeting.

"These medicines are—and always have been—safe at recommended doses," Suydam said.

"These voluntary actions are being taken out of an abundance of caution. The vast majority of parents and caregivers safely use these medicines to help relieve their children's symptoms. But as with all medicines, it's important that parents read over-the-counter medicine labels carefully, use these medicines only as directed, and store them safely out of the reach of children."

CHPA will be launching a major, multi-year national campaign to educate parents and healthcare providers about the safe use of over-the-counter medicines in children, partnering with major physician, nurse, and pharmacist organizations.

More information about the voluntary withdrawal can be found at www.OTCsafety.org.

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CHPA is the 126-year-old-trade association representing U.S. manufacturers and distributors of over-the-counter medicines and nutritional supplement products.

Note to editors: Images of the select group of products being voluntarily withdrawn are available at www.OTCsafety.org.

www.chpa-info.org