

SUBJ: DOD-MMQC-04-1142
CHILDREN'S MOTRIN CONSUMER ALERT/INFORMATION BULLETIN

01. MCNEIL CONSUMER & SPECIALTY PHARMACEUTICALS ANNOUNCES NATIONWIDE CONSUMER ALERT OF CHILDREN'S MOTRIN GRAPE CHEWABLE TABLETS. MANUFACTURER ISSUED A PRESS RELEASE ON MAY 12, 2004, WHICH IS QUOTED BELOW.

QUOTE

MCNEIL CONSUMER & SPECIALTY PHARMACEUTICALS IS ALERTING CONSUMERS THAT ONE MANUFACTURING LOT (LOT # JAM108, EXP 1/06) OF CHILDREN'S MOTRIN (IBUPROFEN) GRAPE CHEWABLE TABLETS MAY MISTAKENLY CONTAIN TYLENOL 8-HOUR® EXTENDED RELEASE (ACETAMINOPHEN) GELTABS. LOT # JAM108 WAS DISTRIBUTED NATIONWIDE TO WHOLESALE AND RETAIL CUSTOMERS BETWEEN FEBRUARY 5 AND APRIL 1, 2004. THE BOTTLES ARE LABELED AS CONTAINING 24 TABLETS.

THE TYLENOL 8-HOUR PRODUCT PROVIDES AN ADULT DOSE OF ACETAMINOPHEN, AND USE OF THIS ADULT PRODUCT COULD PROVIDE MORE THAN THE RECOMMENDED DOSE (OVERDOSE) FOR CHILDREN. THE MISLABELED BOTTLES APPEAR TO BE THE RESULT OF A PACKAGING ERROR FOR THIS ONE LOT. TO DATE, TWO MISLABELED BOTTLES HAVE BEEN IDENTIFIED BUT NO INJURIES HAVE BEEN REPORTED AS A RESULT OF THIS ISSUE. IN THE INTEREST OF PATIENT HEALTH AND SAFETY, MCNEIL, IN CONSULTATION WITH THE U.S. FOOD AND DRUG ADMINISTRATION, IS TAKING THE PRECAUTION OF ALERTING CONSUMERS NATIONWIDE ABOUT THIS ISSUE TO HELP THEM IDENTIFY THE POTENTIALLY AFFECTED PRODUCT. MCNEIL HAS ALSO ALERTED RETAILERS NATIONWIDE.

THE TWO MEDICINES ARE VISIBLY DIFFERENT. CHILDREN'S MOTRIN GRAPE CHEWABLE TABLETS ARE ROUND, PURPLE-COLORED, SCORED TABLETS WITH THE LETTERS MO AND THE NUMBER 50 ON THE TABLET SURFACE. THESE TABLETS HAVE A NON-GLOSSY FINISH AND A GRAPE SMELL. THE TYLENOL 8-HOUR GELTABS ARE HARD, ROUND, GELATIN COATED AND SHINY. THE GELTABS ARE WHITE ON ONE SIDE, RED ON THE OTHER, WITH "8 HOUR" PRINTED IN BLUE ON EITHER THE RED OR THE WHITE SIDE.

CONSUMERS CAN IDENTIFY THE MANUFACTURING LOT NUMBER THAT IS EMBOSSED ON THE CARTON END FLAP, AND PRINTED ON THE BOTTLE LABEL UNDER MCNEIL'S ADDRESS AS "EXP 1/06 JAM108". ANYONE IDENTIFYING ONE OF THE BOTTLES INCLUDED IN THIS CONSUMER ALERT SHOULD CONTACT MCNEIL'S CONSUMER RELATIONSHIP CENTER AT 1-800-962-5357. PARENTS WHO BELIEVE THEIR CHILDREN MAY HAVE TAKEN TYLENOL 8-HOUR GELTABS, BELIEVING THEM TO BE CHILDREN'S MOTRIN GRAPE CHEWABLE TABLETS, SHOULD CONTACT THEIR HEALTH CARE PROVIDER OR A POISON CONTROL CENTER IMMEDIATELY

FOR MORE INFORMATION ON THIS CONSUMER ALERT, OR TO REPORT AN ADVERSE EVENT, PLEASE CALL MCNEIL'S CONSUMER RELATIONSHIP CENTER AT 1-800-962-5357.

END QUOTE

POC'S AT MCNEIL ARE: KATHY FALLON 215-273-7818 AND AMI SCHMITZ-LEVINE
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