

F.D.A. Limits Children's Cold and Cough Medicines

By GARDINER HARRIS, *New York Times* August 15, 2007

WASHINGTON, Aug. 15 – In the first major reassessment of the safety of children's cough and cold medicine in decades, federal drug officials said that the drugs should never be given to children under the age of 2 unless approved by a doctor.

Additional warnings about the drugs could be in the offing, because the Food and Drug Administration announced today that it would convene a meeting of independent experts on Oct. 18. They will advise the agency about whether new label warnings or prohibitions should be undertaken. The committee will also discuss how well parents and caregivers administer the drugs to children.

In higher than normal doses, cold medicines can affect the heart's electrical system, leading to arrhythmias. Some medicines affect the blood vessels and, in high doses, have been associated with high blood pressure and strokes. In rare cases, children have been injured when given recommended doses.

The F.D.A. also advised that children should never be given cold and cough medicines that have been packaged for adults and that parents should closely follow label directions about the appropriate dose to give their children.

"Too much medicine may lead to serious and life-threatening side effects, particularly in children aged 2 years and younger," the advisory stated.

In March, a group of prominent pediatricians and public health officials petitioned the agency to remove from the market medicines intended for children under the age of 6. The petition said that the medicines do not work and that in rare cases they can cause serious injury.

Among the popular medicines covered by the F.D.A.'s advisory are Toddler's Dimetapp, Infant Triaminic and Little Cold. Like hundreds of older drugs, many of the medicines in these products never received thorough safety reviews by the agency.