

Update on OTC Pediatric Cough and Cold Medications

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Americans suffer an estimated 1 billion cases of the common cold each year.¹ Children are affected disproportionately; they have about 6 to 10 colds per year, compared with an average of 2 to 4 per year for adults.¹ A frequently cited 1994 survey found that 35.8% of all 3-year-old children in the United States had been treated with a nonprescription cough and cold preparation during the previous 30 days.² A more recent survey found that 1 in 10 American children uses a cough and cold medication in a given week.³ In that survey, use of antitussives, decongestants, and first-generation antihistamines was highest among children 2 to 5 years of age, followed by children younger than 2 years of age. Multiple-ingredient products accounted for nearly (64.2%) of all cough and cold medications used.

A number of important changes have affected the nonprescription pediatric cough and cold market in recent years. To provide the best care possible to patients and answer questions parents may have, pharmacists need to be aware of these changes and understand the events that precipitated them.

Regulation of Nonprescription Drugs

The manufacturing, distribution, labeling, and marketing of prescription and nonprescription drugs are regulated by the Federal Food, Drug, and Cosmetic (FDCA) Act of 1938 and its subsequent amendments. The FDCA Act required that drug products must be shown to be safe when used as directed before they could be approved for marketing. The 1962 Kefauver-Harris Amendments added a requirement that new drugs also must be proven effective for their intended use.

The current new drug application (NDA) process for approving prescription and nonprescription drugs was established subsequent to the Kefauver-Harris Amendments. Since then, any nonprescription drug product with an active ingredient, dosage form, dosage

strength, or route of administration that is new to the over-the-counter (OTC) marketplace must be proven safe and effective through the NDA process.

But what of the 100,000 to 300,000 nonprescription drug products that were already available before the Kefauver-Harris Amendments went into effect? In 1972, the Food and Drug Administration (FDA) initiated a decades-long scientific review of the safety and effectiveness of the more than 700 active ingredients in those products.⁴ This "OTC Drug Review" is a three-phase public rulemaking process. In the first phase, advisory review panels considered the available evidence and classified ingredients in one of three categories⁵:

- Category I: generally recognized as safe and effective ("GRAS/E") for the claimed therapeutic indication.
- Category II: not generally recognized as safe and effective or unacceptable indications.
- Category III: insufficient data available to permit final classification.

In the second phase, the FDA reviewed the panel's findings—as well as comments from the public and any new data that had become available—and published its conclusions in a proposed rule (known as a tentative final

monograph). The third and final phase of the review process is publication of final regulations in the form of OTC drug monographs. The monographs specify the active ingredients that are GRAS/E for each indication—in other words, the active ingredients that can be included in nonprescription drug products—as well as the permitted dosages, indications, and warnings.⁶ All final OTC drug monographs become part of the Code of Federal Regulations.⁶

A citizen petition is one means for requesting amendments to established OTC drug monographs.

Recent Changes in the Pediatric Nonprescription Cough and Cold Product Market—A Brief Chronology

In March 2007, a group of pediatric health care practitioners and public health officials filed a citizen petition requesting an amendment to the Final Monograph for Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use.⁷ Specifically, the citizen petition requested that the labeling for nonprescription antihistamine, antitussive, expectorant, and nasal decongestant cough and cold products (TABLE 1)—as well as products containing combinations of those active

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