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CHPA Presentation Overview

Joint Meeting of the Drug Safety and Risk Management Advisory Committee, Nonprescription Drugs Advisory Committee, and the Anesthetic and Life Support Drugs Advisory Committee
June 29-30, 2009

CHPA and its member companies—companies that manufacture more than 90 percent of the over-the-counter (OTC) acetaminophen-containing medicines in this country—recognize the risk from acetaminophen overdose as a serious public health concern and share the same goals as the U.S. Food and Drug Administration (FDA) to encourage the safe and appropriate use of all acetaminophen-containing medicines. We agree with FDA that together we can take steps to further minimize this problem. Our presentation today outlines initiatives already underway as well as proposed next steps:

- **We support label enhancements as well as educational efforts to encourage the appropriate use of acetaminophen**. In 2002, CHPA member companies committed to voluntary updates to their acetaminophen-containing products, including: highlighting acetaminophen and its purpose in consumer-friendly terms on the principal display panel of combination products; highlighting all active ingredients—including acetaminophen—on the Drug Facts label; adding an overdose warning regarding liver damage; and warning consumers against taking one acetaminophen-containing product with another.

  Additionally, CHPA is exploring the use of an icon to help consumers more easily identify acetaminophen-containing medicines. The icon would complement the principal display panel and the Drug Facts label.

- **We support the continued OTC availability of combination medicines containing acetaminophen.** As outlined in today's presentation, we are concerned that removing acetaminophen from combination products would not only reduce consumer access to medicines that treat a range of symptoms—including pain and fever—but also could lead to unintended adverse consequences. In addition to effectively treating symptoms of cold,

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combination products simplify dosing when treating multiple concurrent symptoms.

- **We support a broad-based research and education program that includes both OTC and prescription (Rx) medicines.** CHPA is proposing the first industry-wide education program focused specifically on acetaminophen. Because nearly half of all products containing acetaminophen are Rx-only, CHPA is proposing a broad-based education program which importantly includes healthcare partners involved in prescribing and dispensing Rx acetaminophen medicines. This program, the foundation of which already has been laid, is based on research, comprehensive in its approach, consistent in its message and targeted to specific user populations. It will be a tested and validated long-term initiative.

- **We support the continued availability of tablet and liquid dose strengths of OTC acetaminophen ranging from 325 – 500 mg, and of single dose ranging from 325 – 1,000 mg.** While overdose of acetaminophen can lead to hepatotoxicity, CHPA agrees with FDA, which stated that the potential to cause liver toxicity when used improperly is not a reason to discourage proper use of acetaminophen. Put simply, studies show doses of acetaminophen of up to 1,000 mg are safe and not associated with any unacceptable risks**.**

- **We support the inclusion of dosing information for children younger than two years of age on single ingredient acetaminophen-containing product labels and to physicians.** Pediatricians continue to recommend acetaminophen for young children. Having this dosing information on product labels, along with proper dosing device, will better help parents and caregivers to dose correctly.