



September 7, 2010

Submitted Electronically

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**Re: Meeting of the FDA Drug Safety and Risk Management Advisory Committee:
Dextromethorphan, September 14, 2010 (75 Fed. Reg. 23782)**

Docket No: FDA-2010-N-0001

The Food Marketing Institute (FMI) appreciates the opportunity to provide comments to the Food and Drug Administration (FDA) Drug Safety and Risk Management Advisory Committee as it prepares to discuss the abuse potential of dextromethorphan as well as the public health benefits and risks of this ingredient as a cough suppressant.

FMI is the national trade association that conducts programs in public affairs, food safety, research, education and industry relations on behalf of its 1,500 member companies – food retailers and wholesalers – in the United States and around the world. FMI's members in the United States operate approximately 26,000 retail food stores and 15,000 in-store pharmacies. Their combined annual sales volume of \$680 billion represents three-quarters of all retail food store sales in the United States. FMI's retail membership is composed of large multi-store chains, regional firms, and independent supermarkets. Our international membership includes 200 companies from more than 50 countries. FMI's associate members include the supplier partners of its retail and wholesale members.

The Food Marketing Institute takes dextromethorphan abuse very seriously and our members never want to see the medications sold in their stores used inappropriately or abused. We support programs that preserve the significant public health benefit of continued over-the-counter (OTC) access to these important cough medicines.

Dextromethorphan has a demonstrated safety profile as an OTC ingredient with over 50 years of safe, effective use under labeled conditions. Dextromethorphan is the most widely used active

ingredient to relieve cough. Dextromethorphan-containing OTC medicines account for 85-90% of all medicines containing a cough suppressant sold in the United States. Approximately 133 million package units of dextromethorphan-containing OTC medicines were purchased in the last year.¹

The FDA originally approved dextromethorphan as a cough suppressant in 1958, after a thorough review of its safety and effectiveness by an FDA expert OTC review board. Though the expert advisory panel's report noted abuse, it was concluded the ingredient was generally recognized as safe and effective for OTC use and stated with the "low order of toxicity, it is probably the safest antitussive presently available."² The final rule confirming dextromethorphan's status as generally recognized as safe and effective for OTC use was published in 1987.

Additionally, a recent report released by the Department of Health and Human Services found that their data "does not indicate that DXM products are widely abused."³

Need for Continued Over-The-Counter Access to Dextromethorphan

Continued access to OTC medicines that can be used safely by consumers without the need for a healthcare professional's expertise is important. This valuable access to OTC medicines, such as dextromethorphan, enables consumers to take appropriate control of their own healthcare in many situations. Given the prevalence of the common cough, and its disruptiveness to everyday life, we feel strongly about the continued OTC status and availability of dextromethorphan containing products. OTC access provides a public health benefit by allowing self-treatment of acute cough, while saving costly and unnecessary doctor visits and prescription costs.

Support for Teen and Parent Intervention and Education Strategies

As reported by the FDA itself, cough medicine abuse is primarily seen in a limited teen population. Therefore, we support education programs targeted toward teens and their parents that build awareness of the dangers associated with abuse. Targeted measures can work to reduce abuse without having to unnecessarily limit access and increase costs for those who depend on these medicines.

Cough is one of the most common symptoms from which people suffer, yet there are very few OTC options for suppressing cough. Continued over-the-counter availability of these OTC cough

¹ Consumer Healthcare Products Association, August 2010

² 48 Fed. Reg. 48576 (Oct. 19, 1983).

³ FDA Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Abuse, Misuse and Overdose, Dextromethorphan-Containing Products (August 13, 2010). Available at <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/DrugSafetyandRiskManagementAdvisoryCommittee/UCM224446.pdf> p. 121.

medicines not only helps those consumers who rely on them for relief, but also the public health overall.

FMI supports the efforts of the Consumer Healthcare Products Association (CHPA) and its intervention and education strategies to mitigate dextromethorphan abuse among teens. Specifically, CHPA's program has the following goals which we support:

- Raise parental, caregiver, and teen-influencer awareness and involvement as to the abuse and its risks;
- Increase the perception of risk among teens by highlighting the risks of abuse;
- Increase social disapproval of the behavior by emphasizing peers' disapproval of abuse and demonstrating that non-abuse is the norm; and
- Reduce dextromethorphan's availability to teens by:
 - Advocating for legislation to establish a national age restriction (18) on purchases of dextromethorphan-containing medicine;
 - Advocating for legislation to prohibit the sale of bulk, unfinished dextromethorphan to parties not registered with FDA; and
 - Encouraging parents and caregivers to engage in monitoring behaviors, such as safeguarding their medicine cabinets, and making sure other parents do likewise.

Scheduling of Dextromethorphan under the Controlled Substances Act

FMI does not believe scheduling of dextromethorphan under the Controlled Substances Act is warranted. The fifty year safety profile of dextromethorphan is important to keep in mind. There are more targeted, more effective, and less disruptive interventions than scheduling to address dextromethorphan abuse, while preserving consumer access to this important ingredient.

In conclusion, data from 50 years of use demonstrates that OTC medicines containing dextromethorphan are safe and effective when used as directed, and cough medicine abuse is the latest example of good and beneficial medicines becoming the target of bad behavior. We need to address this behavior and build awareness through education to have an impact on abuse.

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Cough medicine abuse is primarily focused in a teen population. This means targeted, more effective measures can work to reduce abuse without having to unnecessarily limit access and increase costs for those who depend on these medicines.

Cough is one of the most common symptoms from which people suffer yet there are very few OTC options for suppressing it. Continued OTC availability of these cough medicines not only helps those consumers who rely on them for relief, but also the public health overall.

Thank you for the opportunity to comment on this important matter.

Sincerely,

A handwritten signature in black ink, appearing to read "Erik R. Lieberman". The signature is fluid and cursive, with the first name "Erik" being the most prominent.

Erik R. Lieberman
Regulatory Counsel