



U.S. Pharmacopeia
The Standard of Quality™

FOR IMMEDIATE RELEASE

CONTACT: Sandra Kim
301-816-8241; sek@usp.org

USP Announces Strengthened Glycerin Standard to Help Protect Consumers from Poisoned Products

Rockville, Md., February 4, 2009 — Strengthening the safety nets that protect consumers from serious and potentially fatal health hazards, the U.S. Pharmacopeial (USP) Convention today announces a revised standard for glycerin that provides a new test for manufacturers and enforcement authorities to use in preventing glycerin diluted with diethylene glycol from entering the U.S. drug supply.

Glycerin is used as a solvent and sweetening agent in many drugs and consumer goods, such as cough syrups, toothpaste and mouthwash. Diethylene glycol (DEG) is a poisonous, less expensive chemical used in industrial solvents and antifreeze. Over the past century, accidental or intentional adulteration of drugs with DEG has occurred many times and in many countries, most recently in Nigeria in 2008 and, notably for the United States, in 1937. The 1937 incident in which DEG was used in a popular medication killed more than 100 American citizens, many of them children, and hastened final enactment in 1938 of the Federal Food, Drug, and Cosmetic Act, the statute that today remains the basis for the Food and Drug Administration (FDA) regulation of these products. In April 2007, FDA asked USP to assess the rigor of the test for DEG, and USP began work on the more specific and sensitive test that is announced today. At that time, FDA also underscored the urgent nature of this effort in a “Guidance for Industry Testing of Glycerin for Diethylene Glycol,” recommending that “drug product manufacturers perform a specific identity test that includes a limit test for DEG on all containers of all lots of glycerin ...because of serious health hazards associated with DEG contamination.”

“This updated identification test for glycerin will provide a much stronger barrier to help keep dangerous ingredients out of the U.S. market,” said Roger L. Williams, M.D., USP’s chief executive officer. “Our work on glycerin also pointed us to other, related substances that are in wide use and are vulnerable to similar tampering. In the interest of patient safety, USP will be updating the monograph, or written, standards for sorbitol solution and propylene glycol, even in the absence of a specific incident. This will offer further protections against unscrupulous manufacturers and other bad actors in the distribution chain, for both consumers and legitimate manufacturers.”

USP has revised the standard to help assure the absence of DEG and ethylene glycol (EG) to a level of 0.10 percent. All drug manufacturers using glycerin must comply with the standard, demonstrating that DEG and EG are not present in their U.S.-marketed drug products. The glycerin revision is posted for public comment on www.usp.org. It is scheduled to become official May 1, 2009.

For more information, contact mediarelations@usp.org.

###

USP—Advancing Public Health Since 1820

The United States Pharmacopeial (USP) Convention is a private, non-profit, standards-setting organization that advances public health through public standards and related programs that help ensure the quality, safety, and benefit of medicines and foods. USP’s standards are recognized and used worldwide. For more information about USP visit <http://www.usp.org/newscenter>. **FY0928**

Headquarters

12601 Twinbrook Parkway
Rockville, Maryland 20852
+1-301-881-0666

Europe/Middle East/Africa

Münchensteinerstrasse 41
CH-4052 Basel, Switzerland
+41 (0)61 316 30 10

USP—India Private Limited

ICICI Knowledge Park
Genome Valley
Labs 7-10, Phase III
Turkapally, Shameerpet
Ranga Reddy District
Hyderabad 500 078, A.P., India
+91-40-2348-0088

USP—China

Building 11
Lane 67 Libing Road
Zhangjiang Hi-Tech Park
Shanghai, 201203, China
+86-21-51370600

USP—Brazil

Avenida Ceci, 1600 - Tamboré
Barueri/SP, Brazil
06460-120
+55-11-3245-6400