U.S. FDA Releases Acetaminophen LiverWarning Final Guidance

On November 17, 2015, the U.S. Food and Drug Administration (FDA) released the final guidance on Organ-Specific Warnings: Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use – Labeling for Products That Contain Acetaminophen. The purpose of the draft guidance document was to provide alternate Liver warning language for products intended for adult use where the maximum daily dose of acetaminophen is less than the maximum daily dose of 4,000 mg. This may occur if the product is only intended for daytime or nighttime use or due to other active ingredients in the product. The Final Guidance differs from the Draft Guidance in one major component; the final guidance also includes an alternate Liver warning statement for products intended for adults and children under 12 years of age.

Per the final guidance document, the FDA will not object for use of the following language:

**Products intended for adult use only:**

*Liver warning*: This product contains acetaminophen. Severe liver damage may occur if you take ● more than 4,000 mg of acetaminophen in 24 hours ● with other drugs containing acetaminophen ● 3 or more alcoholic drinks every day while using this product.

**Products intended for adults and children under 12 years of age:**

*Liver warning*: This product contains acetaminophen. Severe liver damage may occur if ● adult takes more than 4,000 mg of acetaminophen in 24 hours ● child takes more than 5 doses in 24 hours ● taken with other drugs containing acetaminophen ● adult has 3 or more alcoholic drinks every day while using this product.

It should be noted that products intended only for children under 12 years of age shall have the Liver warning language outlined in 21 CFR 201.326(a)(1)(iv) seen below.

**Products intended for children under 12 years of age only:**

*Liver warning*: This product contains acetaminophen. Severe liver damage may occur if your child takes: ● more than 5 doses in 24 hours, which is the maximum daily amount [optional: “for this product”] ● with other drugs containing acetaminophen.

Click to view the Guidance: Organ-Specific Warnings: Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use – Labeling for Products That Contain Acetaminophen:


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For over 35 years, Bureau Veritas has worked successfully with top retailers and manufacturers around the world to help them better manage risk and regulatory compliance. If you have any questions, please contact your customer service representative or email: cps.info@us.bureauveritas.com.