U.S. FDA Releases Guidance Documents on Acetaminophen and Aspirin

The U.S. Food and Drug Administration (FDA) recently published the final guidance document, *Recommended Warning for Over-the-Counter Acetaminophen Containing Drug Products and Labeling Statements Regarding Serious Skin Reactions*, and the draft guidance, *Recommended Statement for Over-the-Counter Aspirin-Containing Drug Products Labeled With Cardiovascular Related Imagery*.

In the final guidance, *Recommended Warning for Over-the-Counter Acetaminophen Containing Drug Products and Labeling Statements Regarding Serious Skin Reactions*, the FDA indicated that they do not intend to take action against products that include the following allergy alert on acetaminophen-containing products:

**Allergy alert:** Acetaminophen may cause severe skin reactions. Symptoms may include: ● skin reddening [bullet] blisters ● rash

If a skin reaction occurs, stop use and seek medical help right away.

The main update from the draft guidance is that it now includes information on how to label products that contain acetaminophen and aspirin with two allergy alert warning statements. Products that contain both acetaminophen and aspirin shall list the allergy alert warnings after the Reye’s syndrome warning and before the Liver and Stomach bleeding warnings.

**Click to view the Guidance:** *Recommended Warning for Over-the-Counter Acetaminophen Containing Drug Products and Labeling Statements Regarding Serious Skin Reactions*:

The draft guidance, *Recommended Statement for Over-the-Counter Aspirin-Containing Drug Products Labeled With Cardiovascular Related Imagery*, states that the FDA does not intend to take action against over-the-counter products containing aspirin that have cardiovascular related imagery (such as the heart image), if the label includes the following statement, “Consult your healthcare provider before using this product for your heart.” The recommended statement shall appear close to the related imagery in 6-point type size on the principal display panel (PDP).

**Click to view the Draft Guidance:** *Recommended Statement for Over-the-Counter Aspirin-Containing Drug Products Labeled With Cardiovascular Related Imagery*:

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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.