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February 2, 2006

TO CLIENTS AND FRIENDS:

RE: **Recommended Maximum Level Of Lead In Candy Consumed By Children**

The Food and Drug Administration (FDA) has requested comments regarding its draft guidance entitled *Lead In Candy Likely To Be Consumed Frequently By Small Children: Recommended Maximum Level And Enforcement Policy*. This document, together with the corresponding *Supporting Document for Recommended Maximum Level for Lead in Candy Likely To Be Consumed Frequently by Small Children*, is intended to assist candy manufacturers in reducing the lead in candies frequently consumed by small children to a level not exceeding 0.1 parts per million.

The findings and recommendations are based on studies dating back to 1994, when it was discovered that certain lead-based ink used in candy packaging contaminated the enclosed candy with lead. FDA is now also reiterating its enforcement policy in that regard: “[I]f lead derived from a lead-based printing ink is found on the portion of the package that directly contacts food or, if such lead could be expected to migrate into the packaged food, the product would likely be regarded as being in violation of the Federal Food, Drug, and Cosmetic Act.”

Subsequent studies have now determined that certain ingredients, such as chili powder and certain types of salt, as well as certain manufacturing processes or conditions may also be contributing to the lead content in candies. Accordingly, the FDA is providing guidance to assist manufacturers in reducing small children’s exposure to lead.

Please advise if you would like us to forward copies of the documents. If you prefer, however, the draft guidance and supporting document may be accessed through these links: <http://www.cfsan.fda.gov/~dms/pbguid2.html>, and <http://www.cfsan.fda.gov/~dms/pbcandy.html>

Comments are due by March 13, 2006; they may be submitted in paper or electronically. If you have any questions or wish to discuss the matter, please do not hesitate to call us.

Firm contact: Barbara Y. Wierbicki (bywierbicki@tdllp.com)

Note: The above comments are intended for general information only, and not as legal advice. Legal advice can only be offered after a review of a client’s specific facts and circumstances, which may affect the applicability of any general comments contained herein.