UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C., 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

April 30, 2007

Ms. Jane Doe
President
XYZ Manufacturing, Inc.
123 Elm Street
Anytown, US 00001

Dear Ms. Doe:

The U.S. Environmental Protection Agency (EPA or Agency) is committed to doing its part to contribute to the federal goal of eliminating childhood lead poisoning by 2010, and is concerned about a number of reports involving lead in toy jewelry and other products intended for use by children.[1] You are receiving this letter because XYZ Manufacturing, Inc.is one of many companies that EPA has identified as having participated in a recall related to lead in a consumer product or a settlement with the State of California last year regarding lead in jewelry. For this reason, EPA is writing to ensure that you are aware of the reporting requirements under the Toxic Substances Control Act (TSCA) section 8(e) (15 U.S.C. § 2607(e)), which provides:

> Any person who manufactures, processes, or distributes in commerce a chemical substance or mixture and who obtains information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment shall immediately inform the Administrator of such information unless such person has actual knowledge that the Administrator has been adequately informed of such information.

Toxicity data that indicate a substantial risk of injury to health or the environment are the most common kinds of information received by EPA under TSCA section 8(e), but the Agency also often receives information on exposure, environmental persistence or other kinds of information that indicate a substantial risk of injury to health or the environment.

The health of consumers who are exposed to lead through use of lead-containing products may be at risk. For example, young children often put objects in their mouths. When those

[1]See e.g., CDC, Morbidity and Mortality Weekly vol. 55, March 23, 2006; available at: http://www.cdc.gov/mmwr/PDF/wk/mm55d323.pdf

objects, such as toy jewelry, contain lead, a child can suffer from lead poisoning as a result of this exposure. Lead may cause a range of health effects, from behavioral problems and learning disabilities, to seizures and death. For more information on the health effects of lead please visit the EPA's lead homepage at www.epa.gov/lead.

As you probably know, the U.S. Consumer Product Safety Commission (CPSC) has authority under the Consumer Product Safety Act and the Federal Hazardous Substances Act to take certain actions to address risks from consumer products. The CPSC has undertaken numerous recalls and other actions in an attempt to reduce risks from lead in toy jewelry. On January 9, 2007, CPSC published an advance notice of proposed rulemaking (72 FR 920) to ban children's metal jewelry containing more than 0.06% lead. EPA also is working to address health risks from lead in children's products, by assessing the problem and gathering information that may be useful in determining future efforts to reduce risks from these products.

Your company can play a role in identifying and reducing these potential risks. In addition to possible obligations under the Consumer Product Safety Act and the Federal Hazardous Substances Act, persons who manufacture, process, or distribute lead in products also may have obligations under TSCA.

With respect to TSCA section 8(e), EPA guidance issued in September 2006 and currently available on the Agency's website[2] states:

> Q.25. Are studies or reports showing absorption from manufactured products or articles of a chemical known to be capable of causing serious health effects potentially reportable under TSCA section 8(e)? For example, are studies or reports showing absorption of lead following oral or dermal exposure to a particular type of article for which it was not previously known that such absorption could occur potentially reportable under TSCA 8(e)?
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> A.25. Yes – The discovery of previously unknown and significant human exposure to a chemical, when combined with knowledge that the subject chemical is recognized or suspected as being capable of causing serious adverse health effects (e.g., cancer, birth defects, neurotoxicity), provides a sufficient basis to require the reporting of the new-found exposure data to EPA under section 8(e).
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> Q.26. Is the discovery of a hazardous or toxic constituent in a product reportable under TSCA section 8(e)?
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> A.26. Reporting of the presence of a hazardous or toxic constituent that was previously unknown to be contained in a product, including manufactured articles, should occur under TSCA section 8(e) where data shows that widespread or significant exposure to the

[2] "September 2006 Frequent Questions," available at http://www.epa.gov/oppt/tsca8e/pubs/frequentlyaskedquestionsfaqs.htm#health2.

toxic component has occurred or is substantially likely to occur, and such exposure presents a substantial risk of injury to health or the environment. Persons subject to TSCA 8(e) reporting should consider the toxicity of the constituent, the constituent's concentration in the product, and whether significant exposure to the toxic component has occurred or is likely to occur at any stage in the product's lifecycle from production through disposal. In cases of extremely toxic chemical substances in products in commerce, exposure may generally be presumed.

We hope this letter will assist you in assessing your company's potential obligations under TSCA. More information on TSCA section 8(e) reporting is available on the TSCA section 8(e) website at www.epa.gov/opptintr/tsca8e; directions on how to send 8(e) submissions to EPA is provided at http://www.epa.gov/oppt/tsca8e/pubs/contactus.htm. Please refer questions on TSCA section 8(e) requirements to Walter Cybulski at (202) 564-2409.

If you have general questions regarding TSCA requirements, please contact the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached via email at tsca-hotline@epa.gov.

Sincerely,

for James B. Willis
Director
Chemical Control Division
Office of Pollution Prevention and Toxics

cc: Lori Saltzman, CPSC