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January 7, 2000

Dr. C.W. Jameson
Report on Carcinogens
NIEHS, MD EC-14
79 Alexander Drive
Building 401, Room 3127
P.O. Box 12233
Research Triangle Park, NC 27709

Re: Production and Use Data for Benzidine Dyes

Dear Dr. Jameson:

On behalf of the Leather Industries of America ("LIA"), pursuant to the National Toxicology Program's ("NTP's") recent request for information, we hereby submit the following comments and information regarding the production and use of Dyes Metabolized to Dimethoxybenzidine and Dimethylbenzidine ("benzidine dyes"). *See* 64 Fed. Reg. 63,326 (Nov. 19, 1999). LIA is concerned primarily about NTP's identification of the leather industry as a primary user of and source of exposure to benzidine dyes, as well as its assertion that leather products may contain these dyes and expose the general population. In fact, the U.S. leather industry has not used benzidine dyes for several years. Accordingly, if these substances are listed in the Report on Carcinogens, NTP should make clear that benzidine dyes are no longer used in the U.S. leather industry.

I. BACKGROUND

LIA is one of the oldest national trade associations, and today represents the vast majority of all domestic facilities engaged in the tanning and finishing of leather. The U.S. tanning industry employs about 12,000 people and produces high quality leathers used mainly in the footwear and upholstery markets. U.S. leather manufacturers tan approximately 20 million cattle hides annually, all of which are free of the benzidine dyes. LIA has long been concerned with ensuring proper regulatory treatment of the leather industry and the chemicals employed in the leather manufacturing process. As discussed below, the U.S. tanning industry has stopped using benzidine dyes.

II. NTP SHOULD NOT IDENTIFY THE U.S. LEATHER INDUSTRY AS A SOURCE OF EXPOSURE TO BENZIDINE DYES

NTP erroneously asserts that benzidine dyes are currently used in the U.S. tanning industry to color leather products. *See* 64 Fed. Reg. at 63,327; NTP, *Report on Carcinogens Background Document for Dyes Metabolized to 3,3'-Dimethoxybenzidine (Draft)* at 5 ("*Dimethoxybenzidine Background Document*"); NTP, *Report on Carcinogens Background Document for Dyes Metabolized to 3,3'-Dimethylbenzidine (Draft)* at 5 ("*Dimethylbenzidine Background Document*"). In addition, NTP states that "[g]eneral population exposure also may occur via contact with . . . leather products containing these dyes." *Dimethoxybenzidine Background Document* at 7; *Dimethylbenzidine Background Document* at 6. NTP's assertions appear to be based on worker exposure data dating back to the early 1980s. *See id.*

In fact, the use of these dyes in the U.S. tanning industry ceased no later than 1997. During 1994, the majority of leather manufacturers stopped using benzidine dyes in the wake of the publication of draft German legislation banning the presence in consumer goods of certain azo dyes, including the benzidine dyes NTP is reviewing. The German legislation, known as the 5th Amendment of the Consumer Goods Ordinance, was finalized on April 17, 1997, and banned the sale after December 31, 1998 of leather and leather goods containing any of the listed azo dyes.[1/] In preparation for this ban, LIA members ceased use of benzidine dyes well in advance of the 1998 deadline.

Similar legislation banning the presence of azo dyes in consumer goods has been adopted or proposed in the Netherlands, Austria, Denmark, and France. In 1999, the European Union ("EU") incorporated the azo dye ban into its criteria for awarding eco-labels to footwear. *See* Commission Decision 1999/179/EC (Feb. 17, 1999) (Attachment 2 to these Comments). While the eco-label program is voluntary, the draft 19th Amendment to EU Directive 76/769/EEC would extend the azo dye ban across Europe, specifically prohibiting the use of benzidine dyes in leather articles that may come into contact with humans. *See* Attachment 3 to these Comments.

Accordingly, the leather industry, both in the U.S. and worldwide, no longer is a source of exposure to benzidine dyes. NTP therefore should revise its background documents to reflect this change, and should ensure that any discussion of the use of benzidine dyes in the *Report on*

1/ *See* Ecological and Toxicological Association of Dyes and Organic Pigments Manufacturers ("ETAD"), *ETAD Information Notice No. 6: German Ban of use of certain azo compounds in some consumer goods* (Oct. 1998) (available at ETAD's website: www.etad.com/inormation_6.html) (Attachment 1 to these Comments).

Carcinogens does not mention the leather industry. Similarly, it is inappropriate for NTP to state that leather products may be a source of benzidine dye exposure for the general population.

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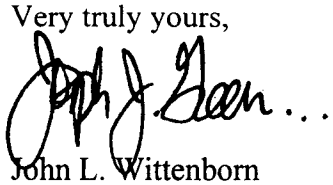
LIA appreciates the opportunity to provide NTP with this information on the use of benzidine dyes in the U.S. leather industry. If you have any questions regarding this information, please feel free to contact John Wittenborn at (202) 342-8514 or Joe Green at (202) 342-8849.

Very truly yours,



John L. Wittenborn
Joseph J. Green
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cc: Dr. Nicholas J. Cory, LIA