SANFORD J. LEWIS, ATTORNEY

July 11, 2001

Bernard A. Schwetz, DVM, Ph.D.
Acting Principal Deputy Commissioner
Food and Drug Administration
Dept. of Health and Human Services
5600 Fishers Ln. Rm. 14-71
Rockville, MD 20857

Subject: Citizen Petition for a Food and Drug Administration
Regulation or Guideline to Label Medical Devices that Leach
Phthalate Plasticizers and to Establish a Program to Promote Alternatives
Docket Number 99P-2077/CP 1

Dear Dr. Schwetz,

I am writing on behalf of Health Care Without Harm, which filed the above-named petition, to ascertain the status of the FDA's response. The petition was filed June 14, 1999, which was more than two years ago. We believe that sufficient time has passed for the FDA to assess the merits of the petition and to take responsive action; we believe that a response is now unreasonably delayed.

In the intervening period, the Center For The Evaluation Of Risks To Human Reproduction of the National Toxicology Program published its Expert Panel report indicating, among other things, "serious concern" regarding reproductive hazards to critically ill neonates exposed to DEHP from medical devices. The NTP recently indicated that this conclusion is not expected to change in the final report.

The NTP expert panel report was released over nine months ago and the FDA has yet to ac on the updated scientific information identifying the risks of DEHP-containing medical devices. Fur er studies have substantiated the serious concerns identified by the NTP panel. For instance, a recent sk assessment of DEHP developed by the Chemical Inspectorate of Sweden, representing the Euro an Commission, concluded that efforts should be undertaken to reduce DEHP exposures from me al devices because of health impact concerns.

The FDA has not repsponded to Health Care Without Harm's 1999 petition to ensure adeq te labeling and promotion of alternatives. Continued delay by the FDA is itself jeopardizing the healt of infants, by failing to ensure adequate notice to health care providers regarding these potential hazard of use.

I have been asked by Health Care Without Harm to consider filing an action to enforce ie petition. In order to assess our course of action, I need to know by when you expect to make a deci n to grant or deny the petition. We would appreciate a reply to this inquiry by the end of July a ie latest.

Thank you.

Sincerely,

Sanford Lewis

99P-2077

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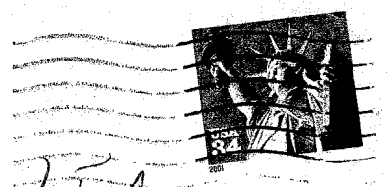

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