

December 5, 2002

Dockets Management Branch  
Division of Management Systems and Policy  
Office of Human Resources and Management Services  
Food and Drug Administration  
5630 Fishers Lane, Room 1061 (HFA-305)  
Rockville, MD 20852

Re: Docket No. 02D-0325: Medical Devices Made with Polyvinylchloride (PVC) Using the Plasticizer di-(2-Ethylhexyl)phthalate (DEHP); Draft Guidance for Industry and FDA

Dear Sir/Madam:

The Phthalate Esters Panel of the American Chemistry Council has submitted comments dated 4 December 2002 in response to the above-referenced draft guidance document released by FDA's Center for Devices and Radiological Health (CDRH) Office of Device Evaluation.

Those comments discussed a yet unpublished study, Schilling et al. 2001, and stated that a copy of the study was being submitted by BASF Corporation. Please find a copy of the full study report attached to this letter.

Kind regards

  
Gerhard Gans

02D-0325

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