



TEKNOR APEX COMPANY

October 30, 2002

Phillip J. Phillips
Deputy Director for Science and Regulatory Policy
Office of Device Evaluation
Food and Drug Administration
9200 Corporate Blvd., HFZ 400
Rockville, MD 20850

Re: Draft Guidance Pertaining to Medical Devices Made with PVC Containing DEHP, Docket No. 02D-0325

Dear Mr. Phillips,

Thank you for the opportunity to meet with you and your staff on October 10, 2002 concerning the above mentioned draft guidance document. That meeting was very productive and informative. We clearly learned the intent behind the CDRH in issuing this draft guidance. It also pointed that the guidance is being read by the DEHP user community with an alternative interpretation than that intended by the FDA.

We are writing this letter to support the letter submitted by the American Chemistry Council's Phthalate Esters Panel (PEP), dated October 22, 2002. Teknor Apex Company supports the recommendations in that letter. Teknor has had direct communications with several device manufacturers that support the comments made by the PEP members at the meeting regarding the user community's interpretation of this document. The user community's interpretation is far different than the one expressed by the FDA at the meeting.

Teknor Apex Company is requesting that this draft guidance be withdrawn. Teknor believes the CDRH's safety assessment and related public health notification dated July 12, 2002 is sufficient information to the device manufacturers of the scientific issues pertaining to the use of PVC containing DEHP in medical devices.

In summary, as we relayed at the meeting it is our belief that:

1. End users are currently being driven by the draft guidance document to hastily seek DEHP and/or PVC replacements out of respect for the FDA's opinion.
2. Many of the non-DEHP plasticizers that will be selected as replacement candidates, will have a greater extractability in aqueous media, than will the DEHP being replaced.
3. There is a serious lack of information available regarding the safety and efficacy of the substitute materials being considered, with only the higher cost being somewhat of a certainty.

02D-0325

C3

4. End users are seeking advice from suppliers like ourselves as to which alternative materials would be favorable to the FDA, and in the absence of data as comprehensive as that compiled for DEHP plasticized PVC, it is unclear how equivalent due diligence will be carried out on the substitute materials.

Thank you for your attention to this letter. We appreciate the opportunity to supply this additional information to the FDA. If you wish to discuss this further, please feel free to contact David Yopak or Peter Galland at 1-401-725-8000 at extensions, 137 or 424 respectively.

Sincerely yours,



Peter Galland, Medical Market Industry Manager
David Yopak, Director of Regulatory Affairs

cc:

Docket No 02D-0325
Docket 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

L. Mammino, Teknor Apex Company
Marian Stanley, Manager, Phthalate Esters Panel
Fred Krause, Senior Advisor, Vinyl Institute
File