



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Re: Draft Guidance to Medical Device Manufacturers for "Medical Devices Made With Polyvinyl Chloride (PVC) Using the Plasticizer di-(2-ethylhexyl) phthalate (DEHP), Docket No. 02D-0325

Dear Sir/Madam:

The Vinyl Institute (VI) would like to submit the following comments in response to the above-referenced guidance document. VI has received numerous calls from its customers expressing confusion over this document and the comments contained in this letter are intended to help clarify what appears to be the Agency's current thinking on the issue based on the September 2001 "Safety Assessment of Di(2-ethylhexyl)phthalate (DEHP) Released from PVC Medical Devices" and the subsequent "Public Health Notification: PVC Devices Containing the Plasticizer DEHP" issued July 12, 2002.

In fact, because FDA has already issued the two aforementioned documents, VI does not believe separate guidance to medical device manufacturers is necessary. These two documents are sufficient to inform manufacturers about potential concerns related to PVC medical devices containing DEHP. As such, VI believes it would be appropriate to withdraw the draft guidance altogether.

However, should FDA decide against withdrawing the guidance, below are VI's three main concerns regarding this draft guidance document:

- 1) **The Draft Guidance appears to go beyond the earlier documents, broadening concern to include all PVC medical devices, and is creating inconsistencies with FDA's Safety Assessment that found the broad use of these products safe.** Although the Draft Guidance states, "FDA recognizes that many devices with PVC containing DEHP are not used in ways that result in significant human exposure to the chemical," it contains numerous statements and recommendations that are

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contradictory, and appear to suggest that all PVC devices containing DEHP should be replaced or labeled. As a result, the Draft Guidance is causing confusion in the marketplace.

- 2) **The Draft Guidance should limit its recommendations to devices used in Neonatal Intensive Care Units (NICUs.)** Although no human toxic and carcinogenic effects have been found from more than 50 years of use of PVC medical devices containing DEHP, FDA has noted some concern for certain potentially sensitive patient populations, most notably neonates. The Draft Guidance states upfront that devices used in NICUs should be a “primary focus” and its recommendations should therefore be clearly consistent with this focus.
- 3) **Recommendations in the Draft Guidance should be consistent with findings in FDA’s Safety Assessment and only apply to devices which have uses where DEHP exposures are expected to exceed the established Tolerable Intake (TI) value.** Specifically, the Draft Guidance document includes intravascular tubing and catheters/cannulae used in IV administration whereas the vast majority of applications for IV administration have DEHP exposure doses below the TI value.

Recommendations to Clarify the Draft Guidance

In order to address the concerns noted above and clarify guidance to medical device manufacturers regarding the design and labeling of medical devices used to treat patients groups with a potentially higher sensitivity to DEHP, most importantly neonates, please consider the following suggestions:

- We recommend that the guidance document make explicitly clear that the vast majority of uses of PVC medical products have been found safe for the general patient population. This statement is consistent with FDA’s September 2001 safety assessment and July 2002 public health notification.

Suggested Language:

On line 38, include the following: *Research has shown that there is little or no risk posed by exposure of the general patient population to DEHP from PVC medical products.*

- Because the vast majority of applications of “IV administration” (line 54) have a DEHP exposure dose below the Tolerable Intake value established by FDA, we recommend that line 54 in the draft guidance state specifically “IV administration for neonates.”
- In order to clarify that concern regarding exposure to DEHP is limited to devices used to treat sensitive patient populations, specifically neonates, we recommend the following:

Suggested Language:

Replace the sentence beginning on line 68 with the following: *Nothing. There is little or no risk posed by exposure of the general population to DEHP from PVC medical products. However, for those devices used to treat neonates, we recommend that you consider all mechanisms to reduce exposure to DEHP.*

- On line 72, the phrase “minimizing patient exposure to DEHP” appears in quotation marks and suggests that this phrase is a citation from 21 CFR 820.30. However, a review of this document makes no mention of minimizing DEHP and therefore the quotation marks are misleading. In order to clarify, we recommend removing the quotation marks and phrasing the sentence in the following way:

Suggested Language:

Manufacturers should consider minimizing exposure to DEHP as a design requirement in their design control procedures for devices used in Neonatal Intensive Care Units.

- In order to clarify FDA’s recommendation regarding labeling, we recommend the following:

Suggested Language:

On line 111, the question should be amended to read: *What if I choose not to change the material in my device used to treat neonates?*

On line 114: *Yes, we recommend that you clearly indicate through user labeling that your device used to treat neonates contains DEHP.*

- The answer to the final question, “Where can I find more information about medical devices and DEHP?” (line 128), should direct readers to FDA’s September 2001 Safety Assessment and July 12, 2002 Public Health Notification both on PVC Devices Containing the Plasticizer DEHP.

Suggested Language:

On line 130: *The Center for Devices and Radiological Health (CDRH) recently released a public health notification, which can be found at <http://www.fda.gov/cdrh/safety/dehp.html> as well as a safety assessment which can be found at <http://www.fda.gov/cdrh/ost/dehp-pvc.pdf>.*

- Finally, we recommend that this guidance document clearly state that it is a “follow-up” document to FDA’s July 12, 2002 notice and September 2001 safety assessment.

Suggested Language:

On line 7: *This document is intended to provide guidance. It represents the Agency’s current thinking on this topic and is a follow-up document to FDA’s July 12, 2002 Public Health Notification on PVC Devices Containing the Plasticizer DEHP and its*

September 2001 Safety Assessment of Di(2-ethylhexyl)phthalate (DEHP) Released from PVC Medical Devices.

Thank you for the opportunity to submit these comments and suggestions. We hope that you will give them due consideration and if you have any questions, please don't hesitate to contact me at 703-741-5665. We look forward to reviewing FDA's final guidance to medical device manufacturers on this issue.

Sincerely,

A handwritten signature in black ink that reads "Tim Burns". The signature is written in a cursive, flowing style.

Tim Burns
President

cc: Philip Phillips
Daniel G. Schultz, MD