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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

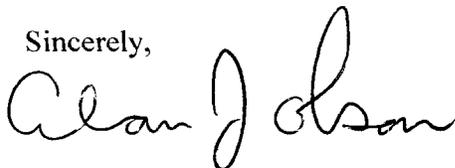
Dear Sir/Madam:

This letter includes the Ferro Corporation's comments on the FDA Draft Guidance "Medical Devices Made With Polyvinyl Chloride (PVC) Using the Plasticizer di-(2-ethylhexyl) phthalate (DEHP), Docket No. 02D-0325.

We suggest editing the Draft Guidance so that it is explicitly clear that recommendations apply only to devices and procedures used to treat sensitive patient populations. Although the document states upfront that FDA is focused on a "small subset of medical devices" and that FDA "recognizes that many devices made with PVC containing DEHP are not used in ways that result in significant human exposure to the chemical," the remainder of the Draft Guidance can be interpreted to apply to *all* PVC medical devices containing DEHP. As a result, the document's real intent is unclear and has confused many of our customers.

Thank you for your consideration and if you have any questions, please contact me at 216-750-6696.

Sincerely,



Alan J. Olson, P.E.
Director of Technology
Ferro Polymer Additives

ALAN J. OLSON, P.E.
DIRECTOR OF TECHNOLOGY



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02D-0325

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