



ADRIAN DOMINICAN SISTERS
1257 East Siena Heights Drive
Adrian, Michigan 49221-1793
517-266-3400 Phone
517-266-3524 Fax
Portfolio Advisory Board

November 19, 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

The Adrian Dominican Sisters submit the following comment regarding the Food and Drug Administration's "Draft Guidance for Industry and FDA on Medical Devices Made With Polyvinylchloride (PVC) Using the Plasticizer di-(2-Ethylhexyl)phthalate (DEHP)."

We urge the FDA to require labeling of all medical devices containing DEHP.

The National Toxicology Program review and the FDA's own Safety Assessment have found that exposure to DEHP during early stages of development may be harmful to the developing male reproductive system. That concern was identified at levels of exposure expected to occur during some routine uses of medical devices. High-risk groups include male fetuses, neonates, and peri-pubertal males.

The FDA identified several procedures that pose the highest risk of exposure to DEHP: exchange transfusions in neonates; ECMO in neonates; total parenteral nutrition (TPN) in neonates (with lipids in the bag); enteral nutrition in neonates and adults; aggregate doses in patients receiving heart transplant or undergoing coronary artery bypass graft surgery; massive infusion of blood into trauma patients; and transfusion in adults undergoing ECMO. The Public Health Notification further recommends considering alternatives to DEHP-containing devices when high-risk procedures are to be performed on male neonates, pregnant women who are carrying male fetuses, and peri-pubertal males.

In its draft Guidance subsequently released to the public, the FDA identified a list of device categories regulated by its Center for Devices and Radiological Health that may contain PVC components and therefore the plasticizer DEHP. Currently, there are only a handful of these devices that are labeled.

The Guidance recommends that manufacturers consider the feasibility of replacing PVC containing DEHP with either alternative materials for plasticizers, or using coatings that may minimize patient exposure to DEHP. If manufacturers choose not to redesign or reformulate their DEHP-containing products, the FDA recommends, but does not require, that manufacturers label their products so that users will be able to identify those products that contain DEHP.

02D-0325

C 2b

This voluntary approach does not provide assurance that devices will be labeled, nor that practitioners will have enough information to make informed decisions. Our dialogues with corporations lead us to believe that without an FDA requirement, many manufacturers will not notify consumers of the presence of DEHP in medical devices. Additionally, obtaining information from manufacturers as to whether or not a product contains DEHP is not always an easy task.

The information already published by the FDA regarding the potential harm of DEHP appears to meet the FDA's definition of when a label should be required - that is, when usage by or affecting children may be harmful to health. The population affected by the needed labeling is not insignificant. Pregnant women, women who may be pregnant, peripubertal males, and neonates constitute a large patient population at risk from DEHP exposure.

We urge the FDA to formulate policies that require practitioners to implement the Public Health Notification issued by your agency. Without labeling, it is difficult to understand how practitioners are to carry out the FDA recommendations. We urge the FDA to give them the tools they need to protect the health of patients.

We also believe that suppliers and distributors should be required to make information about DEHP and/or PVC readily available in catalogs and other materials used in the marketing of medical devices. Without this information, purchasers and health care providers will not be able to make informed purchasing decisions necessary for protecting the health of patients.

Thank you for the opportunity to submit comment.

Sincerely yours,

A handwritten signature in cursive script that reads "Margaret Weber". The signature is written in black ink and is positioned above the typed name and title.

Margaret Weber
Coordinator of Corporate Responsibility
Adrian Dominican Sisters