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

Docket No. 02D-0325

The FDA recently issued a Public Health Notification urging health care practitioners to use alternatives to DEHP-added products whenever possible to reduce potential adverse impacts on patient health. However, the FDA failed to require manufacturers to label such products. Since DEHP and non-DEHP products look virtually the same, how are nurses, physicians, and purchasers to know which ones are safe? We urge the FDA to require labeling of medical devices containing DEHP.

The FDA's draft Guidelines recommends that manufacturers consider the feasibility of replacing PVC containing DEHP with either alternative materials or plasticizers, or using coatings that may minimize patient exposure to DEHP. But if manufacturers choose not to redesign or reformulate their DEHP-containing products, there is currently nothing that requires them to label their products so that users will be able to identify those that contain DEHP. Health care providers would be left in the unfortunate position of not knowing whether or not they were using a DEHP-containing product, making protection of vulnerable patients difficult to impossible.

Without mandatory labeling, practitioners can not carry out the FDA recommendations, jeopardizing the health of a large patient population. We urge the FDA to make labeling a requirement, and also to encourage suppliers and distributors to make information about DEHP and/or PVC readily available in all materials used in the marketing of medical supplies and devices.

Sincerely,  
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Issues Coordinator

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