



APR - 5 2002

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

8054 02 APR -9 19

Sanford J. Lewis, Attorney
P.O. Box 79225
Waverley, Massachusetts 02479

Re: Docket No.: 99P-2077

Dear Mr. Lewis:

This letter is in response to your October 5 petition for reconsideration of our September 5 response to the citizen petition you submitted on behalf of Health Care Without Harm (HCWH) (filed by the Food and Drug Administration (FDA) on June 15, 1999). We also met with you on March 7, 2002, to listen to your concerns, and on March 18 we received an additional letter reiterating your concerns and thanking us for meeting with you.

In our September 5, 2001 letter, we denied your petition to (1) initiate a rulemaking or issue a guidance requiring all polyvinyl chloride (PVC) medical devices that may leach phthalate plasticizers to include a prominent, warning label as to the potential for di(2-ethylhexyl)phthalate (DEHP) or other phthalate plasticizers to leach out the PVC and enter the body and, (2) establish a program to expedite the development and usage of substitutes for PVC medical devices that leach phthalate plasticizers. The petition further suggested that such a program may include actions to expedite review of PVC-free and phthalate plasticizer-free alternative products, encourage FDA-regulated manufacturers to voluntarily shift to usage of materials without PVC and phthalates plasticizers, promote research and development of alternatives, educate and inform health care providers and consumers of the hazards of these products and the availability of alternatives, and maintain and publish an up-to-date inventory of medical devices that leach plasticizers and any FDA-approved alternatives to these devices.

Your October 5 petition appears to be based on your belief that FDA did not adequately consider the safety assessment of the DEHP used in medical devices in its response to you.

Under section §10.33(d) of the FDA administrative practices and procedures regulations (21 CFR 10.33(d)), before granting a petition for reconsideration, FDA must determine that all of the following are true:

1. The petition demonstrates that relevant information or views contained in the administrative record were not previously or not adequately considered.
2. The petitioner's position is not frivolous and is being pursued in good faith.
3. The petitioner has demonstrated sound public policy grounds supporting reconsideration.

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4. Reconsideration is not outweighed by public health or other public interests.

You have not met this burden. You have not demonstrated that FDA did not adequately consider the views and relevant information contained in the administrative record. You have not offered any new policy grounds to support reconsideration. Nor have you shown that public health or other public interests do not outweigh reconsideration.

1. In your petition for reconsideration, you request FDA to grant your petition in part.

In our previous response, we stated that we were denying most of the specific actions you request in your petition. We did agree, however, to implement a risk communication strategy. In your petition for reconsideration, you have not demonstrated that FDA did not adequately consider the views and relevant information contained in the administrative record in denying your other requests.

2. You also request that FDA “take formal action to implement responsive action, including identifying the agency’s commitments including timelines, benchmarks, medical devices and areas of utilization targeted, etc..”

In support of your request, you cite Section 10.30(e)(2)(i) (21 CFR 10.30(e)(2)(i)) of FDA’s administrative practices and procedures regulation which states that, when FDA approves a petition, FDA “shall concurrently take appropriate action ... implementing the approval.” FDA approved your petition only to the extent that FDA agreed to develop a “risk communication strategy.” In our response, we specifically stated that the strategy would be implemented by notifying health care providers of the results of the safety assessment via the FDA website and that FDA had posted a Q and A document on the CDRH Home Page. In fact, FDA did implement its approval immediately by placing this information on the CDRH Home Page.

3. In your petition for reconsideration as well as your original petition, you request that FDA initiate a rulemaking or issue a guidance concerning all PVC medical devices that leach plasticizers. You request that FDA require that the labeling for these devices include a prominent, clearly worded warning as to the potential for DEHP or other phthalate plasticizers to leach and the potential for health effects from exposure to DEHP. FDA carefully considered these requests and addressed them in our earlier response.

As stated in our earlier response, we continue to examine the risks of exposure of DEHP used in medical devices. With regard to requiring labeling, as previously stated, FDA would need to determine that, without such a statement, the device would be misbranded under section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) (The Act). With that in mind, we stated that “we recognize that risk reduction strategies may be necessary for some medical procedures that

employ PVC devices and new labeling... is one regulatory option.” As we told you at the meeting on March 7, 2002, we are considering preparing a guidance document with labeling recommendations for devices containing DEHP. In accordance with our regulation governing good guidance practices (21 CFR 10.115), we will make a draft of this guidance document available for comment before we implement it. We expect to make this guidance available in the very near future.

At this time, and as we stated in our response to your original petition, we do not believe a label for all DEHP containing products is warranted by the scientific evidence we have reviewed. Your petition for reconsideration did not bring any new data for our consideration. If we receive information to support requiring labeling for one or more devices that contain DEHP, we will take the necessary action.

Items 3 (a – f) in your petition for reconsideration are the same as your original petition and were addressed in our earlier response. You have not shown us that we did not adequately consider these points in our earlier response. You merely provided us an expanded version of the original request. We will consider the labeling recommendations in section 3 (g) of your petition in developing our guidance document.

4. You request that FDA develop a market information and education program that informs health-care providers of the potential hazards of DEHP and the availability of DEHP-free or non-leaching DEHP alternatives and that FDA clarify the scope and extent of the agency’s risk communications program and include the petitioner in the development of the program.

We addressed this request in our previous response. You have not provided additional information to support reconsideration of these issues. As we told you in our meeting with you on March 7, 2002, we are considering additional communications with healthcare professionals. If these communications occur they will, of course, be public and we will be interested in any comments you or other interested parties may have to help us communicate effectively.

5. Lastly, you request FDA to establish a program to expedite the development and usage of phthalate-free alternatives to PVC medical devices that leach plasticizers.

As we stated in our response to you of September 5, 2001, we do not believe that it is FDA’s responsibility to establish programs to expedite the development of alternative materials. You have not submitted anything in your petition for reconsideration to show us that we did not adequately consider your previous request. Perhaps the communication and outreach efforts that we are undertaking will result in the development of alternatives by others.

In summary, we reaffirm our decision as stated in our letter of September 5, 2001, and deny your petition for reconsideration. However, as we stated at our meeting with you, we will continue to educate manufacturers and health care professionals and to develop other appropriate responses to this issue. We thank you for your continued input.

Sincerely yours,

A handwritten signature in cursive script that reads "Linda S. Kahan".

Linda S. Kahan
Deputy Director
Center for Devices
and Radiological Health