



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Office of Communications
and Public Liaison
Building 1, Room 344
9000 Rockville Pike
Bethesda, MD 20892-2101

January 31, 2005

Mr. Jerry A. Cook
Technical Director
Chemical Products Corporation
P.O. Box 2470
Cartersville, Georgia 30120-1692

Re: Request for Reconsideration dated July 29, 2004

Dear Mr. Cook:

I am responding to the Request for Reconsideration that you submitted on behalf of the Chemical Products Corporation (CPC) under the National Institutes of Health (NIH) "Guidelines for Ensuring the Quality of Information Disseminated to the Public" (NIH Guidelines), asking that we reconsider our determination that the NIH Guidelines did not apply to your request. After thorough review of your Request for Reconsideration and the NIH Guidelines, I am confirming our earlier determination that the NIH Guidelines do not apply to your request and that the existing public comment process was the appropriate mechanism for handling your comments.

Your Request for Correction concerned a revised National Toxicology Program draft report on toxicology and carcinogenicity studies of anthraquinone, known as Draft TR-494. The NIH Guidelines apply to information that NIH disseminates to the public and represents as "fact or the agency's views." The NIH Guidelines do not apply to information that do not constitute agency views and which contain disclaimers to that effect. *See* Guidelines for Ensuring the Quality of Information Disseminated to the Public, National Institutes of Health, Section II-1. By its very title, Draft TR 494 is draft report, which was posted for public comment before a final is prepared. It was clearly labeled with a disclaimer that indicated that it was a draft and did not represent the official view of the NIH. Consequently, because it was clearly labeled a draft that does not represent NIH's views, challenges to its content are not handled under the NIH Guidelines.

Rather, as our initial determination stated, the appropriate mechanism, and the one employed in your case, is the notice and comment process set forth for draft reports such as Draft TR-494. This is consistent with the NTP process for soliciting input regarding draft reports which the

HHS Guidelines urge NIH to employ. Consequently, your request for correction was considered as a public comment on the Draft Report for consideration by the Subcommittee.

In conclusion, your submission concerned a draft NIH document which is not subject to the NIH Guidelines.

Sincerely,

/s/

John Burklow
Associate Director for Communications
National Institutes of Health