



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

DEC 11 2003

OFFICE OF
RESEARCH AND DEVELOPMENT

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

Re: Request for Correction of the IRIS Barium and Compounds file pursuant to EPA and OMB Information Quality Guidelines (#2293A)

Dear Mr. Cook:

In your original Request for Correction under the EPA Information Quality Guidelines dated October 29, 2002, you stated that the U.S. Environmental Protection Agency (EPA) Integrated Risk Information System (IRIS) assessment of barium does not meet the Office of Management and Budget (OMB) *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies*. EPA maintains that the current IRIS assessment is objective and scientifically sound. Nonetheless, based upon the substantially different information you submitted in your March 14, 2003, Request for Reconsideration (IQG# 2293A) that provides an alternative perspective for interpreting the data, EPA intends to expand the consideration of that alternative approach for its IRIS assessment and solicit additional independent expert peer review on that approach.

As we discussed in our November 5 meeting about process, EPA intends to treat your March 14 request as a Request for Correction due to the fact that your request provided substantially different information. Following an EPA decision on that March 14 Request for Correction, you would then have the opportunity to submit a new Request for Reconsideration if you believe that information EPA disseminates regarding barium fails to comply with the EPA or OMB Information Quality Guidelines.

In addressing your March 14 Request for Correction, I am directing that the Toxicological Review and IRIS Summary for Barium be revised to include a more explicit and transparent analysis of data from animal studies. EPA intends to conduct its independent external peer review of this revision in a manner that is consistent with both EPA's peer review guidelines and EPA and OMB Information Quality Guidelines, which address competent and credible peer review. A peer review panel will be convened and its meetings will be open to the public. The information you provided in your request will be considered when EPA develops charge questions for the peer review panel. The review will focus on whether this additional

analysis is scientifically defensible and utilizes the best available science. EPA will also request that the independent expert peer review panel examine whether the application of specific uncertainty factors is scientifically appropriate and supported by the analysis of the cited studies.

If the expanded analysis does not support the statement currently contained in the Toxicological Review for Barium that, "If one were to solely depend upon data from animal studies demonstrating renal effects as the critical determinants for RfD calculation, the employment of customary uncertainty factors would produce a RfD similar to that produced through the evaluation of data from human studies," EPA will reassess the IRIS Barium and Compounds Substance File according to its standard IRIS health assessment development and review process. If the analysis and expert peer review are supportive of this statement, EPA will revise the IRIS Barium and Compounds Substance File to reflect the expert peer review analysis and any associated conclusions. It is our expectation that the expanded analysis and expert peer review can be completed by June 2004. You can expect a final response on your March 14 Request for Correction shortly thereafter.

If you have any questions, please contact Lisa Matthews in my office at (202) 564-6669.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Paul Gilman". The signature is fluid and cursive, with the first name "Paul" being more prominent than the last name "Gilman".

Paul Gilman, Ph.D.
Assistant Administrator

cc: Kim Nelson
Peter Preuss
Amy Mills
Terry Simpson
Lisa Matthews