

(202) 457-5270

October 7, 1996

MEMORANDUM FOR THE HAP TASK FORCE

Re: Modeling Efforts

As you know, on October 1 there was a public meeting on the proposed hazardous air pollutants (HAP) test rule. Attached, for your information, are the agenda, a fact sheet, CMA comments, and a trade press report. Summary tables on the health effects data for each HAP were also made available. Please let David Bloch (202-457-5612) know if you would like a copy of these tables.

On October 2 EPA hosted a public meeting on enforceable consent agreement (ECA) proposals for pharmacokinetic modeling to meet data needs in connection with the HAP test rule. The agenda is attached. Charles Auer introduced the meeting and said that proposals should be submitted by October 24. Following discussions with Auer and Gary Timm, who suggested that they would be receptive to requests to extend this deadline, I prepared and submitted the attached letter.

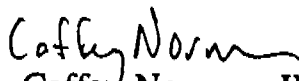
Annie Jarabek made a presentation providing guidance as to pharmacokinetics proposals. The most significant aspect of this presentation was the statement that EPA expects a minimum of an acute and a subchronic inhalation test, conducted according to the guidelines specified in the proposed test rule, for each HAP. She also circulated the attached decision tree which will guide their evaluation of these proposals.

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Mike Gargas presented the first of four chemical-specific discussions, on 1,1,2-trichloroethane. He outlined a proposal to conduct the acute toxicity study, at the same time collecting information to enhance the existing pharmacokinetic model. He then outlined a proposal to model the subchronic, chronic, neurotoxicity, and immunotoxicity data needs. With regard to subchronic, the EPA position requiring the test to be conducted was discussed but not resolved. With regard to the chronic study, Vickie Dellarco raised a number of concerns on the grounds that the study was not a two-year bioassay and that it was via corn oil gavage. I pointed out that, as the study was positive and we were not arguing that the results were not positive, it would appear to be a reasonable basis for a modeling exercise. Mike briefly addressed the issue of converting gavage doses to inhalation exposure and the fact that there would be some lung exposure even in a gavage study. With regard to the neurotoxicity study, Dellarco indicated that there was a question about the histopathology. Finally, Mike noted that the Sanders study from which he would model immunotoxicity is considered adequate by EPA, but he has not yet reviewed how many current measures of immunotoxicity were evaluated in that study.

Following Mike's presentation, there was a more detailed presentation by Mel Andersen of a PK model approach for maleic anhydride.

We will shortly be in touch with the Science Committee (Jim Barter, Jim Knaak, and Dave Penney) to obtain consensus on Gargas' preparation of ECA proposals for 1,1,2-trichloroethane and possibly ethylene dichloride.


W. Caffey Norman, III

Attachments

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