

MEMORANDUM OF TELEPHONE CONVERSATION

BETWEEN: Walt A. Sanders
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and

Gerald M. Rachanow
Regulatory Counsel
Division of Nonprescription Regulation Development
Office of Nonprescription Products

DATE: October 3, 2005

SUBJECT: Request for Extension of Time for Submitting Comments

I called Mr. Sanders in response to his request for extension of time for submitting comments on the proposed rule published on July 13, 2005 (70 FR 40232) for Docket No. 1976N-0052G. The request was dated September 22, 2005 and received by our office on September 30, 2005.

I clarified for Mr. Sanders that the proposed rule primarily applied to cough-cold combination drug products containing an oral bronchodilator [ephedrine] and an expectorant [guaifenesin]. I added that the proposal also mentions products containing an oral bronchodilator and an oral nasal decongestant (e.g., pseudoephedrine). I noted that his request mentioned cold remedies made with ephedrine and pseudoephedrine, but to the best of our knowledge no combination products containing ephedrine and pseudoephedrine are currently being marketed.

I added that in the proposal FDA estimated that there are about 25 manufacturers and distributors/repackers of approximately 50 products that would be affected by the proposed rule. I also informed Mr. Sanders that FDA had provided a 120-day comment period instead of the normal 60 days to hopefully avoid extending the comment period.

I explained that we needed additional information to make a decision on his request. I explained that we would like to know how many manufacturers/distributors he represented in the American Council on Regulatory Compliance that had products affected by the proposal and how many affected products containing this specific combination of ingredients these companies marketed. I also asked if he could clarify the scope of the comments that FDA was likely to receive from the customers in Mississippi, Florida, and Texas who buy these products from the manufacturers and distributors. I asked if he could determine if their comments would relate to economic issues [e.g., lost sales] or scientific issues. I also pointed out that single ingredient ephedrine and guaifenesin products were not affected by this proposal and would remain available for sale.

Mr. Sanders stated that he would have to contact his client to obtain this information and then would send FDA a follow-up letter with the information. I asked if he could mail his response to the same address as the original letter, but send a copy of the signed response as a PDF file attachment to an email to Walter Ellenberg, project manager, as he had done with the September 22, 2005 letter. This request was being made because time is of the essence and our fax machine has not been connected yet in our new office location. Mr. Sanders stated that he would do that. I thanked him, and the call ended amicably.

Gerald M. Rachanow, P.D., J.D.

cc: Docket No. 1976N-0052G