



March 2, 1970

Stearate for Use in Foods" Publication 646 December 1958 and concluded that the material was safe for use at a level adequately sufficient to include the bread use as well as some other minor uses.

However, FDA took the position, presumably from a legal or administrative view, that this material was banned by the Delaney clause even though the effect was secondary due to the bladder stones at the 25% level. While I have no written statement of FDA's position (and it was not challenged), the position of FDA is confirmed by the fact that there were other polyoxyethylene derivatives fed in the same studies that did not produce the bladder stone effect. These other derivatives are permitted for various uses in the Food Additive Regulations.

In attempts to develop bread additives equivalent to polyoxyethylene(8)stearate, food technology laboratories still use polyoxyethylene(8)stearate as the outstanding product for comparison purposes.

It is also interesting to note the polyoxyethylene(8) stearate is permitted for rolls and other non-standardized yeast-raised products in Canada which has no Delaney clause.

On page 2, first complete sentence, I question the advisability of suggesting that the clause could be construed to mean any tumor regardless of its pathological description. My Webster 's for the medical definition limits the same to "malignant" in two places and says specifically carcinoma or sarcoma.

Also, I believe FDA has been pretty consistent in this interpretation. It is my understanding that the final hold up on the FDA cyclamate ruling was to obtain a special panel at NRC to confirm FDA's judgment that the tumors were malignant. Since this was the only question asked, the panel had nothing to say about safety.

Lastly, the proposed change on page 4 seems to me to

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- 3 -

March 2, 1970


be inserted in a rather odd place, namely, at the end of all the exceptions regarding animal feeds. Wouldn't it be better to insert this change after the clause you quote on page 1 (which is really the Delaney Amendment) and then go on with the exceptions regarding animal feeds?

Very truly yours,



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KEM:AG

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*Is this from  
animal feeds, such as feed to  
animals, if judged*

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