

15218 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

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5.

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The first step is a conference that Jean Mayer and Aldo Truant will have with James Grant, the Deputy Commissioner. It is hoped that Mr. Grant will be able to help with F & DA policy and procedural matters and that he can be of help in lining up a conference with these F & DA officials who have specific responsibility for handling the matters in question.

6. The suggestion was made that it might be well to write to the Food & Drug Administration with copies to the local press, to our Congressmen and Senators, expressing our sympathy with their objectives and citing the fact that we have deleted certain of our amphetamine and methamphetamine drugs. While this idea may deserve some consideration, the general feeling of the group was to the effect that this would be an ill-advised move, that we should proceed in a business-like way; that any announcement of our decision to withdraw from the market such products as 'Biphetacel', 'Efroxine', 'Miltron', would be the occasion for an immediate order from the F & DA pressing for our voluntary withdrawal from trade channels all inventories of these items. The expense of carrying out such an order alone negates the idea.
7. In the opinion of Vincent Kleinfeld it will take the F & DA some months after February 8 to evaluate the February 8, 1971 submissions. It is our judgment that we, on this count alone, will be able to continue marketing these products without interruption through the greater part of 1971.
8. Although Vincent Kleinfeld emphasized the fact that the F & DA is definitely hostile toward amphetamine and amphetamine-containing combinations, and that officials react strongly to political pressures, led by the opinion of Jean Mayer there is plenty of room for optimism that expert compliance and presentation of data will win approval.
9. Vincent Kleinfeld had the following to say in answering the question "What recourse do we have if the F & DA rejects approval of our supplemental submissions?" "You have the right to ask for a public hearing within thirty days of the rejection notice. If the request is granted, it must be recognized that the chances of winning are very slight. At the same time that the request for a public hearing is made, attorneys should get on the job of preparing to challenge the F & DA in an appeal to the courts. A request for a public hearing and possible subsequent