



SALSBURY LABORATORIES Charles City, Iowa, 50616

O. H. Peterson, Ph.D.
Vice President

September 25, 1967

Dr. William A. Knapp
Allied Chemical Corporation
P. O. Box 405
Morristown, New Jersey 07960

Dear Doctor Knapp

The Proposed Rule Making of FDA which appeared in the Federal Register on August 8, 1967, has been studied. The following comments are sent to you as advised by Mr. Morgan W. Hoover.

§121.7 (a) (2). A reference is made to submitting application for a new drug or antibiotic according to Form FD 356V. We do not know what this form contains as it apparently has not been released by FDA. We think this form should be available for study long enough before these Food Additives Procedural Regulations become effective so that objections, if any, can be considered by FDA.

§121.9 (c). We agree that analytical methods should not be considered confidential. But, we maintain that data submitted on toxicology should be considered confidential and entitled to protection as trade secrets. If toxicological data becomes public knowledge, this could enable another company to obtain approval of an NDA, utilizing the toxicological data submitted. The development of toxicological data is one of the most costly aspects of obtaining an NDA. The crux of

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this proposed rule is the definition of the word "summary." If the information in the summary is sufficient to substantially aid other companies in obtaining an NDA, then this rule should not be allowed to stand as proposed by FDA.

§121.50 (c). The requirement for use of 8 x 10-1/2 inch pages in an NDA is unnecessary bureaucratic dictation. We use the standard 8-1/2 x 11 page for our records. If the smaller page is dictated by this proposed rule, we must either utilize a smaller page for our experimental records or re-type everything that goes into our NDA's. To utilize the smaller page for our records would require revision of nearly all of our tabular forms and the splitting of tables, which in most cases is undesirable.

We are also opposed to the requirement that all text be double-spaced. In some cases this may be undesirable for the sake of clarity and expediency. Parts of the text are often photocopied from other sources. To double space all of this would require unnecessary typing. The advantages to FDA would not seem to warrant this requirement.

§121.50 (g) (f). The same comments given above for §121.9 (c) apply here.

Sincerely



Oliver H. Peterson, Ph.D.
Vice President - Research

OHP/mw

cc: Hoover
Hulse
Vincent