CSI

CAPTEK SOFTGEL INT'L, INC.

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Dockets Management Branch
Docket No. 96N-0417
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Dear Sir or Madam:

This response is to the public meeting in Las Vegas and the proposed regulations for nutritional supplement manufacturers. Captek is a softgel contract manufacturing business with 105 employees and approximately 13 million dollars in annual sales. We understand the importance and necessity of regulations in the industry, but feel there would be a financial burden to comply with some of the proposed regulations.

One area is the identity test with sufficient specificity for each lot. Captek manufactures 300 different products with 500 active ingredients. To test the different ingredients and products, we would need to invest $120,000 on additional equipment and staff two additional analytical chemists at $80,000 - $90,000 per year. The additional chemists would be involved in determining and validating specific tests to satisfy the identity criteria. The time involved to adequately develop and validate a test method could take 3 to 6 months, especially for situations were no acceptable method or information exists.

Another area is the expiration dating and stability studies. Currently we conduct accelerated stability studies on final products for physical stability. We do not have the necessary equipment, personnel, or validated test methods to conduct chemical stability studies.

Captek would like to comply with the proposed regulations but find this may be a financial challenge, when last year $135,000 was spent on lab equipment. We need additional personnel, space, equipment, and time to develop assays.

Sincerely,

Kevin Kang
QC Manager

Tony McKelvey
QA Manager

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