



"Wherever your talents and the world's needs meet, there you belong."

125 W. Elm • Salina, KS 67401 • (785) 826-6609

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November 29, 2000

Margaret O'Rourke  
Center of Drug Evaluation Research  
Food and Drug Administration  
5630 Fishers Lane, Rm 1061  
Rockville, MD 20857

Dear Ms. O'Rourke:

I am writing concerning the rules and regulations posted December 3, 1999 (volume 64, Number 232) (DOCID:fr03de99-20), which sets up regulations for the acceptance, storage and distribution of drug samples by charitable institutions.

I am the director of a clinic for low-income uninsured residents of Saline County, Kansas. We have served over 4,000 patients in the nearly 10 years we have been open, many of whom have become our long-term patients. We see patients two evenings a week. We rely on samples of medicine to give to our patients who are acutely in need of treatment, and enroll as many as we can in indigent programs operated by the pharmaceutical companies.

In spite of these attempts to curtail our expenditures for prescriptions, last year the cost of prescriptions, which we purchased *AT COST*, was \$87,000.

Our clinic is not funded by any government agency, at either the local, state or federal level. We are dependent on grants and donations by individuals, businesses, and churches. We are staffed almost entirely by volunteers.

For us to comply with the regulations as they are written would be an impossibility without additional paid staff. This would create a budget



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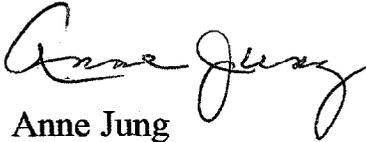
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shortfall. To simply discontinue receiving samples might be our only option, which would also place a great strain on the budget, and on the patients, since they do have a \$6.00 co-pay for medicine obtained outside the clinic itself.

I am hopeful that you will exempt clinics such as ours from compliance.

Sincerely,

A handwritten signature in cursive script, appearing to read "Anne Jung". The signature is written in black ink and is positioned above the printed name and title.

Anne Jung  
Clinic Director