



FAMILY CARE HEALTH CENTERS

PHARMACY DEPARTMENT

6827 S. Broadway

St. Louis Mo. 63111

(314) 481-1615 Ext. 323

Barry A. Wilson
Chief Pharmacy Officer

12/17/02

**Dockets Management Breach
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville MD 20852**

Gentleperson:

Family Care Health Centers is a non-profit 501C3 Federally Qualified Community Health Center serving the uninsured and underinsured of St. Louis City.

We are starting our first pharmacy which will be in the Community Health Center building along with 11 providers. Based on our patient population (uninsured, underinsured, etc.) we would like to have samples available in our pharmacy for these patients.

We would handle the samples as follows:

- 1. Store in area separate from other (non-sample) medications.**
- 2. Log in samples when received and log out samples as dispensed to patients, keeping track of lot numbers and expiration dates.**
- 3. All samples would be dispensed on written (or verbal prescriptions reduced to writing) prescription forms which would be stored separately from other (non-sample) written prescription forms.**
- 4. Access to the Pharmacy sample area would be restricted to individuals licensed by our (Missouri) Board of Pharmacy (Pharmacist or pharmacy technician).**
- 5. Providers would have to authorize the use of samples either by written comment on the prescription form or verbally reduced to writing on the prescription form.**
- 6. There would be no charge to patients for sample medications.**

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7. The pharmacy would be responsible for: proper storage, inventory & accounting, recall procedures, expiration date monitoring, packaging of the samples.

8. Samples will further be handled in accordance with the applicable provisions of Section 503 of the Federal Food, Drug and Cosmetic Act.

Missouri Code of State Regulations 4CSR 220.2.010(7) states that "Except as provided for in section 21 U.S.C. section 353(d)(1)(A)-(C), (d)(2)(A)(I)k-(ii), (B)(I)-(ii) and (d)(3)(A)(I)k-(ii) of the Federal Food, Drug and Cosmetic Act, drug samples shall not be maintained in pharmacies."

We are requesting that Family Care Health Centers Pharmacy be deemed a pharmacy of " other health care entity " within the meaning of Section 503 and allowed to receive, inventory and dispense drug samples to its patients, many of whom are indigent.

Thank you very much for your time and consideration.

Yours very truly,


Barry A. Wilson