From: Hommel, Carolyn - OC
Sent: Thursday, November 30, 2006 10:57 AM
To: [Redacted]
Subject: FW: Question

Hi, [Redacted],

It was good to talk to you this morning. Here's the quote from the Fed Register that I mentioned.

Carolyn

52 FR 8850

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

AGENCY: Food and Drug Administration.

21 CFR Part 312

Investigational New Drug, Antibiotic, and Biological Drug Product Regulations; Treatment Use and Sale

[Docket No. 82N-0394]

52 FR 8850

March 19, 1987

ACTION: Reproposed rule.

8. One comment asked that the sale provisions be clarified to assure that FDA does not regulate hospital charges imposed for the costs of handling, storing, and administering investigational drug products.

The sale provisions pertain to the direct sale of the drug itself, not to incidental charges imposed for services ancillary to the distribution or administration of the drug. Thus, the provision does not apply to charges imposed by hospital pharmacies for handling investigational drug products.