

PETITION
to
Food and Drug Administration

0431 '02 MAY 29 10 18

Dockets Management Branch
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

Action Requested

Petitioner University of Colorado Hospital requests the Food and Drug Administration to interpret §503 of the Federal Food, Drug, and Cosmetic Act (codified at 21 U.S.C. §353)--specifically, the following language of §503(d)(3)(A)(i) and (ii):

"(A) Drug samples may only be distributed--

- (i) to practitioners licensed to prescribe such drugs if they make a written request for the drug samples, or
- (ii) at the written request of such a licensed practitioner, to *pharmacies of hospitals or other health care entities.*"
[Emphasis added.]

Petitioner specifically requests that a unit of the hospital's pharmacy, located in an outpatient facility owned and operated by the hospital, on a campus being redeveloped into a health sciences center, be deemed a "hospital pharmacy" within the meaning of §503 and be allowed to continue to inventory and dispense drug samples to its patients, many of whom are indigent, where:

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- Colorado law defines "University Hospital" to include the hospital's clinics, as further discussed below, and the Hospital's pharmacies and clinics are registered with the DEA as Hospital/Clinic businesses
- The pharmacy in the University of Colorado Hospital's Anschutz Outpatient Pavilion is owned and operated by the Hospital, and is directed by the same management as the pharmacy in the hospital's inpatient facility
- The pharmacy in the Anschutz Outpatient Pavilion has a system in place for carefully managing the samples, as further discussed below
- In any event, a new inpatient hospital building is under construction adjacent to the Anschutz Outpatient Pavilion, where the pharmacy in question is located, and will be opening by the end of 2003

Additionally, or in the alternative, Petitioner requests that the Anschutz Outpatient Pavilion pharmacy of University of Colorado Hospital be deemed a pharmacy of an "other health care entity" within the language of §503(d)(3)(A)(ii), and be allowed to continue to inventory and dispense drug samples to its patients.

Statement of Grounds

General Background. Colo. Rev. Stat. §§23-21-501 through 23-21-528 establish the "University of Colorado Hospital Authority." Consequently, University of Colorado Hospital is a "political subdivision" of the state of Colorado. Colo. Rev. Stat. §23-21-503(1). The mission of the Hospital is to facilitate and support the education, research, and public service activities of the health sciences schools of the University of Colorado, and to provide patient care, including care for the medically indigent. Colo. Rev. Stat. §23-21-501(1).

University of Colorado Hospital is also a §501(c)(3) tax-exempt organization under the Internal Revenue laws and regulations, and is a participant in the federal Disproportionate Share Hospital (DSH) program due to the number of indigent patients treated.

The University of Colorado Hospital inpatient facility is currently located at 4200 East Ninth Avenue, Denver, Colorado. However, in 1995, the United States Army decommissioned the Fitzsimons Army Medical Center in Aurora, Colorado. Aurora is a suburb of Denver, Colorado, and the

Fitzsimons site is approximately 6 miles from the existing University of Colorado Hospital inpatient facility. The federal government then conveyed 217 acres of the Fitzsimons site to the University of Colorado to build a state-of-the-art health sciences center from the ground up.

In the first phase of redevelopment into a health sciences campus, the University of Colorado Hospital constructed the Anschutz Outpatient Pavilion, which opened on December 8, 2000--an 8-story building housing a number of the hospital's outpatient clinics as well as the pharmacy which the state pharmacy inspector cited for drug sample violations, as further described below. The second phase of redevelopment consists of a new 12-floor inpatient University of Colorado Hospital, currently under construction immediately adjacent to the Anschutz Outpatient Pavilion. However, this hospital building is not currently serving inpatients and will not be completed until the end of 2003.

Drug Samples in the University of Colorado Hospital Anschutz Outpatient Pavilion Pharmacy. The hospital owns and operates a pharmacy in the Anschutz Outpatient Pavilion. Physicians on the staff of University of Colorado Hospital request and receive drug samples (i.e., sign for them) and the samples are stored and dispensed from this pharmacy. This system was specifically established by University of Colorado Hospital pharmacy management to track drug samples. The benefits are numerous--patients receive a drug sample that is (1) properly labeled, (2) screened for drug-drug interactions, (3) accompanied by written information, (4) counseled by a registered pharmacist, and (5) dispensed at no charge by prescription only. The pharmacy also has a very reliable mechanism for contacting patients in the event of a medication recall, as per JCAHO requirements.

In January 2002, an inspector from the Colorado State Board of Pharmacy visited the University of Colorado Hospital Anschutz Outpatient Pavilion and cited the pharmacy as follows with respect to drug samples:

"About 200 different drug samples in various quantities were found at this pharmacy. Remove all drug samples from this pharmacy and send or fax a letter to the Board within 14 days stating that this removal was completed, and when and where these drugs were taken. Also, state each drug name, strength, and quantity of drug removed." [Emphasis in original.]

Lance Carmine, Chief Inspector (not the on-site inspector quoted above) of the Colorado State Board of Pharmacy, subsequently stated to University of Colorado Hospital pharmacy management that while the pharmacy in the Anschutz Outpatient Pavilion is UCH-owned, it is not a "hospital pharmacy" within the meaning of §503(d)(3)(A)(ii), because no "hospital" is at the site.

Significantly, however, Colorado law defines "University Hospital" as follows:

"'University Hospital' means the hospital *and clinics* created and operated by the regents of the university of Colorado ..." Colo. Rev. Stat. §23-21-502(11) (emphasis added).

Thus, under Colorado law, University of Colorado Hospital and its respective clinics, including the clinics in the Anschutz Outpatient Pavilion, are one and the same entity and are in fact under the same ownership and management. Consistently, the Hospital's pharmacies and clinics are registered with the DEA as Hospital/Clinic businesses.

In any event, a new inpatient hospital is under construction adjacent to the Anschutz Outpatient Pavilion in which the pharmacy in question is located, and will be opening by the end of 2003.

Finally, it would seem that the Anschutz Outpatient Pavilion of University of Colorado Hospital falls within the "or other health care entities" language of §503(d)(3)(A)(ii), if only for the reason that an outpatient clinic is a health care entity.

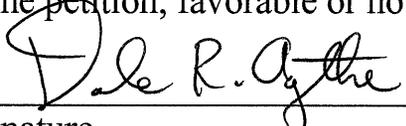
Additional Information

The Colorado State Board of Pharmacy can be reached at:

Colorado State Board of Pharmacy
1560 Broadway, Suite 1310
Denver, CO 80202-5146
303-894-7750

Certification

To the best of my knowledge, this petition includes all information relevant to the petition, favorable or not.



Signature

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**AMENDMENT to PETITION
to
Food and Drug Administration**

Dockets Management Branch
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

0678 02 MAY 35 P2:29

Re: Environmental Impact Statement (EIS):

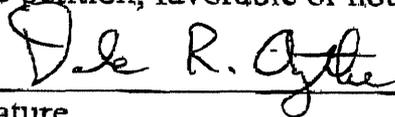
Petitioner claims a categorical exclusion from the environmental impact statement (EIS) requirement, for purposes of its petition requesting that the Food and Drug Administration interpret § 503 of the Federal Food, Drug, and Cosmetic Act, pertaining to the distribution of drug samples by a hospital-owned pharmacy.

The categorical exclusion is claimed pursuant to 21 C.F.R. § 25.31, entitled "Human Drugs and Biologicals," and more specifically, 21 C.F.R. § 25.31(h), "Issuance, revocation, or amendment of a standard for a biologic product."

To the petitioner's knowledge, no extraordinary circumstances exist.

Certification

To the best of my knowledge, this petition includes all information relevant to the petition, favorable or not.



Signature

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June 4, 2002

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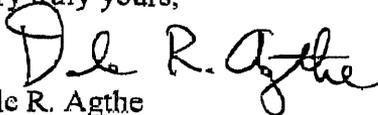
Fax: (301) 827-6870

Dear Ms. Williams,

Thank you for your kind voice-mail message of June 3, 2002, concerning the requirement of an Environmental Impact Statement (EIS) to accompany our Food and Drug Administration Petition, or the need to claim a categorical exclusion therefrom.

Please find attached an Amendment to the Petition claiming a categorical exclusion from this requirement.

Very truly yours,



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UNIVERSITY OF COLORADO
HOSPITAL

FAX TRANSMISSION COVER SHEET

Date: June 4, 2002
To: Ms. Williams, Dockets Management Branch, FDA
Sender: Dale R. Agthe, Legal Research Attorney
Fax number: (301) 827-6870
Re: Environmental Impact Statement

*YOU SHOULD RECEIVE FOUR (4) PAGE(S), INCLUDING THE COVER PAGE
IF YOU DO NOT RECEIVE ALL THE PAGES,
PLEASE CALL MICHELLE STARLING AT (303) 724-5296*

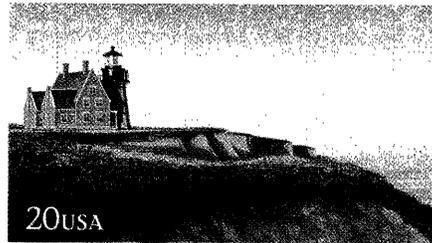
COMMENTS:

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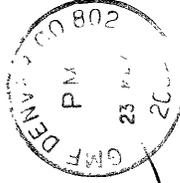
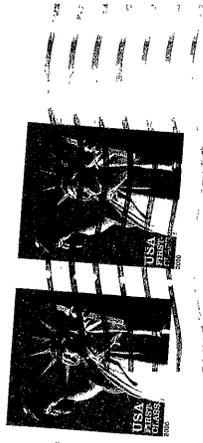
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Food & Drug Administration Petition



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