

8/13/02 09:13 PM

UNIVERSITY OF COLORADO
HOSPITAL

August 13, 2002

Dockets Management Branch
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852
Fax: (301) 827-6870

Re: Petition # 02P-0246/CP 1 (requesting interpretation of §§ 503(d)(3)(A)(i) and (ii))

I am writing to ask if there is any way University of Colorado Hospital might obtain an answer to the above-referenced petition by the middle of September, 2002. Our need for a response by that time is for two very practical reasons:

- 1) The Colorado State Board of Pharmacy has given the petitioner, University of Colorado Hospital, until September 30, 2002, at which time the drug samples which are the subject of the petition must be inventoried and removed from the pharmacy in question. This will adversely impact the indigent patient population served by the Hospital.
- 2) The Hospital will be undergoing JCAHO (Joint Commission on Accreditation of Hospitals) in the fall of 2002. To maintain accreditation, an organization must undergo an on-site survey by a JCAHO survey team at least every three years. JCAHO may well frown on the presence of the drug samples in an unresolved legal context, despite the fact that the State Board of Pharmacy has given the Hospital time to obtain an FDA opinion. In the absence of a response, the Hospital's Pharmacy Director will be obliged to inventory and remove the samples before the JCAHO survey. Again, the dispensing of these drug samples is of great benefit to the indigent patient population served by the Hospital.

Thank you for your kind consideration of this request. Please feel free to contact me directly with any questions or concerns.

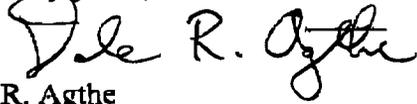
02P-0246

LET 1

OFFICE OF THE GENERAL COUNSEL

P.O. Box 6508 • Mail Stop F415 • Aurora, CO 80045-0508 • Phone: 303-724-5296 • Fax: 303-724-1815

Very truly yours,

A handwritten signature in black ink that reads "Dale R. Agthe". The signature is written in a cursive style with a large, prominent initial "D".

Dale R. Agthe
Legal Research Attorney
Office of the General Counsel
University of Colorado Hospital Administration
PO Box 6508, Mailstop F-415
Aurora, CO 80045-0508

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HOSPITAL

FAX TRANSMISSION COVER SHEET

Date: August 13, 2002
To: Food and Drug Administration
Sender: Dale Agthe, Research Associate
Fax number: (301) 827-6870
Re: Petition #02P-0246/CP 1

*YOU SHOULD RECEIVE THREE (3) 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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