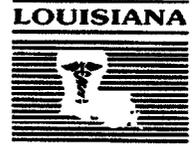




STATE OF LOUISIANA
DEPARTMENT OF HEALTH AND HOSPITALS



Department of
HEALTH and
HOSPITALS

David W. Hood
SECRETARY

M. J. "Mike" Foster, Jr.
GOVERNOR

9779 '05 DEC 22 11:31

December 11, 2003

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

Dear Sir/Madame:

Please review the attached request and reply favorably to it. Send reply to my attention at the address below. If you need additional information please do not hesitate to contact us at 225-342-1630. Thank you for your assistance.

Sincerely,

Andrew P. Twyman
Deputy Assistant Secretary

APT/sef

Attachment

2004P.0036

CP1

PETITION
To
Food and Drug Administration

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

Action Requested

Petitioner Louisiana State Office of Mental Health, a division of the Louisiana Department of Health and Hospitals, 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
at the written request of such a licensed practitioner, to pharmacies of hospitals or other health care entities.

Petitioner specifically requests that the eight outpatient clinic pharmacies operated by the State of Louisiana, Department of Health and Hospitals, Office of Mental Health be deemed pharmacies of other “health care entities” within the language of §503(d)(3)(A)(ii), and be allowed to inventory and dispense drug samples to its patients.

Statement of Grounds

General Background. The Louisiana State Office of Mental Health serves citizens of Louisiana with serious and persistent mental illness and emotionally and behaviorally disordered children. Medication is supplied at no charge to indigent patients without Medicaid from Louisiana state general funds, as well as patient assistance programs, samples and vouchers from pharmaceutical companies. Medications are dispensed from eight licensed pharmacies operated by the Office of Mental Health and located within eight outpatient clinics throughout the state, serving only patients of the Office of Mental Health. These pharmacies are located at: (1) Region I OMH Pharmacy, 210 State St., New Orleans, LA 70118 (permit# 001744); (2) Region IV OMH Pharmacy, 302 Dulles Drive, Lafayette, LA 70506 (permit# 0005); (3) Region V OMHSA Pharmacy-DHH, 4105 Kirkman St., Lake Charles, LA 70607 (permit# 001745); (4) Mental Health Center

of Central Louisiana, 242 W. Shamrock Ave., Pineville, LA (permit#1606) (5) Shreveport Mental Health Center Pharmacy, 1310 N. Hearne Avenue, Shreveport, LA 71107 (permit# 1580); (6) Monroe Regional Mental Health Pharmacy, 4800 S. Grand St., Monroe, LA 71210 (permit# 795); (7) Region IX OMH Pharmacy, 900 Wilkinson St., Mandeville, LA 70448 (permit# 001681); (8) Baton Rouge Mental Health Center, 4615 Government Street, Baton Rouge, LA 70821. The outpatient pharmacy in Region I is located at New Orleans Adolescent Hospital and is housed in a building with both New Orleans Adolescent Hospital as well as an outpatient mental health clinic. This pharmacy is separate from the inpatient pharmacy serving hospital patients.

Due to the increasing cost of drugs, the pharmacy budget provided by state general funds is no longer sufficient to pay for the entire cost of drugs for the population of indigent patients served by the Office of Mental Health. In order to serve these patients, samples have become an increasingly important means of providing medications. Currently, samples are requested and received by physicians employed by the Office of Mental Health and stored in locked sample cabinets outside of the pharmacy. The samples are then dispensed by the physician.

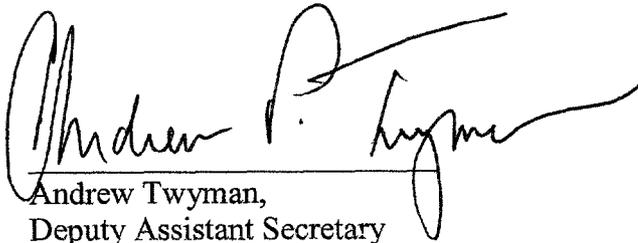
In order to maintain accountability, as well as provide for a more efficient means of inventorying and tracking drug samples, the Louisiana Office of Mental Health seeks to institute a system by which its pharmacists, who are its most knowledgeable staff in this area, would maintain the inventory and be able to dispense sample medications, labeling the samples, screening for drug interactions, supplying written information and counseling, and dispensing the samples upon a written order from the physician to its indigent clients.

Thus, the Louisiana Office of Mental Health petitions the Food and Drug Administration to deem that its eight outpatient pharmacies, as noted above, located within its outpatient mental health clinics, are, in fact, health care entities, as noted in §503(d)(3)(A)(ii), and thus are allowed to distribute drug samples at the written request of a licensed practitioner.

As John M. Taylor, III, Senior Associate Commissioner for Regulatory Affairs, replied in his letter to Mr. Dale R. Agathe of the University of Colorado Hospital regarding Docket No. 02P-0246/CP1 & LET1, "According to §203.3(q), a health care entity is 'any person that provides diagnostic, medical, surgical, or dental treatment, or chronic or rehabilitative care, but does not include any retail pharmacy or any wholesale distributor.'" Pharmacies of the Office of Mental Health are licensed pharmacies which do not dispense drugs on a retail basis and are located in outpatient clinics providing medical treatment to the clients of the Office of Mental Health. Therefore, the Office of Mental Health requests that its outpatient clinics be deemed to be *health care entities* by the Food and Drug Administration and that its pharmacies be deemed pharmacies of those health care entities, and therefore may receive and dispense prescription drug samples under section 503 of the Act.

Certification

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

A handwritten signature in black ink, appearing to read "Andrew P. Twyman". The signature is written in a cursive style with a large initial "A" and a long horizontal stroke extending to the right.

Andrew Twyman,
Deputy Assistant Secretary
Office of Mental Health
Department of Health and Hospitals
State of Louisiana

**AMENDMENT TO PETITION
To
Food and Drug Administration**

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

Re: Environmental Impact Statement:

Petitioner claims a categorical exclusion from the environmental impact statement 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 health care entity.

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.

ROBERT S. FISHER
Robert S. Fisher (COM & Medical Director)

Andrew Twyman, *FOR*
Deputy Assistant Secretary
Office of Mental Health
Department of Health and Hospitals
State of Louisiana