LAW OFFICES
HYMAN, PHELPS & MCNAMARA, P.C.

JAMES R. PHELPS
PAUL M. HYMAN
ROBERT A. DORMER
STEPHEN H. MCNAMARA
ROGER C. THIES
THOMAS SCARLETT
JEFFREY N. GIBBS
BRIAN J. DONATO
FRANK J. SASINOWSKI
DIANE B. MCCOLL
A. WES SIEGNER, JR.
ALAN M. KIRSCHENBAUM
DOUGLAS B. FARQUHAR
JOHN A. GILBERT, JR.
JOHN R. FLEDER
MARC H. SHAPIRO
FRANCES K. WU
JEFFREY N. WASSERSTEIN
DAVID B. CLISSOLD
JOSEPHINE M. TORRENTE
ROBERT T. ANGAROLA
(1945-1996)

700 THIRTEENTH STREET, N.W.
SUITE 1200
WASHINGTON, D. C. 20005-5929
(202) 737-5600
FACSIMILE
(202) 737-9329
www.hpm.com

1856 6 JAN 25 P1:38

JENNIFER B. DAVIS
KIRK L. DOBBINS*
OF COUNSEL

CASSANDRA A. SOLTIS
MICHELLE L. BUTLER
ANNE MARIE MURPHY
PAUL L. FERRARI
LARRY K. HOUCK
DARA S. KATCHER*
KURT R. KARST
JULIE K. TIBBETS
CHRISTINE P. BUMP*
BRIAN J. WESOLOSKI
NOELLE C. SITTHIKUL*

*NOT ADMITTED IN DC

DIRECT DIAL (202) 737-4293

January 23, 2006

VIA FACSIMILE AND REGULAR U.S. MAIL

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, MD 20852

Re: Docket No. 2005N-0479: International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; Butorphanol; Delta-9-tetrahydrocannabinol (Dronabinol); Gamma-Hydroxybutyric Acid; Ketamine; Khat; Tramadol; Zopiclone; Buprenorphine; Oripavine. 70 Fed. Reg. 73,775 (Dec. 13, 2005).

Dear Sirs:

Hyman, Phelps & McNamara, P.C. requests that the attached letter be submitted to the record in the above-referenced docket.

HYMAN, PHELPS & MCNAMARA, P.C.

BY _____
John A. Gilbert

JAG/BJW/dcp

Attachment

2603 MAIN STREET
SUITE 760
IRVINE, CALIFORNIA 92614
(949) 553-7400
FAX. (949) 553-7433

4819 EMPEROR BOULEVARD
SUITE 400
DURHAM, NORTH CAROLINA 27703
(919) 313-4750
FAX: (919) 313-4751

2005N-0479 LET 1

LAW OFFICES
HYMAN, PHELPS & MCNAMARA, P.C.

JAMES R. PHELPS
PAUL M. HYMAN
ROBERT A. DORMER
STEPHEN H. McNAMARA
ROGER C. THIES
THOMAS SCARLETT
JEFFREY N. GIBBS
BRIAN J. DONATO
FRANK J. SASINOWSKI
DIANE B. McCOLL
A. WES SIEGNER, JR.
ALAN M. KIRSCHENBAUM
DOUGLAS B. FARQUHAR
JOHN A. GILBERT, JR.
JOHN R. FLEDER
MARC H. SHAPIRO
FRANCES K. WU
JEFFREY N. WASSERSTEIN
DAVID B. CLISSOLD
JOSEPHINE M. TORRENTE

ROBERT T. ANGAROLA
(1945-1996)

700 THIRTEENTH STREET, N.W.
SUITE 1200
WASHINGTON, D. C. 20005-5929
(202) 737-5600
FACSIMILE
(202) 737-9329
www.hpm.com

JENNIFER B. DAVIS
KIRK L. DOBBINS*
OF COUNSEL

CASSANDRA A. SOLTIS
MICHELLE L. BUTLER
ANNE MARIE MURPHY
PAUL L. FERRARI
LARRY K. HOUCK
DARA S. KATCHER*
KURT R. KARST
JULIE K. TIBBETS
CHRISTINE P. BUMP*
BRIAN J. WESOLOSKI
NOELLE C. SITTHIKUL*

*NOT ADMITTED IN DC

DIRECT DIAL (202) 737-4280

January 21, 2006

BY E-MAIL\CONFIRMATION COPY BY MAIL

Mr. William R. Steiger
Special Assistant to the Secretary for International Affairs
Office of International Affairs
Department of Health and Human Services
Hubert Humphrey Building
200 Independence Avenue, S.W.
Suite 639H
Washington, D.C. 20201

Re: WHO/ECDD matter

Dear Dr. Steiger:

It has come to our attention that WHO has convened a meeting of an ad hoc committee of five scientific "experts" to meet next week, to prepare a report for the upcoming ECDD. The subject of the meeting is buprenorphine. There has been no public notice of this meeting and the details of the meeting are lacking, but what we know at this time provides grounds for serious complaint. We ask that our government intervene to preserve the integrity and fairness of the international drug control process.

2603 MAIN STREET
SUITE 760
IRVINE, CALIFORNIA 92614
(949) 553-7400
FAX: (949) 553-7433

4819 EMPEROR BOULEVARD
SUITE 400
DURHAM, NORTH CAROLINA 27703
(919) 313-4750
FAX: (919) 313-4751

You were told by Dr. Lepakhin that buprenorphine was put on the agenda "... not for review, but because the (ECDD) decided to make a final decision at the forthcoming ECDD." This statement was erroneous, but the misperception at WHO about the intent of the last ECDD is no doubt the reason that WHO did not request the normal range of data in its questionnaire. All WHO requested in the questionnaire was an assessment of the effect, on medical availability, of moving buprenorphine to schedule I of the Single Convention.

In filings made to the docket of FDA, criticism was leveled at WHO for, among many other things, failing to request the full range of data for buprenorphine. It appears that WHO now is attempting to fill that gap by convening an ad hoc committee and asking them to opine about data. Because the data contemplated by the *Guidelines for the WHO review of psychoactive dependence-producing substances for international control* (*Guidelines*) were never requested and therefore are not available, we presume that WHO will look elsewhere; probably data will be used from the embargoed and therefore not-public INCB report for 2005.

Thus, WHO continues a pattern of irregularities and improprieties from the established *Guidelines* to meet the goal of using the funds available for a March meeting.

If the ad hoc committee will analyze the data, from a source not recognized in the *Guidelines*, it will be unnecessary for the next ECDD to exercise its judgment in regard to those data. The question arises: Has the ad hoc committee been convened in compliance with the regulations for expert committees? Have NGOs been invited to participate? Have other organizations and even interested parts of WHO itself been invited to participate? If the most important function of the ECDD, its medical judgment, is being exercised by the ad hoc committee, surely that committee should be constituted according to the relevant rules.

This hastily called meeting of an ad hoc committee cannot legitimize the upcoming March ECDD and in fact, adds to the breakdown in established procedures. The way the ad hoc committee has been called, and the other improprieties in this process, justify the suspicion that buprenorphine is on the agenda to be given a predetermined treatment, in which the biases of some parties are served, to the detriment of good science and good medicine.

These new developments justify our request that you urgently involve our government to protect the process established by the *Guidelines*. Otherwise, the precedents now being established by WHO's actions will effectively eliminate any meaning that the *Guidelines* might have had. The nations that have signed the conventions and the regulated industry cannot and should not support a system in which the sober, deliberate methodology set forth in the *Guidelines* is replaced by the chaos we have seen with the March 2006 ECDD.

Thank you for your attention to this matter.

Sincerely,

FOR

James R. Phelps

cc: Lou Valdez
Ann S. Blackwood
David E. Hohman