DEPARTMENT OF HEALTH & HUMAN SERVICES

Substance Abuse and Mental
Health Services Administration

Center for Substance Abuse Treatment
1 Choke Cherry Road
Rockville, MD 20857

August 4, 2004

«Full_Name»
«Address_line_1»
«Address_line_2»
«City», «State» «Zip_code»

Dear «Full_Name»:

This is in response to your Notification of Intent (NOI)to Use Schedule III, IV, or V opioid drugs for the maintenance and detoxification treatment of opiate addiction in accordance with the Drug Addiction Act of 2000 (DATA 2000) (21 U.S.C. § 823(g)(2)), dated «Submission_date». The Substance Abuse and Mental Health Services Administration's Center for Substance Abuse Treatment (SAMHSA/CSAT) received your NOI on «Date_Received».

New legislation, DATA 2000, section 3502, P.L. 106-310, permits physicians who meet certain conditions to prescribe certain narcotic treatment medications for the treatment of opioid addiction without the separate registration required currently for methadone treatment programs. Under the new legislation, SAMHSA/CSAT must determine within 45 days from the date of receipt of the NOI whether each practitioner meets all the following requirements for a waiver:

- is licensed to practice medicine;
- has a Drug Enforcement Administration (DEA) registration to dispense controlled substances;
- has the capacity to refer patients for counseling and other services;
- will treat no more than 30 patients at any one time;
- is qualified by training and experience to treat opioid addiction.

If you have met these requirements, SAMHSA/CSAT will notify you via U.S. Mail at the address provided on your NOI and convey your unique identification number assigned by the DEA. SAMHSA/CSAT will also notify you if additional information is needed to process your NOI. If SAMHSA/CSAT fails to make a determination on your qualifications, the DEA will assign the unique identification number 45 days after the date the agency received your notification.

As of this writing, the only medications to receive Food and Drug Administration approval for the treatment of opioid addiction that are eligible under DATA 2000 are Subutex® (buprenorphine hydrochloride) and Suboxone® (buprenorphine hydrochloride and naloxone hydrochloride). No other medications—including Buprenex®—are eligible under DATA 2000.

The information you submitted is subject to a Privacy Act System of Records. The enclosed summary details the authorities, purposes, and disclosures associated with this system. In addition, physicians interested in being listed on the SAMHSA Buprenorphine Physician Locator Web site (http://buprenorphine.samhsa.gov/bwns_locator) should call 1-866-BUP-CSAT (1-866-287-2728). Additional information can be obtained, via e-mail at info@buprenorphine.samhsa.gov, or at http://www.buprenorphine.samhsa.gov.

Thank you for your interest in providing opioid addiction treatment in accordance with DATA 2000.

Sincerely,

H. Westley Clark, M.D., J.D., M.P.H.
Director
Center for Substance Abuse Treatment

Enclosure

August 4, 2004

«Full_Name»
«Address_line_1»
«Address_line_2»
«City», «State» «Zip_code»

Dear «Name_Prefix» «Last_Name»:

Thank you for submitting a Notification of Intent (NOI) to Use Schedule III, IV, or V opioid drugs for the maintenance and detoxification treatment of opiate addiction in accordance with the Drug Addiction Treatment Act of 2000 (DATA 2000) (21 U.S.C. § 823(g)(2)), dated «Submission_Date». The Substance Abuse and Mental Health Services Administration's Center for Substance Abuse Treatment (SAMHSA/CSAT) received your NOI on «Date_Received». In order for us to complete the processing of your NOI, you will need to provide the following additional and/or missing information:

«Error_Messages»

We have enclosed a copy of the original NOI form you submitted, and have highlighted the areas listed above. Please complete the highlighted areas, and be sure to *sign* and *date* the form (item 15).

After filling in the information requested, please send your signed and dated NOI form by fax or mail. We will process your notification upon receipt of your completed, signed, and dated form.

Fax number: 240-276-1630

Mailing address: Substance Abuse and Mental Health Services Administration
Division of Pharmacologic Therapies
Attention: Opioid Treatment Waiver Program
1 Choke Cherry Road, Room 2-1063
Rockville, MD 20857

When your NOI is complete, we will then verify the information you submitted, and will notify you if additional information is required. If you meet the requirements for a waiver, under DATA 2000, we will send you a letter confirming your waiver to prescribe and/or dispense Schedule III, IV, or V medications. We also will send a unique DATA 2000 registration prescribing number issued to you by the Drug Enforcement Administration (DEA). DEA will send you an updated registration certificate under separate cover.

As of this writing, the only medications to receive Food and Drug Administration approval for the treatment of opioid addiction that are eligible under DATA 2000 are Subutex® (buprenorphine hydrochloride) and Suboxone® (buprenorphine hydrochloride and naloxone hydrochloride). No other medications—including Buprenex®—are eligible under DATA 2000.

The information submitted on your NOI is subject to the Privacy Act System of Records and may be used only by SAMHSA, according to the Routine Uses noted in the Privacy Act Statement in the enclosure.

Please review the enclosed information about the SAMHSA Buprenorphine Physician Locator Web site. It is a tool that patients, families, and health care providers can use to locate physicians with DATA 2000 waivers. If you have not previously consented to be listed on the Locator Web site and would like to be listed, please check the appropriate box in Item 14 of the NOI. Additional information about DATA 2000, buprenorphine, and the physician locator can be obtained at http://buprenorphine.samhsa.gov.

We appreciate your interest in providing opioid addiction treatment in accordance with DATA 2000.

Sincerely,

H. Westley Clark, M.D., J.D., M.P.H.
Director
Center for Substance Abuse Treatment

Enclosure

August 4, 2004

«First_Name» «Middle_Name» «Last_Name»
«Address_line_1»
«Address_line_2»
«City», «State» «Zip_Code»

Dear Dr. «Last_Name»:

This is in response to your Notification of Intent (NOI) to Use Schedule III, IV, or V opioid drugs for the maintenance and detoxification treatment of opiate addiction in accordance with the Drug Addiction Treatment Act of 2000 (DATA 2000) (21 U.S.C. § 823(g)(2)), dated «Submission_Date». The Substance Abuse and Mental Health Services Administration's Center for Substance Abuse Treatment (SAMHSA/CSAT) received your notification on «Date_Received».

We have reviewed the information on your NOI and determined that you meet all the requirements for a waiver under 21 U.S.C. § 823(g)(2)(B). The Drug Enforcement Administration (DEA) has assigned you prescribing number «DEA_Waiver_Number», and will be sending you an updated registration certificate under separate cover. DEA has issued regulations that will require this number, along with your DEA registration number, to be included on all prescriptions issued for the treatment of opiate addiction.

As of this writing, the only medications to receive Food and Drug Administration approval for the treatment of opioid addiction that are eligible under DATA 2000 are Subutex® (buprenorphine hydrochloride) and Suboxone® (buprenorphine hydrochloride and naloxone hydrochloride). No other medications—including Buprenex®—are eligible under DATA 2000.

According to your NOI, you <<Permission to Publish>> consent to be listed on the SAMHSA Buprenorphine Physician Locator Web site. If you would like to change your status, or for additional information about your listing, please see the enclosure.

The information submitted in your notification is subject to the Privacy Act System of Records and may be used only by SAMHSA, according to the Routine Uses noted in the Privacy Act Statement in the enclosure. For additional information, please contact Mr. Nicholas Reuter in the Division of Pharmacologic Therapies at 240-276-2716.

Thank you for your interest in providing opioid addiction treatment in accordance with DATA 2000.

Sincerely,

H. Westley Clark, M.D., J.D., M.P.H.
Director
Center for Substance Abuse Treatment

cc:
Richard Boyd, Chief
Registration and Program Support Section
DEA-Office of Diversion Control

Enclosure

DEPARTMENT OF HEALTH & HUMAN SERVICES

Substance Abuse and Mental
Health Services Administration

Center for Substance Abuse Treatment
1 Choke Cherry Road
Rockville, MD 20857

January 00, 2007

Dr.
123 National Place
Anywhere, USA 123456

Dear Dr :

This is in response to your second Notification of Intent (NOI) to use Schedule III, IV, or V opioid drugs for the maintenance and detoxification treatment of opioid addiction in accordance with the Drug Addiction Treatment Act of 2000 (DATA 2000) (21 U.S.C. § 823(g)(2)), dated November 3, 2008. The Substance Abuse and Mental Health Services Administration's Center for Substance Abuse Treatment (SAMHSA/CSAT) received your second NOI on November 3, 2008.

Under ONDCPRA (effective December 29, 2006), physicians who meet the following criteria may notify the Secretary of Health and Human Services (HHS) of their need and intent to treat up to 100 patients at any one time: (1) the physician must currently be qualified under DATA 2000; (2) at least one year must have elapsed since the physician submitted the initial notification for authorization; (3) the physician must certify to his or her capacity to refer patients for appropriate counseling and other appropriate ancillary services; and (4) the physician must certify that the total number of patients at any one time will not exceed the applicable number.

We have reviewed the information on your second NOI and acknowledge that you have fulfilled the requirements of ONDCPRA to treat a maximum of 100 patients at one time.

As of this writing, the only Schedule III, IV, or V medications to receive Food and Drug Administration (FDA) approval for the treatment of opioid addiction that are eligible under DATA 2000 are Subutex® (buprenorphine hydrochloride) and Suboxone® (buprenorphine hydrochloride and naloxone hydrochloride). No other medications—including Buprenex®—are eligible for the treatment of opioid addiction under DATA 2000.

The information you submitted is subject to a Privacy Act System of Records. The enclosed summary details the authorities, purposes, and disclosures associated with this system. In addition, physicians interested in being listed on the SAMHSA Buprenorphine Physician and Treatment Program Locator (http://buprenorphine.samhsa.gov/bwns_locator) should call 1-866-BUP-CSAT (1-866-287-2728). Additional information can be obtained via e-mail at info@buprenorphine.samhsa.gov or at http://www.buprenorphine.samhsa.gov.

Thank you for your interest in providing opioid addiction treatment in accordance with DATA 2000.

Sincerely,

H. Westley Clark, M.D., J.D., M.P.H.
Director
Center for Substance Abuse Treatment

Enclosure

DEPARTMENT OF HEALTH & HUMAN SERVICES

Substance Abuse and Mental
Health Services Administration

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