LACHMAN CONSULTANT SERVICES, INC.
CONSULTANTS TO THE PHARMACEUTICAL AND ALLIED INDUSTRIES

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1399 '03 MAR 25 A9:19

March 24, 2003

OVERNIGHT COURIER 3/24/03

Dockets Management Branch
Food and Drug Administration (HFA-305)
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Citizen Petition

Dear Sir or Madam:

The undersigned submits this petition, in quadruplicate, pursuant to Section 505(j)(2)(C) of the Federal Food, Drug and Cosmetic Act and in accordance with 21 CFR 10.30 on behalf of a client requesting the Commissioner of the Food and Drug Administration to declare that the drug products, Methadone Hydrochloride Tablets USP, 15 mg, 20 mg, 30 mg and 40 mg are suitable for consideration in abbreviated new drug applications (ANDAs).

A. Action Requested

The petitioner requests that the Commissioner of the Food and Drug Administration declare that Methadone Hydrochloride Tablets, USP, 15 mg, 20 mg, 30 mg and 40 mg are suitable for submission as ANDAs. The listed reference drug product upon which this petition is based is Methadone Hydrochloride Tablets USP (dispersible), 40 mg approved under NDA 17-058 (see Attachment 1). The petitioner thus seeks a change in strength (from a 40 mg tablet to include tablet strengths of 15 mg, 20 mg, and 30 mg) and a change in dosage form (from a dispersible tablet to a standard tablet (non-dispersible) from that of the reference listed drug product.

B. Statement of Grounds

The reference listed drug (RLD) product is currently available in a dispersible tablet containing 40 mg of Methadone Hydrochloride. The proposed drug products represent non-dispersible tablets that will contain the following strengths of the drug: 15 mg, 20 mg, and 30 mg, as well as the same 40 mg strengths tablet of the RLD. The newly proposed strengths (15 mg, 20 mg and 30 mg) are believed to be consistent with the currently approved RLD product's labeling and will provide a more convenient single solid oral dosage unit to provide the specific dose prescribed by the physician for the individual patient. [Please note that a petition granting new strengths of 15 mg, 20 mg and 30 mg Methadone Hydrochloride Tablets (dispersible) was granted under Docket No. 02P-0481/CP1 approved by the Agency on March 4, 2003 (see Attachment 2).] The petition is thus seeking a change in strength (from 40 mg to include additional tablet strengths of 15 mg, 20 mg and 30 mg), as well as a change in dosage form (from a dispersible tablet to a non-dispersible tablet) from that of the reference listed drug product.

03P-0119 CP1

The approved labeling of the RLD lists two indications for Methadone Hydrochloride Tablets, detoxification treatment and maintenance treatment of narcotic addiction. The dosage and administration section of the labeling reads as follows for the detoxification indication:

> "For detoxification treatment – The drug shall be administered daily under close supervision as follows:
>
> A detoxification treatment course shall not exceed 21 days and may not be repeated earlier than four weeks after completion of the preceding course.
>
> In detoxification, the patient may receive Methadone when there are significant symptoms of withdrawal. The dosage schedules indicated below are recommended, but could be varied in accordance with clinical judgment. Initially, a single oral dose of **15 to 20 mg** of Methadone will often be sufficient to suppress withdrawal symptoms. **Additional** Methadone may be provided if withdrawal symptoms are not suppressed or if symptoms reappear. When patients are physically dependent on high doses, it may be necessary to exceed these levels. **Forty mg / day** in single or divided doses will usually constitute an adequate stabilizing dosage level. Stabilization can be continued for 2-3 days, and then the amount of Methadone normally will be gradually decreased." (Emphasis added)

There are general guidelines for initiation of therapy with Methadone Hydrochloride for narcotic maintenance (i.e., the initial dose should be sufficient to "control the abstinence symptoms that follow withdrawal of narcotic drugs, but should not be so great as to cause sedation, respiratory depression or other signs of intoxication. If a patient has been a heavy user of heroin up to the day of admission, he/she may be given 20 mg, 4 to 8 hours later or 40 mg in a single oral dose.") The labeling indicates that doses are to be individualized according to the response of the patient and usually shall not exceed 120 mg / day. Doses above that level must be justified in the patient's medical record.

It is clear from the labeling of the approved drug product that dosage strengths of 15 mg, 20 mg, 30 mg and 40 mg are clearly contemplated for the approved indications. For detoxification treatment doses of 15 mg, 20 mg and up to (which includes a 30 mg dose) 40 mg as a single dose are appropriate. For maintenance treatment, initial doses are individualized to the patient's response and may be adjusted on a total daily dosage basis of usually up to 120 mg. The availability of various dosage strengths will provide the treating physician and facility with options to select the appropriate strength tablets or combination of tablet doses to fulfill individual patient's needs while eliminating the need to break larger size tablets to obtain the appropriate dose.

The petitioner is seeking the requested changes in strength from the RLD drug product to provide the physician greater flexibility in administering alternate dosage strengths that are consistent with doses contemplated in the approved labeling of the RLD. The goal being to reduce the number of tablets a patient would need to take for a single dose. This will improve patient convenience, compliance and make it easier to achieve the required dose for those patients that either have difficulty in swallowing multiple tablets or because of their illness make multiple tablet administration more difficult.

The petitioner is seeking the dosage form change (from dispersible to non-dispersible tablet) based on the revision of the regulations regarding the use of opioid drugs in the maintenance and detoxification treatment of opiate addiction. Previously, the authority for such programs and the use of such products was governed under 21 CFR 291.505 (for copy of revoked 21 CFR 291.505 see Attachment 3). Under that regulation such orally administered drugs dispensed and used in treatment centers had to be dosed to patients in a liquid form, hence, the utility of the 40 mg dispersible tablet. However, a recent change to the regulations (finalizations of the final rule creating 42 CFR Part 8, see Attachment 4) issued which shifted the administrative responsibility and oversight for narcotic treatment regulations and programs from the FDA to the Substance Abuse and Mental Health Administration (SAMSA). This rule repealed the existing narcotic treatment regulations enforced by the FDA and created a new regulatory system based on an accreditation model, to improve opioid addiction treatment by allowing increased medical judgment in treatment.

The new regulations provide that "Methadone shall be administered or dispensed only in **oral form** and shall be formulated in such a way as to reduce its potential for parenteral abuse" (42 CFR 8.12(h)(3)(i)) (emphasis added). The new regulation, therefore, removed the requirements that the oral product be administered as a liquid. In addition, the petitioner will comply with rule by including insoluble excipients in its formulation that will deter parenteral abuse potential in much the same manner as the innovator.

Copies of labeling of the reference listed drug product upon which this petition is based and draft labeling for the proposed product is included in Attachment 5. The proposed labeling is the "same as" the approved RLD labeling with the exception of changes allowed because the manufacturer of the generic product differs from that of the RLD and in the How Supplied section which lists the new dosage from and additional available strengths sought by this petition. There are no changes in the indications, conditions of use or dosage and administration sections necessary as the approved labeling of the RLD already contemplates the use of all of the proposed dosage strengths.

Therefore, the petitioner requests that the Commissioner find that a change in strength and dosage form (from a 40 mg dispersible tablet to include 15 mg, 20 mg, 30 mg and 40 mg strength tablets (non-dispersible)) for this proposed product raises no questions of safety or effectiveness, and the Agency should then approve the petition.

C. Environmental Impact

The petitioner claims a categorical exclusion under 21 CFR 25.31.

D. Economic Impact

The petitioner does not believe that this is applicable in this case, but will agree to provide such an analysis if requested by the Agency.

E. Certification

The undersigned certifies, that to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner, which are unfavorable to the petition.

Respectfully submitted,

Robert Pollock
PK

Robert. W. Pollock
Vice President
Lachman Consultant Services, Inc.
1600 Stewart Avenue
Westbury, New York 11590

RWP/pk

Attachments:

1. Page 3-235 from the 22nd Edition of the Approved Drug Products with Therapeutic Equivalence Evaluations
2. FDA Petition Approval Letter for Docket 02-0481/CP1
3. Revoked 21 CFR 291.505
4. 42 CFR Part 8
5. Proposed Draft Labeling and Approved Labeling

cc: Gregg Davis (OGD)
Martin Shimer (OGD)
Cecelia Parise (OGD)
Leon Lachman

M03P3083

LACHMAN CONSULTANT SERVICES, INC.
Westbury, NY 11590

ATTACHMENT 1

METHADONE HYDROCHLORIDE

TABLET; ORAL

METHADONE HCL

AA	+ ROXANE	40MG	N17058 001	
AA		40MG	N74081 001	APR 28, 1995

METHADOSE

AA	MALLINCKRODT	5MG	N40050 001	APR 15, 1993
AA		10MG	N40050 002	APR 15, 1993
AA		40MG	N74184 001	APR 29, 1993

METHAMPHETAMINE HYDROCHLORIDE

TABLET; ORAL

DESOXYN

+ ABBOTT	5MG	N05378 002

TABLET, EXTENDED RELEASE; ORAL

DESOXYN

+ ABBOTT	5MG	N05378 004
+	10MG	N05378 003
+	15MG	N05378 005

METHANTHELINE BROMIDE

TABLET; ORAL

BANTHINE

+ SHIRE LABS	50MG	N07390 001	

METHAZOLAMIDE

TABLET; ORAL

METHAZOLAMIDE

AB	COPLEY PHARM	25MG	N40001 001	JUN 30, 1993
AB		50MG	N40001 002	JUN 30, 1993
AB	GENEVA PHARMS	25MG	N40036 001	JUN 30, 1993
AB		50MG	N40036 002	JUN 30, 1993

METHAZOLAMIDE

TABLET; ORAL

METHAZOLAMIDE

AB	INVAMED	25MG	N40102 001	AUG 28, 1996
AB		50MG	N40102 002	AUG 28, 1996
AB	MIKART	25MG	N40062 001	JAN 27, 1994
AB		50MG	N40062 002	JAN 27, 1994

NEPTAZANE

AB	LEDERLE	25MG	N11721 002	NOV 25, 1991
AB	+	50MG	N11721 001	

METHENAMINE HIPPURATE

TABLET; ORAL

HIPREX

AB	+ AVENTIS PHARMS	1GM	N17681 001

UREX

AB	3M	1GM	N16151 001

METHIMAZOLE

TABLET; ORAL

METHIMAZOLE

AB	EON	5MG	N40411 001	MAR 27, 2001
AB		10MG	N40411 002	MAR 27, 2001
AB	GENPHARM	5MG	N40350 001	MAR 29, 2000
AB		10MG	N40350 002	MAR 29, 2000
	+	20MG	N40350 003	JUN 07, 2001
AB	JONES PHARMA	5MG	N40320 001	MAR 31, 2000
AB		10MG	N40320 002	MAR 31, 2000

TAPAZOLE

AB	LILLY	5MG	N07517 002	
AB	+	10MG	N07517 004	

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ATTACHMENT 2

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MAR 0 4 2003

Lachman Consultant Services, Inc.
Attention: Robert W. Pollock
1600 Stewart Avenue
Westbury, NY 11590

Docket No. 02P-0481/CP1

Dear Mr. Pollock:

This is in response to your petition filed on November 12, 2002, requesting permission to file an Abbreviated New Drug Application (ANDA) for the following drug products: Methadone Hydrochloride Tablets USP (Dispersible), 15 mg, 20 mg and 30 mg. The listed drug product to which you refer in your petition is Methadone Hydrochloride Tablets USP (Dispersible), 40 mg, approved under NDA 17-058 held by Roxane Laboratories, Inc.

Your request involves changes in strength from that of the listed drug product (i.e., from 40 mg tablets (dispersible) to 15 mg, 20 mg and 30 mg tablets (dispersible)). The changes you request are the types of changes that are authorized under the Federal Food, Drug, and Cosmetic Act (Act).

We have reviewed your petition under Section 505(j)(2)(C) of the Act and have determined that it is approved. This letter represents the Food and Drug Administration's (FDA) determination that an ANDA may be submitted for the above-referenced drug products.

Under Section 505(j)(2)(C)(i) of the Act, the FDA must approve a petition seeking a strength that differs from the strength of the listed drug product unless it finds that investigations must be conducted to show the safety and effectiveness of the differing strength.

The FDA finds that the changes in strength for the specific proposed drug products do not pose questions of safety or effectiveness because the uses and route of administration of the proposed drug products are the same as that of the listed drug product. The dosing instructions for the reference listed drug indicate that an initial single oral dose of 15 to 20 mg of methadone will be sufficient to suppress withdrawal symptoms when used for detoxification treatment. Additional methadone may be provided if withdrawal symptoms are not suppressed or if symptoms reappear. Forty mg/day in single or divided doses will usually constitute an adequate stabilizing level when used for detoxification. Subsequently, the amount of methadone normally will be gradually decreased. For maintenance treatment, the dose should be adjusted on an individual basis as tolerated up to a level of 120 mg/day.

Therefore, the lower dosage strengths of methadone that you propose are contemplated by the approved labeling of the reference listed drug and are useful for initial treatment as well as for dosage adjustment purposes. The FDA concludes, therefore, that investigations are not necessary in this instance. In addition, if shown to meet bioavailability requirements, the proposed drug products can be expected to have the same therapeutic effect as the listed reference drug product.

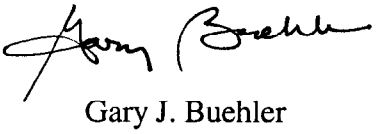
The approval of this petition to allow an ANDA to be submitted for the above-referenced drug products does not mean that the FDA has determined that an ANDA will be approved for the drug products. The determination of whether an ANDA will be approved is not made until the ANDA itself is submitted and reviewed by the FDA.

To permit review of your ANDA submission, you must submit all information required under Sections 505(j)(2)(A) and (B) of the Act. To be approved, the drug product will, among other things, be required to meet current bioavailability requirements under Section 505(j)(2)(A)(iv) of the Act. We suggest that you submit your protocol for this drug product to the Office of Generic Drugs, Division of Bioequivalence, prior to the submission of your ANDA. During the review of your application, the FDA may require the submission of additional information.

The listed drug product to which you refer in your ANDA must be the one upon which you based this petition. In addition, you should refer in your ANDA to the appropriate petition docket number cited above, and include a copy of this letter in the ANDA submission.

A copy of this letter approving your petition will be placed on public display in the Dockets Management Branch, Room 1061, Mail Stop HFA-305, 5630 Fishers Lane, Rockville, MD 20852.

Sincerely yours,



Gary J. Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

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Westbury, NY 11590

ATTACHMENT 3

or deletion of any program service is required to be reported immediately to the Food and Drug Administration.

(ii) *Minimum medical services; designation of medical director and responsibilities.* Each program shall have a designated medical director who assumes responsibility for administering all medical services performed by the program. The medical director and other authorized program physicians are required to be licensed to practice medicine in the jurisdiction in which the program is located. The medical director is responsible for ensuring that the program is in compliance with all Federal, State, and local laws and regulations regarding medical treatment of narcotic addiction. In addition, the medical director or other authorized physicians shall:

(A) Ensure that evidence of current physiologic dependence, length of history of addiction, or exceptions to criteria for admission are documented in the patient's record before the patient receives the initial dose.

(B) Ensure that a medical evaluation including a medical history has been taken, and physical examination has been done before the patient receives the initial dose (except that in an emergency situation, the initial dose may be given before the physical examination).

(C) Ensure that appropriate laboratory studies have been performed and reviewed.

(D) Sign or countersign all medical orders as required by Federal or State law. (Such medical orders include but are not limited to the initial medication orders and all subsequent medication order changes, all changes in the frequency of take-home medication, and prescribing additional take-home medication for an emergency situation.)

(E) Review and countersign treatment plans at least annually as qualified by paragraph (d)(3)(v)(D) of this section.

(F) Ensure that justification is recorded in the patient's record for reducing the frequency of clinic visits for observed drug ingesting, providing additional take-home medication under exceptional circumstances or when there is physicial disability, or prescribing any medication for physical or emotional problems.

(iii) *Use of health-care professionals.* Although the final decision to accept a patient for treatment may be made only by the medical director or other designated program physician, it is recognized that physicians can train program personnel to detect and document narcotic abstinence symptons and that some jurisdictions allow State-licensed or certified health-care professionals; e.g., physician's assistants, nurse practitioners, to perform certain functions—record medical histories, perform physicial examinations, and prescribe, administer, or dispense certain medications—that are ordinarily performed by a licensed physician. These regulations do not prohibit licensed or certified health-care professionals from performing those functions in narcotic treatment programs if it is authorized by Federal, State, and local laws and regulations, and if those functions are delegated to them by the medical director, and records are properly countersigned by the medical director or a licensed physician.

(iv) *Vocational rehabilitation, education, and employment.* Each program shall provide opportunities directly, or through referral to community resources, for patients who either desire or have been deemed by the program staff to be ready to participate in educational job training programs or to obtain gainful employment as soon as possible.

(v) *Authorized dispensers of narcotic drugs; responsibility.* A narcotic drug may be administered or dispensed only by a practitioner licensed under the appropriate State law and registered under the appropriate State and Federal laws to order narcotic drugs for patients, or by an agent of such a practitioner, supervised by and under the order of the practitioner. This agent is required to be a pharmacist, registered nurse, or licensed practical nurse, or any other health care professional authorized by Federal and State law to administer or dispense narcotic drugs. The licensed practitioner assumes responsibility for the amounts of narcotic drugs administered or dispensed and shall record and countersign all changes in dosage schedule.

(5) *Staffing patterns*—(i) *Program personnel.* The person(s) responsible for a program shall determine program personnel requirements after considering the number of patients who are vocationally and educationally impaired; the number of patients with significant psychopathology; the number of patients who are also nonnarcotic drug or alcohol abusers; the number of patients with behavioral problems in the program; and the number of patients with serious medical problems.

(ii) *Supportive services.* The person(s) responsible for the program shall take notice, when considering the staffing pattern, that comprehensive maintenance treatment programs need to establish supportive services in accordance with the varying characteristics and needs of their patient populations. The person(s) responsible for a program shall also take notice of the availability of existing community resources which may complement or enhance the program's delivery of supportive services and then establish a staffing pattern based on a combination of patient needs and available, accessible community resources.

(6) *Use of methadone in a treatment program; frequency of attendance; quantity of take-home medication; dosage of methadone; initial and stabilization*—(i) *Dosage and responsibility.* (A) The person(s) responsible for the program shall ensure that the initial dose of methadone does not exceed 30 milligrams and that the total dose for the first day does not exceed 40 milligrams, unless the program medical director documents in the patient's record that 40 milligrams did not suppress opiate abstinence symptoms.

(B) A licensed physician shall assume responsibility for the amount of the narcotic drug administered or dispensed and shall record, date, and sign in each patient's record each change in the dosage schedule.

(C) The administering licensed physician shall ensure that a daily dose greater than 100 milligrams is justified in the patient's record.

(ii) [Reserved]

(iii) *Form.* Methadone may be administered or dispensed in oral form only when used in a treatment program. Hospitalized patients under care for a medical or surgical condition are permitted to receive methadone in parenteral form when the attending physician judges it advisable. Although tablet, syrup concentrate, or other formulations may be distributed to the program, all oral medication is required to be administered or dispensed in a liquid formulation. The oral dosage form is required to be formulated in such a way as to reduce its potential for parenteral abuse. Take-home medication is required to be labeled with the treatment center's name, address, and telephone number and must be packaged in special packaging as required by 16 CFR 1700.14 in accordance with the Poison Prevention Packaging Act (Pub. L. 91–601, 15 U.S.C. 1471 *et seq.*) to reduce the chances of accidental ingestion. Exceptions may be granted when these provisions conflict with State law with regard to the administering or dispensing of drugs.

(iv) *Take-home medication.* (A) Take-home medication may be given only to a patient who, in the reasonable clinical judgment of the program physician, is responsible in handling narcotic drugs. Before the program physician reduces the frequency of a patient's clinical visits, she or he or a designated staff member shall record the rationale for the decision in the patient's clinical record. If this is done by a designated staff member, a program physician shall review, countersign, and date the patient's record where this information is recorded.

(B) The program physician shall consider the following in determining whether, in his or her reasonable clinical judgment, a patient is responsible in handling narcotic drugs:

(*1*) Absence of recent abuse of drugs (narcotic or nonnarcotic), including alcohol;

(*2*) Regularity of clinic attendance;

(*3*) Absence of serious behavioral problems at the clinic;

(*4*) Absence of known recent criminal activity, e.g., drug dealing;

(*5*) Stability of the patient's home environment and social relationships;

(*6*) Length of time in comprehensive maintenance treatment;

(*7*) Assurance that take-home medication can be safely stored within the patient's home; and

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ATTACHMENT 4

certification or in a separate submission. SAMHSA will approve or deny such exemptions at the time of application, or any time thereafter, if appropriate. SAMHSA shall consult with the appropriate State authority prior to taking action on an exemption request.

(i) *Medication units, long-term care facilities and hospitals.* (1) Certified OTPs may establish medication units that are authorized to dispense opioid agonist treatment medications for observed ingestion. Before establishing a medication unit, a certified OTP must notify SAMHSA by submitting form SMA–162. The OTP must also comply with the provisions of 21 CFR part 1300 before establishing a medication unit. Medication units shall comply with all pertinent state laws and regulations.

(2) Certification as an OTP under this part will not be required for the maintenance or detoxification treatment of a patient who is admitted to a hospital or long-term care facility for the treatment of medical conditions other than opiate addiction and who requires maintenance or detoxification treatment during the period of his or her stay in that hospital or long-term care facility. The terms "hospital" and "long-term care facility" as used in this section are to have the meaning that is assigned under the law of the State in which the treatment is being provided. Nothing in this section is intended to relieve hospitals and long-term care facilities from the obligation to obtain registration from the Attorney General, as appropriate, under section 303(g) of the Controlled Substances Act.

[66 FR 4090, Jan. 17, 2001, as amended at 66 FR 15347, Mar. 19, 2001]

§8.12 Federal opioid treatment standards.

(a) *General.* OTPs must provide treatment in accordance with the standards in this section and must comply with these standards as a condition of certification.

(b) *Administrative and organizational structure.* An OTP's organizational structure and facilities shall be adequate to ensure quality patient care and to meet the requirements of all pertinent Federal, State, and local laws and regulations. At a minimum, each OTP shall formally designate a program sponsor and medical director. The program sponsor shall agree on behalf of the OTP to adhere to all requirements set forth in this part and any regulations regarding the use of opioid agonist treatment medications in the treatment of opioid addiction which may be promulgated in the future. The medical director shall assume responsibility for administering all medical services performed by the OTP. In addition, the medical director shall be responsible for ensuring that the OTP is in compliance with all applicable Federal, State, and local laws and regulations.

(c) *Continuous quality improvement.* (1) An OTP must maintain current quality assurance and quality control plans that include, among other things, annual reviews of program policies and procedures and ongoing assessment of patient outcomes.

(2) An OTP must maintain a current "Diversion Control Plan" or "DCP" as part of its quality assurance program that contains specific measures to reduce the possibility of diversion of controlled substances from legitimate treatment use and that assigns specific responsibility to the medical and administrative staff of the OTP for carrying out the diversion control measures and functions described in the DCP.

(d) *Staff credentials.* Each person engaged in the treatment of opioid addiction must have sufficient education, training, and experience, or any combination thereof, to enable that person to perform the assigned functions. All physicians, nurses, and other licensed professional care providers, including addiction counselors, must comply with the credentialing requirements of their respective professions.

(e) *Patient admission criteria.*—(1) Maintenance treatment. An OTP shall maintain current procedures designed to ensure that patients are admitted to maintenance treatment by qualified personnel who have determined, using accepted medical criteria such as those listed in the Diagnostic and Statistical Manual for Mental Disorders (DSM-IV), that the person is currently addicted to

an opioid drug, and that the person became addicted at least 1 year before admission for treatment. In addition, a program physician shall ensure that each patient voluntarily chooses maintenance treatment and that all relevant facts concerning the use of the opioid drug are clearly and adequately explained to the patient, and that each patient provides informed written consent to treatment.

(2) Maintenance treatment for persons under age 18. A person under 18 years of age is required to have had two documented unsuccessful attempts at short-term detoxification or drug-free treatment within a 12-month period to be eligible for maintenance treatment. No person under 18 years of age may be admitted to maintenance treatment unless a parent, legal guardian, or responsible adult designated by the relevant State authority consents in writing to such treatment.

(3) Maintenance treatment admission exceptions. If clinically appropriate, the program physician may waive the requirement of a 1-year history of addiction under paragraph (e)(1) of this section, for patients released from penal institutions (within 6 months after release), for pregnant patients (program physician must certify pregnancy), and for previously treated patients (up to 2 years after discharge).

(4) Detoxification treatment. An OTP shall maintain current procedures that are designed to ensure that patients are admitted to short- or long-term detoxification treatment by qualified personnel, such as a program physician, who determines that such treatment is appropriate for the specific patient by applying established diagnostic criteria. Patients with two or more unsuccessful detoxification episodes within a 12-month period must be assessed by the OTP physician for other forms of treatment. A program shall not admit a patient for more than two detoxification treatment episodes in one year.

(f) *Required services.*—(1) General. OTPs shall provide adequate medical, counseling, vocational, educational, and other assessment and treatment services. These services must be available at the primary facility, except where the program sponsor has entered into a formal, documented agreement with a private or public agency, organization, practitioner, or institution to provide these services to patients enrolled in the OTP. The program sponsor, in any event, must be able to document that these services are fully and reasonably available to patients.

(2) Initial medical examination services. OTPs shall require each patient to undergo a complete, fully documented physical evaluation by a program physician or a primary care physician, or an authorized healthcare professional under the supervision of a program physician, before admission to the OTP. The full medical examination, including the results of serology and other tests, must be completed within 14 days following admission.

(3) Special services for pregnant patients. OTPs must maintain current policies and procedures that reflect the special needs of patients who are pregnant. Prenatal care and other gender specific services or pregnant patients must be provided either by the OTP or by referral to appropriate healthcare providers.

(4) Initial and periodic assessment services. Each patient accepted for treatment at an OTP shall be assessed initially and periodically by qualified personnel to determine the most appropriate combination of services and treatment. The initial assessment must include preparation of a treatment plan that includes the patient's short-term goals and the tasks the patient must perform to complete the short-term goals; the patient's requirements for education, vocational rehabilitation, and employment; and the medical, psychosocial, economic, legal, or other supportive services that a patient needs. The treatment plan also must identify the frequency with which these services are to be provided. The plan must be reviewed and updated to reflect that patient's personal history, his or her current needs for medical, social, and psychological services, and his or her current needs for education, vocational rehabilitation, and employment services.

(5) Counseling services. (i) OTPs must provide adequate substance abuse counseling to each patient as clinically

necessary. This counseling shall be provided by a program counselor, qualified by education, training, or experience to assess the psychological and sociological background of patients, to contribute to the appropriate treatment plan for the patient and to monitor patient progress.

(ii) OTPs must provide counseling on preventing exposure to, and the transmission of, human immunodeficiency virus (HIV) disease for each patient admitted or readmitted to maintenance or detoxification treatment.

(iii) OTPs must provide directly, or through referral to adequate and reasonably accessible community resources, vocational rehabilitation, education, and employment services for patients who either request such services or who have been determined by the program staff to be in need of such services.

(6) Drug abuse testing services. OTPs must provide adequate testing or analysis for drugs of abuse, including at least eight random drug abuse tests per year, per patient in maintenance treatment, in accordance with generally accepted clinical practice. For patients in short-term detoxification treatment, the OTP shall perform at least one initial drug abuse test. For patients receiving long-term detoxification treatment, the program shall perform initial and monthly random tests on each patient.

(g) *Recordkeeping and patient confidentiality.* (1) OTPs shall establish and maintain a recordkeeping system that is adequate to document and monitor patient care. This system is required to comply with all Federal and State reporting requirements relevant to opioid drugs approved for use in treatment of opioid addiction. All records are required to be kept confidential in accordance with all applicable Federal and State requirements.

(2) OTPs shall include, as an essential part of the recordkeeping system, documentation in each patient's record that the OTP made a good faith effort to review whether or not the patient is enrolled any other OTP. A patient enrolled in an OTP shall not be permitted to obtain treatment in any other OTP except in exceptional circumstances. If the medical director or program physician of the OTP in which the patient is enrolled determines that such exceptional circumstances exist, the patient may be granted permission to seek treatment at another OTP, provided the justification for finding exceptional circumstances is noted in the patient's record both at the OTP in which the patient is enrolled and at the OTP that will provide the treatment.

(h) *Medication administration, dispensing, and use.* (1) OTPs must ensure that opioid agonist treatment medications are administered or dispensed only by a practitioner licensed under the appropriate State law and registered under the appropriate State and Federal laws to administer or dispense opioid drugs, or by an agent of such a practitioner, supervised by and under the order of the licensed practitioner. This agent is required to be a pharmacist, registered nurse, or licensed practical nurse, or any other healthcare professional authorized by Federal and State law to administer or dispense opioid drugs.

(2) OTPs shall use only those opioid agonist treatment medications that are approved by the Food and Drug Administration under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) for use in the treatment of opioid addiction. In addition, OTPs who are fully compliant with the protocol of an investigational use of a drug and other conditions set forth in the application may administer a drug that has been authorized by the Food and Drug Administration under an investigational new drug application under section 505(i) of the Federal Food, Drug, and Cosmetic Act for investigational use in the treatment of opioid addiction. Currently the following opioid agonist treatment medications will be considered to be approved by the Food and Drug Administration for use in the treatment of opioid addiction:

(i) Methadone; and

(ii) Levomethadyl acetate (LAAM).

(3) OTPs shall maintain current procedures that are adequate to ensure that the following dosage form and initial dosing requirements are met:

(i) Methadone shall be administered or dispensed only in oral form and shall

be formulated in such a way as to reduce its potential for parenteral abuse.

(ii) For each new patient enrolled in a program, the initial dose of methadone shall not exceed 30 milligrams and the total dose for the first day shall not exceed 40 milligrams, unless the program physician documents in the patient's record that 40 milligrams did not suppress opiate abstinence symptoms.

(4) OTPs shall maintain current procedures adequate to ensure that each opioid agonist treatment medication used by the program is administered and dispensed in accordance with its approved product labeling. Dosing and administration decisions shall be made by a program physician familiar with the most up-to-date product labeling. These procedures must ensure that any significant deviations from the approved labeling, including deviations with regard to dose, frequency, or the conditions of use described in the approved labeling, are specifically documented in the patient's record.

(i) Unsupervised or "take-home" use. To limit the potential for diversion of opioid agonist treatment medications to the illicit market, opioid agonist treatment medications dispensed to patients for unsupervised use shall be subject to the following requirements.

(1) Any patient in comprehensive maintenance treatment may receive a single take-home dose for a day that the clinic is closed for business, including Sundays and State and Federal holidays.

(2) Treatment program decisions on dispensing opioid treatment medications to patients for unsupervised use beyond that set forth in paragraph (i)(1) of this section, shall be determined by the medical director. In determining which patients may be permitted unsupervised use, the medical director shall consider the following take-home criteria in determining whether a patient is responsible in handling opioid drugs for unsupervised use.

(i) Absence of recent abuse of drugs (opioid or nonnarcotic), including alcohol;

(ii) Regularity of clinic attendance;

(iii) Absence of serious behavioral problems at the clinic;

(iv) Absence of known recent criminal activity, *e.g.*, drug dealing;

(v) Stability of the patient's home environment and social relationships;

(vi) Length of time in comprehensive maintenance treatment;

(vii) Assurance that take-home medication can be safely stored within the patient's home; and

(viii) Whether the rehabilitative benefit the patient derived from decreasing the frequency of clinic attendance outweighs the potential risks of diversion.

(3) Such determinations and the basis for such determinations consistent with the criteria outlined in paragraph (i)(2) of this section shall be documented in the patient's medical record. If it is determined that a patient is responsible in handling opioid drugs, the following restrictions apply:

(i) During the first 90 days of treatment, the take-home supply (beyond that of paragraph (i)(1) of this section) is limited to a single dose each week and the patient shall ingest all other doses under appropriate supervision as provided for under the regulations in this subpart.

(ii) In the second 90 days of treatment, the take-home supply (beyond that of paragraph (i)(1) of this section) is two doses per week.

(iii) In the third 90 days of treatment, the take-home supply (beyond that of paragraph (i)(1) of this section) is three doses per week.

(iv) In the remaining months of the first year, a patient may be given a maximum 6-day supply of take-home medication.

(v) After 1 year of continuous treatment, a patient may be given a maximum 2-week supply of take-home medication.

(vi) After 2 years of continuous treatment, a patient may be given a maximum one-month supply of take-home medication, but must make monthly visits.

(4) No medications shall be dispensed to patients in short-term detoxification treatment or interim maintenance treatment for unsupervised or take-home use.

(5) OTPs must maintain current procedures adequate to identify the theft or diversion of take-home medications,

including labeling containers with the OTP's name, address, and telephone number. Programs also must ensure that take-home supplies are packaged in a manner that is designed to reduce the risk of accidental ingestion, including child-proof containers (see Poison Prevention Packaging Act, Public Law 91-601 (15 U.S.C. 1471 *et seq.*)).

(j) *Interim maintenance treatment.* (1) The program sponsor of a public or nonprofit private OTP may place an individual, who is eligible for admission to comprehensive maintenance treatment, in interim maintenance treatment if the individual cannot be placed in a public or nonprofit private comprehensive program within a reasonable geographic area and within 14 days of the individual's application for admission to comprehensive maintenance treatment. An initial and at least two other urine screens shall be taken from interim patients during the maximum of 120 days permitted for such treatment. A program shall establish and follow reasonable criteria for establishing priorities for transferring patients from interim maintenance to comprehensive maintenance treatment. These transfer criteria shall be in writing and shall include, at a minimum, a preference for pregnant women in admitting patients to interim maintenance and in transferring patients from interim maintenance to comprehensive maintenance treatment. Interim maintenance shall be provided in a manner consistent with all applicable Federal and State laws, including sections 1923, 1927(a), and 1976 of the Public Health Service Act (21 U.S.C. 300x-23, 300x-27(a), and 300y-11).

(2) The program shall notify the State health officer when a patient begins interim maintenance treatment, when a patient leaves interim maintenance treatment, and before the date of mandatory transfer to a comprehensive program, and shall document such notifications.

(3) SAMHSA may revoke the interim maintenance authorization for programs that fail to comply with the provisions of this paragraph (j). Likewise, SAMHSA will consider revoking the interim maintenance authorization of a program if the State in which the program operates is not in compliance with the provisions of §8.11(g).

(4) All requirements for comprehensive maintenance treatment apply to interim maintenance treatment with the following exceptions:

(i) The opioid agonist treatment medication is required to be administered daily under observation;

(ii) Unsupervised or "take-home" use is not allowed;

(iii) An initial treatment plan and periodic treatment plan evaluations are not required;

(iv) A primary counselor is not required to be assigned to the patient;

(v) Interim maintenance cannot be provided for longer than 120 days in any 12-month period; and

(vi) Rehabilitative, education, and other counseling services described in paragraphs (f)(4), (f)(5)(i), and (f)(5)(iii) of this section are not required to be provided to the patient.

§8.13 Revocation of accreditation and accreditation body approval.

(a) *SAMHSA action following revocation of accreditation.* If an accreditation body revokes an OTP's accreditation, SAMHSA may conduct an investigation into the reasons for the revocation. Following such investigation, SAMHSA may determine that the OTP's certification should no longer be in effect, at which time SAMHSA will initiate procedures to revoke the facility's certification in accordance with §8.14. Alternatively, SAMHSA may determine that another action or combination of actions would better serve the public health, including the establishment and implementation of a corrective plan of action that will permit the certification to continue in effect while the OTP seeks reaccreditation.

(b) *Accreditation body approval.* (1) If SAMHSA withdraws the approval of an accreditation body under §8.6, the certifications of OTPs accredited by such body shall remain in effect for a period of 1 year after the date of withdrawal of approval of the accreditation body, unless SAMHSA determines that to protect public health or safety, or because the accreditation body fraudulently accredited treatment programs, the certifications of some or all of the

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ATTACHMENT 5