

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Health Care Financing Administration

[HCFA-3782-NC]

RIN 0938-AG45

Medicare Program; Withdrawal of Proposed Notice and Request for Assessment on the Salitron System for the Treatment of Xerostomia (Dry Mouth) Secondary to Sjogren's Syndrome
AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Withdrawal of Notice, and Request for Comments.

SUMMARY: This notice announces our withdrawal of a prior proposed notice. It also announces a request for the Agency for Health Care Policy and Research to conduct a new technology assessment on the salivary electrostimulation in Sjogren's Syndrome which includes the use of the Salitron System for the treatment of xerostomia (Dry Mouth) secondary to Sjogren's Syndrome.

DATES: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on July 31, 1998.

ADDRESSES: Mail written comments (1 original and 3 copies) to both the following addresses:

Health Care Financing Administration,
Department of Health and Human Services, Attention: HCFA-3782-NC,
PO Box 26688, Baltimore, MD 21207,
and

Agency for Health Care Policy and Research Attention: HCFA-3782-NC,
Willco Building, Suite 309, 6000 Executive Boulevard, Rockville, Maryland 20852.

If you prefer, you may deliver your written comments to one of the following addresses:

Room 309-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or
Room C5-09-26, 7500 Security Boulevard, Baltimore, MD 21244-1850.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HCFA-3782-NC. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 309-G of the Department's offices at 200 Independence Avenue,

SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690-7890).

FOR FURTHER INFORMATION CONTACT: Francina C. Spencer, (410) 786-4614.

SUPPLEMENTARY INFORMATION: On May 23, 1994, we published a notice in the **Federal Register** (59 FR 26653) entitled, "Noncoverage of Electrostimulation of Salivary Glands for the Treatment of Xerostomia (Dry Mouth)." That notice announced our intent not to cover electrostimulation of the salivary glands for the treatment of xerostomia secondary to Sjogren's Syndrome and electrostimulation devices, such as the Salitron System, under the Medicare program. The notice took into account and provided details of a technology assessment submitted to the Health Care Financing Administration in 1990 by the Office of Health Technology Assessment (OHTA).

However, due to the lapse of time from the date the original technology assessment was done (in 1990), we have decided to withdraw the notice that was issued in the **Federal Register** in 1994, (FR Doc. 94-12457) and take no further action pursuant to that notice. Instead, before we make a coverage determination, we believe it would be appropriate to obtain an updated assessment to take into account research and data made available since 1990. Therefore, we have requested the Agency for Health Care Policy and Research (AHCPR), the organization we now deal with for such issues, to do a technology assessment of the Salitron System. We will make a decision regarding the coverage of electrostimulation of the salivary glands for the treatment of xerostomia secondary to Sjogren's Syndrome once we have received and reviewed the new technology assessment from AHCPR.

Any comments or significant data regarding the study of electrostimulation of the salivary glands for the treatment of xerostomia secondary to Sjogren's Syndrome should be submitted to both the Agency for Health Care Policy and Research and HCFA at the addresses provided above.

Until a decision is made, Medicare coverage for electrostimulation of the salivary glands for the treatment of xerostomia secondary to Sjogren's Syndrome and the Salitron System will continue to be at the discretion of the Medicare program durable medical equipment regional carriers.

Response to Comments

Because of the large number of items of correspondence we normally receive on **Federal Register** documents

published for comment, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, if we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

Authority: Secs. 1861 and 1862 of the Social Security Act (42 U.S.C. 1395x and 1395y).

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: April 28, 1998.

Nancy-Ann Min DeParle,
Administrator, Health Care Financing Administration.

Dated: May 13, 1998.

Donna E. Shalala,
Secretary, Department of Health and Human Services.

[FR Doc. 98-14307 Filed 5-29-98; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Substance Abuse and Mental Health Services Administration
Current List of Laboratories Which Meet Minimum Standards To Engage in Urine Drug Testing for Federal Agencies, and Laboratories That Have Withdrawn From the Program

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services notifies Federal agencies of the laboratories currently certified to meet standards of Subpart C of Mandatory Guidelines for Federal Workplace Drug Testing Programs (59 FR 29916, 29925). A similar notice listing all currently certified laboratories will be published during the first week of each month, and updated to include laboratories which subsequently apply for and complete the certification process. If any listed laboratory's certification is totally suspended or revoked, the laboratory will be omitted from updated lists until such time as it is restored to full certification under the Guidelines.

If any laboratory has withdrawn from the National Laboratory Certification Program during the past month, it will be identified as such at the end of the current list of certified laboratories, and

will be omitted from the monthly listing thereafter.

This Notice is now available on the internet at the following website:
http://www.health.org

FOR FURTHER INFORMATION CONTACT: Mrs. Giselle Hersh or Dr. Walter Vogl, Division of Workplace Programs, 5600 Fishers Lane, Rockwall 2 Building, Room 815, Rockville, Maryland 20857; Tel.: (301) 443-6014.

Special Note: Our office moved to a different building on May 18, 1998. The above address is now the correct one to use for all regular mail and correspondence. For all overnight mail service use the following: Division of Workplace Programs, 5515 Security Lane, Room 815, Rockville, Maryland 20852.

SUPPLEMENTARY INFORMATION:

Mandatory Guidelines for Federal Workplace Drug Testing were developed in accordance with Executive Order 12564 and section 503 of Pub. L. 100-71. Subpart C of the Guidelines, "Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies," sets strict standards which laboratories must meet in order to conduct urine drug testing for Federal agencies. To become certified an applicant laboratory must undergo three rounds of performance testing plus an on-site inspection. To maintain that certification a laboratory must participate in a quarterly performance testing program plus periodic, on-site inspections.

Laboratories which claim to be in the applicant stage of certification are not to be considered as meeting the minimum requirements expressed in the HHS Guidelines. A laboratory must have its letter of certification from SAMHSA, HHS (formerly: HHS/NIDA) which attests that it has met minimum standards.

In accordance with Subpart C of the Guidelines, the following laboratories meet the minimum standards set forth in the Guidelines.

ACL Laboratory, 8901 W. Lincoln Ave., West Allis, WI 53227, 414-328-7840 (Formerly: Bayshore Clinical Laboratory)
Aegis Analytical Laboratories, Inc., 345 Hill Ave., Nashville, TN 37210, 615-255-2400
Alabama Reference Laboratories, Inc., 543 South Hull St., Montgomery, AL 36103, 800-541-4931 / 334-263-5745
Alliance Laboratory Services, 3200 Burnet Ave., Cincinnati, OH 45229, 513-569-2051 (Formerly: Jewish Hospital of Cincinnati, Inc.)
American Medical Laboratories, Inc., 14225 Newbrook Dr., Chantilly, VA 20151, 703-802-6900
Associated Pathologists Laboratories, Inc., 4230 South Burnham Ave., Suite 250, Las Vegas, NV 89119-5412, 702-733-7866 / 800-433-2750

Associated Regional and University Pathologists, Inc. (ARUP), 500 Chipeta Way, Salt Lake City, UT 84108, 801-583-2787 / 800-242-2787
Baptist Medical Center—Toxicology Laboratory, 9601 I-630, Exit 7, Little Rock, AR 72205-7299, 501-202-2783 (Formerly: Forensic Toxicology Laboratory Baptist Medical Center)
Cedars Medical Center, Department of Pathology, 1400 Northwest 12th Ave., Miami, FL 33136, 305-325-5784
Clinical Reference Lab, 8433 Quivira Rd., Lenexa, KS 66215-2802, 800-445-6917
Cox Health Systems, Department of Toxicology, 1423 North Jefferson Ave., Springfield, MO 65802, 800-876-3652 / 417-269-3093 (Formerly: Cox Medical Centers)
Dept. of the Navy, Navy Drug Screening Laboratory, Great Lakes, IL, P. O. Box 88-6819, Great Lakes, IL 60088-6819, 847-688-2045 / 847-688-4171
Diagnostic Services Inc., dba DSI 4048 Evans Ave., Suite 301, Fort Myers, FL 33901, 941-418-1700 / 800-735-5416
Doctors Laboratory, Inc., P.O. Box 2658, 2906 Julia Dr., Valdosta, GA 31604, 912-244-4468
DrugProof, Division of Dynacare/Laboratory of Pathology, LLC, 1229 Madison St., Suite 500, Nordstrom Medical Tower, Seattle, WA 98104, 800-898-0180 / 206-386-2672 (Formerly: Laboratory of Pathology of Seattle, Inc., DrugProof, Division of Laboratory of Pathology of Seattle, Inc.)
DrugScan, Inc., P.O. Box 2969, 1119 Mearns Rd., Warminster, PA 18974, 215-674-9310
Dynacare Kasper Medical Laboratories,* 14940-123 Ave., Edmonton, Alberta, Canada T5V 1B4, 800-661-9876 / 403-451-3702
ElSohly Laboratories, Inc., 5 Industrial Park Dr., Oxford, MS 38655, 601-236-2609
Gamma-Dynacare Medical Laboratories,* A Division of the Gamma-Dynacare Laboratory Partnership, 245 Pall Mall St., London, ON, Canada N6A 1P4, 519-679-1630
General Medical Laboratories, 36 South Brooks St., Madison, WI 53715, 608-267-6267
Hartford Hospital Toxicology Laboratory, 80 Seymour St., Hartford, CT 06102-5037, 860-545-6023
LabCorp Occupational Testing Services, Inc., 1904 Alexander Drive, Research Triangle Park, NC 27709, 919-672-6900 / 800-833-3984 (Formerly: CompuChem Laboratories, Inc.; CompuChem Laboratories, Inc., A Subsidiary of Roche Biomedical Laboratory; Roche CompuChem Laboratories, Inc., A Member of the Roche Group)
LabCorp Occupational Testing Services, Inc., 4022 Willow Lake Blvd., Memphis, TN 38118, 901-795-1515/800-223-6339 (Formerly: MedExpress/National Laboratory Center)
LabOne, Inc., 8915 Lenexa Dr., Overland Park, Kansas 66214, 913-888-3927 / 800-728-4064 (Formerly: Center for Laboratory Services, a Division of LabOne, Inc.)
Laboratory Corporation of America, 888 Willow St., Reno, NV 89502, 702-334-3400 (Formerly: Sierra Nevada Laboratories, Inc.)

Laboratory Corporation of America Holdings, 69 First Ave., Raritan, NJ 08869, 800-437-4986 / 908-526-2400 (Formerly: Roche Biomedical Laboratories, Inc.)
Laboratory Specialists, Inc., 1111 Newton St., Gretna, LA 70053, 504-361-8989 / 800-433-3823
Marshfield Laboratories, Forensic Toxicology Laboratory, 1000 North Oak Ave., Marshfield, WI 54449, 715-389-3734 / 800-331-3734
MAXXAM Analytics Inc.,* 5540 McAdam Rd., Mississauga, ON, Canada L4Z 1P1, 905-890-2555 (Formerly: NOVAMANN (Ontario) Inc.)
Medical College Hospitals Toxicology Laboratory, Department of Pathology, 3000 Arlington Ave., Toledo, OH 43614, 419-381-5213
Medlab Clinical Testing, Inc., 212 Cherry Lane, New Castle, DE 19720, 302-655-5227
MedTox Laboratories, Inc., 402 W. County Rd. D, St. Paul, MN 55112, 800-832-3244 / 612-636-7466
Methodist Hospital Toxicology Services of Clarian Health Partners, Inc., Department of Pathology and Laboratory Medicine 1701 N. Senate Blvd., Indianapolis, IN 46202, 317-929-3587
Methodist Medical Center Toxicology Laboratory, 221 N.E. Glen Oak Ave., Peoria, IL 61636, 800-752-1835/309-671-5199
MetroLab-Legacy Laboratory Services, 1225 NE 2nd Ave., Portland, OR 97232, 503-413-4512, 800-950-5295
Minneapolis Veterans Affairs Medical Center, Forensic Toxicology Laboratory, 1 Veterans Drive, Minneapolis, Minnesota 55417, 612-725-2088
National Toxicology Laboratories, Inc., 1100 California Ave., Bakersfield, CA 93304, 805-322-4250
Northwest Toxicology, Inc., 1141 E. 3900 South, Salt Lake City, UT 84124, 800-322-3361 / 801-268-2431
Oregon Medical Laboratories, P.O. Box 972, 722 East 11th Ave., Eugene, OR 97440-0972, 541-341-8092
Pacific Toxicology Laboratories, 1519 Pontius Ave., Los Angeles, CA 90025, 310-312-0056 (Formerly: Centinela Hospital Airport Toxicology Laboratory)
Pathology Associates Medical Laboratories, 11604 E. Indiana, Spokane, WA 99206, 509-926-2400 / 800-541-7891
PharmChem Laboratories, Inc., 1505-A O'Brien Dr., Menlo Park, CA 94025, 650-328-6200 / 800-446-5177
PharmChem Laboratories, Inc., Texas Division, 7610 Pebble Dr., Fort Worth, TX 76118, 817-595-0294 (Formerly: Harris Medical Laboratory)
Physicians Reference Laboratory, 7800 West 110th St., Overland Park, KS 66210, 913-339-0372 / 800-821-3627
Poisonlab, Inc., 7272 Clairemont Mesa Blvd., San Diego, CA 92111, 619-279-2600 / 800-882-7272
Premier Analytical Laboratories, 15201 East I-10 Freeway, Suite 125, Channelview, TX 77530, 713-457-3784 / 800-888-4063 (Formerly: Drug Labs of Texas)
Presbyterian Laboratory Services, 5040 Airport Center Parkway, Charlotte, NC 28208, 800-473-6640 / 704-943-3437

Quest Diagnostics Incorporated, 4444 Giddings Road Auburn Hills, MI 48326, 810-373-9120 / 800-444-0106 (Formerly: HealthCare/Preferred Laboratories, HealthCare/MetPath, CORNING Clinical Laboratories)

Quest Diagnostics Incorporated, National Center for Forensic Science, 1901 Sulphur Spring Rd., Baltimore, MD 21227, 410-536-1485 (Formerly: Maryland Medical Laboratory, Inc., National Center for Forensic Science, CORNING National Center for Forensic Science)

Quest Diagnostics Incorporated, 4770 Regent Blvd., Irving, TX 75063, 800-526-0947 / 972-916-3376 (Formerly: Damon Clinical Laboratories, Damon/MetPath, CORNING Clinical Laboratories)

Quest Diagnostics Incorporated, 875 Greentree Rd., 4 Parkway Ctr., Pittsburgh, PA 15220-3610, 800-574-2474 / 412-920-7733 (Formerly: Med-Chek Laboratories, Inc., Med-Chek/Damon, MetPath Laboratories, CORNING Clinical Laboratories)

Quest Diagnostics Incorporated, 2320 Schuetz Rd., St. Louis, MO 63146, 800-288-7293 / 314-991-1311 (Formerly: Metropolitan Reference Laboratories, Inc., CORNING Clinical Laboratories, South Central Division)

Quest Diagnostics Incorporated, 7470 Mission Valley Rd., San Diego, CA 92108-4406, 800-446-4728 / 619-686-3200 (Formerly: Nichols Institute, Nichols Institute Substance Abuse Testing (NISAT), CORNING Nichols Institute, CORNING Clinical Laboratories)

Quest Diagnostics Incorporated, One Malcolm Ave., Teterboro, NJ 07608, 201-393-5590 (Formerly: MetPath, Inc., CORNING MetPath Clinical Laboratories, CORNING Clinical Laboratory)

Quest Diagnostics Incorporated, 1355 Mittel Blvd., Wood Dale, IL 60191, 630-595-3888 (Formerly: MetPath, Inc., CORNING MetPath Clinical Laboratories, CORNING Clinical Laboratories, Inc.)

Scientific Testing Laboratories, Inc., 463 Southlake Blvd., Richmond, VA 23236, 804-378-9130

Scott & White Drug Testing Laboratory, 600 S. 31st St., Temple, TX 76504, 800-749-3788 / 254-771-8379

S.E.D. Medical Laboratories, 500 Walter NE, Suite 500, Albuquerque, NM 87102, 505-727-8800 / 800-999-LABS

SmithKline Beecham Clinical Laboratories, 3175 Presidential Dr., Atlanta, GA 30340, 770-452-1590 (Formerly: SmithKline Bio-Science Laboratories)

SmithKline Beecham Clinical Laboratories, 8000 Sovereign Row, Dallas, TX 75247, 214-637-7236 (Formerly: SmithKline Bio-Science Laboratories)

SmithKline Beecham Clinical Laboratories, 801 East Dixie Ave., Leesburg, FL 34748, 352-787-9006 (Formerly: Doctors & Physicians Laboratory)

SmithKline Beecham Clinical Laboratories, 400 Egypt Rd., Norristown, PA 19403, 800-877-7484 / 610-631-4600 (Formerly: SmithKline Bio-Science Laboratories)

SmithKline Beecham Clinical Laboratories, 506 E. State Pkwy., Schaumburg, IL 60173, 847-447-4379/800-447-4379 (Formerly: International Toxicology Laboratories)

SmithKline Beecham Clinical Laboratories, 7600 Tyrone Ave., Van Nuys, CA 91405, 818-989-2520 / 800-877-2520

South Bend Medical Foundation, Inc., 530 N. Lafayette Blvd., South Bend, IN 46601, 219-234-4176

Southwest Laboratories, 2727 W. Baseline Rd., Tempe, AZ 85283, 602-438-8507

Sparrow Health System, Toxicology Testing Center, St. Lawrence Campus, 1210 W. Saginaw, Lansing, MI 48915, 517-377-0520 (Formerly: St. Lawrence Hospital & Healthcare System)

St. Anthony Hospital Toxicology Laboratory, 1000 N. Lee St., Oklahoma City, OK 73101, 405-272-7052

Toxicology & Drug Monitoring Laboratory, University of Missouri Hospital & Clinics, 2703 Clark Lane, Suite B, Lower Level, Columbia, MO 65202, 573-882-1273

Toxicology Testing Service, Inc., 5426 N.W. 79th Ave., Miami, FL 33166, 305-593-2260

TOXWORX Laboratories, Inc., 6160 Variel Ave., Woodland Hills, CA 91367, 818-226-4373/800-966-2211 (Formerly: Laboratory Specialists, Inc.; Abused Drug Laboratories; MedTox Bio-Analytical, a Division of MedTox Laboratories, Inc.)

UNILAB, 18408 Oxnard St., Tarzana, CA 91356, 800-492-0800/818-996-7300 (Formerly: MetWest-BPL Toxicology Laboratory)

Universal Toxicology Laboratories, LLC, 10210 W. Highway 80, Midland, Texas 79706, 915-561-8851/888-953-8851

UTMB Pathology-Toxicology Laboratory, University of Texas Medical Branch, Clinical Chemistry Division, 301 University Boulevard, Room 5.158, Old John Sealy, Galveston, Texas 77555-0551, 409-772-3197

Richard Kopanda,

Executive Officer, Substance Abuse and Mental Health Services Administration.

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* The Standards Council of Canada (SCC) voted to end its Laboratory Accreditation Program for Substance Abuse (LAPSA) effective May 12, 1998. Laboratories certified through that program were accredited to conduct forensic urine drug testing as required by U.S. Department of Transportation (DOT) regulations. As of that date, the certification of those accredited Canadian laboratories will continue under DOT authority. The responsibility for conducting quarterly performance testing plus periodic on-site inspections of those LAPSA-accredited laboratories was transferred to the U.S. DHHS, with the DHHS' National Laboratory Certification Program (NLCP) contractor continuing to have an active role in the performance testing and laboratory inspection processes. Other Canadian laboratories wishing to be considered for the NLCP may apply directly to the NLCP contractor just as U.S. laboratories do. Upon finding a Canadian laboratory to be qualified, the DHHS will recommend that DOT certify the laboratory (Federal Register, 16 July 1996) as meeting the minimum standards of the "Mandatory Guidelines for Workplace Drug Testing" (59 Federal Register, 9 June 1994). After receiving the DOT certification, the laboratory will be included in the monthly list of DHHS certified laboratories and participate in the NLCP certification maintenance program.

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4349-N-22]

Submission for OMB Review: Comment Request

AGENCY: Office of the Assistant Secretary for Administration, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: Comments due date: July 1, 1998.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comment must be received within thirty (30) days from the date of this Notice. Comments should refer to the proposal by name and/or OMB approval number and should be sent to: Joseph F. Lackey, Jr., OMB Desk Officer, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Wayne Eddins, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street, Southwest, Washington, DC 20410, telephone (202) 708-1305. This is not a toll-free number. Copies of the proposed forms and other available documents submitted to OMB may be obtained from Mr. Eddins.

SUPPLEMENTARY INFORMATION: The Department has submitted the proposal for the collection of information, as described below, to OMB for review, as required by the Paperwork Reduction Act (44 U.S.C. Chapter 35).

The Notice lists the following information: (1) the title of the information collection proposal; (2) the office of the agency to collect the information; (3) the OMB approval number, if applicable; (4) the description of the need for the information and its proposed use; (5) the agency form number, if applicable; (6) what members of the public will be affected by the proposal; (7) how frequently information submissions will be required; (8) an estimate of the total number of hours needed to prepare the information submission including number of respondents, frequency of response, and hours of response; (9) whether the proposal is new, an extension, reinstatement, or revision of an information collection requirement;