DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1385]

Draft Guidance for Industry on Refractive Implants: Investigational Device Exemptions (IDE's) and Premarket Approval Applications (PMA's); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Refractive Implants: Investigational Device Exemptions (IDE's) and Premarket Approval Applications (PMA's).'' This guidance is neither final nor in effect at this time. This draft guidance describes preclinical and clinical information that may be used in support of IDE's and PMA's.

DATES: Submit written comments concerning this guidance by October 30, 2000.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the draft guidance entitled ''Refractive Implants: Investigational Device Exemptions (IDE's) and Premarket Approval Applications (PMA's)'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. Submit written comments concerning this guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Ashley A. Boulware, Center for Devices and Radiological Health (HFZ–460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2053.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance entitled ''Refractive Implants: Investigational Device Exemptions (IDE's) and Premarket Approval Applications (PMA's).'' This draft guidance is intended to provide detailed information about the type of preclinical testing that can support both clinical investigations and marketing applications for new refractive implants. This draft guidance also is intended to provide the basic principles that should be applied in the conduct of a clinical study for refractive implants. Parts of this guidance document were discussed at an Ophthalmic Devices Panel meeting in October 1998.

II. Significance of Guidance

This guidance document represents the agency's current thinking on submissions for refractive implants. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statute, regulations, or both.

The agency has adopted good guidance practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This guidance document is issued as a Level 1 guidance consistent with GGP's.

III. Electronic Access

In order to receive ''Refractive Implants: Investigational Device Exemptions (IDE's) and Premarket Approval Applications (PMA's)'' via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number (1145) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes ''Refractive Implants: Investigational Device Exemptions (IDE's) and Premarket Approval Applications (PMA's),'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh. ''Refractive Implants: Investigational Device Exemptions (IDE's) and Premarket Approval Applications (PMA's)'' is available at http://www.fda.gov/cdrh/ode/guidance/1145.pdf.

IV. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance by October 30, 2000. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 17, 2000.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 00–19337 Filed 7–31–00; 8:45 am]

BILLING CODE 4160–01–F

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 listed at the end, and will be omitted from the monthly listing thereafter.

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

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, Fax: (301) 443–3031.

Special Note: Please use the above address for all surface mail and correspondence. For all overnight mail service use the following address: 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 Laboratories, 8901 W. Lincoln Ave., West Allis, WI 53227. 414–328–7840/800–877–7016, (Formerly: Bayshore Clinical Laboratory)

Advanced Toxicology Network, 3560 Air Center Cove, Suite 101, Memphis, TN 38118, 901–794–5770/888–290–1150

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, 513–585–9000, (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

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)

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, Building 38–H, P.O. Box 88–6819, Great Lakes, IL 60088–6819, 847–688–2045/847–688–4171

Diagnostic Services Inc., dba DSI, 12700 Westlinks Drive, Fort Myers, FL 33913, 941–561–8200/800–735–5416

Doctors Laboratory, Inc., P.O. Box 2658, 2906 Julia Dr., Valdosta, GA 31602, 912–244–4468

DrugProof, Division of Dynacare/Laboratory of Pathology, LLC, 1229 Madison St., Suite 500, Nordstrom Medical Tower, Seattle, WA 98104, 206–386–2672/800–898–0180, (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, 780–451–3702/800–661–9876

ElSohly Laboratories, Inc., 5 Industrial Park Dr., Oxford, MS 38655, 662–236–2609

Gamma-Dynacare Medical Laboratories *, A Division of the Gamma-Dynacare Laboratory Partnership, 245 Pall Mall St., London, ONT, 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

Integrated Regional Laboratories, 5361 NW 33rd Avenue, Fort Lauderdale, FL 33309, 954–777–0018, 800–522–0232, (Formerly: Cedars Medical Center, Department of Pathology)

Kroll Laboratory Specialists, Inc., 1111 Newton St., Gretna, LA 70053, 504–361–8989/800–433–3823, (Formerly: Laboratory Specialists, Inc.)

LabOne, Inc., 10101 Renner Blvd., Lenexa, KS 66219, 913–888–3927/800–728–4064, (Formerly: Center for Laboratory Services, a Division of LabOne, Inc.)

Laboratory Corporation of America Holdings, 1904 Alexander Drive, Research Triangle Park, NC 27709, 919–572–6900/800–833–3984, (Formerly: LabCorp Occupational Testing Services, Inc., CompuChem Laboratories, Inc.; CompuChem Laboratories, Inc., A Subsidiary of Roche Biomedical Laboratory; Roche CompuChem Laboratories, Inc., A Member of the Roche Group)

Laboratory Corporation of America Holdings, 4022 Willow Lake Blvd., Memphis, TN 38118, 901–795–1515/800–233–6339, (Formerly: LabCorp Occupational Testing Services, Inc., MedExpress/National Laboratory Center)

Laboratory Corporation of America Holdings, 69 First Ave., Raritan, NJ 08869, 908–526–2400/800–437–4986, (Formerly: Roche Biomedical Laboratories, Inc.)

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 43699, 419–383–5213

MedTox Laboratories, Inc., 402 W. County Rd. D, St. Paul, MN 55112, 651–636–7466/800–832–3244

MetroLab-Legacy Laboratory Services, 1225 NE 2nd Ave., Portland, OR 97232, 503–413–5295/800–950–5295

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, 661–322–4250/800–350–3515

NWT Drug Testing, 1141 E. 3900 South, Salt Lake City, UT 84124, 801–293–2300/800–322–3361, (Formerly: NorthWest Toxicology, Inc.)

One Source Toxicology Laboratory, Inc., 1705 Center Street, Deer Park, TX 77536, 713–920–2559, (Formerly: University of Texas Medical Branch, Clinical Chemistry Division; (UTMB Pathology-Toxicology Laboratory)
Oregon Medical Laboratories, P.O. Box 972, 722 East 11th Ave., Eugene, OR 97440–0972, 541–687–2134
Pacific Toxicology Laboratories, 6160 Variel Ave., Woodland Hills, CA 91367, 818–598–3110/800–328–6942, (Formerly: Centinela Hospital Airport Toxicology Laboratory)
Pathology Associates Medical Laboratories, 11604 E. Indiana Ave., 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, 7606 Pebble Dr., Forth Worth, TX 76118, 817–215–8800, (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, 858–279–2600/800–882–7272
Quest Diagnostics Incorporated, 3175 Presidential Dr., Atlanta, GA 30340, 770–452–1590, (Formerly: SmithKline Beecham Clinical Laboratories, SmithKline Bio-Science Laboratories)
Quest Diagnostics Incorporated, 4444 Giddings Road, Auburn Hills, MI 48326, 248–373–9120/800–444–0106, (Formerly: HealthCare/Preferred Laboratories, HealthCare/MetPath, CORNING Clinical Laboratories)
Quest Diagnostics Incorporated, 8000 Sovereign Row, Dallas, TX 75247, 214–638–1301, (Formerly: SmithKline Beecham Clinical Laboratories, SmithKline Bio-Science Laboratories)
Quest Diagnostics Incorporated, 4770 Regent Blvd., Irving, TX 75063, 972–916–3376/800–526–0947, (Formerly: Damon Clinical Laboratories, Damon/MethPath, CORNING Clinical Laboratories)
Quest Diagnostics Incorporated, 801 East Dixie Ave., Leesburg, FL 34748, 352–787–9006, (Formerly: SmithKline Beecham Clinical Laboratories, Doctors & Physicians Laboratory)
Quest Diagnostics Incorporated, 400 Egypt Rd., Norristown, PA 19403, 610–631–4600/800–877–7484, (Formerly: SmithKline Beecham Clinical Laboratories, Bio-Science Laboratories)
Quest Diagnostics Incorporated, 506 E. State Pkwy., Schaumburg, IL 60173, 800–669–6995/847–885–2010, (Formerly: SmithKline Beecham Clinical Laboratories, International Toxicology Laboratories)
Quest Diagnostics Incorporated, 7470 Mission Valley Rd., San Diego, CA 92108–4406, 619–686–3200/800–446–4728, (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, 7600 Tyrone Ave., Van Nuys, CA 91405, 818–989–2520/800–877–2520, (Formerly: SmithKline Beecham Clinical Laboratories)
San Diego Reference Laboratory, 6122 Nancy Ridge Dr., San Diego, CA 92121, 800–677–7995/858–677–7970
Scientific Testing Laboratories, Inc., 463 Southlake Blvd., Richmond, VA 23236, 804–378–9130
Scott & White Drug Testing Laboratory, 600 S. 25th St., Temple, TX 76504, 254–771–8379/800–749–3788
S.E.D. Medical Laboratories, 5601 Office Blvd., Albuquerque, NM 87108, 505–727–6300/800–999–5227
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, 602–438–8507/800–279–0027
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
UNILAB, 18408 Oxnard St., Tarzana, CA 91356, 818–996–7300/800–339–4299, (Formerly: Met–West-BPL Toxicology Laboratory)
Universal Toxicology Laboratories, LLC, 10210 W. Highway 80, Midland, Texas 79706, 915–561–8851/888–953–8851

The following laboratory will be voluntarily withdrawing from the National Laboratory Certification Program on August 12, 2000:

Quest Diagnostics Incorporated, National Center for Forensic Science, 1901 Sulphur Spring Rd., Baltimore, MD 21227, 410–536–13485, (Formerly: Maryland Medical Laboratroy, Inc., National Center for Forensic Science, CORNING National Center for Forensic Science) *

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 Durg Testing'' (59 **Federal Register**, 9 June 1994, Pages 29908–29931). 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.

Richard Kopanda,

Executive Officer, Substance Abuse and Mental Health Services Administration.

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BILLING CODE 4160–20–M

* 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 direclty to the NLCP contractor just as U.S. Laboratories do.

DEPARTMENT OF THE INTERIOR

Fish and Wildlife

Notice of Availability of Draft Comprehensive Conservation Plan and Environmental Assessment for Necedah National Wildlife Refuge, Wood and Juneau Counties, Wisconsin

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability.

SUMMARY: Pursuant to the Refuge Improvement Act of 1997, the U.S. Fish