National Toxicology Laboratories, Inc., 1100 California Avenue, Bakersfield, CA 93304, 805–322–4250
Nichols Institute Substance Abuse Testing (NISAT), 7470–A Mission Valley Road, San Diego, CA 92108–4406, 800–446–4728/619–686–3200 (formerly: Nichols Institute)
Northwest Toxicology, Inc., 1141 E. 3900 South, Salt Lake City, UT 84124, 800–322–3361
Occupational Toxicology Laboratories, Inc., 2002 20th Street, Suite 204A, Kenner, LA 70062, 504–465–0751
Oregon Medical Laboratories, P.O. Box 972, 722 East 11th Avenue, Eugene, OR 97440–0972, 503–687–2134
Pathology Associates Medical Laboratories, East 11604 Indiana, Spokane, WA 99206, 509–926–2400
PDLA, Inc. (Princeton), 100 Corporate Court, So. Plainfield, NJ 07080, 908–769–8500/800–237–7352
PharmChem Laboratories, Inc., 1505–A O'Brien Drive, Menlo Park, CA 94025, 415–328–6200/800–446–5177
PharmChem Laboratories, Inc., Texas Division, 7606 Pebble Drive, Fort Worth, TX 76118, 817–595–0294 (formerly: Harris Medical Laboratory)
Physicians Reference Laboratory, 7800 West 110th Street, Overland Park, KS 66210, 913–338–4070/800–821–3627 (formerly: Physicians Reference Laboratory Toxicology Laboratory)
Poisonlab, Inc., 7272 Clairemont Mesa Road, San Diego, CA 92111, 619–279–2600/800–882–7272
Precision Analytical Laboratories, Inc., 13300 Blanco Road, Suite #50, San Antonio, TX 78216, 210–493–3211
Puckett Laboratory, 4200 Mamie Street, Hattiesburgh, MS 39402, 601–264–3856/800–844–8378
Regional Toxicology Services, 15305 N.E. 40th Street, Redmond, WA 98052, 206–882–3400
Resource One, Inc., Seven Pointe Circle, Greenville, SC 29615, 803–233–5639
Roche Biomedical Laboratories, 1801 First Avenue South, Birmingham, AL 35233, 205–581–4170
Roche Biomedical Laboratories, Inc., 1120 Stateline Road, Southaven, MS 38671, 601–342–1286
Roche Biomedical Laboratories, Inc., 69 First Avenue, Raritan, NJ 08869, 800–437–4986
Saint Joseph Hospital Toxicology Laboratory, 601 N. 30th Street, Omaha, NE 68131–2197, 402–449–4940
Scott & White Drug Testing Laboratory, 600 S. 25th Street, Temple, TX 76504, 800–749–3788
S.E.D. Medical Laboratories, 500 Walter NE, Suite 500, Albuquerque, NM 87102, 505–848–8800
Sierra Nevada Laboratories, Inc., 888 Willow Street, Reno, NV 89502, 800–648–5472
SmithKline Beecham Clinical Laboratories, 7600 Tyrone Avenue, Van Nuys, CA 91045, 818–376–2520
SmithKline Beecham Clinical Laboratories, 3175 Presidential Drive, Atlanta, GA 30340, 404–934–9205 (formerly: SmithKline Bio-Science Laboratories)
SmithKline Beecham Clinical Laboratories, 506 E. State Parkway, Schaumburg, IL 60173, 708–885–2010 (formerly: International Toxicology Laboratories)
SmithKline Beecham Clinical Laboratories, 11636 Administration Drive, St. Louis, MO 63146, 314–567–3905
SmithKline Beecham Clinical Laboratories, 400 Egypt Road, Norristown, PA 19403, 800–523–5447 (formerly: SmithKline Bio-Science Laboratories)
SmithKline Beecham Clinical Laboratories, 8000 Sovereign Row, Dallas, TX 75247, 214–638–1301 (formerly: SmithKline Bio-Science Laboratories)
South Bend Medical Foundation, Inc., 530 N. Lafayette Boulevard, South Bend, IN 46601, 219–234–4176
Southwest Laboratories, 2727 W. Baseline Road, Suite 6, Tempe, AZ 85283, 602–438–8507
St. Anthony Hospital (Toxicology Laboratory), P.O. Box 205, 1000 N. Lee Street, Oklahoma City, OK 73102, 405–272–7052
St. Louis University Forensic Toxicology Laboratory, 1205 Carr Lane, St. Louis, MO 63104, 314–577–8628
Toxicology & Drug Monitoring Laboratory, University of Missouri Hospital & Clinics, 301 Business Loop 70 West, Suite 208, Columbia, MO 65203, 314–882–1273
Toxicology Testing Service, Inc., 5426 N.W. 79th Avenue, Miami, FL 33166, 305–593–2260
UNILAB, 18408 Oxnard Street, Tarzana, CA 91356, 800–492–0800/818–343–8191 (formerly: MetWest-BPL Toxicology Laboratory)

The following laboratory is withdrawing from the National Laboratory Certification Program on December 6, 1993:

Roche Biomedical Laboratories, 1957 Lakeside Parkway, Suite 542, Tucker, GA 30084, 404–939–4811

Richard Kopanda,

Acting Executive Officer, Substance Abuse and Mental Health Services Administration.

[FR Doc. 93–29536 Filed 12–2–93; 8:45 am]

BILLING CODE 4160–20–U

Centers for Disease Control and Prevention

[Announcement No. 401A]

Fiscal Year 1994 Preventive Health Services; Addendum to 401; STD Accelerated Prevention Campaign Project Grants

Introduction

The Centers for Disease Control and Prevention (CDC) announces the anticipated availability of fiscal year (FY) 1994 supplemental funds for programs to prevent infertility caused by sexually transmitted diseases (STDs). This is an addendum to Announcement Number 401. Because of the high rates of chlamydia and gonorrhea in adolescents and young adults and the frequent progression of these infections to upper tract infection and scarring in women, these STDs are a leading cause of preventable infertility.

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a PHS-led national activity to reduce morbidity and mortality and to improve the quality of life. This Program focuses on the priority areas of STD, HIV Infection, and Maternal and Infant Health. (For ordering a copy of Healthy People 2000, see the section **WHERE TO OBTAIN ADDITIONAL INFORMATION.**)

Authority

This program is authorized under sections 318 (b) and (c) and 318A of the Public Health Service Act [42 U.S.C. 247c (b) and (c) and 247c–1], as amended.

Eligibility

Eligible applicants for this program are current recipients of STD Accelerated Prevention Campaign project grants in HHS Regions III, VII, VIII, and X. Because of the limited availability of funds, eligibility is limited to those HHS Regions that have developed region-wide chlamydia and other STD-related infertility control action plans.

Availability of Funds

Approximately $5,600,000 is expected to be available in FY 1994, to supplement up to 22 grants. The average award is expected to be $255,000, ranging from $50,000 to $750,000. The project period will be up to five years. The funding estimates outlined may differ and are subject to change.

Use of Grant Funds

Project grant funds may be used for costs associated with conducting STD Accelerated Prevention Campaign chlamydia or gonorrhea activities described in the program requirements and funding priority sections of this announcement.

Federal funds are intended to supplement current state and local resources and must be used to assist state and local areas to conduct high-priority activities in targeted areas and populations. Federal funds cannot be used to replace existing state and local support. These funds will be awarded competitively.

Funds to supplement the performance of routine diagnostic tests, the maintenance of STD central registries, the provision of diagnostic and treatment facilities and services, the purchase of automated data processing

equipment, or other expenses normally supported by the grantee must be specifically approved for that purpose.

Purpose

The purpose of the STD Accelerated Prevention Campaign is to stimulate high-quality, interdisciplinary, collaborative STD prevention efforts among relevant health programs and between health programs and communities. This will be accomplished by developing systematic, region-wide, innovative approaches that link programmatic, clinical, laboratory, and epidemiologic activities in order to prevent transmission of STDs and their sequelae. Populations that are disproportionately affected, such as women, infants, and adolescents, will be emphasized. Priority for these supplemental funds will focus on prevention of chlamydia. In addition, existing gonorrhea prevention activities may be augmented in specific high-risk population subgroups.

Program Requirements

The recipient will be responsible, with state and local resources supplemented with Federal assistance, for developing or modifying a comprehensive state STD Accelerated Prevention Campaign chlamydia and gonorrhea action plan. This plan should be developed in coordination with the regional plans currently being developed in each of the four regions in conjunction with state and local health department staff. These plans are to deliver chlamydia and gonorrhea screening services to detect these infections among as many adolescent girls and young adult women as possible. These plans should provide for the following nine program activities.

1. Screening women for chlamydia and gonococcal infections and for secondary conditions (PID) resulting from these infections.

a. Selecting providers to conduct screening activities. Programs should develop local information systems to permit the selection of providers for screening according to chlamydia and gonorrhea prevalence by individual provider or provider category. Pending the development of local information, facilities in the following categories should be identified and recruited in the order listed:

(1) Short-term plans should address each of the following categories of facilities during the first budget year:

(a) Family planning and prenatal clinics since the organization exists to deliver prevention services to the large numbers of adolescents and young adult women who attend these clinics.

(b) STD clinics where high risk women and their partners are seen and other Federal, state or local services are not available.

(c) If possible, short-term plans should also include teen/adolescent clinics, abortion clinics, detention facilities, and/or substance abuse programs due to the high-risk behavior and increased risk of salpingitis among individuals attending these facilities.

(2) Long-term plans should address strategies to involve other providers in the delivery of screening services from the second budget year onward; these providers include:

(a) Those listed in (1)(c) above, if they were not included in the short-term plan;

(b) Primary care clinics, including community, rural, and migrant health centers, emergency rooms, Native American health care centers, and gynecology clinics, where a mixture of high- and low-risk women receive care.

(c) Private physicians caring for sexually active young women.

b. Developing patient selection criteria and data systems to monitor the results of screening. Long-term plans should address developing the capability to evaluate patient selection criteria locally. In choosing patient selection criteria, consideration should include, but not be limited to: presence of mucopurulent cervicitis, young age, new or multiple sex partners, and failure to use barrier contraceptives. Results should be monitored and examined regularly to insure a cost-effective choice of selection criteria and providers.

c. Developing laboratory support systems to ensure the selection of sensitive and specific tests (including confirmation), pursuit of competitive pricing of screening tests, training of laboratory staff, and establishment of adequate quality assurance.

2. Providing treatment to women with known and presumptive chlamydia and gonorrhea, including female sex partners of infected males.

3. Providing counseling to women on the prevention and control of chlamydia and gonorrhea (including counseling on the benefits of locating and assuring treatment for any individual from whom the woman may have contracted chlamydia or gonorrhea and for any individual whom the woman may have exposed to chlamydia or gonorrhea).

4. Providing follow-up services. Initially, patients continuing to meet screening criteria should be retested at least annually. However, systems should be established locally to evaluate the need for such follow-up services.

5. Referrals for other medical services (including reproductive health or substance abuse treatment) for women screened pursuant to paragraph 1, including referrals for evaluation and treatment with respect to HIV infection and other sexually transmitted diseases. Preferably, there should be integration of those services whenever possible.

6. In the case of any woman receiving services described in paragraphs 1 through 5, providing to the sex partner(s) of the women with chlamydia or gonorrhea infection the services described in such paragraphs as appropriate.

Project areas are encouraged to develop information systems to determine the proportion of sex partners that actually receive treatment.

7. Providing outreach services to inform women of availability of the services described in paragraphs 1 through 6. Educational services are needed to alert women to the symptoms of cervical infections and PID, the frequent lack of symptoms and consequent need for screening and partner referral, and the sources of these services.

8. Disseminating information to persons at high risk and providing education on the prevention and control of chlamydia and gonorrhea to the public. In particular, adolescents and young adults need to be made aware of the high prevalence of chlamydia and gonococcal infections and the interventions to prevent them.

9. Providing training to health care providers described in paragraph 1 in carrying out activities described in paragraphs 1 through 6 and to laboratory staff in carrying out the screening described in paragraph 1.

If contracts are to be used to support these activities, they can be awarded only if the applicant and the agencies through which these activities will be conducted agree to maintain expenditures of non-Federal amounts for such activities at a level that is at least the average annual level of such expenditures maintained by the applicant during the state fiscal years, 1992 and 1993. In addition, memoranda of agreement that set out the exact nature of the interstate, regional, and local collaborations must be submitted as part of the application for conducting activities 1 through 9.

Funding Priorities

Priority is given to PHS Region III, VII, VIII, and X applicants, since chlamydia represents their greatest STD problem. As indicated above, project areas should give priority to chlamydia prevention with these funds. Because of

time constraints, comments are not being solicited on these funding priorities.

Award Criteria

Funding will be based on the quality of the required STD Accelerated Prevention Campaign application and the supplemental application requested in this announcement, chlamydia and gonorrhea action plans, the degree of innovation of each application, and the specific needs of individual project areas.

Evaluation Criteria

These applications will be evaluated as a part of the STD Accelerated Prevention Campaign review using the criteria for the required activities described in the guidance for the STD Accelerated Campaign (**Federal Register** Announcement 401, [58 FR 28973], May 18, 1993).

Executive Order 12372 Review

STD Accelerated Prevention Campaign applications are subject to review as governed by Executive Order 12372, Intergovernmental Review of Federal Programs. E.O. 12372 sets up a system for state and local government review of proposed Federal assistance applications. Applicants should contact their state Single Point of Contact (SPOC) as early as possible to alert them to the prospective applications and receive any necessary instructions on the state process. A current list of SPOCs is included in the application kit. If SPOCs have any state process recommendations on applications submitted to Centers for Disease Control and Prevention (CDC), they should forward them no later than 60 days from the due date of the application to Elizabeth Taylor, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., room 300, Atlanta, GA 30305.

Public Health System Reporting Requirements

This program is not subject to the Public Health System Reporting Requirements.

Catalog of Federal Domestic Assistance Number

The Catalog of Federal Domestic Assistance Number is 93.977, Preventive Health Services-Sexually Transmitted Disease Control.

Application Submission and Deadline

The Program Announcement and application kit were sent to all eligible applicants in September 1993.

Where To Obtain Additional Information

Information on application procedures, copies of application forms, and other material may be obtained from Linda Long, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road NE., room 300, Atlanta, GA 30305, telephone (404) 842–6511.

Announcement 401A, "Project Grants for Preventive Health Services-STD Accelerated Prevention Campaign Supplement," must be referenced in all requests for information on these projects.

Programmatic assistance in the preparation of applications may be obtained from Gary West, Division of STD/HIV Prevention, National Center for Prevention Services, Centers for Disease Control and Prevention (CDC), Atlanta, GA 30333, telephone (404) 639–8315.

Potential applicants may obtain a copy of Healthy People 2000 (Full Report, Stock No. 017–001–00474–0) or Healthy People 2000 (Summary Report, Stock No. 017–001–00473–1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325, telephone (202) 783–3238.

Dated: November 29, 1993.

Robert L. Foster,

Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

[FR Doc. 93–29582 Filed 12–2–93; 8:45 am]

BILLING CODE 4160–18–P

Advisory Committee to the Director, Centers for Disease Control and Prevention: Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting.

Name: Advisory Committee to the Director, CDC.

Time and date: 8:30 a.m.–3 p.m., January 25, 1994.

Place: CDC, Auditorium A, 1600 Clifton Road, NE, Atlanta, Georgia 30333.

Status: Open to the public, limited only by the space available.

Purpose: This committee advises the Director, CDC, on policy issues and broad strategies that will enable CDC, the Nation's prevention agency, to fulfill its mission of preventing unnecessary disease, disability, and premature death, and promoting health. The committee recommends ways to incorporate prevention activities more fully into health care. It also provides guidance to help CDC work more effectively with its various constituents, in both the private and public sectors, to make prevention a practical reality.

Matters to be discussed: The agenda will include introductory remarks from the new CDC Director, David Satcher, M.D., Ph.D., and the remainder of time will be used to allow all committee members to present their perspectives of what they believe Dr. Satcher's priorities should be for CDC. Agenda items are subject to change as priorities dictate.

Contact person for more information: Martha F. Katz, Executive Secretary, Advisory Committee to the Director, CDC, 1600 Clifton, Road, NE, Mailstop D–23, Atlanta, Georgia 30333, telephone 404/639–3243.

Dated: November 29, 1993.

Elvin Hilyer,

Associate Director for Policy Coordination, Centers for Disease Control and Prevention (CDC).

[FR Doc. 93–29579 Filed 12–2–93; 8:45 am]

BILLING CODE 4160–18–M

Food and Drug Administration

[Docket No. 93F–0404]

Hüls America, Inc.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Hüls America, Inc., has filed a petition proposing that the food additive regulations be amended to change certain specifications for the safe use of glyceryl tristearate.

FOR FURTHER INFORMATION CONTACT: Martha D. Peiperl, Center for Food Safety and Applied Nutrition (HFS–217), Food and Drug Administration, 200 C St. SW., Washington, DC 20204–0002, 202–254–9511.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 3A4403) has been filed by Hüls America, Inc., Turner Pl., P. O. Box 365, Piscataway, NJ 08855–0365. The petition proposes to amend the food additive regulations in § 172.811 *Glyceryl tristearate* (21 CFR 172.811) to provide broader specifications for the safe use of glyceryl tristearate including

the: acid number, saponification number, and melting point.

The agency has determined under 21 CFR 25.24(a)(9) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: November 23, 1993.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 93–29543 Filed 12–2–93; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 93G–0359]

Teepak, Inc.; Filing of Petition for Affirmation of GRAS Status

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Teepak, Inc., has filed a petition (GRASP 3G0397) proposing to affirm that collagen fiber is generally recognized as safe (GRAS) as an ingredient in human food.

DATES: Written comments by February 1, 1994.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Mary E. Lavecchia, Center for Food Safety and Applied Nutrition (HFS–217), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–254–9519.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (secs. 201(s) and 409 (21 U.S.C. 321(s) and 348)) and the regulations for affirmation of GRAS status in § 170.35 (21 CFR 170.35), notice is given that Teepak, Inc., c/o 1001 G St. NW., suite 500 West, Washington, DC 20001, has filed a petition (GRASP 3G0397) proposing that collagen fiber be affirmed as GRAS for use as an ingredient in human food.

The petition has been placed on display at the Dockets Management Branch (address above).

Any petition that meets the requirements outlined in §§ 170.30 and 170.35 is filed by the agency. There is no prefiling review of the adequacy of data to support a GRAS conclusion. Thus, the filing of a petition for GRAS affirmation should not be interpreted as a preliminary indication of suitability for GRAS affirmation.

The potential environmental impact of this action is being reviewed. If the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c).

Interested persons may, on or before February 1, 1994, review the petition and file comments with the Dockets Management Branch (address above). Two copies of any comments should be filed and should be identified with the docket number found in brackets in the heading of this document. Comments should include any available information that would be helpful in determining whether the substance is, or is not, GRAS for the proposed use. In addition, consistent with the regulations promulgated under the National Environmental Policy Act (40 CFR 1501.4(b)), the agency encourages public participation by review of and comment on the environmental assessment submitted with the petition that is the subject of this notice. A copy of the petition (including the environmental assessment) and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 18, 1993.

Douglas L. Archer,

Deputy Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 93–29544 Filed 12–2–93; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 93D–0312]

Guideline for Submitting Documentation for Sterilization Process Validation in Applications for Human and Veterinary Drug Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a guideline entitled "Guideline for Submitting Documentation for Sterilization Process Validation in Applications for Human and Veterinary Drug Products." This guideline is intended to provide guidance for the submission of information and data in support of the efficacy of sterilization processes described in drug applications for both human and veterinary drugs.

DATES: Written comments by January 3, 1994.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Regarding human drug products: Peter Cooney, Center for Drug Evaluation and Research (HFD–160), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5818.

Regarding veterinary drug products: Patricia Leinbach, Center for Veterinary Medicine (HFV–143), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1672.

SUPPLEMENTARY INFORMATION: In this document, FDA is publishing a guideline for submitting documentation for sterilization process validation in applications for human and veterinary drug products. This guideline is intended to provide guidance for the submission of information and data in support of the efficacy of sterilization processes described in drug applications for both human and veterinary drugs. These recommendations apply to applications (new drug applications, new animal drug applications, abbreviated new drug applications, abbreviated antibiotic applications, and abbreviated new animal drug applications) for sterile drug products. They also apply to previously approved applications when supplements associated with the sterile processing of approved drugs are submitted. Information and data in support of sterility assurance also may be necessary in investigational new drug and investigational new animal drug applications.

The Center for Drug Evaluation and Research's (CDER's) and the Center for Veterinary Medicine's (CVM's) review of the validation of the sterilization process consists of a scientific evaluation of the studies submitted in applications. This evaluation, which is conducted by FDA's review staff, is part of a cooperative effort between the review staff, compliance staff, and field investigators to ensure the overall state of control of the sterile processing of veterinary and human drug products.

This guideline does not bind the agency, and it does not create or confer any rights, privileges, or benefits for or on any person.

Interested persons may, on or before January 3, 1994, submit to the Dockets Management Branch (address above) written comments regarding the guideline. Two copies of any comments are to be submitted, except that