

Toxic Substances and Disease Registry, Mailstop E-29, 1600 Clifton Road, NE., Atlanta, Georgia 30333.

Written comments and other data submitted in response to this notice and the draft toxicological profile should bear the docket control number ATSDR-29. Send one copy of all comments and five copies of all supporting documents to the Division of Toxicology at the above address by the end of the comment period. All written comments and draft profiles will be available for public inspection at the ATSDR, Building 33, Executive Park Drive, Atlanta, Georgia (not a mailing address), from 8 a.m. until 4:30 p.m., Monday through Friday, except for legal holidays. Because all public comments regarding ATSDR toxicological profiles are available for public inspection, no confidential business information should be submitted in response to this notice.

FOR FURTHER INFORMATION CONTACT:

Susie Tucker, Agency for Toxic Substances and Disease Registry, Division of Toxicology (E-29), 1600 Clifton Road, NE., Atlanta, Georgia 30333; Telephone: (404)-639-6001 or FTS 236-6001.

SUPPLEMENTARY INFORMATION: The Superfund Amendments and Reauthorization Act (SARA) (Pub. L. 99-499) amends the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or Superfund) (42 U.S.C. 9601 et seq.) by establishing certain requirements for the ATSDR and the Environmental Protection Agency (EPA) with regard to hazardous substances which are most commonly found at facilities on the CERCLA National Priorities List (NPL). Among these statutory requirements is a mandate for the Administrator of ATSDR to prepare toxicological profiles for each substance included on the priority lists of hazardous substances. These lists identified the 250 hazardous substances which both Agencies determined pose the most significant potential threat to human health. The lists were published in the *Federal Register* on April 17, 1987 (52 FR 12866); October 20, 1988 (53 FR 41280); October 26, 1989 (54 FR 43615); and October 17, 1990 (55 FR 42067).

Section 104(i)(3) of CERCLA outlines the content of these profiles. Each profile is required to include an examination, summary and interpretation of available toxicological information and epidemiologic evaluations. This information and data are to be used to ascertain the levels of significant human exposure for the substance and the associated health effects. The profiles must also include a

determination of whether adequate information on the health effects of each substance is available or in the process of development. When adequate information is not available, ATSDR, in cooperation with the National Toxicology Program (NTP), is required to assure the initiation of a program of research designed to determine these health effects.

Although we are confident that the key studies for each of the substances were considered during the profile development process, this *Federal Register* notice seeks to solicit any additional studies, particularly unpublished data and ongoing studies, which will be evaluated for possible addition to the Fluoride Profile now or in the future. CERCLA requires ATSDR to prepare (1) lists of hazardous substances in order of priority, (2) toxicological profiles of those substances, and (3) a research program to fill data gaps associated with the substances.

The following draft toxicological profile is now available for public comment. The profile has undergone an additional administrative review in order to coordinate its public comment review period with the release of the Department of Health and Human Services document, *Review of Fluoride: Benefits and Risks*.

| Document | Hazardous substance | CAS No. |
|----------|------------------------|------------|
| 1. | Fluorides..... | 16984-48-8 |
| | Hydrogen Fluoride..... | 7664-39-3 |
| | Fluorine (F)..... | 7782-41-4 |

All profiles issued as "Drafts for Public Comment" represent the agency's best efforts to provide important toxicological information on priority hazardous substances in compliance with the substantive and procedural requirements of section 104(i)(3) of CERCLA. As in the past, we are seeking public comments and additional information which may be used to supplement this profile. ATSDR remains committed to providing a public comment period for these documents as a means to best serve public health and our constituency.

Dated: September 5, 1991.

Walter R. Dowdle,

Acting Administrator, Agency for Toxic Substances and Disease Registry.

[FR Doc. 91-21930 Filed 9-11-91; 8:45 am]

BILLING CODE 4160-70-M

Centers for Disease Control

Meetings

The National Center for Environmental Health and Injury Control (NCEHIC), Centers for Disease Control (CDC), announces the following meetings:

Name: The Use of Folic Acid for the Prevention of Spina Bifida and Other Neural Tube Defects.

Times and Dates: First meeting: 8 a.m.-4 p.m., September 26, 1991. Second Meeting: 8 a.m.-4 p.m., September 27, 1991.

Place: CDC, 1600 Clifton Road, NE, Atlanta, Georgia 30333. The September 26 meeting will be held in Auditorium A and the September 27 meeting will be held in the Lobby Conference Room.

Status: Open to the public for observation and comment, limited only by space available. Both meeting rooms accommodate approximately 35 people.

Purpose: Neural tube defects are common serious birth defects in the United States and contribute substantially to worldwide infant mortality and disability. A recently completed randomized prevention trial by the British Medical Research Council (MRC) Vitamin Study Group indicated that daily oral supplementation with folic acid before conception and during pregnancy substantially reduces the risk of neural tube defects among women who have had a previously affected pregnancy. Based on these findings and other scientific evidence, on August 2, 1991, CDC released interim recommendations for supplementation with folic acid to prevent the recurrence of neural tube defects.

An invited group of qualified individuals will review the MRC findings along with other scientific evidence during the September 26 meeting. These individuals will provide CDC with their individual recommendations regarding the formulation of guidelines for the use of folic acid supplementation for the prevention of the occurrence of neural tube defects in women who have not had previously affected pregnancy.

At the September 27 meeting, in light of this new scientific evidence, a second group of invited qualified individuals will provide CDC with their individual recommendations regarding the final study design of the Randomized Controlled Trial in China of the Use of Periconceptional Vitamin Supplements to Prevent Spina Bifida and Anencephaly.

At the conclusion of each morning and afternoon session, all attendees will have an opportunity to provide oral and/or written comments for the record.

For a period of 15 days following the meetings, through October 12, 1991, the official record of the meetings will remain open in order that written

comments may be submitted and be made part of the record. Comments may be mailed to the contact person listed below.

Contract Person for Additional Information: J. David Erickson, D.D.S., Ph.D., Chief, Birth Defects and Genetic Diseases Branch, Division of Birth Defects and Developmental Disabilities, Mailstop F45, NCEHIC, CDC, 1600 Clifton Road, NE, Atlanta, Georgia 30333, telephone 404/488-4370 or FTS 236-4370.

Dated: September 6, 1991.

Elvin Hilyer,

*Associate Director for Policy Coordination,
Centers for Disease Control.*

[FR Doc. 91-21931 Filed 9-11-91; 8:45 am]

BILLING CODE 4160-18-M

Food and Drug Administration

[Docket No. 91N-0360]

Drug Export; Blood Grouping Reagents: Murine Monoclonal Anti-A, Anti-B, and Anti-A,B

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Organon Teknika Corp. has filed an application requesting approval for the export of the biological product Murine Monoclonal Anti-A, Anti-B, and Anti-A,B Blood Grouping Reagents to The Netherlands.

ADDRESSES: Relevant information on this application may be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, and to the contact person identified below. Any future inquiries concerning the export of human biological products under the Drug Export Amendments Act of 1986 should also be directed to the contact person.

FOR FURTHER INFORMATION CONTACT: Boyd Fogle, Jr., Center for Biologics Evaluation and Research (HFB-120), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8191.

SUPPLEMENTARY INFORMATION: The Drug Export Amendments Act of 1986 (Pub. L. 99-660) (section 802 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 382)) provides that FDA may approve applications for the export of biological products that are not currently approved in the United States. Section 802(b)(3)(B) of the act sets forth the requirements that must be met in an application for approval. Section

802(b)(3)(C) of the act requires that the agency review the application within 30 days of its filing to determine whether the requirements of section 802(b)(3)(B) have been satisfied. Section 802(b)(3)(A) of the act requires that the agency publish a notice in the *Federal Register* within 10 days of the filing of an application for export to facilitate public participation in its review of the application. To meet this requirement, the agency is providing notice that Organon Teknika Corp., 100 Akzo Ave., Durham, NC 27704, has filed an application requesting approval for the export of the biological product Murine Monoclonal Anti-A, Anti-B, and Anti-A,B Blood Grouping Reagents to The Netherlands. BCA Monoclonal Blood Grouping Reagents Anti-A, Anti-B, and Anti-A,B Blend are prepared from monoclonal antibodies secreted by murine hybridoma cell lines grown in tissue culture medium. The Anti-A, Anti-B, and Anti-A,B reagents are used for the detection of the A and B antigens and their subgroups on human red blood cells. The application was received and filed in the Center for Biologics Evaluation and Research on August 16, 1991, which shall be considered the filing date for purposes of the act.

Interested persons may submit relevant information on the application to the Dockets Management Branch (address above) in two copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. These submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

The agency encourages any person who submits relevant information on the application to do so by September 23, 1991, and to provide an additional copy of the submission directly to the contact person identified above, to facilitate consideration of the information during the 30-day review period.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (section 802 (21 U.S.C. 382)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Biologics Evaluation and Research (21 CFR 5.44).

Dated: August 29, 1991.

Thomas S. Bozzo,

Director, Office of Compliance, Center for Biologics Evaluation and Research.

[FR Doc. 91-21941 Filed 9-11-91; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 91N-0362]

Drug Export; OPUS* Anti HIV 1 + 2

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that PB Diagnostic Systems, Inc., has filed an application requesting approval for the export of the biological product OPUS* Anti HIV 1 + 2 to Denmark, Ireland, The Netherlands, Norway, Sweden, and The United Kingdom.

ADDRESSES: Relevant information on this application may be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, and to the contact person identified below. Any future inquiries concerning the export of human biological products under the Drug Export Amendments Act of 1986 should also be directed to the contact person.

FOR FURTHER INFORMATION CONTACT: Boyd Fogle, Jr., Center for Biologics Evaluation and Research (HFB-120), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8191.

SUPPLEMENTARY INFORMATION: The Drug Export Amendments Act of 1986 (Pub. L. 99-660) (section 802 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 382)) provides that FDA may approve applications for the export of biological products that are not currently approved in the United States. Section 802(b)(3)(B) of the act sets forth the requirements that must be met in an application for approval. Section 802(b)(3)(C) of the act requires that the agency review the application within 30 days of its filing to determine whether the requirements of section 802(b)(3)(B) have been satisfied. Section 802(b)(3)(A) of the act requires that the agency publish a notice in the *Federal Register* within 10 days of the filing of an application for export to facilitate public participation in its review of the application. To meet this requirement, the agency is providing notice that PB Diagnostic Systems, Inc., 151 University Ave., Westwood, MA 02090, has filed an application requesting approval for the export of the biological product OPUS* Anti HIV 1 + 2 to Denmark, Ireland, The Netherlands, Norway, Sweden, and The United Kingdom. OPUS* Anti HIV 1 + 2 is an in vitro qualitative enzyme immunoassay for the detection of circulating antibodies to Human Immunodeficiency Virus, Types 1 and 2 (HIV-1 and HIV-2) in serum and plasma

of blood donors at unknown risk for HIV infection. The application was received and filed in the center for Biologics Evaluation and Research on August 23, 1991, which shall be considered the filing date for purposes of the act.

Interested persons may submit relevant information on the application to the Dockets Management Branch (address above) in two copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. These submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

The agency encourages any person who submits relevant information on the application to do so by September 23, 1991, and to provide an additional copy of the submission directly to the contact person identified above, to facilitate consideration of the information during the 30-day review period.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (section 802 (21 U.S.C. 382)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Biologics Evaluation and Research (21 CFR 5.44).

Dated: August 30, 1991.

Thomas S. Bozzo,

Director, Office of Compliance, Center for Biologics Evaluation and Research.

[FR Doc. 91-21942 Filed 9-11-91; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 91N-0361]

Drug Export; Vironostika HIV-1 Antigen Microelisa System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: the Food and Drug Administration (FDA) is announcing that Organon Teknika Corp. has filed an application requesting approval for the export of the biological product Vironostika HIV-1 Antigen Microelisa System to The Netherlands.

ADDRESSES: Relevant information on this application may be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, and to the contact person identified below. Any future inquiries concerning the export of human biological products under the Drug Export Amendments Act of 1986 should also be directed to the contact person.

FOR FURTHER INFORMATION CONTACT: Boyd Fogle, Jr., Center for Biologics

Evaluation and Research (HFB-120), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8191.

SUPPLEMENTARY INFORMATION: The Drug Export Amendments Act of 1986 (Pub. L. 99-660) (section 802 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 382)) provides that FDA may approve applications for the export of biological products that are not currently approved in the United States. Section 802(b)(3)(B) of the act sets forth the requirements that must be met in an application for approval. Section 802(b)(3)(C) of the act requires that the agency review the application within 30 days of its filing to determine whether the requirements of section 802(b)(3)(B) have been satisfied. Section 802(b)(3)(A) of the act requires that the agency publish a notice in the **Federal Register** within 10 days of the filing of an application for export to facilitate public participation in its review of the application. To meet this requirement, the agency is providing notice that Organon Teknika Corp., 100 Akzo Ave., Durham, NC 27704, has filed an application requesting approval for the export of the biological product Vironostika HIV-1 Antigen Microelisa System to The Netherlands. Vironostika HIV-1 Antigen Microelisa System is an enzyme-linked immunosorbent assay (ELISA) for the qualitative and semiquantitative detection of the p24 core antigen of Human Immunodeficiency Virus Type 1 (HIV-1) in human serum, plasma, or cell culture supernatant. The application was received and filed in the Center for Biologics Evaluation and Research on August 23, 1991, which shall be considered the filing date for purposes of the act.

Interested persons may submit relevant information on the application to the Dockets Management Branch (address above) in two copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. These submissions may be seen in the Dockets Management Branch between 9 a.m., and 4 p.m., Monday through Friday.

The agency encourages any person who submits relevant information on the application to do so by September 23, 1991, and to provide an additional copy of the submission directly to the contact person identified above, to facilitate consideration of the information during the 30-day review period.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (section 802 (21 U.S.C. 382)) and under authority

delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Biologics Evaluation and Research (21 CFR 5.44).

Dated: August 30, 1991.

Thomas S. Bozzo,

Director, Office of Compliance, Center for Biologics Evaluation and Research.

[FR Doc. 91-21943 Filed 9-11-91; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 91F-0324]

Goodyear Tire & Rubber Co.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the Goodyear Tire & Rubber Co. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of the acid-catalyzed condensation reaction product of *p*-nonylphenol, formalin, and 1-dodecanethiol as an antioxidant for adhesives and rubber articles intended for repeated use in food packaging.

FOR FURTHER INFORMATION CONTACT: Marvin D. Mack, Center for Food Safety and Applied Nutrition (HFF-335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5690.

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 petition (FAP 1B4259) has been filed by the Goodyear Tire & Rubber Co., Akron, OH 44316-0001. The petition proposes to amend the food additive regulations in § 178.2010 Antioxidants and/or stabilizers for polymers (21 CFR 178.2010) to provide for the safe use of the acid-catalyzed condensation reaction product of *p*-nonylphenol, formalin, and 1-dodecanethiol as an antioxidant for adhesives, listed under 21 CFR 175.105, and rubber articles, listed under 21 CFR 177.2600, intended for repeated use in food packaging.

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).

Dated: August 30, 1991.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 91-21944 Filed 9-11-91; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[NV-930-91-4333-11; NV5-91-34]

Nevada; Temporary Closure of Certain Public Lands in the Las Vegas District for Management of the 1991 Gold Coast 300 Off-Highway Vehicle (OHV) Race

ACTION: Temporary closure of certain Public Lands in Clark County, Nevada, on and adjacent to the 1991 GOLD COAST 300 race course on October 12, 1991. Access will be limited to race officials, entrants, law-enforcement and emergency personnel, licensed permittee(s) and right-of-way grantees.

SUPPLEMENTARY INFORMATION: Certain public lands in the Las Vegas District, Clark County, Nevada will be temporarily closed to public access from 0001 hours, October 12, 1991, to 2400 hours, October 12, 1991, to protect persons, property, and public land resources on and adjacent to the High Desert Racing Association (HDRA) 1991 GOLD COAST 300 OHV race course. Spectators are restricted to the Start/Finish, and the high speed test section, miles 55.0 to 59.3 along the paved frontage road only.

These temporary closures and restrictions are made pursuant to 43 CFR Part 8364. The public lands to be closed or restricted are those lands adjacent to and including roads, trails and washes identified as the 1991 Gold Coast 300 OHV race course.

The following public lands restricted or closed are described as: The Sloan area, T. 23 S., R. 61 E., all of sections 31, 32, and 33; T. 23 S., R. 60 E., all of section 36. The Hidden Valley area, T. 24 S., R. 61 E., all of sections 1 through 36. The Erie area, T. 24 S., R. 60 E., all of sections 1 through 36. The Jean area, T. 25 S., R. 59 E., all of sections 1 through 36. The Jean Lake area, T. 25 S., R. 60 E., all of sections 1 through 36. The McCullough Pass area, T. 25 S., R. 61 E., all of sections 1 through 36. The Roach Lake area, T. 26 S., R. 59 E., all of sections 1 through 36. The Beer Bottle Pass area, T. 26 S., R. 60 E., all of sections 1 through 36.

The above legal land descriptions are for public lands within Clark County, Nevada. A map showing specific areas

closed to public access is available from the following BLM office: The Las Vegas District Office, P.O. Box 26569, Las Vegas, Nevada 89126 (702) 647-5000. Any person who fails to comply with this closure order issued under 43 CFR Part 8364 may be subject to the penalties provided in 43 CFR 8360.7.

Dated August 29, 1991.

Ben F. Collins,

District Manager, Las Vegas District.

[FR Doc. 91-21955 Filed 9-11-91; 8:45 am]

BILLING CODE 4310-HC-M

[AZ-020-01-4212-12; AZA 25666]

Realty Action: Exchange of Public Land; Pinal and Pima Counties, Arizona

BLM proposes to exchange public land in order to achieve more efficient management of the public land through consolidation of ownership.

Portions of all public lands within the following townships, ranges and sections are being considered for disposal by exchange pursuant to section 206 of the Federal Land Policy and Management Act of October 21, 1976, 43 U.S.C. 1716.

Gila and Salt River Meridian, Arizona

(a) Pinal County

T. 9 S., R. 6 E., sec. 5.
T. 10 S., R. 6 E., sec. 30, 31.

(b) Pima County

T. 11 S., R. 6 E., secs. 3, 5, 6, 7, 10.
T. 11 S., R. 8 E., secs. 1, 3.
T. 11 S., R. 9 E., secs. 6, 10, 11, 12, 13, 14, 15, 21, 22, 23, 24, 25, 26, 35, 36.
T. 11 S., R. 10 E., sec. 19, 20, 29, 30.
T. 12 S., R. 9 E., sec. 1.
T. 12 S., R. 10 E., secs. 6, 7, 18, 23.
T. 14 S., R. 9 E., secs. 33, 34.
T. 14 S., R. 10 E., secs. 31, 33.
T. 14 S., R. 11 E., sec. 4.
T. 15 S., R. 9 E., secs. 1, 3, 4, 9, 10, 11, 30.
T. 15 S., R. 10 E., secs. 3, 4, 5, 6.
Containing 24,580.23 acres, more or less.

Final determination on disposal will await completion of an environmental analysis.

In accordance with the regulations of 43 CFR 2201.1(b), publication of this Notice will segregate the affected public lands, as described in this Notice, from appropriation under the public land laws and the mining laws, but not the mineral leasing laws or Geothermal Steam Act.

The segregation of the above-described lands shall terminate upon issuance of a document conveying such lands or upon publication in the Federal Register of a notice of termination of the segregation; or the expiration of two

years from the date of publication, whichever occurs first.

For a period of forty-five (45) days, interested parties may submit comments to the District Manager, Phoenix District Office, 2015 West Deer Valley Road, Phoenix, Arizona 85027.

Dated: August 30, 1991.

Henri R. Bisson,

District Manager.

[FR Doc. 91-21915 Filed 9-11-91; 8:45 am]

BILLING CODE 4310-32-M

[UT-060-01-4333-12]

September 3, 1991.

TITLE: Requirement for Grand Gulch Permit and Fee.

AGENCY: Bureau of Land Management, Moab.

ACTION: Requirement for Special Recreation Permit and Fee for Non-commercial Recreational Use of the Grand Gulch portion of the Cedar Mesa Special Recreation Management Area.

SUMMARY: Beginning October 1, 1991, the Bureau of Land Management will require special recreation permits and fees for overnight, non-commercial recreation use in the Grand Gulch portion of the Cedar Mesa Special Recreation Management Area. The area where these requirements will be in effect corresponds to the area designated by the Secretary of the Interior as the Grand Gulch Primitive Area located in San Juan County, Utah.

The permit requirement will provide information useful in the development of a more intensive resources protection program for the Grand Gulch. Fees collected from individual, non-commercial visitors will be used to augment protection of the Grand Gulch's outstanding cultural and primitive recreation values.

SUPPLEMENTARY INFORMATION: The Grand Gulch contains the greatest concentration of Anasazi Indian cultural remnants contained on the Public Lands managed by the Bureau of Land Management and is known for its excellent backpacking opportunities. The Grand Gulch has been managed to protect these values since 1970 when the Secretary of the Interior designated it as a Primitive Area. The Grand Gulch is the most well-known portion of the Cedar Mesa Area of Critical Environmental Concern and is included within the boundary of the Grand Gulch Complex Wilderness Study Area.

In the last five-year period, the Grand Gulch has experienced a rapid growth in recreation use. Increased visitation to this sensitive area has magnified the