

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: March 10, 2003.

**Linda Arey Skladany,**  
*Associate Commissioner for External Relations.*

[FR Doc. 03-6369 Filed 3-17-03; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Science Board to the Food and Drug Administration; Notice of Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* Science Board to the Food and Drug Administration.

*General Function of the Committee:* To provide advice and recommendations to the agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on April 9, 2003, from 8 a.m. to 4:30 p.m.

*Location:* Food and Drug Administration, rm. 1066, 5630 Fishers Lane, Rockville, MD 20857.

*Contact Person:* Susan Bond, Office of the Commissioner, Food and Drug Administration (HF-33), 5600 Fishers Lane, Rockville, MD 20857, 301-827-6687, sbond@oc.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12603. Please call the Information Line for up-to-date information on this meeting.

*Agenda:* The board will hear and discuss the FDA's launched initiative to improve the development and availability of innovative medical products, specifically in the area of pharmacogenomics. The board will also hear updates on the pharmaceutical manufacturing initiative.

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by March 28, 2003. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral

presentations should notify the contact person before March 28, 2003, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Susan Bond at least 7 days in advance of the meeting.

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Dated: March 10, 2003.

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*Associate Commissioner for External Relations.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Indian Health Service

#### Redesignation of Contract Health Service Delivery Area

**AGENCY:** Indian Health Service, HHS.

**ACTION:** Notice.

**SUMMARY:** This notice advises the public that the Indian Health Service (IHS) is redesignating the geographic boundaries of the Contract Health Service Delivery Area (CHSDA) for the Rosebud Sioux Tribe ("The Tribe"). The Tribe's CHSDA was comprised of Bennett, SD, Cherry, NE, Mellette, SD, Todd, SD and Tripp, SD counties in South Dakota and Nebraska. These counties were designated as the Tribe's CHSDA when the IHS published its updated list of CHSDAs in the **Federal Register** of January 10, 1984 (49 FR 1291). It is proposed that the redesignated CHSDA be comprised of seven counties in the States of South Dakota and Nebraska, Bennett, SD, Cherry, NE, Mellette, SD, Todd, SD, Tripp, SD, Gregory, SD and Lyman, SD. This notice is issued under authority of 43 FR 34654, August 4, 1978.

**DATES:** Comments must be received on or before April 17, 2003.

**ADDRESSES:** Comments may be mailed to Betty Gould, Regulations Officer,

Division of Regulatory and Legal Affairs, Indian Health Service, 12300 Twinbrook Parkway, Suite 450, Rockville, MD 20857, Telephone 301-443-7899 (This is not a toll-free number). Comments received will be available for inspection at the address above from 9 a.m. to 3 p.m., Monday through Friday, beginning approximately two weeks after publication.

#### FOR FURTHER INFORMATION CONTACT:

Leslie Morris, Director, Division of Regulatory and Legal Affairs, Office of Management Support, Indian Health Service, 12300 Twinbrook Parkway, Suite 450, Rockville, MD 20857, Telephone 301-443-1116. (This is not a toll-free number.)

**SUPPLEMENTARY INFORMATION:** On August 4, 1978, the IHS published regulations establishing eligibility criteria for receipt of contract health services and for the designation of CHSDAs (43 FR 34654, codified at 42 CFR 136.22, last published in the 2002 version of the Code of Federal Regulations). On September 16, 1987, the IHS published new regulations governing eligibility for IHS services. Congress has repeatedly delayed implementation of the new regulations by imposing annual moratoriums. Section 719(a) of the Indian Health Care Amendments of 1988, Pub. L. 100-713, explicitly provides that during the period of the moratorium placed on implementation of the new eligibility regulations, the IHS will provide services pursuant to the criteria in effect on September 15, 1987. Thus, the IHS contract health services program continues to be governed by the regulations in effect on September 15, 1987. *See* 42 CFR 136.21, *et seq.* (2002).

As applicable to the Tribe, these regulations provide that, unless otherwise designated, a CHSDA shall consist of a county which includes all or part of a reservation and any county or counties which have a common boundary with the reservation (42 CFR 136.22). The regulations also provide that after consultation with the tribal governing body or bodies of those reservations included in the CHSDA, the Secretary may, from time to time, redesignate areas within the United States for inclusion in or exclusion from a CHSDA. The regulations require that certain criteria must be considered before any redesignation is made. The criteria are as follows:

(1) The number of Indians residing in the area proposed to be so included or excluded;

(2) Whether the tribal governing body has determined that Indians residing in the area near the reservation are socially

and economically affiliated with the tribe;

(3) The geographic proximity to the reservation of the area whose inclusion or exclusion is being considered; and

(4) The level of funding which would be available for the provision of contract health services.

Additionally, the regulations require that any redesignation of a CHSDA must be made in accordance with the procedures of the Administrative Procedure Act (5 U.S.C. 553). In compliance with this requirement, we are publishing this proposal and requesting public comment.

Pursuant to a Tribal Resolution 2000–32, dated March 9, 2000, the Tribe requested the IHS to redesignate their current CHSDA, which incorporates Mellette, Bennett, Todd, Trip and Cherry Counties in the State of South Dakota and Nebraska, to include Gregory and Lyman counties. In applying the aforementioned CHSDA redesignated criteria required by 42 CFR 136.22, the following findings are made:

(1) The Tribe enrollment and census records identify 519 tribal members residing in Gregory County and 0 tribal members residing in Lyman County.

(2) The Tribe has determined that contract health services would be available to all its members and members of other federally recognized tribes who reside in Gregory County and Lyman County having close social and economic ties with the Tribe.

(3) Gregory County is presently a CHSDA county for the Yankton Sioux Tribe. There are 159 Tribal members, of the 519 total, who are eligible for the Yankton Sioux CHS program because of close economic-social ties. The Yankton Sioux and Rosebud Sioux CHS programs will work together on the eligibility and CHS coverage on a case-by-case basis. Lyman County is presently a CHSDA county for the Lower Brule Sioux Tribe. There are 0 Tribal members who are eligible for the Lower Brule Sioux CHS program. The Lower Brule and Rosebud CHS program will work together on the eligibility and CHS coverage on a case-by-case basis if/when there are Rosebud Sioux residing within Lyman County.

(4) At this time, although Gregory County does not border the Rosebud Sioux's reservation, Gregory County was within the original boundaries of the reservation and continues to have a significant population of Rosebud Sioux. The Tribe chose to include Lyman County in the expansion even though, at the time of the analysis, there were no Rosebud Sioux tribal members residing in Lynn County. The close

proximity to the original boundaries of the reservation was considered because there could be members residing in Lyman County in the future.

(5) The 519 tribal members residing in Gregory County presently utilize the Rosebud Indian Health Service facility's direct care services. Therefore, the clinical work load units will not be impacted. It is estimated that the current eligible contract health service population will be increased by 519 in Gregory County. The Rosebud CHS program has a recurring CHS funding base of \$4,233,730. The formula used to determine what impact the additional 519 members, residing in Gregory County, would have on the Rosebud CHS fund is determined by using the Aberdeen Area's type of facility per capita of  $\$327 \times 519 = \$169,713$ . The 0 number residing in Lyman County would have no impact at this time. The Rosebud Indian Health Service facility recognizes that there will be no additional CHS funding for this CHSDA expansion but they do not expect a significant impact on their present funding and support the tribe's CHSDA expansion and redesignation. The expansion and redesignation of the CHSDA to include both Gregory County and Lyman County is within the present available resources.

Accordingly, after considering the Tribe's request in light of the criteria specified in the regulations I am proposing to redesignate the CHSDA of the Tribe to consist of Bennett, SD, Cherry, NE, Mellette, SD, Todd, SD, Tripp, SD, Gregory, SD and Lyman, SD, Counties of South Dakota and Nebraska.

This notice does not contain reporting or recordkeeping requirements subject to prior approval by the Office of Management and Budget under the Paperwork Reduction Act of 1980.

Dated: March 10, 2003.

**Charles W. Grim,**

*Assistant Surgeon General, Interim Director, Indian Health Service.*

[FR Doc. 03–6398 Filed 3–17–03; 8:45 am]

**BILLING CODE 4160–16–M**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **National Institutes of Health**

#### **Government-Owned Inventions; Availability for Licensing**

**AGENCY:** National Institutes of Health, Public Health Service, DHHS.

**ACTION:** Notice.

**SUMMARY:** The inventions listed below are owned by agencies of the U.S.

Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

**ADDRESSES:** Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7057; fax: 301/402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

#### **Development of a Novel High Throughput Assay To Measure Cell Infection With Vaccinia Strains Expressing Reporter Genes**

Hana Golding (FDA).

U.S. Provisional Patent Application 60/429,767 filed 27 Nov 2002.

*Licensing Contact:* Peter Soukas; 301/435–4646; [soukasp@od.nih.gov](mailto:soukasp@od.nih.gov).

Critical to developing a vaccine against viral infections is an assay to measure the neutralizing antibody present in blood of vaccine recipients. The currently available tests are labor intensive and require 5–6 days to complete. The inventors have designed a high throughput vaccinia neutralization assay, which offers several advantages over the assays that are currently used. It is completed in as little as 24 hours, it is sensitive, highly reproducible, requires only 50 µl of plasma and uses automated readout. This assay is based on the use of recombinant vaccinia virus (vSC56) expressing a bacterial gene coding for the enzyme b-galactosidase (b-Gal) under the control of a synthetic early/late promoter. Another recombinant virus expressing an inducible reporter gene (EGFP) is also being tested in neutralization assay. These assays may be of value in the clinical trials of new smallpox vaccines, for evaluations of new vaccinia immunoglobulin (VIG) and anti-viral agents under development. The technology itself may be adapted for construction of neutralization assays for other viruses and intracellular pathogens.

#### **Method of Separating Recombinant Immunotoxin**

Hua Jiang et al. (NCI).

DHHS Reference No. E–209–2002/0–US–01 filed 07 Nov 2002.