
(2) Federal Register Notice of Letter of Intent

- June 22, 1982

infectious diseases caused by bacteria, rickettsia, viruses, and parasites; and (3) immunologic processes which may lead to morphologic alteration.

Develops biochemical and biophysical methodology and bioassays for application to the control of existing and newly developed biological products derived from recombinant DNA technology.

Reviews scientific data supporting license applications and amendments for biological products and provides staff having appropriate expertise for the product under consideration to serve on licensing committees.

Carries out control test and reviews manufacturers' protocols to insure that specific requirements for release are satisfied.

Participates in the inspection of manufacturers of biological products.

Assists in collaborative research and management of contract-supported activities.

(n-4-viii) *Division of Product Quality Control (HFNCH)*. Plans and conducts a developmental testing program of biological products such as vaccines, cell-derived antiviral and antitumor substances, and various blood components to develop standards designed to insure the safety, purity, potency, and efficacy of such products and to improve the existing test procedures.

Plans and conducts sterility, general safety, pyrogen, and potency tests on biological products submitted for release or in support of license applications; and when required, performs safety, neurovirulence, and potency tests on biological products using nonhuman primates and certain other animals; reviews manufacturer's protocols with respect to such tests.

Removes various tissues from primates and other animals as required for control testing and research as well as for the preparation of cell cultures.

Administers the biological products release program; coordinates processing of protocols submitted for licensing and for the release of lots of biologics manufactured under existing licenses; receives, maintains, and distributes accompanying samples of biological products for testing within the Office; reviews recommendations by laboratory divisions concerning compliance with regulatory requirements and issues notification of release or rejection.

Establishes and distributes control preparations and reference reagents to licensed manufacturers, health agencies, and other control groups.

Recommends criteria for acceptability pertaining to the development of

regulatory standards and reference reagents for new biological products.

Provides technical training for representatives of domestic and foreign biological establishments in relation to control testing procedures.

Inspects manufacturers of biological products and laboratories conducting nonclinical studies involving investigational new drugs.

Reviews scientific data included in license applications for new biological products and amendments for old products.

Serves as custodian for official complaint samples and coordinates testing and compilation of results.

Coordinates testing and reporting of tests performed as a WHO Reference Center.

Assists in collaborative research and management of contract-supported activities.

Prior Delegations of authority. Pending further delegations, directives, or orders by the Commissioner of Food and Drugs all delegations of authority to the Director of the Bureau of Drugs and the Director of the Bureau of Biologics are vested in the Director of the National Center for Drugs and Biologics and all delegations to any other officer or employee of the merged bureaus in effect prior to the date of this order shall continue in effect in them or their successors.

Dated: June 7, 1982.

Richard S. Schweiker,
Secretary.

[FR Doc. 82-17002 Filed 6-21-82; 8:54 am]
BILLING CODE 4160-01-M

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Receipt of Petition for Federal Acknowledgment of Existence as an Indian Tribe

June 3, 1982.

This notice is published in the exercise of authority delegated by the Secretary of the Interior to the Assistant Secretary—Indian Affairs by 209 DM 8.

Pursuant to 25 CFR 83.8(a) (formerly 25 CFR 54.8(a)) notice is hereby given that the Golden Hill Paugussett Tribe, c/o Mr. Aurelius H. Piper, 427 Shelton Road, Trumbull, Connecticut 06611 has filed a petition for acknowledgment by the Secretary of the Interior that the group exists as an Indian tribe. The petition was received by the Bureau of Indian Affairs on April 13, 1982. The petition was forwarded and signed by members of the group's governing body.

This is a notice of receipt of petition and does not constitute notice that the petition is under active consideration. Notice of active consideration will be by mail to the petitioner and other interested parties at the appropriate time.

Under § 83.8(d) formerly § 54.8(d) of the Federal regulations, interested parties may submit factual or legal arguments in support of or in opposition to the group's petition. Any information submitted will be made available on the same basis as other information in the Bureau of Indian Affairs files.

The petition may be examined by appointment in the Division of Tribal Government Services, Bureau of Indian Affairs, Department of the Interior, 18th and C Streets, N.W., Washington, D.C. 20242.

Roy H. Sampsel,

Deputy Assistant Secretary, Indian Affairs.

[FR Doc. 82-16831 Filed 6-21-82; 8:45 am]

BILLING CODE 4310-02-M

Lessees and Operators of Indian Oil and Gas Leases; Approval of Communitization Agreements

June 7, 1982.

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of adoption of guidelines relating to approval of communitization agreements.

SUMMARY: On April 23, 1982, the Deputy Assistant Secretary—Indian Affairs (Operations) transmitted to all Area Directors new guidelines to assist them in exercising their authority to approve communitization agreements affecting Indian oil and gas leases. The guidelines are based upon a judicial determination of the scope of that authority in a recent decision of the U.S. Court of Appeals for the 10th Circuit. The purpose of this notice is to inform lessees and operators about the guidelines adopted, with particular emphasis on the need in the future to submit communitization agreements to the appropriate Bureau office not less than 90 days prior to the date of expiration of the first Indian lease within the proposed unit.

ADDRESS: Request for copies of the guidelines for approval of communitization agreements may be obtained from the Chief, Division of Energy and Minerals Office of Trust Responsibilities, Bureau of Indian Affairs, P.O. Box 26268, Belmar Branch, Lakewood, CO 83705.

FOR FURTHER INFORMATION CONTACT: David Baldwin (303) 234-6961, or Tom Riggs, (202) 343-3722.

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