6. Hamwi, A. et al., ''Cyclosporine Metabolism in Patients After Kidney, Bone Marrow, Heart-Lung, and Liver Transplantation in the Early and Late Posttransplant Periods,'' *American Journal of Clinical Pathology*, 114:536–543, 2000.

7. Fernandez-Marmiesse, A. et al., ''Comparison of Predose vs 2-h Postdose Blood Metabolites/Cyclosporine Ratios in Kidney and Liver Transplant Patients,'' *Clinical Biochemistry*, 33:383–386, 2000.

8. Halloran, P. F., ''Molecular Mechanisms of New Immunosuppressants,'' *Clinical Transplantation*, 10:118–123, 1996.

9. Braun, F. et al., ''Clinical Relevance of Monitoring Tacrolimus: Comparison of Microparticle Enzyme Immunoassay, Enzyme-Lined Immunosorbent Assay and Liquid Chromatography Mass Spectrometry in Renal Transplant Recipients Converted From Cyclosporine to Tacrolimus,'' *Transplantation Proceedings*, 28:3175–3176, 1996.

10. Jusko, W. J. et al., ''Consensus Document: Therapeutic Monitoring of Tacrolimus (FK–506),'' *Therapeutic Drug Monitoring*, 17:606–614, 1995.

List of Subjects in 21 CFR Part 862

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 862 be amended in subpart B as follows:

PART 862—CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES

1. The authority citation for 21 CFR part 862 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 862.1235 is added to subpart B to read as follows:

§ 862.1235 Cyclosporine test system.

(a) *Identification.* A cyclosporine test system is a device intended to quantitatively determine cyclosporine concentrations as an aid in the management of transplant patients receiving therapy with this drug. This generic type of device includes immunoassays and chromatographic assays for cyclosporine.

(b) *Classification.* Class II (special controls). The special control is ''Class II Special Controls Guidance Document: Cyclosporine and Tacrolimus Assays; Guidance for Industry and FDA.''

3. Section 862.1678 is added to subpart B to read as follows:

§ 862.1678 Tacrolimus test system.

(a) *Identification.* A tacrolimus test system is a device intended to quantitatively determine tacrolimus concentrations as an aid in the management of transplant patients receiving therapy with this drug. This generic type of device includes immunoassays and chromatographic assays for tacrolimus.

(b) *Classification.* Class II (special controls). The special control is ''Class II Special Controls Guidance Document: Cyclosporine and Tacrolimus Assays; Guidance for Industry and FDA.''

Dated: February 11, 2002.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

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DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

25 CFR Parts 112, 116, 121, 123, 125, 154, 156, 178, and 243

RIN 1076–AD20

Trust Management Reform: Repeal of Outdated Rules

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Proposed removal of rules with request for comments.

SUMMARY: The Department of the Interior, Bureau of Indian Affairs (BIA) proposes to repeal nine parts of Title 25 CFR Chapter 1. These revisions are meant to further fulfill the Secretary's responsibility to federally-recognized tribes and individual Indians by ensuring that all regulations, policies, and procedures are up-to-date. The parts proposed for repeal include regulations relating to distribution of tribal funds among tribal members, establishment of private trusts for the Five Civilized Tribes, distribution of Osage Judgment Funds, assignment of future income from the Alaska Native Fund, payment of Sioux benefits, preparation of a competency roll of Osage Indians, reallotment of lands to Indian children, resale of lands within the Badlands Air Force Range, and registration of reindeer ownership in Alaska. In the interests of economy of administration, and because all of the regulations proposed to be repealed are outdated, they are included in one rulemaking vehicle.

DATES: Comments must be submitted in writing and received by us no later than April 22, 2002.

ADDRESSES: Comments should be addressed to Linda L. Richardson, Trust Policies and Procedures Subproject, Bureau of Indian Affairs, 1849 ''C'' Street, NW., MS–4070–MIB, Washington, DC 20240. Comments will also be accepted by telefax at the following telephone number: 202–208–6426.

FOR FURTHER INFORMATION CONTACT: Linda L. Richardson, 202–208–6411.

SUPPLEMENTARY INFORMATION:

I. Background

As described in the Department's ''Trust Management Improvement Project—High Level Implementation Plan,'' proper management of Indian trust assets has been hampered by a lack of comprehensive, consistent, up-to-date regulations, policies, and procedures covering the entire trust cycle. Last year, the BIA began revising its trust management regulations by issuing proposed revisions to regulations governing probate, trust funds, leasing, and grazing. Updated regulations affecting these functions became effective on March 23, 2001.

In April 2001, BIA submitted a report to the Department's Trust Policy Council that provided a comprehensive review of regulations, manuals and handbooks that guide trust operations. The report included recommended actions to bring all policies and procedures current and outlined a multi-year schedule to accomplish this goal. The review identified a number of regulations still on the books that are no longer operative, either because all actions required by law have been fully implemented or because the regulation no longer comports with Federal Indian policy.

II. Part-by-Part Analysis

A. 25 CFR Part 112—Pro Rata Shares of Tribal Funds

During the late 19th and early 20th centuries, the Federal Government attempted to weaken tribal governments by dividing or allotting tribal land among tribal members. A corollary to the allotment policy was a provision (March 2, 1907, c. 2523, 34 Stat. 1221; 25 U.S.C. 119, 121) that authorized the Secretary of the Interior—

''to designate any individual Indian belonging to any tribe or tribes whom he may deem to be capable of managing his or her affairs, and he may cause to the apportioned and allotted to any such Indian his or her pro rata share of any tribal or trust funds on deposit in the Treasury of the United States to the credit of the tribe or tribes of which said Indian is a member. * * *''

The regulations in part 112 established the criteria used by the BIA to determine whether to approve an individual's application for a pro rata share of tribal funds.

The Federal policy of attempting to assimilate individual Indians and weaken tribal governments was reversed in 1934 with the passage of the Indian Reorganization Act (June 18, 1934; 48 Stat. 984–988; 25 U.S.C. 461 *et seq.*). This statute ended the allotment of tribal lands to individual tribal members and authorized restoration of so-called ''surplus'' lands to tribal ownership. The Indian Reorganization Act did not specifically repeal the various laws that had previously authorized the allotment of tribal lands to individual members; it did, however, render those laws inoperative: '' * * * hereafter no land of any Indian reservation * * * shall be allotted in severalty to any Indian.'' Similarly, we believe that the Secretary's discretionary authority to distribute pro rata shares of tribal funds was also made inoperative by Section 4 of the Indian Reorganization Act: '' * * * no sale, devise, gift, exchange or other transfer of restricted Indian lands or of shares in the assets of any Indian tribe * * * shall be made or approved * * *'' (25 U.S.C. 464).

A number of Indian tribes make per capita payments to tribal members from tribal trust funds. Repeal of part 112 will not affect tribal decisions over the use of tribal funds. Repeal will only eliminate the Secretary's discretionary authority to withdraw tribal funds, without tribal consent, and give those funds to a tribal member.

B. Part 116—Trusts for the Five Civilized Tribes

In 1933 Congress passed a law (47 Stat. 777) giving the Secretary of the Interior discretionary authority to approve agreements between members of the Five Civilized Tribes (FCT) and private banks or trust companies to manage trust assets for members of the FCT. The regulations in part 116 establish the procedures for eligible Indians to apply for the establishment of a trust; identify the obligations of the trust company; specify allowable investments; require an annual accounting; and establish the trustee's compensation.

A subsequent law, the Act of August 4, 1947 (61 Stat. 731), provided in section 5: ''That all funds and securities now held by, or which may hereafter come under the supervision of the Secretary of the Interior * * * are hereby declared to be restricted and shall remain subject to the jurisdiction of said Secretary * * *'' (61 Stat. 733). While this law did not specifically repeal section 2 of the Act of January 27, 1933 (Act) 1933, the authority conveyed by that section of the Act is clearly discretionary (''The Secretary of the Interior be, and he is hereby, authorized to permit, in his discretion and subject to his approval * * *'').

Current federal policy, as provided in 25 CFR part 115, allows adult Indians, with the exception of those who are *non compos mentis* or who are determined to need assistance in managing their finances, ready access to any and all funds held in trust. When an adult withdraws money from an Individual Indian Money account, the individual Indian may freely determine how that money will be spent or reinvested. As a policy matter, the Secretary has determined that the same treatment should be extended to members of the Five Civilized Tribes.

C. Part 121—Distribution of Judgment Funds Awarded to the Osage Tribe of Indians in Oklahoma

Public Law 92–586 (25 U.S.C. 883) directed how the Secretary of the Interior was to distribute judgment funds awarded by the Indian Claims Commission to the Osage Tribe of Indians in Oklahoma and authorized the Secretary to issue regulations to carry out the terms of the law. The regulations in part 121 provided notice of the eligibility requirements for per capita payments; established a 1974 deadline for filing a claim; and described how the money would be distributed. As all per capita payments subject to these regulations were disbursed more than 25 years ago, the regulations are no longer required.

D. Part 123—Alaska Native Fund

The Alaska Native Claims Settlement Act, Public Law 92–203, as amended, (ANCSA) required that payments be made over a period of years to the Regional Corporations that were established by the Act. Subsequent provisions allowed the Regional Corporations to assign future income due under ANCSA.

The regulations in part 123 established the procedures to request an assignment of future income. As the last payments due under ANSCA were made almost 20 years ago, there is no future income subject to assignment and the regulations should be repealed.

E. Part 125—Payment of Sioux Benefits

Between 1889 and 1934, Congress passed a number of laws authorizing benefit payments to Sioux tribal members. The regulations in part 125 identified eligibility requirements, established an application procedure and an appeals procedure. All payments due under the various statutes have been paid and the regulations are no longer required.

F. Part 154—Osage Roll, Certificate of Competency

In 1948 Congress passed a law (62 Stat. 18) that required the Secretary of the Interior to issue certificates of competency to any adult member of the Osage Tribe of less than one-half Indian blood. The regulations in part 154 described the process used by the BIA to prepare a competency roll including how the degree of Indian blood and determination of age would be computed. The 1948 law was repealed 30 years later by Public Law 95–496 (92 Stat. 1660). As there is no longer a statutory basis for the regulations, part 154 is proposed for repeal.

G. Part 156—Reallotment of Lands to Unallotted Indian Children

Section 3 of a 1910 statute (36 Stat. 855–863) provided that an Indian who had an allotment could relinquish all or part of the allotment to any of his or her children to whom no allotment had been made. The regulations in part 156 prescribe the process that the original allottee must follow to relinquish the allotment to one or more children.

The provision of both the statute and the regulations cover only those Indians who had allotments in 1910. As allottees had to be at least 21 years of age, any persons currently eligible for coverage by this provision or these regulations would be at least 112 years of age.

The BIA has broader regulations in Part 152—Issuance of Patents in Fee,

Certificates of Competency, Removal of Restrictions, and Sale of Certain Indian Lands. The regulatory authority included in part 156 is covered by § 152.17, (s)ales, exchanges, and conveyances by or with the consent of the individual Indian owner. Among the authorities cited in this subsection is the Act of June 25, 1910 (36 Stat. 855) that is the basis for the narrower regulations in part 156. As part 152 provides all required regulatory authority, part 156 can be repealed.

H. Part 178—Resale of Lands Within the Badlands Air Force Gunnery Range (Pine Ridge Aerial Gunnery Range)

The Badlands National Monument Boundary Revision Act (82 Stat. 663) provided an opportunity for former land owners to reacquire lands that had been purchased from them by the Federal Government. The regulations in part 178 defined those eligible to purchase the lands, prescribed the application and conveyance process, and identified allowable land uses. As the deadline to file an application to reacquire the lands expired in 1969, these regulations are no longer necessary.

I. Part 243—Reindeer in Alaska

The Reindeer Industry Act of 1937, 25 U.S.C. 500 *et seq.*, required all non-Natives in Alaska who owned reindeer to file a declaration of ownership. The regulations in part 243 notify such owners of the form to be used and designate the General Reindeer Supervisor in Nome, AK as the agent to receive such declarations. As the deadline for filing the notices under these regulations expired on September 1, 1938, the regulations are no longer required.

III. Public Comment Procedures

The regulatory repeal proposed in this rulemaking eliminates nine regulations that are no longer necessary. These changes are proposed to ensure that all regulations governing provision of trust services to Indian tribes and individual Indians are current and accurately reflect departmental principles for managing Indian trust assets. The public is invited to make substantive comment on any of these proposed changes.

Comments should be submitted in writing to the address indicated in the **ADDRESSES** section of this document. Comments may also be telefaxed to the following telephone number: 202–208–6426. All comments received will be available for public inspection at the Bureau of Indian Affairs, Policies and Procedures Subproject, Room 4552, 1849 C Street, NW., Washington, DC 20240. All written comments received by the date indicated in the **DATES** section of this document and all other relevant information in the record will be carefully assessed and fully considered prior to publication of the final rule. Any information considered to be confidential must be so identified and submitted in writing. We will not consider comments submitted anonymously. However, if you wish us to withhold your name and/or address, you must state this prominently at the beginning of your comment. The BIA reserves the right to determine the confidential status of the information and to treat it according to our determination (see 10 CFR 1004.11).

IV. Procedural Requirements

A. Review Under Executive Order 12866 (Regulatory Planning and Review)

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the BIA must determine whether the regulatory action is ''significant'' and therefore subject to OMB review and the requirements of the Executive Order. The Order defines a ''significant regulatory action'' as one that is likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

The Proposed rule would repeal a number of outdated regulations. As such, it does not impose a compliance burden on the economy generally or on any person or entity. Accordingly, this rule is not a ''significant regulatory action'' from an economic standpoint, and it does not otherwise create any inconsistencies or budgetary impacts to any other agency or Federal program.

B. Review Under Executive Order 12988 (Civil Justice Reform)

With respect to the review of existing regulations and the promulgation of new regulations, subsection 3(a) of Executive Order 12988, ''Civil Justice Reform,'' 61 FR 4729 (February 7, 1996), imposes on Executive agencies the general duty to adhere to the following requirements: (1) Eliminate drafting errors and ambiguity; (2) write regulations to minimize litigation; and (3) provide a clear legal standard for affected conduct rather than a general standard and promote simplification and burden reduction.

With regard to the review of proposed regulations, subsection 3(b) of Executive Order 12988 specifically requires that Executive agencies make every reasonable effort to ensure that the regulation: (1) Clearly specifies the preemptive effect, if any; (2) clearly specifies any effect on existing Federal law or regulation; (3) provides a clear legal standard for affected conduct while promoting simplification and burden reduction; (4) specifies the retroactive effect, if any; (5) adequately defines key terms; and (6) addresses other important issues affecting clarity and general draftsmanship under any guidelines issued by the Attorney General.

Subsection 3(c) of Executive Order 12988 requires agencies to review proposed regulations in light of applicable standards in section 3(a) and section 3(b) to determine whether they are met or it is unreasonable to meet one or more of them. The BIA has determined that the proposed regulation meets the relevant standards of Executive Order 12988.

C. Review Under Executive Order 12291 and the Regulatory Flexibility Act

Because this proposed rule would repeal outdated regulations, the BIA has determined that this rule is not a significant rule under Executive Order 12991. This proposed rule was also reviewed under the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, which requires preparation of a regulatory flexibility analysis for any rule which is likely to have significant economic impact on a substantial number of small entities.

This proposed rule updates the Department's policies and procedures that apply to certain Indian trust resources by eliminating unneeded regulatory requirements. Accordingly, the BIA has determined that this proposed regulation will not have a significant economic impact on a substantial number of small entities, and, therefore, no regulatory flexibility analysis has been prepared.

D. Review Under the Small Business Regulatory Enforcement Fairness Act of 1996

This proposed rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This proposed rule will not result in an annual effect on the

economy of $100,000,000 or more. The effect of this proposed rulemaking will be to streamline and modernize policies, procedures and management operations of the BIA by eliminating unnecessary regulations. No increases in costs for administration will be realized, and no prices would be affected through these revisions as, in practice, the regulations proposed for repeal are already inoperative.

This proposed rulemaking will not result in any significant adverse effects on competition, employment, investment, productivity, or innovation, nor on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets. These administrative revisions to BIA policy and procedure will not have an impact on any small business businesses or enterprises.

E. Review Under the Paperwork Reduction Act

This rule is exempt from the requirements of the Paperwork Reduction Act, since it repeals existing regulations. An OMB form 83–1 is not required.

F. Review Under Executive Order 13132 (Federalism)

This proposed rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. While this proposed rule may be of interest to tribes, there is no Federalism impact on the trust relationship or balance of power between the United States government and the various tribal governments affected by this rulemaking. Therefore, in accordance with Executive Order 13132, it is determined that this rule will not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

G. Review Under the National Environmental Policy Act of 1969

This proposed rule does not constitute a major Federal action significantly affecting the quality of the human environment. Therefore, neither an Environmental Assessment nor an Environmental Impact Statement is necessary for this proposed rule.

H. Review Under the Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995, Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on state, local, and tribal governments and the private sector. Under section 202 of the Act, the BIA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures to state, local, and tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year. This proposed rule will not result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year.

I. Review Under Executive Order 12630 (Takings Implication Assessment)

In accordance with Executive Order 12630, this proposed rule does not have significant takings implications. This rule does not involve the ''taking'' of private property interests.

J. Review Under Executive Order 13175 (Tribal Consultation)

The BIA determined that, because the proposed repeal of current regulations has tribal implications, it was an appropriate topic for consultation with tribal governments. This consultation is in keeping with Executive Order 13175, ''Consultation and Coordination with Indian Tribal Governments.'' In April 2001, BIA sent all tribal leaders a report that documents the results of a BIA review of existing regulations, policies, and procedures that affect delivery of trust services to tribal governments and individual Indians. Included in the report was a multi-year schedule for bringing all trust regulations, policies and procedures up-to-date. In May 2001, the BIA sent all tribal leaders a letter describing identifying ten parts of Title 25 CFR that we were considering for repeal. Regional directors followed up to determine if there were tribal concerns with any aspects of the proposal.

Several tribes expressed opposition to the suggested repeal of Part 140—Licensed Indian Traders. As a result, we have not included that Part in this proposed rulemaking. Two tribes asked that we not repeal Part 156—Reallotment of Lands to Unallotted Children. We have included that Part in this rulemaking, however, as the regulations in Part 152—Issuance of Patents in Fee, Certificates of Competency, Removal of Restrictions, and Sale of Certain Indian Lands, provides all necessary authority that is otherwise provided under part 156.

One tribe objected to the proposed repeal of Part 125—Payment of Sioux Benefits, as they do not consider all Sioux claims to be resolved. Part 125 regulated payments authorized under various laws that were passed between 1889 and 1934. All monies due under those statutes have been paid. In 1973, Congress passed the Indian Tribal Judgment Funds Use or Distribution Act, that covers all subsequent judgment awards. The regulations implementing that law are found in part 87, therefore we believe that part 125 should be repealed.

Following publication of this proposed rule, BIA will again notify tribal governments of the substance of this rule making through a direct mailing. This will enable tribal officials and the affected tribal constituency throughout Indian Country to have meaningful and timely input in the development of the final rule.

List of Subjects

25 CFR Part 112

Indians—business and finance.

25 CFR Part 116

Estates, Indians—business and finance, Trusts and trustees.

25 CFR Part 121

Indians—claims, Indians—judgment funds.

25 CFR Part 123

Alaska, Indian—claims.

25 CFR Part 125

Indians—claims, Reporting and recordkeeping requirements.

25 CFR Part 154

Indians—lands.

25 CFR Part 156

Indians—lands.

25 CFR Part 178

Indians—lands.

25 CFR Part 243

Alaska, Indians—business and finance, Reindeer.

Accordingly, under the authority in 25 U.S.C. 9, we propose to amend 25 CFR chapter 1 by removing parts 112, 116, 121, 123, 125, 154, 156, 178, and 243.

Dated: February 14, 2002.

Neal A. McCaleb,

Assistant Secretary—Indian Affairs.

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