

# Federal Register

may submit to FDA comments, data, and information to assist the agency in assessing the benefits, costs, and need for revision of its investigational device exemption (IDE) regulations.

**DATE:** Comments, data, and information by November 21, 1986.

**ADDRESS:** Written comments, data, and information to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-82, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Raymond F. Coakley, Jr., Center for Devices and Radiological Health (HFZ-83), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3428.

**SUPPLEMENTARY INFORMATION:** In the Federal Register of July 25, 1986 (51 FR 26830), FDA published a notice requesting submission of comments, data, and information on FDA's IDE regulations (21 CFR Part 812) to assist the agency in assessing the benefits, costs, and need for revision of these regulations as part of FDA's retrospective review of regulations. In that notice, FDA provided a comment period of 60 days (until September 23, 1986). In response to receiving requests for extension of this comment period from a professional association and a trade association, FDA is extending the comment period on this notice for 60 days (until November 21, 1986). FDA is closing the extended comment period on November 21, 1986, to match the close of the reopened and extended comment period FDA is providing in a related notice, as shown below.

In the Federal Register of April 1, 1986 (51 FR 11266), FDA published a notice announcing the agency's receipt from the American Society for Artificial Internal Organs of a citizen petition requesting FDA to amend its IDE regulations. In that notice, FDA provided a comment period of 90 days (until June 30, 1986). Elsewhere in this issue of the Federal Register, FDA is publishing a notice reopening the comment period on the notice of April 1, 1986. FDA is closing the reopened comment period on November 21, 1986.

In accordance with section 520(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(d)) and the agency's administrative practices and procedures regulations (21 CFR Part 10), FDA believes that good cause exists to extend the comment period on the notice of July 25, 1986, to provide a total comment period in excess of 90 days.

Interested persons may, on or before November 21, 1986, submit to the Dockets Management Branch (address above) written comments, data, or

information on the retrospective review of the IDE regulations. Two copies of any comments should be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 29, 1986.

John M. Taylor,  
*Acting Associate Commissioner for  
Regulatory Affairs.*

[FR Doc. 86-22514 Filed 10-3-86; 8:45 am]

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## DEPARTMENT OF THE INTERIOR

### Bureau of Indian Affairs

#### 25 CFR Part 120

#### Reimbursement of the Ute Tribe of the Uintah and Ouray Reservation, Utah

August 21, 1986.

**AGENCY:** Bureau of Indian Affairs, Interior.

**ACTION:** Proposed removal of rule..

**SUMMARY:** The Bureau of Indian Affairs is publishing a proposed rule that removes 25 CFR Part 120, Reimbursement of the Ute Tribe of Uintah and Ouray Reservation, Utah. It has been determined that there is no further need for or applicability of the rule.

**DATE:** Comments must be received on or before November 5, 1986.

**ADDRESSES:** Send written comments to Director, Office of Administration, Bureau of Indian Affairs, Room 4143—Main Interior, 1951 Constitution Avenue, NW., Washington, DC 20245; telephone number (202) 343-4174.

**FOR FURTHER INFORMATION CONTACT:** Mitchell Parks, Division of Accounting Management, Bureau of Indian Affairs, Room 4623, N. Interior, 1951 Constitution Avenue, NW., Washington, DC 20245, telephone number: (202) 343-4594 (FTS 343-4594).

**SUPPLEMENTARY INFORMATION:** The authority to remove this rule and regulation is vested in the Secretary of the Interior by 5 U.S.C. 301 and 25 U.S.C. 2 and 9. This proposed rule is published in exercise of rulemaking authority delegated by the Secretary of the Interior to the Assistant Secretary—Indian Affairs in the Departmental Manual at 209 DM 8..

This regulation, found at 25 CFR Part 120, Reimbursement of the Ute Tribe of the Uintah and Ouray Reservation,

Utah, is being removed because it has been determined that there is no further need for the rule. The rule governed the one-time payment to those persons whose names appeared on the final roll of mixed blood-Indians that was prepared pursuant to Section 8 of the Act of August 27, 1954 (68 Stat. 868) or to their heirs or legatees. Claims for reimbursement were required to be filed not later than September 18, 1973. Final payments were made and no claims or appeals have been filed with the Bureau of Indian Affairs since that date. Therefore, there is no further need for or applicability of this rule.

The Department of the Interior has determined that this rule is not a major rule under Executive Order 12291 and certifies that this document will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

This rule does not constitute a major federal action significantly affecting the quality of the human environment under the National Environmental Policy Act of 1969.

The Office of Management and Budget has informed the Bureau of Indian Affairs that the information collections contained in this regulation need not be reviewed by them under the Paperwork Reduction Act.

#### List of Subjects in 25 CFR Part 120

Indians-claims, Indians-judgment funds.

#### PART 120—[REMOVED]

Accordingly, Part 120 of Chapter 1 of Title 25 of the Code of Federal Regulations is hereby proposed to be removed.

Ross O. Swimmer,

*Assistant Secretary—Indian Affairs.*

[FR Doc. 86-22579 Filed 10-3-86; 8:45 am]

BILLING CODE 4310-02-M

## Office of Surface Mining Reclamation and Enforcement

### 30 CFR Part 917

#### Public Comment and Opportunity for Public Hearing on a Modification to the Kentucky Permanent Regulatory Program

**AGENCY:** Office of Surface Mining Reclamation and Enforcement (OSMRE), Interior.

**ACTION:** Proposed rule.

**SUMMARY:** OSMRE is announcing procedures for the public comment