urinary excretion on 3 or more consecutive days to establish that steady-state conditions are achieved.

* * * * *

(e) * * *

(3) Other methods based on valid scientific reasons should be used to determine the bioavailability or bioequivalence of a drug product having dose-dependent kinetics (nonlinear system).

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13. Section 320.29 is amended by revising the section heading and paragraph (a) to read as follows:

§ 320.29 Analytical methods for an vivo bioavailability or bioequivalence study.

(a) The analytical method used in an in vivo bioavailability or bioequivalence study to measure the concentration of the active drug ingredient or therapeutic moiety, or its metabolite(s), in body fluids or excretory products, or the method used to measure an acute pharmacological effect shall be demonstrated to be accurate and of sufficient sensitivity to measure, with appropriate precision, the actual concentration of the active drug ingredient or therapeutic moiety, or its metabolite(s), achieved in the body.

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14. Section 320.30 is amended by revising paragraph (c) to read as follows:

§ 320.30 Inquiries regarding bioavailability and bioequivalence requirements and review of protocols by the Food and Drug Administration.

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(c)(1) General inquiries relating to in vivo bioavailability requirements and methodology shall be submitted to the Food and Drug Administration, Center for Drug Evaluation and Research, Office of Clinical Pharmacology and Biopharmaceutics (HFD–850), 5600 Fishers Lane, Rockville, MD 20857.

(2) General inquiries relating to bioequivalence requirements and methodology shall be submitted to the Food and Drug Administration, Center for Drug Evaluation and Research, Division of Bioequivalence (HFD–650), 7500 Standish Pl., Rockville, MD 20855–2773.

§ 320.31 [Amended]

15. Section 320.31 *Applicability of requirements regarding an ''Investigational New Drug Application* is amended in the introductory text of paragraph (b) by adding after the word ''bioavailability'' the phrase ''or bioequivalence''.

Dated: November 5, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–30880 Filed 11–18–98; 8:45 am]

BILLING CODE 4160–01–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[WA 67–7142b; FRL–6188–2]

Approval and Promulgation of State Implementation Plans: Washington

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The EPA proposes to approve the State Implementation Plan (SIP) revision submitted by the State of Washington for the purpose of including a variance to a permit issued to the U.S. Army for the operation of three heat recovery incinerators located at Fort Lewis by local air pollution control agency, the Puget Sound Air Pollution Contol Agency (PSAPCA). In the Final Rules Section of this **Federal Register**, the EPA is approving the State's SIP submittal as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal amendment and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this action, no further activity is contemplated. If the EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. The EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time.

DATES: Written comments must be received in writing by December 21, 1998.

ADDRESSES: Written comments should be addressed to Montel Livingston, Environmental Protection Specialist (OAQ–107), Office of Air Quality, at the EPA Regional Office listed below. Copies of the documents relevant to this proposed rule are available for public inspection during normal business hours at the following locations. The interested persons wanting to examine these documents should make an appointment with the appropriate office at least 24 hours before the visiting day.

Environmental Protection Agency, Region 10, Office of Air Quality, 1200 6th Avenue, Seattle, WA 98101

The Washington State Department of Ecology, Air Quality Program, 300 Desmond Drive, Lacey, WA 98503

FOR FURTHER INFORMATION CONTACT: Mahbubul Islam, Office of Air Quality (OAQ–107), EPA, 1200 6th Avenue, Seattle, WA 98101, (206) 553–6985.

SUPPLEMENTARY INFORMATION: See the information provided in the Direct Final action which is located in the Rules Section of this **Federal Register**.

Dated: November 3, 1998.

Jane S. Moore,

Acting Regional Administrator, Region 10.

[FR Doc. 98–30848 Filed 11–18–98; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 216

[I.D. 110998A]

Regulations Governing the Taking and Importing of Marine Mammals; Threatened Fish and Wildlife; Cook Inlet Beluga Whales

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of intent to conduct a status review and request for information.

SUMMARY: NMFS is initiating a status review of the Cook Inlet beluga whale (*Delphinapterus leucas*) to determine whether designation under the Marine Mammal Protection Act (MMPA) or a change in listing classification under the Endangered Species Act (ESA) is warranted. NMFS intends to undertake the review in conjunction with the Alaska Beluga Whale Committee and the Cook Inlet Marine Mammal Council. The review will give consideration to the current status of Cook Inlet belugas, their distribution, abundance and trends, food habits, biohealth parameters, and reproductive parameters. The effects of the Native subsistence harvest, and the potential effects of other humanly induced impacts, as well as beluga natural mortality will also be examined. To ensure that the review is comprehensive, NMFS is requesting that interested parties submit pertinent information and comments regarding