SUMMARY: The Food and Drug Administration (FDA) is proposing to revise the regulation that sets forth the requirements for the carcinogenicity testing of compounds used in food-producing animals to allow the agency and sponsors greater flexibility when choosing the types of studies used for testing the carcinogenicity of compounds used in food-producing animals. FDA is proposing to revise the study requirements because FDA recognizes that advances in models used to assess the carcinogenicity of compounds have been made. The specific requirement that a sponsor must conduct oral, chronic, dose-response studies would be deleted under the proposed regulation. Sponsors would have more options for testing the carcinogenicity of compounds used in food-producing animals. This proposal implements the goals stated by the National Performance Review.

DATES: Written comments by September 3, 1996.

ADDRESSES: Written comments to the Dockets Managements Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Comments should be identified with the docket number found in brackets in the heading of this document. Received comments may be seen at the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Margaret A. Miller, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0205.

SUPPLEMENTARY INFORMATION: Section 500.80(b) (21 CFR 500.80(b)) sets forth the requirements for the carcinogenicity testing of compounds used in food-producing animals. Specifically, the regulation states, ''The bioassays that a sponsor conducts must be oral, chronic, dose-response studies and must be designed to assess carcinogenicity and to determine the quantitative aspects of any carcinogenic response.''

At the time that this regulation was written, a chronic study was considered to be the standard test for carcinogenicity. However, FDA recognizes that advances in models used to assess carcinogenicity have been made in recent years. For example, scientists now agree that, depending on the compound, a chronic study (as required under current regulations) may not measure the appropriate time point necessary to assess carcinogenicity. Study designs other than chronic may result in a better evaluation of the compound. Thus, FDA is proposing to remove the requirement for oral, chronic, dose-response studies to allow sponsors the option of using other study designs when assessing carcinogenicity of compounds used for food-producing animals.

This proposal is aligned with the goals stated by the National Performance Review. This proposed rule is a result of the President's directive to conduct a comprehensive review of all rules to identify those that are obsolete and burdensome and to delete or revise them. The agency has determined that this rule is in need of revision as described herein.

I. Environmental Impact

The agency has carefully considered the potential environmental effects of this action. FDA has determined that this action is categorically excluded under 21 CFR 25.24(a)(8). The procedure for testing the carcinogenicity of compounds used for food-producing animals is being revised. This revision will not cause an increase in the existing level of use or cause a change in the intended uses of the product or its substitutes. Therefore, neither an environmental assessment nor an environmental impact statement is required.

II. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the proposed rule would clarify FDA policy and simplify the process for submitting certain applications, the agency certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

III. Paperwork Reduction Act of 1995

The agency has determined that this proposed rule contains no collection of information requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35).

IV. Federalism

FDA has analyzed this proposal in accordance with the principles and criteria set forth in Executive Order 12612 and has determined that this proposal does not warrant the preparation of a Federalism Assessment.

V. Request for Comments

Interested persons may, on or before September 3, 1996 submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to 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 are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 500

Animal drugs, Animal feeds, Cancer, Labeling, Polychlorinated biphenyls (PCB's).

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 500 is amended as follows:

Part 500—General

1. The authority citation for 21 CFR part 500 continues to read as follows:

Authority: Secs. 201, 301, 402, 403, 409, 501, 502, 503, 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 351, 352, 353, 360b, 371).

§ 500.80 [Amended]

2. Section 500.80 *Scope of this subpart* is amended in paragraph (b) by removing the phrase ''must be oral, chronic, dose-response studies and.''

Dated: June 13, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–15725 Filed 6–19–96; 8:45 am]

BILLING CODE 4160–01–F

INTERNATIONAL BOUNDARY AND WATER COMMISSION

22 CFR Part 1102

United States and Mexico, United States Section, Freedom of Information Act: Uniform Fee Schedule and Administrative Guidelines

AGENCY: United States Section, International Boundary and Water Commission.

ACTION: Proposed rule.

SUMMARY: This proposed rule will revise the United States Section, International Boundary and Water Commission (IBWC) regulations that implement the Freedom of Information Act (FOIA) fee schedule. This revision pertains to the charge for recovery of the full, allowable direct costs of searching for and reviewing records requested under the FOIA and section 1102.4 of the IBWC rules, unless such fees are restricted or waived in accordance with section 1102.6. These fees are being revised to correspond to modifications of rates of pay approved by the U.S. Congress.

DATES: All comments received on or before July 22, 1996, will be considered before final action is taken on this proposed rule.

ADDRESSES: Please submit any written comments to the Freedom of Information Act Officer, International Boundary and Water Commission, United States Section, The Commons, Bldg. C, Suite 310, 4171 N. Mesa, El Paso, TX 79902–1441, telephone: (915) 534–6697.

FOR FURTHER INFORMATION CONTACT: Dell Driver, telephone (915) 534–6697.

SUPPLEMENTARY INFORMATION: The IBWC is modifying section 1102.4(a) of the rules which pertains to the charges for searching and reviewing records requested under the Freedom of Information Act (FOIA).

The FOIA requires Federal agencies to establish a schedule of fees for the processing of requests for agency records in accordance with fee guidance issued by the Office of Management and Budget (OMB). In 1987, OMB issued its Uniform Freedom of Information Act Fee Schedule and Guidelines. However, since the FOIA requires that each agency's fees be based upon its direct costs of providing FOIA services, OMB did not provide a unitary, government wide selection of fees.

List of Subjects in 22 CFR Part 1102

Freedom of information.

For the reasons set out in the preamble, part 1102.4(a)(1) of title 22 of the Code of Federal Regulations is proposed to be amended as follows:

PART 1102—FREEDOM OF INFORMATION ACT

1. The authority for this part continues to read as follows:

Authority: 5 U.S.C. 552 (Pub. L. 90–23, as amended by Pub. L. 93–502 and Pub. L. 99–570).

2. Section 1102.4 (a)(1) and (a)(2) are revised to read as follows:

§ 1102.4 Fees.

(a) The following shall be applicable with respect to services rendered to the public under this subpart:

(1) Fee Schedule.

(i) Searching for records, per hour or fraction thereof, per individual:

Professional	$23.71
Technical	$16.57
Clerical	$13.38

Includes the salary of the category of employee who actually performs the search computed at Step 5 of each grade level plus an additional 24% of that rate for personnel benefits. These fees will be periodically modified to correspond to changes in pay approved by Congress.

(ii) The cost for computer searches will be calculated based on the salary of the category of employee who actually performs the computer search, plus 24% of that rate to include personnel benefits, plus the direct costs of the central processing unit, input-output devices, and memory capacity of the actual computer configuration.

(iii) Reproduction fees:

Pages no larger than 8½×14 inches when reproduced by routine electrostatic copying: $0.10 per page.

Pages requiring reduction, enlargement, or other special services will be billed at direct cost to the Section. Reproduction by other than routine electrostatic copying will be billed at direct cost to the Section.

(iv) Certification of each record as a true copy—$1.00.

(v) Duplication of architectural photographs and drawings:

Blueprinting	$1.00 per sq. ft.
Vellum Reproducible from blueprints	$5.00 per sq. ft.

(vi) *Postage and handling.* Full costs will be recovered from the requestor if special mailing such as express mail is indicated. Otherwise, records will be sent by first-class certified mail, domestic addresses only, direct cost paid by the U.S. Section.

(2) Only requesters who are seeking documents for commercial use will be charged for time spent reviewing records to determine whether they are exempt from mandatory disclosure. The cost for review will be calculated based on the salary of the category of the employee who actually performed the review plus 24% of the rate to cover personal benefits. Charges will be assessed only for the initial review (i.e., review undertaken the first time in order to analyze the applicability of specific exemption(s) to a particular record or portion of record) and not review at the administrative appeal level of the exemption(s) already applied.

Dell Driver,

Freedom of Information Act Officer.

[FR Doc. 96–15344 Filed 6–19–96; 8:45 am]

BILLING CODE 7010–01–M

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

25 CFR Part 142

RIN 1076 AD66

Operation of U.S.M.S.''North Star'' Between Seattle, Washington, and Stations of the Bureau of Indian Affairs and Other Government Agencies, Alaska

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Proposed rule.

SUMMARY: The Bureau of Indian Affairs (BIA) is proposing to revise its regulations in Alaska Resupply Operation as mandated by Executive Order 12866 to streamline the regulatory process and enhance the planning and coordination of existing regulations.

DATES: Comments must be received on or before August 19, 1996.

ADDRESSES: Mail comments to Warren Heisler, Assistant Area Director, Juneau Area Office, Bureau of Indian Affairs, Department of the Interior, 709 West 9th Street, Juneau, Alaska 99802; OR, hand deliver them to the above address. Comments will be available for inspection at this address from 9:00 a.m. to 4:00 p.m., Monday through Friday beginning approximately two weeks after publication of this document in the Federal Register.

FOR FURTHER INFORMATION CONTACT: Warren Heisler, Assistant Area Director, Juneau Area Office, Bureau of Indian Affairs at telephone (907) 586–7177.

SUPPLEMENTARY INFORMATION:

Background

The U.S.M.S. North Star has been decommissioned. However, the need for a resupply operation in Alaska continues. The Juneau Area Office