

*Parties:* Georgia Ports Authority, Hapag-Lloyd A.G. (HL), Gulf Container Line, Compagnie Generale Maritime.

*Synopsis:* The Agreement amends the basic agreement (Agreement No. 224-200262) to provide a rate schedule for rail loading and unloading. It also provides a rate schedule, applicable only to HL, for stack utilization and computer service for customs releases.

By Order of the Federal Maritime Commission.

Joseph C. Polking,  
Secretary.

Dated: July 27, 1989.

[FR Doc. 17936 Filed 7-31-89; 8:45 am]

BILLING CODE 6730-01-M

### Agreement(s) Filed

The Federal Maritime Commission hereby gives notice that the following agreement(s) has been filed with the Commission pursuant to section 15 of the Shipping Act, 1916, and section 5 of the Shipping Act of 1984.

Interested parties may inspect and obtain a copy of each agreement at the Washington, DC Office of the Federal Maritime Commission, 1100 L Street, NW., Room 10325. Interested parties may submit protests or comments on each agreement to the Secretary, Federal Maritime Commission, Washington, DC 20573, within 10 days after the date of the Federal Register in which this notice appears. The requirements for comments and protests are found in § 560.7 and/or 572.603 of Title 46 of the Code of Federal Regulations. Interested persons should consult this section before communicating with the Commission regarding a pending agreement.

Any person filing a comment or protest with the Commission shall, at the same time, deliver a copy of that document to the person filing the agreement at the address shown below.

*Agreement No.:* 224-003813-012.

*Title:* Hawaii Terminal Agreement.

*Parties:* Department of Transportation of the State of Hawaii (Port), Matson Terminals, Inc. (MTI)

*Filing Party:* Edward Y. Hirata, Director of Transportation, State of Hawaii, Department of Transportation, 869 Punchbowl Street, Honolulu, Hawaii 96813

*Synopsis:* The Agreement amends the basic agreement providing for the Port's lease to MTI of certain terminal facilities at Honolulu, Hawaii. The purpose of the amendment is to (1) enlarge the area under lease by the addition of Easement K and L; (2) increase the annual ground rental proportionately; (3) substitute revised

exhibits; and (4) restate § 3.3(1)(i) to add the purpose, area and ground rental of various parcels and easements.

By Order of the Federal Maritime Commission.

Joseph C. Polking,  
Secretary.

Dated: July 27, 1989.

[FR Doc. 89-17937 Filed 7-31-89; 8:45 am]

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### FEDERAL TRADE COMMISSION

[Docket No. 8818]

#### The Firestone Tire and Rubber Company, Inc.

**AGENCY:** Federal Trade Commission.

**ACTION:** Notice of period for public comment on petition to reopen and modify the order.

**SUMMARY:** The Firestone Tire and Rubber Company, Inc., a corporate respondent in the order in Docket No. 8818, has petitioned the Federal Trade Commission to vacate or modify certain parts of a 1972 order against Firestone concerning the misrepresentation of automobile tires. This document announces the public comment period on the petition.

**DATE:** Deadline for filing comments in this matter is August 20, 1989.

**ADDRESS:** Comments should be sent to the Office of the Secretary, Federal Trade Commission, 6th Street and Pennsylvania Avenue, NW., Washington, DC 20580. Requests for copies of the request should be sent to the Public Reference Branch, Room 130.

**FOR FURTHER INFORMATION CONTACT:** Terrence J. Boyle, Attorney, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, Washington, DC 20580, (202) 326-3016.

**SUPPLEMENTARY INFORMATION:** The order against Firestone in Docket No. 8818 was published at 37 FR 22,977 on October 27, 1972. The petitioner, Firestone, is a tire manufacturer. The order prohibits Firestone from representing that any tire is safe under all conditions of use or free from defects, requiring Firestone to make certain disclosures when it makes any representations concerning tire safety, and requires Firestone to substantiate fully and completely all safety or performance of superior quality claims. The petition to modify was placed on the public record on July 21, 1989.

Donald S. Clark,

Secretary.

[FR Doc. 89-17902 Filed 7-31-89; 8:45 am]

BILLING CODE 6750-01-M

### GENERAL SERVICES ADMINISTRATION

#### Agency Information Collection Activities Under OMB Review

The GSA hereby gives notice under the Paperwork Reduction Act of 1980 that it is requesting the Office of Management and Budget (OMB) to approve a new information collection, titled Procurement Integrity. This requires offerors for a contract, modification or extension, in excess of \$100,000 to certify that neither the firm, nor its officers, employees, agents or consultants, during the conduct of a Federal agency procurement offered future employment opportunities or a gratuity to a Government Procurement official, or solicited proprietary or source selection information from any official of that agency.

**AGENCY:** Office of GSA Acquisition Policy and Regulations (V), GAS.

**ADDRESSES:** Send comments to Bruce McConnell, GSA Desk Officer, Room 3235, NEOB, Washington, DC, 20503, and to Mary L. Cunningham, GSA Clearance Officer, General Services Administration (CAIR), F Street at 18th, NW, Washington, DC 20405.

*Annual Reporting Burden:* Firms responding, 800; responses, 1 per year; average hours per response, .0834; burden hours, 66.7.

*For Further Information Contact:* Edward McAndrew, 202-566-1224.

*Copy of Proposal:* A copy of the proposal may be obtained from the Information Collection Management Branch (CAIR), Room 3014, GS Bldg., Washington, DC 20405, or by telephoning 202-535-7691.

Dated: July 21, 1989.

Emily C. Karam,

Director, Information Management Division (CAI).

[FR Doc. 89-17849 Filed 7-31-89; 8:45 am]

BILLING CODE 6820-61-M

### DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### National Institutes of Health

**National Cancer Institute; Opportunity for a Cooperative Research and Development Agreement (CRADA) for the Scientific and Commercial Development of Taxol as an Anticancer Agent**

**AGENCY:** National Institutes of Health, PHS, DHHS.

**ACTION:** Notice.

**SUMMARY:** The Department of Health and Human Services (DHHS) seeks a pharmaceutical company which can effectively pursue the clinical development of taxol for the treatment of cancer. The National Cancer Institute has established that this agent may be effective in treating several types of cancers including those of ovarian origin. The selected sponsor will be awarded a CRADA for the co-development of this agent.

**ADDRESS:** Questions about this opportunity may be addressed to Dale Shoemaker, Ph.D., Executive Secretary, Taxol Selection Committee, Division of Cancer Treatment, NCI, EPN, Room 718, Bethesda, Maryland 20892 (301) 496-7912, from whom further information including a summary copy of the preclinical and clinical data may be obtained.

**DATE:** In view of the important priority of developing new drugs for the treatment of cancer, this notice is active until September 15, 1989.

**SUPPLEMENTARY INFORMATION:** The Government is seeking a pharmaceutical company which, in accordance with the requirements of the regulations governing the transfer of Government-developed agents (37 CFR 404.8), can develop taxol to a marketable status to meet the needs of the public and with the best terms for the Government. Taxol is a novel chemically defined compound which has shown promising antitumor activity in several clinical trials. The drug has never been patented and classifies as an orphan agent. Isolation of the material is a long (2 years) process. The Division of Cancer Treatment (DCT), NCI, currently owns all of the harvested raw material and hence, all the taxol which will be in clinical trials for the next 2 years. The Cooperative Research and Development Agreement (CRADA) will allow a pharmaceutical company to provide resources in collaboration with the DCT, NCI, for the continuing preclinical and clinical development work in return for the exclusive rights to the source data from the pivotal Phase III clinical trials.

Specifically, taxol is a novel compound which is isolated from the bark of *Taxus brevifolia*, the Pacific or Western Yew, which is a very slow growing tree found only in the Pacific Northwest. Bark has only been collected from trees growing in the wild, and the stripping of bark results in the death of these trees. An alternative source has not been developed; a method of synthesis has not been established. Although it may be possible to obtain taxol from commercial propagation, this has not yet been attempted.

Demand for the drug has been increasing based on the promising antitumor activity that has been observed to date. During the Phase I evaluation of this agent, responses were seen in patients with non-small cell lung cancer, melanoma, head and neck carcinoma, gastric carcinoma, and ovarian carcinoma. Approximately a 30% objective response rate was observed in a recently completed Phase II trial in patients with relapsed or refractory ovarian cancer, a disease generally considered resistant to chemotherapy. Based on the increasing level of clinical interest, there is an urgent need to obtain greater quantities of taxol and to begin to develop this agent for potential commercial distribution. The Division of Cancer Treatment, NCI, is interested in establishing a CRADA with a pharmaceutical company to assist in the continuing development of Taxol. The government will provide all available expertise and information to date and will jointly pursue new trials as required giving the pharmaceutical company exclusive rights to the New Drug Application-directed clinical data from Phase III trials. The successful pharmaceutical company will provide the necessary financial and organizational support to complete further development of taxol to establish clinical efficacy and possible commercial status.

Sufficient bark (approximately 60,000 pounds) has been collected to provide taxol for a broad Phase II evaluation (which would permit definition of the tumor types in which this compound is active) and a randomized Phase III comparison against standard therapy in ovarian cancer. The extraction, isolation and purification of taxol from this collection is in various stages of completion. We have also initiated a procurement of an additional 60,000 pounds of the bark which may require approximately two years to obtain the pharmaceutical grade taxol for clinical use. Some financial support of these processes will be a condition of the CRADA.

The role of the Division of Cancer Treatment, NCI, includes the following:

1. The government has initiated a contract request for the collection of 60,000 pounds of *Taxus* bark. The successful pharmaceutical company will be allowed access to this resource.
2. The government will provide remaining crude extracts of the *Taxus* bark (approximately 25,000 pounds) for isolation and purification of taxol.
3. The government will provide information concerning the previous

procedures employed to extract and isolate taxol.

4. The government will provide information concerning pharmaceutical manufacturing and controls and including dosage form development data.

5. The government will allow the pharmaceutical company to review and cross-file the Division's IND; it is likely that the company would wish to undertake trials independently.

6. The government will make the Division's IND proprietary under such circumstances.

7. The government will continue the clinical development of this compound under its extramural clinical trials network, thus insuring the clinical evaluation of the compound at no additional cost to the pharmaceutical company.

The role of the successful pharmaceutical company under the CRADA will include the following:

1. Provide the necessary funds and resources to complete the collection of the 60,000 pounds of *Taxus* bark.
2. Provide the necessary funds or resources for the isolation of taxol from the available bark.
3. Provide plans to independently secure future continuing supplies of taxol to assure continued clinical development.
4. Provide funds for formulation of the clinical product and offer necessary supplies to the DCT, NCI, for continued clinical development of this compound. The present dosage form of taxol contains a cremophor vehicle system which may be undesirable for very large trials and commercial use. Therefore, it is suggested that some consideration for new product development is needed.

5. Provide plan and support for clinical development leading to FDA approval for marketing.

Criteria for choosing the pharmaceutical company include the following:

1. Experience in the development of natural products for clinical use.
2. Experience in preclinical and clinical drug development.
3. Experience and ability to produce, package, market and distribute pharmaceutical products in the United States and to provide the product at a reasonable price.
4. Experience in the monitoring, evaluation and interpretation of the data from investigational agent clinical studies under an IND.
5. A willingness to cooperate with the Public Health Service in the collection, evaluation, publication and maintaining

of data from clinical trials of investigational agents.

6. A willingness to cost share in the development of taxol as outlined above. This includes acquisition of raw material and isolation or synthesis of taxol in adequate amounts as needed for future clinical trials and marketing.

7. An agreement to be bound by the DHHS rules involving human and animal subjects.

8. The aggressiveness of the development plan, including the appropriateness of milestones and deadlines for preclinical and clinical development.

9. Provisions for equitable distribution of patent rights to any inventions. Generally the rights of ownership are retained by the organization which is the employer of the inventor, with (1) an irrevocable, nonexclusive, royalty-free license to the Government (when a company employee is the sole inventor) or (2) an exclusive or nonexclusive license to the company on terms that are appropriate (when the Government employee is the sole inventor).

Dated: July 24, 1989.

James B. Wyngaarden,

Director, National Institutes of Health.

[FR Doc. 89-17911 Filed 7-31-89; 8:45 am]

BILLING CODE 4140-01-M

## DEPARTMENT OF THE INTERIOR

### Office of the Secretary

#### National Environmental Policy Act; Proposed Implementing Procedures (516 DM 6, Appendix 8)

**AGENCY:** Department of the Interior.

**ACTION:** Notice of proposed additions to the Department of the Interior's Categorical Exclusions for the Office of Surface Mining Reclamation and Enforcement.

**SUMMARY:** This notice announces proposed additions to the categorical exclusions included in the Departmental Manual 516 DM 6, Appendix 8, that lists actions excluded from the National Environmental Policy Act (NEPA) procedures for the Office of Surface Mining Reclamation and Enforcement (OSMRE). The proposed categorical exclusions pertain to activities conducted under the Surface Mining Control and Reclamation Act (SMCRA).

**DATE:** Comments due August 31, 1989.

**ADDRESS:** Comments to John Farrell, Acting Director of Environmental Project Review, MS 4239, Department of the Interior, Washington, DC 20240.

#### FOR FURTHER INFORMATION CONTACT:

Mr. John Farrell, address above, telephone (202) 343-2116. For OSMRE, Catherine Roy, (202) 343-5143.

**SUPPLEMENTARY INFORMATION:** The proposed categorical exclusions would be added to the list of categorical exclusions in the Department of the Interior's Manual (516 DM 6, Appendix 8). They would exclude certain activities conducted under Title IV of SMCRA from further review for compliance with NEPA. Title IV sets out provisions for the reclamation of abandoned mines and authorizes the Secretary to provide grants to States for this purpose. The proposed exclusions are similar to Departmental categorical exclusion 1.3, which excludes actions such as routine financial transactions and transfers of funds.

The Department has previously reviewed the activities authorized under Title IV and excluded certain decisions relative to the approval of grants under the abandoned mine land (AML) program. The Department has now reviewed additional activities relating to the AML grants program and proposes to add three new categorical exclusions as subparagraphs 8.4.B(30), (31), and (32) to Appendix 8. The excluded activities would be limited to: (1) Administrative grants for the development or review of project proposals rather than to the actual operation or conduct of AML reclamation projects, (2) the transfer of AML funds to States and Tribes to be used in a special trust for future AML projects, and (3) the transfer of AML funds to be used as seed money for State-administered insurance for subsidence damage. These additional activities are categories of actions which do not individually or cumulatively have a significant effect on the human environment. If any of the exceptions to categorical exclusions listed in Appendix 2 to 516 DM 2 apply to individual actions within these proposed exclusions, however, an environmental document must be prepared.

Appendix 8 must be taken in conjunction with the Department's procedures (516 DM 1-6) and the Council on Environmental Quality regulations implementing the procedural provisions of NEPA (40 CFR 1500-1508). The Department's procedures were published in the *Federal Register* on April 29, 1980 (45 FR 27541) and revised on May 21, 1984 (49 FR 21437). Appendix 8 for OSMRE was published on January 23, 1981 (46 FR 7487).

*Proposed Categorical Exclusion 30: Administrative Grants for the Development of Project Proposals for*

*AML Grants.* The Secretary may award grants to States or Indian Tribes for activities to reclaim and restore land and water resources damaged by past coal mining, including abandoned surface mine areas, abandoned coal processing areas, sealing and filling abandoned deep mine entries and voids, planting of lands adversely affected by past coal mining to prevent erosion and control of water pollution created by coal mine drainage (section 401(c)(1) of SMCRA). The grants are awarded in two separate, independent stages.

First, OSMRE awards administrative grants to States or Indian tribes for the development of a construction grant application, or project proposal. Approval these grants in no way commits OSMRE to award a grant for the construction project. The primary work resulting from these "first-stage" grants is administrative in nature, as it involves the development of an AML grant proposal and has no effect on the human environment.

In the second stage, OSMRE awards grants for the actual construction project. The decision on which construction grants to award is based in part on the results of the analysis in a NEPA document prepared on the proposed project. This document examines the specific environment of the proposed reclamation project and identifies both short-term and long-term effects on the environment expected from the project. Impacts from activities such as closing and sealing a specific portal are examined for their potential effects on wildlife in the area, particularly threatened and endangered bats or rodent species, and mitigation plans are identified.

The proposed categorical exclusion includes only the decision to award grants for the purpose of developing a construction grant application. The decision to award a construction grant would be subject to the NEPA process.

*Proposed Categorical Exclusion 31: Use of AML funds to allow States or Tribes to set aside State share funds in a special trust fund for future AML projects.* The Secretary may allow States or Tribes with approved AML plans to retain up to 10 percent of their annual State-share allocation in a special interest bearing trust fund to be used after August 3, 1992, for AML activities. This action would not have any effect on the human environment because it merely transfers monies to a State fund and no projects are identified for use of the funds. In the event that the authority to collect AML fees is not extended past the 1992 date, the future