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Friday
July 2, 1982

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Environmental Protection Agency
Animal Drugs
Food and Drug Administration
Antitrust
Federal Trade Commission
Cotton
Agricultural Marketing Service
Fisheries
National Oceanic and Atmospheric Administration
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Selected Subjects

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Questions and requests for specific information may be directed to the telephone numbers listed under INFORMATION AND ASSISTANCE in the READER AIDS section of this issue.

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Agricultural Marketing Service

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Agricultural Stabilization and Conservation Service

Medical Devices
Food and Drug Administration

Quarantine
Animal and Plant Health Inspection Service

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Presidential Documents

Title 3—

The President

Proclamation 4950 of June 30, 1982

National NCO/Petty Officer Week, 1982

By the President of the United States of America

A Proclamation

Time has not altered the basic duties and responsibilities of the majority of our Armed Forces personnel since the very foundation of our country was laid in 1776. For more than two hundred years, the American men and women who have so proudly served—and are currently serving—as Noncommissioned Officers and Petty Officers have been regarded as the backbone of the Armed Forces of the United States.

We all should recognize the great sacrifices and significant contributions made to the Nation by our fellow citizens whose traditional role of service to the Nation as soldiers, sailors, airmen, marines, and coast guardsmen is older than the Nation itself. Their spirit and devotion to duty is evident in the long list of recipients of the Medal of Honor and other decorations of personal valor. They are the heart of our Armed Forces which sustain our freedom and way of life. The duties they perform in accomplishing their mission are a necessary and permanent part of this country's defense mechanism. Upon their shoulders lies the defense of our Nation.

By House Joint Resolution 518, the Congress has designated the week commencing with the fourth Monday in June 1982, as "National NCO/Petty Officer Week."

NOW, THEREFORE, I, RONALD REAGAN, President of the United States of America, do hereby proclaim the week commencing with the fourth Monday in June 1982 as "National NCO/Petty Officer Week." I call on all Americans, State and local officials and private organizations to join in honoring Noncommissioned Officers and Petty Officers who serve and have served our Nation's defense objectives and to observe this week with appropriate ceremonies and activities.

IN WITNESS WHEREOF, I have hereunto set my hand this 30th day of June in the year of our Lord nineteen hundred and eighty-two, and of the Independence of the United States of America the two hundred and sixth.

Ronald Reagan

[FR Doc. 82-18203
Filed 6-30-82; 4:26 pm]
Billing code 3195-01-M

Presidential Documents

Proclamation 4951 of June 30, 1982

National Children's Day, 1982

By the President of the United States of America

A Proclamation

As the inventors, artists, teachers, farmers, businessmen and women, decision-makers, and leaders of tomorrow, children are our most important resource.

But children need parental love and guidance to reach their fullest potential, and they function most successfully when parents define values, set goals, and provide stability for them.

As parents fulfill their responsibility to love, encourage, and guide their children, youngsters have the opportunity to develop the self-esteem and competence that equip them to make sound decisions when they become adults.

National Children's Day provides a time for us to recognize the value, vitality, and potential of our young people. It is a day to recommit ourselves to nurturing our youth and to helping them achieve a healthy and happy future. We must strive to encourage our children to take advantage of opportunities for positive educational experiences and training, for the manner in which our children grow and learn will dramatically affect how our Nation is able to meet its future challenges.

NOW, THEREFORE, I, RONALD REAGAN, President of the United States, in accordance with House Joint Resolution 191 (Public Law 97–29), do hereby proclaim August 8, 1982, as National Children's Day. I call upon the people of the United States to observe this day with appropriate activities in their homes and communities.

IN WITNESS WHEREOF, I have hereunto set my hand this 30th day of June in the year of our Lord nineteen hundred and eighty-two, and of the Independence of the United States of America the two hundred and sixth.

Ronald Reagan

[FR Doc. 82–18204
Filed 6–30–82; 4:27 pm]
Billing code 3195–01–M

Presidential Documents

Executive Order 12369 of June 30, 1982

President's Private Sector Survey on Cost Control in the Federal Government

By the authority vested in me as President by the Constitution and laws of the United States of America, and in order to establish, in accordance with the provisions of the Federal Advisory Committee Act, as amended (5 U.S.C. App. I), an advisory committee to study cost control in the Federal Government, it is hereby ordered as follows:

Section 1. *Establishment.* (a) There is established the Executive Committee of the President's Private Sector Survey on Cost Control in the Federal Government. The Committee shall be composed of not more than 150 members appointed by the President from among citizens in private life.

(b) The President shall designate a Chairman from among the members of the Committee.

Sec. 2. *Functions.* (a) The Committee shall conduct a private sector survey on cost control in the Federal Government and shall advise the President and the Secretary of Commerce, and other Executive agency heads with respect to improving management and reducing costs.

(b) The Committee shall conduct in-depth reviews of the operations of the Executive agencies as a basis for evaluating potential improvements in agency operations.

(c) In fulfilling its functions the Committee shall consider providing recommendations in the following areas:

(1) Opportunities for increased efficiency and reduced costs in the Federal Government that can be realized by Executive action or legislation;

(2) Areas where managerial accountability can be enhanced and administrative control can be improved;

(3) Opportunities for managerial improvements over both the short and long term;

(4) Specific areas where further study can be justified by potential savings; and

(5) Information and data relating to governmental expenditures, indebtedness, and personnel management.

Sec. 3. *Administration.* (a) The heads of Executive agencies shall, to the extent permitted by law, provide to the Secretary of Commerce, the Committee and its staff units such information, including that relating to the structure, organization, personnel and operations of the Executive agencies, as may be required for carrying out the purposes of this Order.

(b) Members of the Committee shall serve without compensation.

(c) A management office may provide overall administrative staff support to the Committee, guide the day-to-day operations of the Survey and provide liaison with the Executive Office of the President; separate unit staffs may be utilized to provide such staff support as is necessary to accomplish reviews of individual agencies.

(d) The Secretary of Commerce shall, to the extent permitted by law and subject to the availability of funds, provide the Committee with such informa-

tion, administrative services, facilities, staff and other support services it may require.

(e) The Committee is to be funded, staffed and equipped, to the extent practicable and permitted by law, by the private sector without cost to the Federal Government. To accomplish this objective, it is expected that the Secretary of Commerce will engage in a joint project, with a nonprofit organization, pursuant to Section 1 of Public Law 91–412 (15 U.S.C. 1525), for the purpose of providing staff support to the Committee as described in Section 3(c).

Sec. 4. *General Provisions.* (a) Notwithstanding the provisions of any other Executive order, the responsibilities of the President under the Federal Advisory Committee Act, as amended, except that of reporting annually to the Congress, which are applicable to the Committee established by this Order, shall be performed by the Secretary of Commerce in accordance with guidelines and procedures established by the Administrator of General Services.

(b) In accordance with the Federal Advisory Committee Act, as amended, the Committee shall terminate on December 31, 1982, unless sooner extended.

Ronald Reagan

THE WHITE HOUSE,
June 30, 1982.

[FR Doc. 82–18205
Filed 6–30–82; 4:28 pm]
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Rules and Regulations

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This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.
The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each month.

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 213

Excepted Service

AGENCY: Office of Personnel Management.

ACTION: Final rule; technical amendment.

SUMMARY: The Office of Personnel Management (OPM) is issuing a technical amendment to correct an administrative oversight in its regulations which inadvertently removed from Title 5 of the Code of Federal Regulations (5 CFR) certain excepted appointing authorities established by OPM under Schedule A, B, and C of the Excepted Service. The amendment to 5 CFR Part 213 which appeared in the **Federal Register** of April 3, 1981, (46 FR 20146–20148) was intended to remove only those appointing authorities granted to specific agencies under Schedule A, B, and C. However, the regulations also removed excepted appointing authorities available to the Entire Executive Civil Service under Schedule A and B. Provisions concerning publication of notices regarding the specific single-agency appointing authorities which were discussed in the Supplementary Information on April 3, 1981, were also omitted from the regulations. This amendment restores the authorities that are available for use by all agencies to Part 213 and adds provisions for publication of notices of specific single-agency authorities established or revoked. The amendment also restates the waiver of proposed rulemaking procedures and the 30-day delay in effectiveness in the case of establishment, amendment, or revocation of Schedule A, B, or C excepted appointing authorities specifically applicable to a single agency.

EFFECTIVE DATE: July 2, 1982.

FOR FURTHER INFORMATION CONTACT: William Bohling, 202–632–6000.

SUPPLEMENTARY INFORMATION: Excepted appointing authorities established solely for use by one specific agency do not meet the standard of general applicability prescribed by the Federal Register Act for regulations published in either the **Federal Register** or the Code of Federal Regulations. Frequent changes to these excepted appointing authorities make regulations published annually in 5 CFR out of date almost immediately. Therefore, final regulations published April 3, 1981, provided that excepted authorities approved by the Director of the Office of Personnel Management solely for use by a specific agency would be published only as notices in the **Federal Register** and would not be incorporated in 5 CFR. The Supplementary Information to those regulations stated that notice of authorities established and revoked would be published monthly and that a consolidated notice of all authorities, current as of June 30, would be published annually. These publication requirements were omitted from the April 3, 1981, regulations, but are reflected in the revised regulations.

A different situation exists with respect to excepted appointing authorities in Schedules A, B, and C which are available for use by all agencies. (These authorities appear under the headings "Entire Executive Civil Service" in Schedules A, B, and C and "Temporary Organizations" in Schedule A.) Because these authorities have general applicability, that is, they are available for use by all agencies, their publication as regulations in the **Federal Register** and their incorporation in 5 CFR are appropriate. And, because establishment, revocation, or amendment of these authorities is usually proposed by OPM or by only one agency and does not involve direct participation by all affected agencies, the comment and delay provisions of 5 U.S.C. 553 are also appropriate. For these reasons, the final regulations of April 3, 1981, spoke of "individual appointing authorities" and did not remove the general appointing authority in Schedule C § 213.3302 from 5 CFR. The regulations did, however, remove Schedule A §§ 213.3102 and 213.3199 and Schedule B § 213.3202. The revised regulations correct this omission. Establishment, revocation, and amendment of any authority in these generally applicable sections will continue to be accomplished through rulemaking procedures and will be published in 5 CFR.

The revised regulations also reflect a change in the numbering system designating Schedule C excepted appointing authorities. The regulations will now permit OPM to assign each such authority either a number between §§ 213.3302 and 213.3399 or other appropriate number, because numbers used in the automated control system for single-agency Schedule C authorities are more readily recognizable to agencies.

Provisions of the Administrative Procedure Act, codified in section 553 of title 5, United States Code, require that notice of proposed rulemaking be published and comments solicited for any change to regulations, and further require that final regulations be published 30 days before they may become effective. In issuing the final regulations of April 3, 1981, which removed agency excepted appointing authorities from 5 CFR, the Director found that neither the comment period nor the delay in effectiveness serves any practical purpose in the case of specific single-agency appointing authorities. The reasons for this determination were discussed both in those final regulations and in proposed regulations issued December 23, 1980, (45 FR 84808). However, as these discussions did not specifically cite the legal authority for the determination, the waiver is restated here to clarify how actions regarding single-agency authorities meet the criteria for waiver contained in 5 U.S.C.

Pursuant to sections 553(b)(B) and 553(d)(3) of title 5, United States Code, the Director finds that good cause exists to waive the general notice of proposed rulemaking and to make this amendment effective in less than 30 days. The regulation is being made effective immediately because it does not change the substance of the regulations issued April 3, 1981, but merely updates and clarifies these regulations and corrects technical omissions. The Director further finds that good cause exists to waive the general notice of proposed rulemaking and the 30-day delay in effectiveness for all regulations which establish, amend,

or revoke Schedule A, B, or C excepted appointing authorities applicable to a single agency. Because all such regulations are negotiated with, and usually requested by, the affected agency, the required comments are obtained and adequate time to implement the regulation is provided during the negotiation process.

EO 12291, Federal Regulation

OPM has determined that this is not a major rule as defined under Section 1(b) of E.O. 12291, Federal Regulation.

Regulatory Flexibility Act

I certify that this regulation will not have a significant economic impact on a substantial number of small entities because it affects only the procedures used to publicize excepted service appointing authorities. It does not affect the nature or number of Federal jobs filled in the excepted service.

List of Subjects in 5 CFR Part 213

Government employees.

Office of Personnel Management.

Donald J. Devine,

Director.

PART 213—EXCEPTED SERVICE

Accordingly, the U.S. Office of Personnel Management is correcting 5 CFR Part 213 by adding §§ 213.103, 213.3102, 213.3199, and 213.3202, and by revising § 213.3301 to read as follows:

§ 213.103 Publication of excepted appointing authorities in Schedules A, B, and C.

(a) Schedule A, B, and C appointing authorities available for use by all agencies shall be published as regulations in the **Federal Register** and the Code of Federal Regulations. These authorities shall also be published in the Federal Personnel Manual.

(b) Establishment and revocation of Schedule A, B, and C appointing authorities applicable to a single agency shall be published monthly in the Notices section of the **Federal Register.**

(c) A consolidated listing of all Schedule A, B, and C authorities current as of June 30 of each year, with assigned authority numbers, shall be published annually as a notice in the **Federal Register.**

* * * * *

§ 213.3102 Entire executive civil service.

(a) Positions of Chaplain and Chaplain's Assistant.

(b) Cooks, except at fixed locations such as hospitals, quarantine stations, and penal institutions.

(c) Positions to which appointments are made by the President without confirmation by the Senate.

(d) Attorneys.

(e) Law clerk trainee positions. Appointments under this paragraph shall be confined to graduates of recognized law schools or persons having equivalent experience and shall be for periods not to exceed 14 months pending admission to the bar. No person shall be given more than one appointment under this paragraph. However, an appointment which was initially made for less than 14 months may be extended for not to exceed 14 months in total duration.

(f) Chinese, Japanese, and Hindu interpreters.

(g) Any nontemporary position the duties of which are part-time or intermittent in which the appointee will receive compensation during his/her service year that aggregates not more than 40 percent of the annual salary rate for the first step of grade GS–3. This limitation on compensation includes any premium pay such as for overtime, night, Sunday, or holiday work. It does not, however, include any mandatory within-grade salary increases to which the employee becomes entitled subsequent to appointment under this authority. Appointments under this authority may not be for temporary project employment.

(h) Positions in Federal mental institutions when filled by persons who have been patients of such institutions and have been discharged and are certified by an appropriate medical authority thereof as recovered sufficiently to be regularly employed but it is believed desirable and in the interest of the persons and the institution that they be employed at the institution.

(i) Subject to prior approval of OPM, positions requiring temporary, part-time, or intermittent employment in wage board type occupations (i.e., positions excluded from Classification Act coverage by section 202(7) of the Act) on construction or repair work, where the activity is carried on in localities where examination coverage for the positions has not been provided and where because of employment conditions there is a shortage of available candidates for the positions. Appointments under this paragraph shall not extend beyond 1 year and the employment thereunder shall not exceed 180 working days a year. Seasonal employments of a recurring nature are not authorized under this paragraph.

(j) [Reserved]

(k) Positions without compensation provided appointments thereto meet the requirements of applicable laws relating to compensation.

(l) Positions requiring the temporary or intermittent employment of professional, scientific, or technical experts for consultation purposes.

(m) Nonsupervisory positions of custodial laborer (levels 1, 2, and 3) and general laborer (levels 2 and 3) in field establishments outside central office and regional office cities of OPM where examination coverage has not been provided for the positions, as follows:

(1) For temporary, intermittent, or seasonal employment (exclusive of positions covered by paragraph (l) of this section) not to exceed 180 working days a year in the Departments of Agriculture, Commerce, Interior, and Energy, in the Federal Aviation Administration, and in the International Boundary and Water Commission: or

(2) When it is specifically held by OPM that this authority is applicable for employment in localities that are isolated with respect to labor supply and where there is a shortage of available candidates for the positions.

(n) Any local physician, surgeon, or dentist employed under contract or on a part-time or fee basis.

(o) Positions of a scientific, professional, or analytical nature when filled by bona fide members of the faculty of an accredited college or university who have special qualifications for the positions to which appointed. Employment under this provision shall not exceed 130 working days a year.

(p) Positions of a scientific, professional or analytical nature when filled by bona fide graduate students at accredited colleges or universities provided that the work performed for the agency is to be used by the student as a basis for completing certain academic requirements toward a graduate degree. Appointments under this authority may not exceed 1 year, but may be extended for additional period(s) not to exceed 1 year as long as the conditions for appointment continue to be met. The appointment of any individual under this authority shall terminate upon the individual's completion of requirements for the graduate degree.

(q) Positions at grade GS–7 and below when appointees are to assist scientific, professional, or technical employees. Persons employed under this provision shall be: (1) Bona fide high school science or mathematics teachers or (2) bona fide students at high schools or accredited colleges or universities who are pursuing courses related to the field in which employed. The appointment of

any individual under this authority shall terminate upon the individual's ceasing to be enrolled in a qualifying educational program or to be employed as a teacher. No person shall be employed under this provision in (i) positions of a routine clerical type or (ii) in excess of 1040 working hours a year; except that the 1040 working-hours-a-year limitation shall not apply to positions at grade GS–4 and below which are established in connection with associate degree cooperative education programs. Students enrolled in bachelor's degree cooperative education programs as defined in § 213.3202(a) shall not be employed under this provision. Appointments under this authority may be made only to positions for which qualification standards established under Part 302 of this chapter are consistent with the education and experience standards established for comparable positions in the competitive service. Appointments under this authority may not be used to extend the service limits contained in any other appointing authority.

(r)–(s) [Reserved]

(t) Positions when filled by mentally retarded persons in accordance with written agreements executed between an agency and the OPM. Provisions to be included in such agreements are specified in the Federal Personnel Manual. Upon completion of 2 years of satisfactory service under this authority, the employee may qualify for conversion to competitive status under the provisions of Executive Order 12125 and implementing regulations issued by the Office.

(u) Positions when filled by severely physically handicapped persons who: (1) Under a temporary appointment have demonstrated their ability to perform the duties satisfactorily; or (2) have been certified by counselors of State vocational rehabilitation agencies or the Veterans Administration as likely to succeed in the performance of the duties. Upon completion of 2 years of satisfactory service under this authority, the employee may qualify for conversion to competitive status under the provisions of Executive Order 12125 and implementing regulations issued by the Office.

(v) Between May 13 and September 30 only, temporary Summer Aid positions the duties of which involve work of a routine nature not regularly covered under the General Schedule requiring no specific knowledge or skills, when filled by youths, either (1) appointed under economic needs standards prescribed by the Office of Personnel Management or (2) who are mentally retarded or severely physically handicapped. Youths may not be appointed unless they have reached their 16th birthday. This paragraph shall apply only to positions for which pay is fixed at the highest Federal minimum wage rate established by the Fair Labor Standards Act of 1938, as amended.

(w) Part-time or intermittent positions the duties of which involve routine work up to and including the GS–4 level of difficulty or equivalent under the Federal Wage System, when filled by bona fide students appointed under the Stay-in-School Program. Students may be appointed if they need the earnings from this employment to continue in school or if they are mentally retarded or severely physically handicapped, provided that the following conditions are met:

(1) Appointees are enrolled in or accepted for enrollment as a resident student in a secondary school (or other appropriate school for mentally retarded students) or an institution of higher learning not above the baccalaureate level, accredited by a recognized accrediting body;

(2) Employment does not exceed 20 hours in any calendar week except that students may work full-time whenever their school is officially closed and during any school vacation period;

(3) While employed, appointees continue to maintain an acceptable school standing, although they need not attend school during the summer;

(4) Appointees meet the economic criteria prescribed by the Office of Personnel Management, except that this requirement does not apply to mentally retarded or severely physically handicapped students; and

(5) Salaries are fixed by the agency head at a level commensurate with the duties assigned and the expected level of performance.

Appointments under this authority may not extend beyond 1 year. However, such appointments may be made for additional periods of not to exceed 1 year, each, if the conditions for initial appointment are still met. Student may not be appointed under this authority unless they have reached their 16th birthday. No new appointments may be made between May 13 and August 31, inclusive.

(x) Positions for which a local recruiting shortage exists when filled by inmates of Federal, District of Columbia and State (including the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Trust Territory of the Pacific Islands) penal and correctional institutions under work-release programs authorized by the Prisoner Rehabilitation Act of 1965, the District of Columbia Work Release Act, or under work-release programs authorized by the States. Initial appointments under the authority may not exceed 1 year. An initial appointment may be extended for one or more periods not to exceed 1 additional year each upon a finding that the inmate is still in a work-release status and that a local recruiting shortage still exists. No person may serve under this authority longer than 1-year beyond the date of that person's release from custody.

(y) Positions at grade GS–2 and below for summer employment as defined in § 213.3101(d), of assistants to scientific, professional, and technical employees, when filled by finalists in national science contests.

(z) Not to exceed 30 positions of assistants to top-level Federal officials when filled by persons designated by the President as White House Fellows.

(aa) Scientific and professional research associate positions at GS–11 and above when filled on a temporary basis by persons having a doctoral degree in an appropriate field of study for research activities of mutual interest to appointees and their agencies. Appointments are limited to persons referred by the National Research Council under its post-doctoral research associate program and may be made initially for 1 year only. An agency may extend an appointment made under this authority for up to 1 additional year when the program committee at the laboratory concerned determines that extension will benefit both the associate and the laboratory.

(bb) Positions when filled by aliens in the absence of qualified citizens. Appointments under this authority are subject to prior approval of the Office except when the authority is specifically included in a delegated examining agreement with the Office.

(cc) Positions at GS–15 and below when filled by persons identified as Interchange Executives by the President's Commission on Personnel Interchange. Appointments made under this authority may not extend beyond 2 years.

(dd)–(ee) [Reserved]

(ff) Not to exceed 24 positions when filled in accordance with an agreement between OPM and the Department of Justice by persons in programs administered by the Attorney General of the United States under Pub. L. 91–452 and related statutes. A person appointed under this authority may continue to be employed under it after he ceases to be in a qualifying program only as long as

he remains in the same agency without a break in service.

(gg) [Reserved]

(hh) Positions as needed not in excess of GS–13, whose incumbents will implement the Young Adult Conservation Corps program and are to be paid out of funds allocated under title VIII of the Comprehensive Employment and Training Act of 1973, as amended, or other appropriated funds receiving direct benefits. Employment under this authority is not to exceed September 30, 1982.

(ii) Positions of Presidential Intern, GS–9 and 11, in the Presidential Management Intern program. Initial appointments must be made at the GS–9 level. No one may serve under this authority for more than 2 years. Upon completion of 2 years of satisfactory service under this authority, the employee may qualify for conversion to competitive appointment under the provisions of Executive Order 12008, in accordance with requirements published in the Federal Personnel Manual. Recommendation for conversion may be submitted within 90 days before completion of the service requirement, and conversion will be effective on the date the service requirement is met. Except for the requirement concerning competitive selection from a register, appointments under this paragraph are subject to all the requirements and conditions governing career-conditional appointment, including investigation by OPM to establish an appointee's qualifications and suitability.

(jj) Legal intern positions. Appointments under this paragraph shall be confined to bona fide students at recognized law schools who are candidates for J.D. or LL.B. degrees. Appointments under this authority may not exceed 1 year, but may be extended for additional period(s) not to exceed 1 year as long as the conditions for appointment continue to be met. The appointment of any individual under this authority shall terminate upon the individual's graduation from law school.

(kk) [Reserved]

(ll) Positions as needed of readers for blind employees, interpreters for deaf employees and personal assistants for handicapped employees, filled on a full time, part-time, or intermittent basis.

§ 213.3199 Temporary organizations.

(a) Positions at GS–15 and below on the staffs of temporary boards and commissions which are established by law or Executive order for specified periods not to exceed 4 years to perform specific projects. A temporary board or commission originally established for less than 4 years and subsequently extended may continue to fill its staff positions under this authority as long as its total life, including extension(s), does not exceed 4 years. No board or commission may use this authority for more than 4 years to make appointments and position changes unless prior approval of the Office is obtained.

(b) Positions at GS–15 and below on the staffs of temporary organizations established within continuing agencies when all of the following conditions are met:

(1) The temporary organization is established by an authority outside the agency, usually by law or Executive order;

(2) The temporary organization is established for an initial period of 4 years or less and, if subsequently extended, its total life including extension(s) will not exceed 4 years;

(3) The work to be performed by the temporary organization is outside the agency's continuing responsibilities; and

(4) The positions filled under this authority are those for which other staffing resources or authorities are not available within the agency.

An agency may use this authority to fill positions in organizations which do not meet all of the above conditions or to make appointments and position changes in a single organization during a period longer than 4 years only with prior approval of the Office.

* * * * *

§ 213.3202 Entire executive civil service.

The provisions established under paragraphs (a) through (i) of this section are authorized under provisions of E.O. 12015 and support career-related work-study programs. OPM's requirements relating to appointment under paragraphs (a) through (i) will be published in the Federal Personnel Manual. Further, appointments under paragraphs (a) through (i) are subject to all the requirements and conditions governing career or career-conditional appointments, including investigation by OPM to establish an appointee's qualifications and suitability. Appointments of participants may be converted to career or career-conditional at any time within a 120-day period after satisfactory completion of a career-related work-study program.

(a) Student positions established in connection with a bachelor's degree cooperative education program which provide for a formally arranged schedule of attendance at an institution of higher learning combined with at least 26 weeks, or 1040 hours, of study-related work in a Federal agency. The periods of work and study together must satisfy requirements for a bachelor's degree and must provide the experience necessary for a career or career-conditional appointment to administrative, professional or technical positions in the Federal career service upon the student's graduation.

(b) Student positions established in support of cooperative education programs for graduate students which provide for scheduled periods of attendance at a graduate school combined with at least 16 weeks or 640 hours of study-related work in a Federal agency. The periods of work and study must satisfy requirements for the graduate degree and provide experience necessary for career or career-conditional appointment in the Federal career service upon the student's graduation.

(c) Student positions established in connection with associate degree cooperative education programs which provide for formally arranged schedules of attendance at a recognized 2-year educational institution combined with at least 26 weeks or 1040 hours of study-related work in a Federal agency. The periods of work and study together must satisfy the requirements for graduation and must provide the experience necessary for career or career-conditional appointment in selected occupations in the Federal career service upon the student's graduation.

(d) Student positions established in connection with the Harry S Truman Foundation Scholarship Program under the provisions of Pub. L. 93–842 to permit scheduled periods of attendance at institutions of higher education combined with at least 26 weeks or 1040 hours of study-related work in a Federal agency. The periods of work and study must satisfy requirements of programs established by agreement between the Harry S Truman Scholarship Foundation and the employing agency and provide the experience necessary for career or career-conditional appointment in the Federal career service upon the student's graduation.

(e) Positions at shipyards, air rework facilities and other major industrial activities in the Department of the Navy which prepare students at the high school level, upon satisfactory completion of a cooperative education program of at least 1,040 hours for employment in preapprentice positions or in helper positions at the WG–5 level as pipefitters, marine machinist, inside machinist, welder, sheet metal mechanic, and such other occupations where the journeyman level is WG–9 or above as the Associate Director, Staffing Group, shall have approved,

provided that: (1) Not more than 25 percent of the positions in covered occupations will be filled annually at any single installation through this conversion authority, and (2) the maximum time during which any student will be employed in the program is 18 months, and (3) except for conditions specified in this authority, students will be subject to instructions governing all other high school vocational education students in cooperative education programs, and (4) any student who completes a program without a diploma must have an authenticated certificate from the school indicating satisfactory completion in his/her personnel folder.

(f) Positions under the Federal Junior Fellowship Program, a career-related work-study program covered under the provisions of E.O. 12015.

(g) Positions with the Social Security Administration, Department of Health and Human Services, in a 2-year pilot, career-related work-study program under the provisions of E.O. 12015 for students employed under the Stay-in-School Program. Under this program, the number of annual conversions to competitive service entry level clerk-typist, clerk-stenographer, other general clerical positions, and technician positions related to computer science and the graphic arts are limited to not more than 10 percent of the positions filled in these occupations by the agency annually.

(h)-(i) [Reserved]

(j) Special executive development positions established in connection with Senior Executive Service candidate development programs which have been approved by OPM. A Federal agency may make new appointments under this authority for any period of employment not exceeding 3 years for one individual.

(k) Positions at grades GS–15 and below when filled by individuals who: (1) are placed at a severe disadvantage in obtaining employment because of a psychiatric disability evidenced by hospitalization or outpatient treatment and have had a significant period of substantially disrupted employment because of the disbility; and (2) are certified to a specific position by a State vocational rehabilitation counselor or a Veterans Administration counseling psychologist (or psychiatrist) who indicates that they meet the severe disadvantage criteria stated above, that they are capable of functioning in the positions to which they will be appointed, and that any residual disability is not job related. Employment of any individual under this authority may not exceed 2 years following each significant period of mental illness.

* * * * *

§ 213.3301 Positions of a confidential or policy-determining character.

Upon specific authorization by OPM, or under the terms of an agreement with OPM, agencies may make appointements under this section to positions in grades GS–15 and below which are policy-determining or which involve a close and confidential working relationship with the head of an agency or other key appointed officials. Positions filled under the authority are excepted from the competitive service and constitute Schedule C. Each position authorized under this section will be assigned a number from 213.3302 to 213.3399, or other appropriate number, to be used by the appointing agency in recording appointments made under that authorization.

* * * * *

(5 U.S.C. 3301, 3302; EO 10577, 3 CFR 1954–1958 Comp., p. 218)

[FR Doc. 82–18028 Filed 7–1–82; 8:45 am]
BILLING CODE 6325–01–M

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5 CFR Parts 315 and 316

Noncompetitive Appointment of Certain Former Overseas Employees

AGENCY: Office of Personnel Management.

ACTION: Interim regulations with comments invited for final rulemaking.

SUMMARY: These interim regulations implement Executive Order 12362, Overseas Employment, which permits noncompetitive appointment of certain former overseas employees to competitive civil service positions in the United States. The interim regulations define eligibility for appointment under this order and prescribe the conditions under which eligibles may be appointed.

DATE: Effective Date: July 2, 1982, and until final regulations are issued. Comment Date: Written comments will be considered if received no later than September 30, 1982.

ADDRESS: Send or deliver written comments to Assistant Director for Policy Analysis and Development, Staffing Group, Office of Personnel Management, 1900 E Street, NW., Room 6526, Washington, D.C. 20415.

FOR FURTHER INFORMATION CONTACT: Ed McHugh, (202) 632–6817.

SUPPLEMENTARY INFORMATION: On May 12, 1982, the President issued Executive Order 12362 on overseas employment. The Order allows spouses and certain other dependents of military personnel and Federal civilian employees who work in local hire jobs at U.S. military bases and embassies overseas to qualify for direct appointments in the competitive civil service when they return to the United States.

This Executive Order is designed to overcome the growing reluctance of U.S. Government employees and military personnel to accept overseas assignments because of the lack of career employment opportunities for their spouses. A July, 1980 survey of overseas Federal agencies and employees surfaced this problem as a matter of great concern within the foreign affairs and military communities. During congressional consideration of the Foreign Service Act of 1980, the Office of Personnel Management was asked to review policies affecting federally-employed spouses and dependents of overseas U.S. Government military and civilian personnel in order to provide them with an equitable opportunity to earn career status.

Employment opportunities for military and civilian dependents overseas are generally confined to embassies or military bases, because most foreign governments restrict private sector employment to local citizens. Positions available to military and civilian dependents within U.S. activities are usually non-permanent, low-grade jobs which though similar to Stateside career positions in terms of job qualification and classification requirements, do not provide civil service status. Thus dependents who are rotated back to the United States after working for several years in overseas positions, have been unable to use their overseas service to obtain a career civil service appointment. There would be no need for direct appointment eligibility if more overseas positions were filled through career civil service appointments, but for a variety of reasons this is not possible. Many of the dependents serve in "local national" jobs which under treaty would normally be filled by residents of the host country, but are temporarily given back to the United States specifically for the employment of dependents. These jobs would probably be lost to the U.S. if an attempt were made to fill them under career appointments. Use of career appointments for filling local hire positions in the overseas area would also necessitate an expansion of personnel staff to deal with the more complex examining system required and could increase costs for various relocation and cost of living allowances

not now provided to non-career employees.

The Executive Order provides that eligible dependents who accumulate 24 months of service in a local hire overseas position(s) after January 1, 1980, and meet certain other requirements, can receive direct civil service appointments to positions for which they qualify in the United States.

Because of the retroactive feature of the Order providing eligibility to former overseas employees who accumulated 24 months of service after January 1, 1980, the Director of the Office of Personnel Management finds that, pursuant to section 553 of title 5 of the United States Code, good cause exists to waive the general notice of proposed rulemaking and to make this amendment effective in less than 30 days. This will enable eligibles to be appointed immediately and will avoid hardship which would otherwise occur.

E.O. 12291 Federal Regulation

OPM has determined that this is not a major rule as defined under Section 1(b) of E.O. 12291, Federal Regulation.

Regulatory Flexibility Act

I certify that this regulation will not have a significant economic impact on a substantial number of small entities because it only affects Federal employees.

List of Subjects in 5 CFR Parts 315 and 316

Government employees.

U.S. Office of Personnel Management

Donald J. Devine,

Director.

Accordingly, the Office of Personnel Management is amending Parts 315 and 316 of Title 5, Code of Federal Regulations, as follows:

PART 315—CAREER AND CAREER-CONDITIONAL EMPLOYMENT

1. In subpart F, § 315.608 is added to read as follows:

§ 315.608 Noncompetitive appointment of certain former overseas employees.

(a) An agency in the executive branch may appoint noncompetitively to a competitive service position within the United States a United States citizen who:

(1) Accumulated 24 months of overseas service in an appropriated fund position(s) under a local hire appointment(s) after January 1, 1980, within a ten-year period from the date of initial appointment;

(2) Received a satisfactory or better performance rating for such overseas service;

(3) Is currently a family member of a civilian employee or of a member of a uniformed service (the civilian or uniformed sponsor) who was officially assigned to the overseas area, and was in this status while serving in the overseas position(s);

(4) Accompanied the civilian or uniformed sponsor on official assignment to the overseas post of duty while serving in the overseas position(s);

(5) Exercises eligibility for noncompetitive appointment within two years of returning to the United States from the overseas tour of duty during which he or she acquired eligibility; and

(6) Meets all qualification requirements for the position in the United States for which he or she is applying.

(b) *Definitions*

"Accompanied the civilian or uniformed sponsor on official assignment to an overseas post of duty" means a family member physically residing with a member of a uniformed service or Federal civilian employee officially assigned to the overseas area while serving in the overseas position or positions.

"Family member" means spouses and unmarried children (under 23 years of age) of a member of a uniformed service or Federal civilian employee officially assigned to the overseas area.

"Federal civilian employee" means employees of the executive, judicial, and legislative branches of the Government of the United States who are officially assigned to the overseas area and serve in appropriated fund positions.

"Local hire" appointments are overseas limited appointments, excepted appointments under Schedule A § 213.3106(b)(6), an "American Family Member" or "Part-time-Intermittent-Temporary" appointment in U.S. diplomatic establishments, or any other nonpermanent appointment in the competitive or excepted service, so designated by the Office of Personnel Management in the Federal Personnel Manual, which is made from applicants residing in the overseas area.

"Member of a uniformed service" means personnel of the Armed Forces (including the Coast Guard), the commissioned corps of the Public Health Service, and the commissioned corps of the National Oceanic and Atmospheric Administration officially assigned to the overseas area.

"Overseas area" means duty locations outside the 50 States of the United States, the District of Columbia, Guam, Puerto Rico and the Virgin Islands.

"United States" means the 50 States, the District of Columbia, Guam, Puerto Rico and the Virgin Islands.

(c) *Conditions* (1) OPM shall publish in the Federal Personnel Manual, uniform local hire procedures for assuring merit selection of eligible overseas employees as well as procedures for assuring that eligible employees have fully satisfactory or better performance ratings for their overseas service.

(2) Any law, Executive order or regulation that disqualifies an applicant for appointment also disqualifies an applicant for appointment under this section.

(d) *Tenure of Appointment* A person appointed under this section becomes a career-conditional employee.

(e) *Acquisition of Competitive Status* A person appointed under this section acquires competitive status automatically upon completion of probation.

* * * * *

PART 316—TEMPORARY AND TERM EMPLOYMENT

2. In Subpart C, § 316.302(c)(3) is revised to read as follows:

§ 316.302 Selection of term employees.

(c) * * *

(3) A person eligible for career or career-conditional appointment under §§ 315.601, 315.605, 315.606 or § 315.608 of this chapter;

* * * * *

3. In Subpart D, § 316.402(b)(2) is revised to read as follows:

§ 316.402 Authorities for temporary appointments.

(b) * * *

(2) A person eligible for career or career-conditional appointment under §§ 315.601, 315.605, 315.606, 315.607 or § 315.608 of this chapter;

* * * * *

(E.O. 12362)

[FR Doc. 82-18070 Filed 7-1-82; 8:45 am]

BILLING CODE 6325-01-M

MERIT SYSTEMS PROTECTION BOARD

5 CFR Part 1201

Practices and Procedures; Interim Rule

AGENCY: Merit Systems Protection Board.

ACTION: Interim regulation; request for comment.

SUMMARY: This regulation amends the procedures of the Merit Systems Protection Board with respect to discovery and subpenas. This action provides a simplified procedure for discovery as an aid to parties in preparing their cases for hearing.

DATES: Effective July 2, 1982. Comments should be submitted in writing on or before August 2, 1982.

ADDRESS: Comments should be submitted in writing and addressed to Robert E. Taylor, Secretary, Merit Systems Protection Board, c/o Legal Publications Division, 5205 Leesburg Pike, Suite 1404, Falls Church, VA 22041.

FOR FURTHER INFORMATION CONTACT: Charles J. Stanislav, (202) 653–8900.

SUPPLEMENTARY INFORMATION: This amendment makes it clear that parties are expected to cooperate with each other voluntarily to produce relevant documents and to make witnesses available without the need to resort to orders or subpenas. The amendment also establishes a time frame for discovery.

Subpart B—Hearing Procedures for Appellate Cases.

Discovery

§ 1201.71. Statement of purpose.

This paragraph has been revised to more clearly state the purpose of discovery and to make clear that the parties are expected to proceed without Board intervention.

§ 1201.72. Explanation and scope.

Paragraph (a) has been revised to distinguish discovery from the hearing and to make clear that relevant information not otherwise provided may be obtained from another person and/or party.

Paragraph (b) has been revised to clarify the scope of discovery by requiring that the information sought must reasonably appear to lead to admissible evidence.

Paragraph (c) has been added to identify acceptable discovery methods.

§ 1201.73. Procedures governing discovery.

This section has been retitled and has been completely revised.

Paragraph (a) sets forth the procedures for obtaining discovery from a party.

Paragraph (b) sets forth the procedures for obtaining discovery from a nonparty and describes what is required to obtain the Board's approval, if necessary, to seek discovery of nonparties.

Paragraph (c) describes what is expected in response to discovery requests and what the requesting party may do in the event of a failure or refusal to respond.

Paragraph (d) sets forth time limits for initiating and completing discovery.

§ 1201.74. Orders for discovery.

This section has been retitled and has been completely revised.

Paragraph (a) requires that motions for orders compelling discovery or for appearance of nonparties must be submitted to the presiding official.

Paragraph (b) describes the content of an order compelling discovery.

§ 1201.75. Taking of depositions.

This section has been revised to allow depositions to be taken before any person designated by the Board.

Subpenas

§ 1201.81. Motions for subpenas.

Paragraph (b) has been revised to delete unnecessary information and/or requirements and paragraphs (c) and (d) are removed.

§ 1201.82. Motions to quash.

This section has been revised to delete unnecessary information and/or requirements.

§ 1201.83. Service.

This section has been revised to delete redundant information.

§ 1201.84. Return of service.

This section has been revised to conform with current practice.

§ 1201.85. Enforcement.

This section has been revised to make it clear that requests for enforcement are to be directed to the presiding official.

Regulatory Flexibility Act

The Chairman, Merit Systems Protection Board, certifies that the Board is not required to prepare an initial or final regulatory analysis of this proposed rule, pursuant to section 603 or 604 of the Regulatory Flexibility Act, because of his determination that this rule would not have a significant economic impact on a substantial number of small entities, including small business, small organizational units, and small governmental jurisdictions.

List of Subjects in 5 CFR Part 1201

Administrative practice and procedure, civil rights, government employees.

Accordingly, the Merit Systems Protection Board amends 5 CFR by revising Part 1201, Subpart B, as follows:

PART 1201—PRACTICES AND PROCEDURES

Discovery

1. Section 1201.71 is revised to read as follows:

§ 1201.71 Statement of purpose.

Proceedings before the Board shall be conducted as expeditiously as possible with due regard to the rights of the parties. Discovery is designed to enable a party to obtain relevant information needed for presentation of the party's case. These regulations are intended to provide a simple method of discovery. They will be interpreted and applied so as to avoid delay and to facilitate adjudication of the case. The parties are expected to initiate and complete needed discovery with a minimum of Board intervention.

2. Section 1201.72, paragraphs (a) and (b) are revised and a new paragraph (c) added to read as follows:

§ 1201.72. Explanation and scope.

(a) Explanation: Discovery is the process apart from the hearing whereby a party may obtain relevant information from another person, including a party, which has not otherwise been provided. Relevant information means evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence. This information is obtained for the purpose of assisting the parties in developing, preparing, and presenting their cases. The Federal Rules of Civil Procedure may be used as a general guide for discovery practices in proceedings before the Board where appropriate except as to matters sepcifically covered by these regulations. The federal rules shall be interpreted as instructive rather than controlling in any event.

(b) Scope: Any person may be examined pursuant to § 1201.72(c) regarding any nonprivileged matter which is relevant to the issue under appeal including the existence, description, nature, custody, condition, and location of documents or other tangible things and the identity and location of persons having knowledge of relevant facts. The information sought must appear reasonably calculated to lead to the discovery of admissible evidence.

(c) Methods: Discovery may be obtained by one or more of the methods provided under the Federal Rules of Civil Procedure, including: written interrogatories, depositions, production

of documents or things for inspection or copying, and requests for admission addressed to parties.

3. Section 1201.73 is retitled and revised to read as follows:

§ 1201.73. Procedures governing discovery.

(a) Discovery from a party or a nonparty federal agency. A party seeking discovery from another party or from a federal agency not a party shall initiate the process by serving a request for discovery on the other party or the nonparty agency. The request for discovery shall—

(1) State the time limit for responding, as prescribed in § 1201.73(d) and

(2) In the case of a request for deposition of a party or an employee of a federal agency (i) shall specify the time and place of the taking of the deposition and (ii) shall also be served on the person to be deposed.

When a request for discovery is directed to an officer or employee of a federal agency, the agency shall make the officer or employee available on official time for the purpose of responding to the request and shall assist the officer or employee as necessary in providing relevant information that is available to the agency. For purposes of discovery under these regulations, a party includes an intervenor.

(b) Discovery from a nonparty. Parties are encouraged to attempt to obtain voluntary discovery from nonparties whenever possible. A party seeking discovery from a nonparty may initiate the process by serving a request for discovery on that party. Absent such a request or upon failure to obtain voluntary cooperation, discovery from a nonparty may be initiated by a written motion directed to the presiding official, showing the relevance, scope and materiality of the particular information sought, and in the case of a deposition, the date, time, and place of the proposed deposition. A ruling on the motion will be issued by an authorized official of the Board and served on the moving party accompanied by a subpena directed to the individual or entity from which discovery is sought, and specifying the manner and time limit for compliance. It shall be the responsibility of the moving party to serve or arrange for service of a Board-approved discovery request and subpena on the individual or entity.

(c) Responses to discovery requests.

(1) A party, or a federal agency which is not a party, shall answer a discovery request within the time provided by § 1201.73(d)(2) of these regulations either by furnishing to the requesting party the information or testimony requested or agreeing to make deponents available to testify within a reasonable time or by stating an objection to the particular request and the reasons for objection.

(2) Upon the failure or refusal of a party to respond in full to a discovery request, or a nonparty to respond in full to Board-approved discovery, the requesting party may file with the presiding official a motion to compel. The motion shall be accompanied by:

(i) A copy of the original request served on the other party and a statement showing the relevancy and materiality of the information sought.

(ii) A copy of the objections to discovery or, where appropriate, a verified statement that no response has been received.

(d) Time limits.

(1) Requests or motions for discovery shall be initiated within 30 days after the date the petition for appeal was filed.

(2) A party or nonparty shall respond to a discovery request within 15 days after filing of the request or order of the Board. Deposition witnesses shall give their testimony at the time and place stated in the notice of deposition taking or in the subpena.

(3) Motions to depose nonparties (along with a request for a subpena) shall be submitted to the presiding official within the time limits set forth in paragraph (d)(1) above or as otherwise directed.

(4) Motions for an order compelling discovery shall be filed with the presiding official within 7 days of filing of objections or within 5 days of the expiration of the time limits for response when no response is received.

(5) Discovery shall be completed by the time designated by the presiding official but no later than 65 days of the filing of the appeal. A later date may be set by the presiding official after due consideration of the particular situation including the dates set for hearing and closing of the case record.

(6) The time limits prescribed in this section may be altered by the presiding official for good cause.

4. Section 1201.74 is retitled and revised to read as follows:

§ 1201.74 Orders for discovery.

(a) Motion for an Order Compelling Discovery. Motions for orders compelling discovery and motions for appearance of nonparties shall be submitted to the presiding official as set forth at section 1201.73 (c)(2) and (d)(4) above.

(b) Content of Order. Any order issued may include, where appropriate:

(1) Provision for notice to the person to be deposed as to the time and place of such deposition;

(2) Such conditions or limitations concerning the conduct or scope of the proceedings or the subject matter as may be necessary to prevent undue delay or to protect any party or deponent from undue expense, embarrassment or oppression;

(3) Limitations upon the time for conducting depositions, answering written interrogatories, or producing documentary evidence; and

(4) Other restrictions upon the discovery process as determined by the presiding official.

5. Section 1201.75 is retitled and revised to read as follows:

§ 1201.75. Taking of depositions.

Depositions may be taken before any person not interested in the outcome of the proceedings who is authorized by law to administer oaths.

Subpenas

6. Section 1201.81(b) is revised to read as follows:

§ 1201.81. Motions for subpenas.

* * * * *

(b) Form. Motions for subpenas shall be submitted in writing to the presiding official and shall specify with particularity the books, papers, or testimony desired and shall be supported by a showing of general relevance and reasonable scope and a statement of the facts expected to be proven thereby.

7. Section 1201.82 is revised to read as follows:

§ 1201.82. Motion to quash.

Any person against whom a subpena is directed may file a motion to quash or limit the subpena setting forth the reasons why the subpena should not be complied with or why it should be limited in scope. This motion shall be filed with the presiding official.

8. Section 1201.83 is revised to read as follows:

§ 1201.83. Service.

Service of subpena may be made by a United States Marshal or Deputy Marshal or by any person who is over 18 years of age.

9. Section 1201.84 is revised to read as follows:

§ 1201.84. Return of service.

When service of subpena is effected by a person other than a United States Marshal or Deputy Marshal, that person shall certify on the return of service that service was made either: (1) In person,

(2) by registered or certified mail, or (3) by delivery to a responsible person (named) at the residence or place of business (as appropriate) of the person to be served, and that the prescribed fees have been tendered or provided for.

10. Section 1201.85 is revised to read as follows:

§ 1201.85. Enforcement.

In the case of contumacy or failure to obey a subpena issued, the Board, pursuant to 5 U.S.C. 1205(c), may request enforcement of the subpena in the appropriate United States district court. A party desiring enforcement may apply to the presiding official by oral or written request accompanied by a showing of contumacy or failure to obey a subpena.

Dated: June 24, 1982.

For the Board.

Herbert E. Ellingwood,

Chairman.

[FR Doc. 82-18033 Filed 7-1-82; 8:45 am]

BILLING CODE 7400-01-M

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

7 CFR Part 210

National School Lunch Program; Meat Alternate Equivalencies

AGENCY: Food and Nutrition Service, USDA.

ACTION: Notice of Delay of Implementation Date.

SUMMARY: This notice announces a delay in implementation of the meat alternate equivalencies for cooked dry beans or peas and eggs published on May 16, 1980 (45 FR 32502). The Department recently proposed (47 FR 28106; June 29, 1982) that these equivalencies be returned to their lower pre-May 1980 levels. The proposal was prompted by reports from schools and manufacturers experiencing difficulties meeting the larger equivalencies. To provide for an adequate comment period on the proposal, the Department is delaying the July 1, 1982, implementation date until comments are analyzed and the proposed rulemaking process is complete.

DATE: The implementation date is delayed until further notice.

FOR FURTHER INFORMATION CONTACT: Cynthia H. Ford, Branch Chief, Room 602, Technical Assistance Branch, Nutrition and Technical Services Division, Food and Nutrition Service, USDA, Alexandria, Virginia 22302, or by telephone: 703-756-3556.

SUPPLEMENTARY INFORMATION: As required by the National School Lunch Act, the Department has established minimum nutritional requirements for lunches served in the National School Lunch Program (NSLP). One of the four lunch components is the meat/meat alternate component. Schools may serve cooked dry beans or peas and eggs to satisfy the meat/meat alternate component.

On May 16, 1980, a final rule was published (45 FR 32502) which increased the equivalencies (portion sizes) of cooked dry beans or peas and eggs. Those schools whose suppliers could not quickly comply with the larger equivalencies were exempt from the July 1, 1980 implementation date for one year. Exemptions were later extended to July 1, 1982 (Notice July 17, 1981; 46 FR 37017). As the July 1, 1982 deadline drew near, schools and food manufacturers were still encountering difficulties in reformulating their products to comply with the larger equivalencies. Therefore, on June 29, 1982, a proposal was published (47 FR 28106) to return the equivalencies for cooked dry beans or peas and eggs to their pre-May 1980 levels.

To provide for an adequate comment period for this proposed rule, the Department must further delay the July 1, 1982 implementation date until comments are analyzed and this proposed rulemaking process is complete. Schools and institutions supplied by food manufacturers who are unable to comply with the May 1980 equivalencies may consider a one-half cup of cooked dry beans or peas, or one large egg, as providing the two ounces of the meat/meat alternate lunch component in the NSLP. Adjustments shall be made where appropriate for age/grade groups I, II, III, and V.

List of subjects in 7 CFR Part 210—Food assistance programs, National School Lunch Program, Grant programs, Social programs, Nutrition, Children, Reporting and recordkeeping requirements, Surplus agricultural commodities.

(Catalog of Federal Domestic Assistance No. 10.555) (Sec. 9, Pub. L. 79-386, 60 Stat. 233, (42 U.S.C. 1758(a))

Samuel J. Cornelius,

Administrator Food and Nutrition Service.

[FR Doc. 82-17996 Filed 7-1-82; 8:45 am]

BILLING CODE 3410-30-M

Animal and Plant Health Inspection Service

[Docket No. 82-322]

7 CFR Part 301

Mediterranean Fruit Fly

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Interim rule.

SUMMARY: The Mediterranean Fruit Fly Quarantine and Regulations quarantine California and impose restrictions on the movement of regulated articles from regulated areas in California. This document amends the quarantine and regulations by deleting all of Alameda County and a portion of Santa Clara County from the list of regulated areas. The effect of this action is to delete restrictions on the interstate movement (movement from California into or through any other State, Territory, or District of the United States) of regulated articles from all of Alameda County and a portion of Santa Clara County. This action is warranted because such restrictions are no longer necessary for the purpose of preventing the artificial spread of the Mediterranean fruit fly.

DATES: Effective date of amendment July 7, 1982. Written comments concerning this rule must be received on or before August 31, 1982.

ADDRESSES: Written comments should be submitted to Thomas Lanier, Assistant Director, Regulatory Services Staff, Plant Protection and Quarantine, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Room 643 Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782. Written comments received may be inspected at Room 641 of the Federal Building between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays.

FOR FURTHER INFORMATION CONTACT: B. Glen Lee, Emergency Programs Coordinator, Plant Protection and Quarantine, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Room 610 Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, 301-436-6365.

SUPPLEMENTARY INFORMATION:

Executive Order 12291

This interim rule is issued in conformance with Executive Order 12291, and has been determined to be not a "major rule." Based on information compiled by the Department, it has been determined that this proposed rule would have an annual effect on the

economy of less than $50,000; would not cause a major increase in costs or prices for consumers, individual industries, Federal, State or local government agencies, or geographic regions; and would not have a significant adverse effect on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

For this rulemaking action, the Office of Management and Budget has waived the review process required by Executive Order 12291. Also, the Assistant Secretary for Marketing and Inspection Services has waived the requirements of Secretary's Memorandum 1512–1.

Certification Under the Regulatory Flexibility Act

Harry C. Mussman, Administrator of the Animal and Plant Health Inspection Service, has determined that this action will not have a significant economic impact on a substantial number of small entities. This action affects the interstate movement of regulated articles from all of Alameda County and a portion of Santa Clara County in California. There are thousands of small entities that move such articles interstate from California and many more thousands of small entities that move such articles interstate from other States. However, based on information compiled by the U.S. Department of Agriculture, it has been determined that fewer than 10 small entities move such articles interstate from the previously regulated areas in Alameda and Santa Clara Counties. Further, the overall economic impact from this action is estimated to be less than $50,000.

Emergency Action

Harvey L. Ford, Deputy Administrator of the Animal and Plant Health Inspection Service for Plant Protection and Quarantine, has determined that an emergency situation exists which warrants publication of this document without opportunity for a public comment period because otherwise there would be unnecessary restrictions imposed on the interstate movement of certain articles. This situation requires immediate action to delete such unnecessary restrictions.

Therefore, pursuant to the administrative procedure provisions in 5 U.S.C. 553, it is found upon good cause that notice and other public procedure with respect to this rule are impracticable and contrary to the public interest and good cause is found for making this action effective less than 30 days after publication of this document in the **Federal Register.** Comments are being solicited for 60 days after publication of this document, and a final document discussing comments received and any changes required will be published in the **Federal Register** as soon as possible.

Background

Because of infestations of the Mediterranean fruit fly found in areas in California, the Mediterranean fruit fly quarantine and regulations were made effective on July 20, 1981 (46 FR 37706–37713), and amendments to the quarantine and regulations were made effective on August 7, August 19, September 2, 1981, and on June 1 and June 17, 1982 (46 FR 40203–40205, 42072–42073, 44144–44145; 47 FR 23682–23683 and 26121–26122). The quarantine and regulations are set forth in 7 CFR 301.78 through 301.78–10.

For the purpose of preventing the artificial spread of the Mediterranean fruit fly to noninfested areas in the United States, the quarantine and regulations restrict the interstate movement (movement from California into or through any other State, Territory, or District of the United States) of articles designated as regulated articles from areas designated as regulated areas. The quarantine and regulations currently list as regulated areas all of San Mateo County and portions of Santa Clara and Santa Cruz Counties. Also, prior to the effective date of this document, the quarantine and regulations listed as regulated areas all of Alameda County and a larger portion of Santa Clara County.

Based on trapping and sampling surveys conducted by inspectors of the U.S. Department of Agriculture and State agencies of California, it has now been determined that the Mediterranean fruit fly has been eradicated from Alameda and Santa Clara Counties, except for the following portions of Santa Clara County:

Santa Clara County. That portion of the county beginning at a point where Interstate 280 intersects the San Mateo-Santa Clara County line; then southeasterly along Interstate 280 to its intersection with El Monte Avenue; then northeasterly along said avenue to its intersection with Foothill Expressway; then southeasterly along said expressway to its intersection with Fremont Avenue; then east on Fremont Avenue to its intersection with Hollenbeck Avenue; then north on Hollenbeck Avenue to its intersection with El Camino Real; then southeasterly on El Camino Real to its intersection with Fair Oaks Avenue; then northerly on said avenue to its intersection with Central Expressway; then easterly on said expressway to its intersection with Lawrence Expressway; then northerly on Lawrence Expressway to its intersection with State Route 237; then due north from said intersection along an imaginary line to its intersection with the Alameda-Santa Clara County line; then westerly along said county line to the San Mateo-Santa Clara County line; then southerly along said county line to the point of beginning. Also, that portion of the county beginning at a point where Old Santa Cruz Highway intersects the Santa Cruz-Santa Clara county line; then northeasterly along an imaginary line from said intersection to Mt. Thayer; then southeasterly along an imaginary line from Mt. Thayer to the north end of Loma Prieta Road; then southerly along Loma Prieta Road to its intersection with the Santa Cruz-Santa Clara County line; then northerly along said line to the point of beginning.

Under these circumstances there is no longer a basis for imposing restrictions on the movement of articles from Alameda and Santa Clara Counties, except for the portion of Santa Clara County described above. Therefore, in order to relieve unnecessary restrictions on the interstate movement of articles, it is necessary as an emergency measure to delete from the list of regulated areas all of Alameda County and those areas in Santa Clara County that are not included in the description set forth above.

List of Subjects in 7 CFR Part 301

Agricultural commodities, Plant pests, Plants (agriculture), Quarantine, Transportation.

PART 301—DOMESTIC QUARANTINE NOTICES

Accordingly, § 301.78–3(c) of the Mediterranean fruit fly quarantine and regulations (7 CFR 301.78–3(c)) is revised to read as follows:

§ 301.78–3 Regulated Areas.

* * * * *

(c) The areas described below are designated as regulated areas:

California.

San Mateo County. The entire county.

Santa Clara County. That portion of the county beginning at a point where Interstate 280 intersects the San Mateo-Santa Clara County line; then southeasterly along Interstate 280 to its intersection with El Monte Avenue; then northeasterly along said avenue to its intersection with Foothill Expressway; then southeasterly along said expressway to its intersection with Fremont Avenue; then east on Fremont Avenue to its intersection with Hollenbeck Avenue; then

north on Hollenbeck Avenue to its intersection with El Camino Real; then southeasterly on El Camino Real to its intersection with Fair Oaks Avenue; then northerly on said avenue to its intersection with Central Expressway; then easterly on said expressway to its intersection with Lawrence Expressway; then northerly on Lawrence Expressway to its intersection with State Route 237; then due north from said intersection along an imaginary line to its intersection with the Alameda-Santa Clara County line; then westerly along said county line to the San Mateo-Santa Clara County line; then southerly along said county line to the point of beginning. Also, that portion of the county beginning at a point where Old Santa Cruz Highway intersects the Santa Cruz-Santa Clara county line; then northeasterly along an imaginary line from said intersection to Mt. Thayer; then southeasterly along an imaginary line from Mt. Thayer to the north end of Loma Prieta Road; then southerly along Loma Prieta Road to its intersection with the Santa Cruz-Santa Clara County line; then northerly along said line to the point of beginning.

Santa Cruz County. That portion of the county north and west of a line beginning at a point where Loma Prieta Road intersects the Santa Clara-Santa Cruz County line; then southerly along an imaginary line from said intersection to the northeast corner boundary line of the Forest of Nisene Marks State Park; then southerly along the eastern boundary of said State park to its intersection with Aptos Creek Road; then southerly along Aptos Creek Road to its intersection with Soquel Drive; then westerly along Soquel Drive to its intersection with State Route 1; then westerly along State Route 1 to it intersection with Swift Street; then southerly along Swift Street to the Pacific Ocean where the line ends.

(Secs. 8 and 9, 37 Stat. 318, as amended (7 U.S.C. 161, 162); 37 FR 28464, 28477, as amended; 38 FR 19141)

Done at Washington, D.C., this 29th day of June 1982.

Harvey L. Ford,

Deputy Administrator, Plant Protection and Quarantine Animal and Plant Health Inspection Service.

[FR Doc. 82-18071 Filed 7-1-82; 8:45 am]

BILLING CODE 3410-34-M

Agricultural Stabilization and Conservation Service

7 CFR Part 724

Fire-Cured, Dark Air-Cured, Virginia Sun-Cured, Cigar-Binder (Types 51 and 52), Cigar-Filler and Binder (Types 42, 43, 44, 54, and 55) Tobacco Acreage Allotment Regulations

AGENCY: Agricultural Stabilization and Conservation Service, USDA.

ACTION: Final Rule.

SUMMARY: Except for technical changes, the interim rule published in the Federal Register on March 12, 1982 (47 FR 10771) is adopted as a final rule. The interim rule amended the regulations at 7 CFR 724.79 to implement the provisions of section 320 of the Agricultural Adjustment Act of 1938, as amended by section 1108 of the Agriculture and Food Act of 1981 (Pub. L. 97-98). Effective on December 22, 1981, nonquota tobacco which is produced in a State where marketing quotas are in effect for a kind of tobacco will be subject to the marketing quota for such kind of tobacco, with certain exceptions.

EFFECTIVE DATE: July 2, 1982.

FOR FURTHER INFORMATION CONTACT: Harry D. Millner, Program Specialist, (202) 447-4281. A Final Regulatory Impact Analysis is available upon request from Mr. Millner.

SUPPLEMENTARY INFORMATION: This final rule has been reviewed in conformance with Executive Order 12291 and Secretary's Memorandum No. 1521-1 and has been classified as "not major". The provisions of this rule will not result in: (1) An annual effect on the economy of $100 million or more; (2) major increases in costs or prices for consumers, individual industries, Federal, State or local governments, or a geographical region; or (3) significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

The title and number of the Federal Assistance Program to which this rule applies as set forth in the Catalog of Federal Domestic Assistance are: Title: Commodity Loan and Purchases, Number: 10.051. This final rule will not have a significant impact specifically on area and community development. Therefore, review as established by OMB Circular A-95 was not used to assure that units of local government are informed of this action.

It has been determined that the Regulatory Flexibility Act is not applicable to this final rule since the Agricultural Stabilization and Conservation Service is not required by 5 U.S.C. 553 or any other provision of law to publish a notice of proposed rulemaking with respect to the subject matter of this rule.

Section 320 of the 1938 Act was originally enacted in 1974 and is designed to preserve the effectiveness of the tobacco program by discouraging the production of tobacco not under quota in areas of the nation where tobacco farmers have elected to comply with marketing quotas.

Section 320 of the 1938 Act was amended by Section 1108 of the Agriculture and Food Act of 1981 effective December 22, 1981. As amended, section 320 provides that, with certain exceptions, any nonquota tobacco produced in an area where quotas for any kind of tobacco are in effect shall be considered to be a quota kind. If marketing quotas are in effect in an area for more than one kind of quota tobacco, nonquota tobacco produced in the area shall be subject to the quota for the kind of tobacco produced in the area having the highest price support under the Agricultural Act of 1949, as amended.

On March 12, 1982, an interim rule was published in the **Federal Register** (47 FR 10771) amending the regulations at 7 CFR 724.79 to implement the recent amendments to Section 320 of the 1938 Act pertaining to the production of nonquota tobacco in quota areas. The public was afforded 60 days to comment on the interim rule. However, no comments were received during the comment period which ended on May 11, 1982. Thus, the interim rule published on March 12, 1982, is adopted as a final rule, except for technical changes in 7 CFR 724.79(c)(4).

List of Subjects in 7 CFR Part 724

Acreage allotments, Disaster assistance, Marketing quotas, Penalties, pesticides and pests; Reporting requirements, Tobacco.

Final Rule

PART 724—FIRE-CURED, DARK AIR-CURED, VIRGINIA SUN-CURED, CIGAR-BINDER (TYPES 51 AND 52) CIGAR-FILLER AND BINDER (TYPES 42, 43, 44, 53, 54, AND 55) TOBACCO

Accordingly, the interim rule published at 47 FR 10771 which amended the regulations at 7 CFR 724.79 is hereby adopted as a final rule, except that 7 CFR 724.79(c)(4) is amended to read as follows:

§ 724.79 Identification of tobacco subject to quota

* * * * *

(c)(4) tobacco produced in a quota State that is represented to be nonquota tobacco and that is readily and distinguishably different from all kinds of quota tobacco, as determined by the Agricultural Marketing Service, U.S. Department of Agriculture, through application of the standards issued by the Secretary for the inspection and identification of tobacco. Such inspection and identification shall be made prior to removal of the tobacco from the State where it was produced.

[Sec. 301, 313, 314, 320, 372, 375, 52 stat. 38, as amended, 88 stat. 1089, as amended, (7 U.S.C. 1301, 1313, 1314, 1314(f), 1372, 1375)]

Signed in Washington, D.C., on June 24, 1982.

Everett Rank,

Administrator, Agricultural Stabilization and Conservation Service.

[FR Doc. 82-17746 Filed 7-1-82; 8:45 am]

BILLING CODE 3410-05-M

7 CFR Part 725

[Amdt. 2]

Flue-Cured Tobacco Acreage Allotment and Marketing Quota Regulations

AGENCY: Agricultural Stabilization and Conservation Service, USDA.

ACTION: Final rule.

SUMMARY: Except for technical changes, the interim rule published in the **Federal Register** on March 12, 1982 (47 FR 10772) is adopted as a final rule. The interim rule amended the regulations at 7 CFR 725.85 to implement the provisions of Section 320 of the Agricultural Adjustment Act of 1938, as amended by Section 1108 of the Agriculture and Food Act of 1981 (Pub. L. 97-98). Effective on December 22, 1981, nonquota tobacco which is produced in a State where marketing quotas are in effect for a kind of tobacco will be subject to the marketing quota for such kind of tobacco, with certain exceptions.

EFFECTIVE DATE: July 2, 1982.

FOR FURTHER INFORMATION CONTACT: Thomas R. Burgess, Program Specialist, (202) 447-2715. A Final Regulatory Impact Analysis is available upon request from Mr. Burgess.

SUPPLEMENTARY INFORMATION: This final rule has been reviewed in conformance with Executive Order 12291 and Secretary's Memorandum No. 1521-1 and has been classified as "not major". The provisions of this rule will not result in: (1) An annual effect on the economy of $100 million or more; (2) major increases in costs or prices for consumers, individual industries, Federal, State or local governments, or a geographical region; or (3) significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

The title and number of the Federal Assistance Program to which this rule applies as set forth in the Catalog of Federal Domestic Assistance are: Title: Commodity Loan and Purchases, Number: 10.051. This final rule will not have a significant impact specifically on area and community development. Therefore, review as established by OMB Circular A-95 was not used to assure that units of local government are informed of this action.

It has been determined that the Regulatory Flexibility Act is not applicable to this final rule since the Agricultural Stabilization and Conservation Service is not required by 5 U.S.C. 553 or any other provision of law to publish a notice of proposed rulemaking with respect to the subject matter of this rule.

Section 320 of the 1938 Act was originally enacted in 1974 and is designed to preserve the effectiveness of the tobacco program by discouraging the production of tobacco not under quota in areas of the nation where tobacco farmers have elected to comply with marketing quotas.

Section 320 of the 1938 Act was amended by Section 1108 of the Agriculture and Food Act of 1981 effective December 22, 1981. As amended, Section 320 provides that, with certain exceptions, any nonquota tobacco produced in an area where quotas for any kind of tobacco are in effect shall be considerd to be a quota kind. If marketing quotas are in effect in an area for more than one kind of quota tobacco, nonquota tobacco produced in the area shall be subject to the quota for the kind of tobacco produced in the area having the highest price support under the Agricultural Act of 1949, as amended.

On March 12, 1982, an interim rule was published in the **Federal Register** (47 FR 10772) amending the regulations at 7 CFR 725.85 to implement the recent amendments to Section 320 of the 1938 Act pertaining to the production of nonquota tobacco in quota areas. The public was afforded 60 days to comment on the interim rule. However, no comments were received during the comment period which ended on May 11, 1982. Thus, the interim rule published on March 12, 1982, is adopted as a final rule, except for technical changes in 7 CFR 725.85(c)(4).

List of Subjects in 7 CFR Part 725

Acreage allotments, Disaster assistance, Marketing quotas, Penalties, Pesticides and pests, Reporting requirements, Tobacco.

Final Rule

PART 725—FLUE-CURED TOBACCO

Accordingly, the interim rule published at 47 FR 10772 which amended the regulations at 7 CFR 725.85 is hereby adopted as a final rule, except that 7 CFR 725.85(c)(4) is amended to read as follows:

§ 725.85 Identification of tobacco subject to quota

* * * * *

(c)(4) Tobacco produced in a quota State that is represented to be nonquota tobacco and that is readily and distinguishably different from all kinds of quota tobacco, as determined by the Agricultural Marketing Service, U.S. Department of Agriculture, through application of the standards issued by the Secretary for the inspection and identification of tobacco. Such inspection and identification shall be made prior to removal of the tobacco from the State where it was produced.

(Secs. 301, 313, 314, 320, 317, 372, 375, 52 Stat. 38, as amended, 88 Stat. 1089, as amended, (7 U.S.C. 1301, 1313, 1314, 1314(c), 1314(f), 1372, 1375))

Signed in Washington, D.C., on June 24, 1982.

Everett Rank,

Administrator, Agricultural Stabilization and Conservation Service.

[FR Doc. 82-17745 Filed 7-1-82; 8:45 am]

BILLING CODE 3410-05-M

7 CFR Part 726

[Amdt. 2]

Burley Tobacco Marketing Quota Regulations

AGENCY: Agricultural Stabilization and Conservation Service, USDA.

ACTION: Final rule.

SUMMARY: Except for technical changes, the interim rule published in the **Federal Register** on March 12, 1982 (47 FR 10773) is adopted as a final rule. The interim rule amended the regulations at 7 CFR 726.80 to implement the provisions of Section 320 of the Agricultural Adjustment Act of 1938, as amended by Section 1108 of the Agriculture and Food Act of 1981 (Publ L. 97-98). Effective on December 22, 1981, nonquota tobacco which is produced in a State where marketing quotas are in effect for a kind of tobacco will be subject to the marketing quota for such kind of tobacco, with certain exceptions.

EFFECTIVE DATE: July 2, 1982.

FOR FURTHER INFORMATION CONTACT: Harry D. Millner, Program Specialist, (202) 447-4281. A Final Regulatory Impact Analysis is available upon request from Mr. Millner.

SUPPLEMENTARY INFORMATION: This final rule has been reviewed in conformance with Executive Order

12291 and Secretary's Memorandum No. 1521-1 and has been classified as "not major". The provisions of this rule will not result in: (1) An annual effect on the economy of $100 million or more; (2) major increases in costs or prices for consumers, individual industries, Federal, State or local governments, or a geographical region; or (3) significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of the United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

The title and number of the Federal Assistance Program to which this rule applies as set forth in the Catalog of Federal Domestic Assistance are: Title: Commodity Loan and Purchases, Number: 10.051. This final rule will not have a significant impact specifically on area and community development. Therefore, review as established by OMB Circular A-95 was not used to assure that units of local government are informed of this action.

It has been determined that the Regulatory Flexibility Act is not applicable to this final rule since the Agriculture Stabilization and Conservation Service is not required by 5 U.S.C. 553 or any other provision of law to publish a notice of proposed rulemaking with respect to the subject matter of this rule.

Section 320 of the 1938 Act was originally enacted in 1974 and is designed to preserve the effectiveness of the tobacco program by discouraging the production of tobacco not under quota in areas of the nation where tobacco farmers have elected to comply with marketing quotas.

Section 320 of the 1938 Act was amended by Section 1108 of the Agriculture and Food Act of 1981 effective December 22, 1981. As amended, Section 320 provides that, with certain exceptions, any nonquota tobacco produced in an area where quotas for any kind of tobacco are in effect shall be considered to be a quota kind. If marketing quotas are in effect in an area for more than one kind of quota tobacco, nonquota tobacco produced in the area shall be subject to the quota for the kind of tobacco produced in the area having the highest price support under the Agricultural Act of 1949, as amended.

On March 12, 1982, an interim rule was published in the **Federal Register** (47 FR 10773) amending the regulations at 7 CFR 726.80 to implement the recent amendments to Section 320 of the 1938 Act pertaining to the production of nonquota tobacco in quota areas. The public was afforded 60 days to comment on the interim rule. However, no comments were received during the comment period which ended on May 11, 1982. Thus, the interim rule published on March 12, 1982, is adopted as a final rule, except for technical changes in 7 CFR 726.80(c)(4).

List of Subjects in 7 CFR Part 726

Disaster assistance, Marketing quotas, Penalties, Pesticides and pests, Reporting requirements, Tobacco.

PART 726—BURLEY TOBACCO

Final Rule

Accordingly, the interim rule published at 47 FR 10773 which amended the regulations at 7 CFR 726.80 is hereby adopted as a final rule, except that 7 CFR 726.80(c)(4) is amended to read as follows:

§ 726.80 Identification of Tobacco Subject to Quota

* * * * *

(c)(4) Tobacco produced in a quota State that is represented to be nonquota tobacco and that is readily and distinguishably different from all kinds of quota tobacco, as determined by the Agricultural Marketing Service, U.S. Department of Agriculture, through application of the standards issued by the Secretary for the inspection and identification of tobacco. Such inspection and identification shall be made prior to removal of the tobacco from the State where it was produced.

(Secs. 301, 313, 314, 320, 372, 375, 52 Stat. 38, as amended, 88 Stat. 1089, as amended, (7 U.S.C. 1301, 1313, 1314, 1314(c), 1314(f), 1372, 1375))

Signed in Washington, D.C., on June 24, 1982.

Everett Rank,

Administrator, Agricultural Stabilization and Conservation Service.

[FR Doc. 82-17748 Filed 7-1-82; 8:45 am]

BILLING CODE 3410-05-M

Agricultural Marketing Service

7 CFR Part 910

[Lemon Reg. 366]

Lemons Grown in California and Arizona; Limitation of Handling

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This regulation establishes the quantity of fresh California-Arizona lemons that may be shipped to market during the period July 4-10, 1982. Such action is needed to provide for orderly marketing of fresh lemons for this period due to the marketing situation confronting the lemon industry.

EFFECTIVE DATE: July 4, 1982.

FOR FURTHER INFORMATION CONTACT: William J. Doyle, Acting Chief, Fruit Branch, F&V, AMS, USDA, Washington, D.C. 20250, telephone 202-447-5975.

SUPPLEMENTARY INFORMATION: This rule has been reviewed under Secretary's Memorandum 1512-1 and Executive Order 12291 and has been designated a "non-major" rule. This regulation is issued under the marketing agreement, as amended, and Order No. 910, as amended (7 CFR Part 910), regulating the handling of lemons grown in California and Arizona. The agreement and order are effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601-674). The action is based upon the recommendations and information submitted by the Lemon Administrative Committee and upon other available information. It is hereby found that this action will tend to effectuate the declared policy of the act.

This action is consistent with the marketing policy for 1981-82. The marketing policy was recommended by the committee following discussion at a public meeting on July 7, 1981. The committee met again publicly on June 29, 1982, at Los Angeles, California, to consider the current and prospective conditions of supply and demand and recommended a quantity of lemons deemed advisable to be handled during the specified week. The committee reports the demand for lemons is good.

It is further found that it is impracticable and contrary to the public interest to give preliminary notice, engage in public rulemaking, and postpone the effective date until 30 days after publication in the **Federal Register** (5 U.S.C. 553), because of insufficient time between the date when information became available upon which this regulation is based and the effective date necessary to effectuate the declared purposes of the act. Interested persons were given an opportunity to submit information and views on the regulation at an open meeting. It is necessary to effectuate the declared purposes of the act to make these regulatory provisions effective as specified, and handlers have been apprised of such provisions and the effective time.

List of Subjects in 7 CFR Part 910

Agricultural marketing service, Marketing agreements and orders, California, Arizona, Lemons.

PART 910—LEMONS GROWN IN CALIFORNIA AND ARIZONA

Section 910.666 is added as follows:

§ 910.666 Lemon regulation 366.

The quantity of lemons grown in California and Arizona which may be handled during the period July 4, 1982, through July 10, 1982, is established at 275,000 cartons.

(Secs. 1–19, 48 Stat. 31, as amended; 7 U.S.C. 601–674)

Dated: July 1, 1982.

D. S. Kuryloski,

Deputy Director, Fruit and Vegetable Division, Agricultural Marketing Service.

[FR Doc. 82-18309 Filed 7-1-82; 12:43 pm]

BILLING CODE 3410-02-M

Agricultural Marketing Service

7 CFR Part 925

[California Desert Grape Regulation 2, Amendment 1]

Grapes Grown in a Designated Area of Southeastern California; Amendment of Handling Requirements

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This final rule amends the regulation currently in effect for grapes grown in Southeastern California by authorizing a packing holiday on July 5, 1982, and authorizing the California Desert Grape Administrative Committee to modify or suspend such holiday regulation without the need for further rulemaking. Such action is necessary to promote orderly marketing in the interest of producers and consumers.

EFFECTIVE DATE: July 2, 1982.

FOR FURTHER INFORMATION CONTACT: William J. Doyle, Acting Chief, Fruit Branch, F&V, AMS, USDA, Washington, D.C. 20250, telephone 202–447–5975.

SUPPLEMENTARY INFORMATION: This final rule has been reviewed under Secretary's Memorandum 1512–1 and Executive Order 12291, and has been designated a "non-major" rule. William T. Manley, Deputy Administrator, Agricultural Marketing Service, has determined that this action will not have a significant economic impact on a substantial number of small entities because it would not measurably effect costs for the directly regulated handlers.

This amended regulation is issued under marketing agreement and Order No. 925 (7 CFR Part 925), regulating the handling of grapes grown in a designated area of Southeastern California. This marketing agreement and order are effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674). This action is based upon the recommendation and information submitted by the California Desert Grape Administrative Committee, established under the marketing agreement and order, and upon other information. It is hereby found that this action will tend to effectuate the declared policy of the act.

The amended regulation would prohibit the packing of grapes on July 5, 1982, while authorizing the committee to modify or suspend such prohibition at its discretion if marketing conditions warrant without the necessity of further rulemaking. This packing holiday is designed to prevent an accumulation of excessive supplies of grapes at distribution points during and immediately following the long July 4th holiday weekend, when demand is expected to be reduced.

It is further found that it is impracticable and contrary to the public interest to give preliminary notice, engage in public rulemaking, and postpone the effective date until 30 days after publication in the **Federal Register** (5 U.S.C. 553), because of insufficient time between the date when information became available upon which this amended regulation is based and the effective date necessary to effectuate the declared policy of the act. It is necessary to effectuate the declared purpose of the act to make these regulatory provisions effective as specified, and handlers have been apprised of such provisions and the effective time.

List of Subjects in 7 CFR Part 925

Agricultural Marketing Service, Marketing agreements and orders, Grapes, California.

PART 925—GRAPES GROWN IN A DESIGNATED AREA OF SOUTHERN CALIFORNIA

Therefore, § 925.301 is amended by revising the first sentence of the introductory text of the section and paragraph (f) to read as follows:

§ 925.301 California Desert Grape Regulation 2.

During the period May 1, 1982, through July 31, 1982, no person shall handle any variety of grapes unless such grapes are handled in accordance with the requirements of this section, and no person shall pack any such grapes on any Saturday or Sunday, or on July 5, 1982, unless approved in accordance with paragraph (f). * * *

* * * * *

(f) *Suspension of packing holidays.* Upon approval of the committee, the prohibition against packing grapes on any Saturday or Sunday or on July 5, 1982, may be modified or suspended to permit the handling of grapes provided such handling complies with procedures and safeguards specified by the committee.

(Secs. 1–19, 48 Stat. 31, as amended; 7 U.S.C. 601–674)

Dated: June 29, 1982.

D. S. Kuryloski,

Deputy Director, Fruit and Vegetable Division, Agricultural Marketing Service.

[FR Doc. 82-18072 Filed 7-1-82; 8:45 am]

BILLING CODE 3410-02-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Tylosin and Sulfamethazine

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplement to a new animal drug application (NADA) filed by Quali-Tech Products, Inc., providing for safe and effective use of a premix containing 5 grams per pound each of tylosin and sulfamethazine for making complete swine feeds.

EFFECTIVE DATE: July 2, 1982.

FOR FURTHER INFORMATION CONTACT: Jack C. Taylor, Bureau of Veterinary Medicine (HFV–136), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5247.

SUPPLEMENTARY INFORMATION: Quali-Tech Products, Inc., 318 Lake Hazeltine Dr., Chaska, MN 55318, submitted a supplement to their approved NADA 97–981. The supplement provides for use of a premix containing 5 grams per pound each of tylosin (as tylosin phosphate) and sulfamethazine for making complete swine feeds to be used for (1) maintaining weight gains and feed efficiency in the presence of atrophic rhinitis, (2) lowering the incidence and severity of *Bordetella bronchiseptica* rhinitis, (3) preventing swine dysentery (vibrionic), and (4) controlling swine pneumonias caused by bacterial

pathogens (*Pasteurella multocida* and/or *Corynebacterium pyogenes*).

Elanco Products Co. has authorized use of the safety and effectiveness data contained in their approved NADA's 12–491 and 41–275 to support this approval. Approval of this supplement is based on this data. Because approval of this supplement does not change the approved use of the drug, it poses no increased human risk from exposure to residues of the animal drug.

Accordingly, under the Bureau of Veterinary Medicine's supplemental approval policy (42 FR 64367; December 23, 1977), this supplement is a Category II supplemental NADA which does not require reevaluation of the safety and effectiveness data in NADA's 12–491 and 41–275. The supplement is approved and the regulations are amended accordingly.

In accordance with the freedom of information provisions of Part 20 (21 CFR Part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, from 9 a.m. to 4 p.m., Monday through Friday.

The agency has determined pursuant to 21 CFR 25.24(d)(1)(i) (proposed December 11, 1979; 44 FR 71742) that this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This action is governed by the provisions of 5 U.S.C. 556 and 557 and is therefore excluded from Executive Order 12291 by section 1(a)(1) of the Order.

List of Subjects in 21 CFR Part 558

Animal drugs; Animal feeds.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

§ 558.630 [Amended]

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Bureau of Veterinary Medicine (21 CFR 5.83), Part 558 is amended in § 558.630 *Tylosin and sulfamethazine* by removing drug labeler code "016968" from paragraph (b)(3) and by adding it, in numerical sequence, to paragraph (b)(8).

Effective date. July 2, 1982.

(Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)))

Dated: June 24, 1982.

Robert A. Baldwin,

Associate Director for Scientific Evaluation.

[FR Doc. 82–17737 Filed 7–1–82; 8:45 am]

BILLING CODE 4160–01–M

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Hygromycin B

Correction

In FR Doc. 82–11758, published on page 18593, on Friday, April 30, 1982, in the second column, under § 558.274, in the tenth line "50782" should be corrected to read "050782".

BILLING CODE 1505–01–M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[T.D. 7822]

Income Tax; Taxable Years Beginning After December 31, 1953; Treatment of Certain Interests in Corporations as Stock or Indebtedness

AGENCY: Internal Revenue Service, Treasury.

ACTION: Amendment of final regulations.

SUMMARY: Section 385 of the Internal Revenue Code relates to the treatment of certain interests in corporations as stock or indebtedness. Final regulations under this section were published in the **Federal Register** on December 31, 1980. This document amends the December 31, 1980 rules by changing the effective date of those rules for the third time. The effective date is changed from July 1, 1982 to 90 days after publication of the revisions proposed in January as final rules, or January 1, 1983, whichever is later.

EFFECTIVE DATE: June 30, 1982.

FOR FURTHER INFORMATION CONTACT: Carolyn Swift of the Legislation and Regulations Division, Office of the Chief Counsel, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC 20224 (Attention: CC:LR:T, 202–566–3458, not a toll-free call).

SUPPLEMENTARY INFORMATION:

Background

Section 385 of the Internal Revenue Code relates to the treatment of certain interests in corporations as stock or indebtedness. Final regulations under section 385 were published in the **Federal Register** for Wednesday, December 31, 1980 (45 FR 86438) as T.D. 7747. These regulations generally would have applied to certain interests in corporations created after April 30, 1981. However, at the invitation of the Treasury and Internal Revenue Service, several public comments on the final regulations were received after December 31, 1980. The comments recommended changes in several areas of these regulations. In order for the Treasury and Internal Revenue Service to have sufficient time to examine these comments and determine whether changes should be made, the regulations were amended to apply to certain interests in corporations only if they were created after December 31, 1981. (T.D. 7774, published in the **Federal Register** for May 1, 1981 (46 F.R. 24945)).

After further examination of the comments and re-evaluation of the regulations, a decision was made to revise provisions of the regulations under section 385. In order to allow Treasury and the Internal Revenue Service additional time to prepare and publish revisions to certain provisions of the regulations, the regulations were amended so that, in general, they would apply to certain interests in corporations only if they were created after June 30, 1982. (T.D. 7801, published in the **Federal Register** for January 5, 1982 (47 FR 147)). Proposed amendments to the regulations were also published as a Notice of Proposed Rulemaking in the **Federal Register** for January 5, 1982 (47 FR 164). Many comments on the proposed amendments were received. In order to allow further consideration of the comments received and to prepare revisions in accordance with the comments for publication as a final rule, the regulations are again amended so that, in general, they will apply to certain interests in corporations only if the interests are created later than 90 days after the publication of the revisions as a final rule, but in no event will they apply to interests created earlier than January 1, 1983. It should also be noted that although this Treasury decision refers to both preferred stock and guaranteed loans, the proposed revisions to the regulations under section 385, which are expected to be finalized soon, remove the provisions relating to preferred stock and to guaranteed loans. It is expected that the regulations under section 385 as revised by the final rule will become effective 90 days after the revisions proposed in January 1982 are published in the **Federal Register** as a final rule but in no event earlier than January 1, 1983.

Regulatory Flexibility Act And Executive Order 12291

The Commissioner of Internal Revenue has determined that this final rule is not a major rule defined in Executive Order 12291 and that a Regulatory Impact Analysis is, therefore, not required. This document is not preceded by a notice of proposed rulemaking. Accordingly, no regulatory flexibility analysis is required.

Drafting Information

The principal author of this regulation is Carolyn Swift of the Legislation and Regulations Division of the Office of Chief Counsel, Internal Revenue Service. However, personnel from other offices of the Internal Revenue Service and Treasury Department participated in developing the regulations, both on matter of substance and style.

List of Subjects in 26 CFR 1.301–1—1.385–10

Income taxes, corporations, corporate distributions, corporate adjustments, and reorganizations.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR Part 1 is amended as follows:

PART 1—INCOME TAX; TAXABLE YEARS BEGINNING AFTER DECEMBER 31, 1953

Paragraph (a)(1) of § 1.385–1 is revised to read as follows:

§ 1.385–1 Stock or indebtedness.

(a) *Effective date*—(1) *In general.* The regulations under section 385 apply to instruments (as defined in § 1.385–3 (c)) and preferred stock issued after 90 days after publication of the final revisions to the section 385 regulations in the Federal Register, or, if later, December 31, 1982, and to loans described in § 1.385–7 and guaranteed loans made after 90 days after publication of the final revisions to the section 385 regulations in the Federal Register, or, if later, December 31, 1982.

* * * * *

There is a need for immediate guidance with respect to the provisions contained in this Treasury decision. For this reason, it is found impractical to issue it with notice and public procedure under subsection (b) of section 553 of Title 5 of the United States Code or subject to the effective date limitation of subsection (d) of that section.

This Treasury decision is issued under the authority contained in sections 385 and 7805 of the Internal Revenue Code of 1954 (83 Stat. 613 and 68A Stat. 917; 26 U.S.C. 385 and 7805).

James I. Owens,

Acting Commissioner of Internal Revenue.

Approved: June 28, 1982.

John E. Chapoton,

Assistant Secretary of the Treasury.

[FR Doc. 82–18067 Filed 6–29–82; 4:11 pm]

BILLING CODE 4830–01–M

DEPARTMENT OF LABOR

Employment Standards Administration

29 CFR Part 5

Labor Standards Provisions Applicable to Contracts Covering Federally Financed and Assisted Construction (Also Labor Standards Provisions Applicable to Nonconstruction Contracts Subject to the Contract Work Hours and Safety Standards Act)

AGENCY: Wage and Hour Division, Employment Standards Administration, Labor.

ACTION: Final rule.

SUMMARY: This rule amends Labor Department regulations to provide a variation from the overtime pay requirements of the Contract Work Hours and Safety Standards Act, with respect to pilots and copilots of fixed-wing and rotary-wing aircraft employed by a contractor or subcontractor on government contracts, the principle purpose of which is the furnishing of fire fighting or suppression and related services. This amendment is found to be necessary and proper in the public interest to prevent hardship and to avoid serious impairment of Government business.

EFFECTIVE DATE: August 2, 1982. The newly adopted provisions of paragraph (d) (4) of § 5.15 shall be applicable to contracts entered into pursuant to negotiations concluded or invitations for bids issued on or after August 2, 1982.

FOR FURTHER INFORMATION CONTACT: Dorothy P. Come, Assistant Administrator, Wage and Hour Division, Employment Standards Administration, U.S. Department of Labor, Room S–3502, 200 Constitution Avenue, NW., Washington, D.C. 20210, Telephone: 202–523–8333.

SUPPLEMENTARY INFORMATION: On January 8, 1982, a proposal was published in the Federal Register (47 FR 966) to add a new paragraph (4) to § 5.14(d) of regulations, 29 CFR Part 5, to provide a conditional variation from the requirements of section 102 of the Contract Work Hours and Safety Standards Act for the payment of one and one-half times the basic rate of pay for all hours worked in excess of eight in a day and 40 in a workweek with respect to pilots and copilots of fixed-wing and rotary-wing aircraft employed by a contractor or subcontractor on government contracts, the principal purpose of which is the furnishing of fire fighting or suppression and related services. The National Air Tankers Association requested an exemption from the Act's overtime pay requirements based upon their submission that (1) pilots and copilots engaged in fire fighting and related activities are generally paid substantial amounts as a result of receiving a regular salary plus additional amounts for hours of flying time, (2) the majority of overtime hours are caused by fire needs and involve significant amounts of highly paid flying time, and therefore pilots in effect generally receive a premium pay for working overtime, (3) the contractor often has little control over the hours worked by his employees as this is dictated by the Government based upon the current fire danger and the Government's common contractual right to dispatch aircraft and crew from their designated home base to alternate bases throughout the United States, (4) the calculation of overtime pay would be costly and extremely difficult for an employer because the hours of overtime worked vary greatly from week to week, and the pilots are not only often located at a considerable distance from the employer's principal base of operation but are moved from one location to another in response to the needs of the Government, and (5) an exemption would be consistent with the intent of Congress expressed in other statutes involving labor standards for fire fighting activities.

Given these circumstances the Secretary of Labor finds that a conditional variance from the overtime provisions of the Act for contractors and subcontractors employing pilots and copilots of fixed and rotary-wing aircraft on government contracts for fire fighting and related services is necessary and proper in the public interest to prevent hardship and to avoid serious impairment of the conduct of Government business.

Under the variation, qualifying contractors and subcontractors would not be subject to the overtime pay requirement provided certain conditions are met: (1) Pursuant to written agreement between the contractor and employee, the employee must receive gross wages of not less than $300 per week regardless of the total number of hours worked, and the amount of wages

paid the employee in a workweek must not be less than the amount the employee would receive if he were paid the minimum hourly wage required by the Service Contract Act plus one and one-half times the minimum for all overtime hours worked; and (2) the contractor must maintain accurate records of the hours worked by each pilot and copilot.

The enumerated conditions to the variance insure the wage protection for the employees involved and conform with the Act's remedial purposes.

Interested persons were afforded the opportunity to submit comments to the Wage and Hour Division on or before August 2, 1982 publication of the proposal in the **Federal Register.** One comment favoring the proposed amendment was submitted on behalf of the National Air Tankers Association. No other comments were received on the proposal and the proposed amendment is hereby adopted without change except to renumber the amendment as § 5.15(d) in accordance with a final regulation published on May 28, 1982 (47 FR 23658).

Classification

This rule is not classified as a "major rule" under Executive Order 12291 on Federal Regulations, because it is not likely to result in (1) an annual effect on the economy of $100 million or more; (2) a major increase in cost or prices for consumer, individual industries, Federal, State, or local government agencies, or geographic regions; or (3) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets. Accordingly, no regulatory impact analysis is required.

The Department believes that the rule will have no "significant economic impact upon a substantial number of small entities" within the meaning of section 3(a) of the Regulatory Flexibility Act, Pub. L. No. 96-354, 91 Stat. 1164 (to be codified at 5 U.S.C. 605(b)). The Secretary has certified to the Chief Counsel for Advocacy of the Small Business Administration to this effect. This conclusion is reached because the number of affected business entities is not substantial. Accordingly, no regulatory flexibility analysis is required. However, the variation will relieve a substantial administrative burden on the impacted entities and obviate the possible necessity of altering existing pay structures. Therefore, the regulation is within the spirit of the Regulatory Flexibility Act.

Paperwork Reduction Act

Information collection requirements contained in this regulation have previously been approved by the Office of Management and Budget under the provisions of the Paperwork Reduction Act of 1980 (Pub. L. 96-511) and have been assigned OMB control number 1215-0017.

Regulatory Flexibility Act Certification

I, Raymond J. Donovan, Secretary of Labor, hereby certify, pursuant to 5 U.S.C. 605(b), that the rule contained in 29 CFR 5.15(d)(4) concerning a conditional variation from the Contract Work Hours and Safety Standards Act will not have a significant economic impact on a substantial number of small entities.

Signed at Washington, D.C. this 28th day of June 1982.

Raymond J. Donovan,

Secretary of Labor.

This document was prepared under the direction and control of Dorothy P. Come, Assistant Administrator, Wage and Hour Division, Employment Standards Administration, U.S. Department of Labor.

List of Subjects in 29 CFR Part 5

Government contracts, Investigations, Labor, Minimum wages, Penalties, Recordkeeping requirements, Reporting requirements, Wages.

Signed at Washington, D.C. this 28th day of June 1982.

William M. Otter,

Administrator.

PART 5—LABOR STANDARDS PROVISIONS APPLICABLE TO CONTRACTS COVERING FEDERALLY FINANCED AND ASSISTED CONSTRUCTION (ALSO LABOR STANDARDS PROVISIONS APPLICABLE TO NONCONSTRUCTION CONTRACTS SUBJECT TO THE CONTRACT WORK HOURS AND SAFETY STANDARDS ACT)

Accordingly, 29 CFR 5.15 is amended by adding a new paragraph (d)(4) of § 5.15 as set forth below.

§ 5.15 Limitations, variations, tolerances, and exemptions under the Contract Work Hours and Safety Standards Act.

* * * * *

(d) *Variations.* * * *

(4) Any contractor or subcontractor performing on a government contract the principal purpose of which is the furnishing of fire fighting or suppression and related services, shall not be deemed to be in violation of Section 102 of the Contract Work Hour and Safety Standards Act for failing to pay the overtime compensation required by Section 102 of the Act in accordance with the basic rate of pay as defined in subsection (c)(1) of this section, to any pilot or copilot of a fixed-wing or rotary-wing aircraft employed on such contract if:

(i) Pursuant to a written employment agreement between the contractor and the employee which is arrived at before performance of the work.

(A) The employee receives gross wages of not less than $300 per week regardless of the total number of hours worked in any workweek, and

(B) Within any workweek the total wages which an employee receives are not less than the wages to which the employee would have been entitled in that workweek if the employee were paid the minimum hourly wage required under the contract pursuant to the provisions of the Service Contract Act of 1965 and any applicable wage determination issued thereunder for all hours worked, plus an additional premium payment of one-half times such minimum hourly wage for all hours worked in excess of 8 hours in any calendar day or 40 hours in the workweek;

(ii) The contractor maintains accurate records of the total daily and weekly hours of work performed by such employee on the government contract. In the event these conditions for the exemption are not met, the requirements of section 102 of the Contract Work Hours and Safety Standards Act shall be applicable to the contract from the date the contractor or subcontractor fails to satisfy the conditions until completion of the contract. (Approved by the Office of Management and Budget under OMB control number 1215-0017.)

(40 U.S.C. 327-332; Reorganization Plan No. 14 of 1950, 5 U.S.C. Appendix; 5 U.S.C. 301)

[FR Doc. 82-18167 Filed 7-1-82; 8:45 am]

BILLING CODE 4510-27-M

Occupational Safety and Health Administration

29 CFR Part 1952

Approval of Supplements to the Indiana State Plan; Correction

AGENCY: Occupational Safety and Health Administration, Labor.

ACTION: Final rule; correction.

SUMMARY: The present 29 CFR 1952.324, completed developmental steps, contains one undesignated paragraph stating that the Indiana poster was

approved by the Assistant Secretary on March 2, 1976. On October 6, 1981 numerous additional developmental supplements were approved by the Assistant Secretary (46 FR 49116). The October 6, 1981 notice designated the additional approved supplements as paragraphs (b) through (m) of 29 CFR 1952.324; through an administrative oversight the existing first paragraph of the section remained undesignated. This document corrects 29 CFR 1952.324 by designating the first paragraph as paragraph (a).

FOR FURTHER INFORMATION CONTACT:
Dennis J. Lubow, Project Officer, Office of State Programs, Occupational Safety and Health Administration, 200 Constitution Avenue NW., Room N-3613, Washington, D.C. 20210, (202) 523-6021.

PART 1925—SAFETY AND HEALTH STANDARDS FOR FEDERAL SERVICE CONTRACTS

Accordingly, 29 CFR 1952.324 is corrected by designating the first paragraph thereof as paragraph (a). As corrected, paragraph (a) is revised to read as follows:

§ 1952.324 Completed developmental steps.

(a) In accordance with the requirements of § 1952.10, the Indiana poster was approved for use until Federal enforcement authority and standards become inapplicable to issues covered under the plan, by the Assistant Secretary on March 2, 1976.

* * * * *

(Sec. 18, Pub. L. 91-596, 84 Stat. 1600, 1608 (29 U.S.C. 667))

Signed at Washington, D.C. this 29th day of June 1982.

Thorne G. Auchter,

Assistant Secretary.

[FR Doc. 82-18051 Filed 6-30-82; 8:45 am]

BILLING CODE 4510-26-M

POSTAL SERVICE

39 CFR Part 233

Rewards

AGENCY: Postal Service.

ACTION: Final rule; correction.

SUMMARY: Postal Service Notice 96, which prescribes the maximum rewards for information leading to the arrest and conviction of any peson for certain postal offenses, has been corrected to remove an inadvertently inserted "not" from the statement of the maximum reward in connection with the robbery of a mail custodian. This document corrects the text of that notice as reproduced in the final rule published June 22, 1982 (47 FR 26831).

FOR FURTHER INFORMATION CONTACT:
C. P. Nelson, (202) 245-5449.

W. Allen Sanders,

Associate General Counsel, Office of General Law and Administration.

PART 233—INSPECTION SERVICE AUTHORITY

Accordingly, the Postal Service is correcting the note to 39 CFR 233.2 to read as follows:

§ 233.2 Circulars and rewards.

* * * * *

(b) * * *

(2) * * *

Note. * * *

The United States Postal Service offers a reward up to the amounts shown for information and services leading to the arrest and conviction of any person for the following offenses:

Robbery, $10,000. Robbery or attempted robbery of any custodian of any mail, or money or other property of the United States under the control and jurisdiction of the United States Postal Service, if such custodian is wounded or killed, or the custodian's life jeopardized; but NOT TO EXCEED $5,000 if the custodian is not wounded or killed, or his life jeopardized.

* * * * *

(39 U.S.C. 401(2), 404(8), 410(b)(2))

[FR Doc. 82-18096 Filed 7-1-82; 8:45 am]

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GENERAL SERVICES ADMINISTRATION

41 CFR Parts 5-3, 5A-3, and 5B-3

Procurement by Negotiation

AGENCY: General Services Administration.

ACTION: Final rule.

SUMMARY: The General Services Administration Procurement Regulations, Chapter 5, are amended to transfer policies and procedures regarding procurement by negotiation from Chapter 5A and 5B. This transfer is part of the action to incorporate appropriate material in Chapters 5A and 5B into Chapter 5. The intended effect is to have a single GSA-wide procurement regulation.

EFFECTIVE DATE: July 30, 1982.

FOR FURTHER INFORMATION CONTACT:
Mr. Philip G. Read, Director, Federal Procurement Regulations Directorate, Office of Acquisition Policy (202) 523-4755.

List of Subjects in 41 CFR Part 5-3

Government procurement, Procurement by negotiation, Cost accounting standards, and Accounting.

CHAPTER 5—GENERAL SERVICES ADMINISTRATION PROCUREMENT REGULATIONS

[APD 2800.2 CHGE 22]

1. Part 5-3 is added as follows:

PART 5-3—PROCUREMENT BY NEGOTIATION

Subpart 5-3.1—Use of Negotiation

Sec.

5-3.103 Dissemination of procurement information.

Subpart 5-3.2—Circumstances Permitting Negotiation

5-3.202 Public exigency.
5-3.203 Purchases not in excess of $10,000.
5-3.210 Impracticable to secure competition by formal advertising
5-3.270 Negotiation after termination for default.

Subpart 5-3.3—Determinations, Findings, and Authorities

5-3.302 Determinations and findings required.

Subpart 5-3.4—Types of Contracts

5-3.405-5 Cost-plus-a-fixed-fee contract.
5-3.408 Letter contract.

Subpart 5-3.6—Small Purchases

5-3.600 Scope of subpart.
5-3.603 Competition.
5-3.603-1 Solicitation.
5-3.603-2 Data to support small purchases.
5-3.605 Purchase order forms.
5-3.605-1 Standard Form 44, Purchase Order-Invoice-Voucher.
5-3.606 Blanket purchase arrangements.
5-3.606-1 General.
5-3.606-4 Documentation.
5-3.606-50 Advance establishment of supply sources by blanket purchase arrangements.
5-3.652 Oral purchases (supplies and services).
5-3.653 Small purchase procedure using GSA Form 2049, Contractor's Certificate of Conformance.

Subpart 5-3.8—Price Negotiation Policies and Techniques

5-3.802 Preparation for negotiation.
5-3.805 Selection of offerors for negotiation and award.
5-3.805-1 General.
5-3.805-2 Cost-reimbursement type contracts (construction contracts).
5-3.807-3 Cost or pricing data.
5-3.807-6 Refusal to provide cost or pricing data.
5-3.850 Contracts requiring Central Office approval.

Subpart 5-3.50—Solicitation of Offers

5-3.5001 Preparation of solicitation of offers.
5-3.5002 Oral solicitations.

Sec.
5-3.5003 Bidders mailing lists (except ADTS).
5-3.5003-1 Publicizing ADTS procurement actions.
5-3.5004 Recording of bids.

Authority: Sec. 205(c), 63 Stat. 390; 40 U.S.C. 486(c).

Subpart 5-3.1—Use of Negotiation

§ 5-3.103 Dissemination of procurement information.

(a) Business Service Centers shall be furnished copies, as issued, of each written request for proposals for a procurement estimated to exceed $5,000.

(b) During the preaward period, no information contained in any proposal or quotation or information regarding the number or identity of the offerors shall be made available to the public or to anyone within the Government not having a legitimate interest therein.

(c) The provisions of § 5-2.407-59 regarding notification of proposed substantial awards and awards involving congressional interest shall be followed for negotiated procurements.

(d) The provisions of § 5-1.350 regarding the issuance of advance notices of award shall be followed for all negotiated contracts.

(e) When awards are made on the basis of initial offers received, i.e., no discussions or negotiations are conducted with any offeror, a tabulation sheet shall be prepared and a legible copy shall be furnished to the local Business Service Center within one workday after the award of public examination. Tabulations may be typed or handwritten. They shall include the applicable solicitation numbers, names of offerors, prices offered (including any discounts), successful offeror, and the total dollar amount of the award.

(f) When awards are made following discussions with offerors, only the names of successful offerors and the award prices, including discounts, may be publicly disclosed.

(g) Information concerning unsuccessful offerors may only be released to individual requesters, in accordance with GSA Order ADM 7900.3, GSA Regulations, pursuant to the "Freedom of Information Act". This information may include identity and final prices, including discounts.

(h) The provisions of § 5-2.407-1(b)(5) also apply to negotiated procurements.

(i) Awards involving the Public Buildings Services are subject to the following requirements.

(1) Except for classified procurements negotiated under § 1-3.212, which should not be publicly disclosed procurement activities shall notify Business Service Centers of all completed procurements made by negotiation, including, whenever practicable, small purchases.

(2) Notifications on small purchases which exceed $5,000 shall be accomplished by furnishing the Business Service Centers with copies of procurement documents or by such other form of notification that will provide the Business Service Centers with the significant details of the completed procurement actions.

Subpart 5-3.2—Circumstances Permitting Negotiation

§ 5-3.202 Public exigency.

(a) When contracts are awarded on behalf of other agencies, the public exigency negotiation authority may be used only when the requisitioning agencies have furnished sufficient information for the execution of the findings and determinations required by § 1-3.202(b). Delivery dates which are not supported by further information do not constitute adequate justifications for the use of the authority.

(b) Military purchase requests citing an issue priority designator assigned in accordance with DOD Uniform Material Movement and Issue Priority System (UMMIPS) as prescribed by DOD Directive 4410.6, and civilian agency purchase requests citing a priority designator 03 or 06, prescribed by the FEDSTRIP Operating Guide, Ch. 2-15, may justify negotiation under this or other negotiation authority. The specific circumstances must be set forth in the findings and determination to be made by the contracting officer, in accordance with Comptroller General Decision B-192574, April 13, 1979 (58 Comp. Gen. 415). These issue priority designators are to be generated and provided only by the requisitioning activity to a requester and cannot be generated by anyone else for the purpose of conforming or upgrading the priority designator to a requested delivery date.

§ 5-3.203 Purchases not in excess of $10,000.

Full purchase prices shall be used in determining whether the aggregate amount of a transaction exceeds $10,000. Prompt payment discounts or trade-in values may not be deducted.

§ 5-3.210 Impracticable to secure competition by formal advertising.

This authority shall not be used where negotiation is authorized under §§ 1-3.211, 1-3.212, 1-3.213, or 1-3.214.

§ 5-3.270 Negotiation after termination for default.

(a) Repurchases, following terminations for default, may be effected by formal advertising or negotiation as provided in §§ 1-8.602-6 and 5-8.602-6. However, formal advertising should be employed when feasible.

(b) When the repurchase is negotiated, the contracting officer shall include a statement in the contract file justifying the use of negotiation.

Subpart 5-3.3—Determinations, Findings, and Authorities

§ 5-3.302 Determinations and findings required.

A determination that an advance payment is in the public interest or in the interest of the national defense and is necessary and appropriate (as required by section 305(c) of the Federal Property and Administrative Services Act) must be supported by written findings.

Subpart 5-3.4—Types of Contracts

§ 5-3.405-5 Cost-plus-a-fixed-fee contract.

The fixed fees which may be paid under cost reimbursement contracts are subject to the limitations in § 1-3.405-5 and 41 U.S.C. 254(b) and are as follows:

(a) *General.* Except as provided in (b), below, fixed fees shall not exceed 10 percent of the estimated cost of the contract, exclusive of the fee.

(b) *Experimental, development, or research work.* Fixed fees for experimental, developmental, or research work shall not exceed 15 percent of the estimated cost of the contract, exclusive of the fee.

(c) *Fees.* Fees shall be determined by the head of the procuring activity as defined in § 5-1.206.

§ 5-3.408 Letter contract.

(a) *General.* Letter contracts shall not be used unless it is determined by the contracting officer that no other type of contract is suitable and prior approval has been obtained from the head of the procuring activity, as defined in § 5-1.206.

(b) *Limitation of effectiveness.* A letter contract shall be superseded by a definitive contract not more than 90 days from the date of its execution unless prior approval to extend the letter contract beyond 90 days is obtained from the head of the procuring activity.

(c) *Limitation of liability.* The maximum liability of the Government in a letter contract shall not exceed 50 percent of the total estimated cost of the procurement, except in cases when the cost of specialized equipment or materials (such as mechanical or electrical) to be acquired by the contractor as a part of the contract

exceeds 50 percent of the total estimated cost. The cost of the specialized equipment and material shall be the limitation in those cases when it exceeds the 50 percent limitation.

(d) *Conditions for use.* Letter contracts may be used only on the basis of compliance with the following:

(1) Each letter and definitive contract shall contain all mandatory and other clauses necessary to protect fully the interest of the Government.

(2) Each letter contract shall contain the total estimated cost of the procurement and a provision for further negotiation of the cost.

(3) The fixed fee in a cost-reimbursement type of letter contract shall not exceed the limitations set forth in § 1–3.405–5. In establishing the fixed fee, consideration shall be given to the following:

(i) The degree of risk to the contractor.

(ii) The estimated cost of material, subcontracting, purchased parts, and "off-the-shelf" items as compared with the total estimated definitive contract price.

(iii) The size of the proposed contract.

(4) The profit to be paid shall be consistent with the protection given the contractor in minimizing or removing risk to the contractor and the profit policies prescribed in § 1–3.806.

Subpart 5–3.6—Small Purchases

§ 5–3.600 Scope of subpart.

The following limitations on small purchases are prescribed by this subpart:

(a) Small purchases shall be set aside for small business as provided in § 1–3.603–3 and as required by Public Law 95–507, October 24, 1978.

(b) Small purchases of supplies and materials by organizations other than Federal Supply Service (see GSA Order ADM 2800.10, dated April 29, 1982), in an aggregate amount of not more than $10,000 may be effected in accordance with the provisions of Subpart 1–3.6 when either:

(1) The items required are not available from GSA stock, Federal Supply Schedules, term contracts, or through nearby FSS self-service stores, or

(2) Public exigency precludes the use of FSS sources.

(c) Small business—small purchase set—aside contracts valued in excess of $2,000, for repair, alteration, improvements, painting or decorating of a building, must comply with the statutory requirements applicable to such contracts (see §§ 1–3.603–3, 5–1.706(a), 5–3.203(a), and 1–18.302).

(d) Service contracts are subject to requirements of the Service Contract Act of 1965 (see Subpart 1–12).

§ 5–3.603 Competition.

§ 5–3.603–1 Solicitation.

(a) Supplies and Services (other than construction).

(1) Quotations on small purchases may be solicited orally by telephone or personal contact when the estimated amount does not exceed $5,000.

(2) When written solicitations are required (see § 1–3.603–1), one of the following forms shall be used.

(i) *Standard Form 18, Request for Quotations* (See § 1–16.201). Except as provided in (ii) below, this form shall be used for requesting written quotations. When it is considered advantageous to obtain a firm offer which, upon acceptance by the Government, results in a bilateral contract, the appropriate standard contract forms shall be employed.

(ii) *GSA Form 3188, Request for Quotation* (See § 5–16.950–3188). GSA Form 3188 is authorized for use by the Federal Supply Service with the FSS–19 system in lieu of Standard Form 18.

(iii) *GSA Form 2097, Offer and Acceptance Small Purchase.* GSA Form 2097, Offer and Acceptance—Small Purchase (illustrated in § 5–16.950–2097), is authorized for use by the Federal Supply Service when firm offers are to be solicited.

(A) Buyers shall complete the Request for Offer part of GSA Form 2097. If additional space is needed, Standard Form 36, Continuation Sheet, shall be used.

(B) Upon receipt of offers, the purchase from the successful offeror will be completed by executing the Acceptance portion of GSA Form 2097 and returning to the offeror one manually signed copy of the completed form.

(2) *GSA Form 300, Purchase Order.* When this form is used for small purchases (see § 5–1.7301(a)), the following provision shall be included:

Supplemental Terms and Conditions

This purchase is also subject to the clause entitled Disputes in § 1–7.102–12 of the Federal Procurement Regulations (see FPR Temporary Regulation 55, May 23, 1980). In addition, if the purchase exceeds $5,000, the following clauses are also applicable: (a) Changes (41 CFR 1–7.102–2), (b) Default (41 CFR 1–8.707) and (c) Termination for Convenience of the Government (41 CFR 1–8.705–1). These clauses are incorporated by reference as fully as if set forth at length herein.

(End of Provision)

(b) Construction, alteration, and repair.

(1) Quotations on small purchases of the nature described in § 5–3.600(b) may be solicited orally by telephone or personal contact when:

(i) The estimated cost does not exceed $5,000, and

(ii) The requirement is so simple that it can be accurately and fully conveyed orally, with reasonable assurance that sources will submit quotations that are, in fact, on a competitive footing, and in compliance with all statutory and regulatory requirements.

(2) Quotations shall not be solicited orally for the following:

(i) Contracts over $2,500 which are subject to the Service Contract Act.

(ii) Contracts over $2,000 for construction, alteration, and repair which are subject to the Davis-Bacon Act, Contract Work Hours and Safety Standards Act, or the Copeland (Anti-kickback) Act.

(iii) Contracts over $25,000 which are subject to the Miller Act.

(3) In an emergency, when a procurement is estimated not to exceed $10,000 and a written solicitation is required, competition may be solicited by having prospective sources visit the site and by orally informing them, together, of the exact requirements, to enable the sources to prepare estimates for submitting quotations while the written solicitation is being prepared by the Government. The written solicitation must be issued before written quotations are received to allow prospective offerors to effect any necessary changes in the event that there has been any misunderstanding of the oral description of the work encompassed. Emergencies, for the purpose of this subsection, include situations which, if not corrected promptly, will result in unnecessary expenditure of funds, property damage, personal injury, serious loss of agency efficiency in operations, or interruption of agency functions, any of which could be avoided by immediate corrective action. For emergency procurements which exceed $10,000, see § 1–3.202.

(c) Competition.

(1) The criteria set forth below are designed to provide interested small business concerns an opportunity to participate in small purchases (see §§ 1–3.602(f) and 1–3.603–3 regarding small business-small purchase set-asides).

(2) When the estimated dollar amount does not exceed $500, competitive quotations are desirable but not required. These purchases may be accomplished on the basis of a currently verified quotation from a single supplier, if the price is reasonable and no significant advantage would result from soliciting additional suppliers. However,

such purchases shall be distributed equitably among qualified suppliers.

(3) When the estimated dollar amount of the purchase exceeds $500, quotations should be requested from at least five qualified sources, if that number of sources is available. If more than five qualified sources are normally in active competition and expect to be included in price solicitations, the firms solicited shall be rotated or the number solicited should be increased to include the additional sources to the extent commensurate with the value of the purchase, the potential for additional price savings, and the additional administrative costs involved.

§ 5-3.603-2 Data to support small purchases.

(a) When other than the lowest quotation is accepted, the reason(s) for rejecting any lower quotation shall be entered in the purchase case file.

(b) Purchasing activities shall establish small purchase source lists from a formal mailing list, established in accordance with § 1-2.205, trade publications, Thomas Register, and other comparable publications.

(c) Each small purchase file must include notes explaining how it was determined that the price is reasonable.

§ 5-3.605 Purchase order forms.

§ 5-3.605-1 Standard Form 44, Purchase Order-Invoice-Voucher.

(a) *General.* Use of the Standard Form 44, Purchase Order-Invoice-Voucher (illustrated at § 1-16.901-44), will not serve the best interest of either the Government or business when the accounting system of the seller requires production of an invoice as a matter of routine. In these cases, whichever of the other authorized methods of making small purchases is most appropriate shall be used. Whenever possible, within the dollar value limitations of each method, preference shall be given to the use of imprest funds and blanket purchase arrangements (see § 5-3.606).

(b) *Authorization for using form.* Where necessary, responsible using Standard Form 44 in accordance with this subpart. Purchases over $150 using SF 44 may be made only by contracting officers. (See ADM 2851.3, December 18, 1979, Establishment of GSA-wide Contracting Officer Warrant Program (COWP).)

(c) *Issuance of books from stock.* Issuances of books from stock shall be made only to the appropriate Assistant Commissioners in the Central Office and Assistant Regional Administrators, or to their designees. These officials shall be responsible for the custody and issuance of the books to the users and shall maintain a simple card record for each book issued.

§ 5-3.606 Blanket purchase arrangements.

§ 5-3.606-1 General.

All blanket purchase arrangements are subject to the requirements of small business-small purchase set-asides as set forth in § 1-3.603-3.

§ 5-3.606-4 Documentation.

(a) Blanket purchase arrangements (BPAs) normally shall be documented on a purchase order form. Each blanket purchase arrangement shall contain appropriate provisions relating to the following:

(1) Authorization to the supplier to furnish the supplies or services described in general terms in the arrangement when called for by a contracting officer or person(s) authorized by a contracting officer and listed therein.

(2) Individual call orders against such arrangements shall not exceed $5,000.

(3) The Government will be obligated only to the extent of the call orders actually made against the blanket purchase arrangement by persons authorized by a contracting officer.

(4) Suppliers shall submit an invoice as required, but not more than once a month. The original of each delivery ticket shall accompany the invoice.

(5) The blanket purchase arrangement should specify the place(s) to which deliveries are to be made. (Usually the arrangement will provide for delivery to the requiring activity.)

(6) The arrangement should state the discount terms which will apply to orders placed against the blanket purchase arrangement.

(7) Total anticipated value of purchases under a BPA may not exceed $10,000 (see § 1-3.602(f)).

(8) Certificate of conformance-type shipments may be arranged (see § 5-3.653).

(b) Only officials authorized by a contracting officer and designated in the blanket purchase arrangement shall be permitted to request deliveries. Delivery (call) orders shall usually be made by telephone or in person. Prior to placing calls against the blanket purchase arrangement, each requirement shall be screened for availability from mandatory sources of supply. Necessary controls shall be maintained by the person placing call orders under the blanket purchase arrangement to ensure that any limitation stated therein is not exceeded. The blanket purchase arrangement identification, and requisition number, if any, should be specified each time a delivery is requested.

(c) Each blanket purchase arrangement shall be numbered or otherwise identified in an appropriate manner and shall include the statement, "Negotiation authority—section 302(c)(3), Federal Property and Administrative Services Act of 1949."

(d) When deliveries are made, the receiving activity will retain one copy of the related delivery ticket and return the remaining copies to the supplier; one copy of which is to be signed. Each delivery ticket must contain the following information: blanket purchase arrangement identification; requisition number, if any; the name of the person placing the call; an itemized listing of the materials furnished; and the quantity, price and extension of each item.

§ 5-3.606-50 Advance establishment of supply sources by blanket purchase arrangements.

(a) The following instructions are designed to reduce the administrative costs in connection with processing small purchases. These instructions apply primarily to the purchasing of the following types of requirements:

(1) Low dollar value items for which requirements are too sporadic to be carried in stock or be included in Federal Supply Schedules or term contracts; and

(2) Low dollar value items which are listed in Federal Supply Schedules or term contracts but which are not available from these sources because the quantity required is smaller than the minimum order limitation specified in these contracts and the established contractor is unwilling to accept such an order.

(b) Sections 1-3.606 and this 5-3.606 contain instructions for making small purchases by blanket purchase arrangements (BPAs). This section provides an additional application for the BPA as a single source instrument.

(c) When BPAs are issued to multiple sources, orders are rotated among these sources to achieve an even spread of orders, provided prices are within a narrow competitive range. When prices vary widely, buyers make individual determinations every time they place an order to give the order to that source which offers the best terms (e.g., earlier delivery, if required). Dealing with only a single source during the effective period of the single source BPA would lower the administrative costs. Single source BPAs shall be awarded in accordance with subsection (d).

(d) Generally for any single source BPA, Standard Form 18, Request for Quotations, shall be used for obtaining price information. The request for quotation should make it clear that a BPA will be issued to that responsive quoter who offers the best terms to the Government for the entire requirement, at a stated level of quality, price and other factors considered. To obtain a common denominator for the evaluation of quotations, requirements must be expressed in terms of minimum acceptable quality (applicable specifications, brand names or equal, manufacturer catalogs, etc.). Single source BPAs shall be issued for an entire line of estimated requirements, based on best discounts from established contractors' catalogs and price lists, after assurance that the catalog items of the low quoters are comparable in quality to the items offered by other quoters. Delivery requirments should be stated within a range from immediately to not later than 10 calendar days after receipt of order. The BPA shall contain a provision that no single order placed thereunder shall exceed $5,000, and that no order from another source shall be placed for any item covered by an established Government contract source except (i) when the requirement is below the minimum order quantity stated in the contract and the established contractor is unwilling to accept such an order, or (ii) the requirement is urgent and the established contractor cannot meet the delivery requirement.

(e) The $5,000 individual purchase limitation in (d), above, does not limit orders issued under BPAs established with a Government contractor (e.g. Federal Supply Schedule or term contract), in which case the terms of the applicable contract will govern (see § 1–3.606–1).

(f) Delivery orders under single source BPAs shall be issued on any authorized purchase order form or orally in accordance with this § 5–3.606–50.

§ 5–3.652 Oral purchases (Supplies and services).

(a) When advantageous to the Government, supplies or services may be procured orally in accordance with § 1–3.603–3, from local suppliers at the site of work or use point, or by a supply distribution facility when authorized, using vendors' invoices in lieu of purchase orders.

(b) Oral purchases shall be effected only in accordance with §§ 1–3.6 and 5–3.6, subject to the following:

(1) The amount of any one purchase is $500 or less;

(2) A purchase order is not required by either the supplier or the Government; (In practice, confirming purchase orders are frequently used but are not required by this regulation.) and

(3) Appropriate invoices are obtainable from the supplier.

(c) The items to be purchased shall be domestic source end products, except as provided in § 1–6.1. For special rules governing purchases of hand and measuring tools and stainless steel flatware see §§ 5–6.104–50, 5–6.104–51, and 5–6.104.52.

(d) Each ordering office using this purchasing technique shall require the supplier to submit immediately properly prepared invoices which itemize property or services furnished.

(e) Invoices which evidence receipt of the property or services shall be endorsed by an authorized Government representative.

(f) Informal records shall be maintained by the ordering office when necessary (including identification of the person placing the order) to ensure that the personal property or nonpersonal services ordered are actually received. (See also § 1–3.603.)

(g) To facilitate payment of invoices, ordering offices should advise the paying office when oral purchase arrangements are authorized.

§ 5–3.653 Small purchase procedure using GSA Form 2049, Contractor's Certificate of Conformance.

(a) *General.*

(1) The small purchase procedure using GSA Form 2049, Contractor's Certificate of Conformance, provides for payment for supplies based on the contractor's submission of an invoice with an attached copy of a completed GSA Form 2049 certifying that the supplies have been delivered to the post office, common carrier, or point of first receipt by the Government, and that the contractor agrees to replace, repair, or correct supplies not received at destination, damaged in transit, or not conforming to purchase requirements.

(2) Blanket purchase arrangements may include provisions for using certificate-of-conformance-type shipments.

(b) *Conditions for use.* Subject to the following conditions, careful consideration shall be given to the feasibility of using the certificate-of-conformance for any small purchase procurement which requires direct delivery to a customer:

(1) The value of individual direct shipment orders shall be limited to $10,000 or less;

(2) The title to supplies will vest in the Government upon delivery to the post office or common carrier for mailing or shipment to destination or upon receipt by the Government when shipment is by means other than U.S. Mail or common carrier;

(3) The contractor agrees to replace, repair, or correct at his expense supplies not received at destination, damaged in transit, or not conforming to purchase requirements, provided replacement instructions are furnished the contractor within 90 days from the date of shipment; and

(4) The contractor will perform in accordance with the terms of the purchase order.

(c) *Preparation and execution.*

(1) Purchase orders using the certificate-of-conformance procurement method may be issued on any authorized purchase order form in accordance with Subpart 5–3.6, except that calls against blanket purchase arrangements shall be issued in accordance with § 5–3.606.

(2) Each purchase order using this certificate-of-conformance procedure shall contain the following provision:

> This purchase order is subject to and includes the terms and conditions of GSA Form 2049, Contractor's Certificate of Conformance, a copy of which is attached or available upon request to the Contracting Officer.
>
> (End of Provision)

(3) Special data to be included in purchase orders or blanket purchase arrangements using certificate-of-conformance purchase order procedures include the following:

(i) A requirement to ship the supplies prepaid by common carrier or parcel post;

(ii) A requirement that, when shipment is made by parcel post (U.S. Postal Service) or common carrier, to (A) cite on invoice(s) and copies thereof, the shipment date, name and address of carrier, and bill of lading number or other shipment document number or (B) attach copies of such documents to invoice as evidence of shipment. The invoice(s) shall also be prominently marked "CERTIFICATE OF CONFORMANCE";

(iii) A requirement where delivery is by other than parcel post or common carrier, to attach a receipted copy of the contractor's delivery document to the contractor's invoice(s) and invoice copies;

(iv) A requirement that each invoice under a purchase order using the certificate-of-conformance procedure must be accompanied by GSA Form 2049, Contractor's Certificate of Conformance, completed and signed by the contractor.

(v) A requirement to include the following statement on the consignee's copy of the contractor's invoice(s):

Consignee's Notification to Procurement Division of Nonreceipt, Damage, or Nonconformance

Consignee shall promptly notify the Contracting Officer, after purchase order delivery date, of supplies not received, damaged in transit, or not conforming with purchase order specifications.

(End of Statement)

Subpart 5-3.8—Price Negotiation Policies and Techniques

§ 5-3.802 Preparation for negotiation.

When time does not permit the use of written solicitations, telegraphic solicitations may be used when specifically authorized by § 5-2.201-53. Telephonic solicitations may be used in urgency situations in accordance with §§ 1-3.202, 5-3.202 and 5-3.5002. Telegraphic and telephonic request must make specific reference to all terms and conditions which will apply. The reasons for the use of telegraphic or telephonic requests shall be entered in the file (see § 1-3.802(c)(5)).

§ 5-3.805 Selection of offerors for negotiation and award.

§ 5-3.805-1 General.

The determining criteria for proposal evaluation and award (when other than the lowest price) should be determined in advance of solicitation. The solicitation shall identify the evaluation criteria (factors) and provide a reasonable idea or specific numerical identification of their relative importance. When percentages or weights are not specified, the evaluation criteria shall be listed in descending order of importance.

§ 5-3.805-2 Cost-reimbursement type contracts (construction contracts).

The considerations and discussions during negotiations of construction contracts shall include, to the extent necessary to resolve uncertainties, such matters as:

(a) The location, size, and character of the work and the estimated cost;

(b) The general conditions for the cost-plus-a-fixed-fee contract and the procedures to be followed thereunder;

(c) The organization the contractor will use at the site and proposed salaries for those employees;

(d) The types and amount of contractor's own equipment available for the project;

(e) The amount and character of work to be performed by the contractor's own forces and by subcontract;

(f) The time for completion, liquidated damages (if specified), insurance, and bonds;

(g) The fixed fee and the basis upon which its amount was predicated. (All of these factors, (a) through (f), affect the amount of the fee.)

§ 5-3.807-3 Cost or pricing data.

(a) Approval of the appropriate procuring director shall be obtained in all cases when it is determined that the requirement for cost or pricing data may be waived (see § 1-3.807-3(b)).

(b) Excuse for failure to submit subcontractor cost and pricing data except when limited to the allowing of additional time, shall require approval of the appropriate procuring director. (See § 1-3.807-3(d)(2)).

§ 5-3.807-6 Refusal to provide cost or pricing data.

Whenever a contractor refuses to provide cost or pricing data, the matter shall be referred to the appropriate procuring director. (See § 1-3.807-6).

§ 5-3.850 Contracts requiring Central Office approval.

Requirements for Central Office approval of regional contracts are set forth in the GSA Delegations of Authority Manual, (ADM P 5450.39B). The following types of contracts shall also be submitted for Central Office approval:

(a) Contracts involving advance payment by the Government; and

(b) All cost, cost-plus-a-fixed-fee, or incentive-type contracts.

Subpart 5-3.50—Solicitation of Offers

§ 5-3.5001 Preparation of solicitation of offers.

(a) In addition to the forms prescribed in Subpart 1-16.2 for negotiated supply contracts, the basic forms to be used for soliciting offers (requests for proposals) on negotiated contracts shall be the same forms prescribed in Subpart 1-16.1 for use when soliciting offers (invitations for bids) under advertised contracts. Generally, a solicitation of offers shall be in writing. However, in appropriate cases as prescribed in § 5-3.5002, proposals or quotations may be solicited orally, provided that the resulting definitive contract is prepared on the prescribed contract form.

(b) Solicitations shall contain the information necessary to enable a prospective offeror to prepare an offer. All such information shall be set forth in full in the solicitation except that Standard Form 32, General Provisions (Supply Contract), Standard Form 33A, Solicitation Instructions and Conditions, and authorized GSA forms, if applicable, may be incorporated by reference after ensuring that the forms have been received by the offerors.

§ 5-3.5002 Oral solicitations.

(a) Oral solicitations, other than for small purchases (see paragraph (b)) are authorized in cases when the processing of a written solicitation would delay the furnishing of the supplies or services to the detriment of the Government. Examples of such circumstances are listed in § 1-3.202. However, an oral solicitation is not to be considered justified solely because a high issue priority designator has been assigned to the requirement or because of public exigency.

(b) Oral solicitations are authorized for small purchases (see Subparts 1-3.603-1(d) and 5-3.603), for the procurement of perishable subsistence, and as indicated in paragraph (a).

(c) In addition to the documentation requirements of Subpart 1-3.3, the contract record should include a summary of the circumstances which constituted the basis for the use of an oral solicitation, the item description, quantity, deliveries required, sources solicited, prices quoted (including name of individual contacted), date and time of contact, and the solicitation number which was provided to the prospective sources. Should the issuance of the resulting contractual instrument be unduly delayed, the contract file shall be documented to describe the reasons for the delay and to justify award based on the oral solicitation.

(d) Oral solicitations shall not be used without prior approval at a level higher than the contracting officer and in accordance with the Contractor Officer Warrent Program in GSA Order ADM 2851.3, December 18, 1979.

(e) The use of oral solicitations does not relieve contracting officers from the obligation to comply with all applicable procurement regulations (e.g., post award notices to offerors, § 1-3.103), price negotiation policies and techniques (Subparts 1-3.8 and 5-3.8), submission of the same terms and conditions to all offerors, etc. In communications with potential contractors, contracting officers shall make it clear that quotations are subject to all applicable procurement regulations, although not expressly detailed, and that prices quoted are for items of domestic origin unless otherwise indicated and include only Federal, State and local taxes applicable to Federal Government transactions.

§ 5-3.5003 Bidders mailing lists (except ADTS).

Bidders mailing lists for negotiated procurements shall be established, maintained, and utilized in accordance with §§ 1-2.205 and 5-2.205.

§ 5-3.5003-1 Publicizing ADTS procurement actions.

Generally, ADTS procurements shall be publicized in the Commerce Business Daily as provided in Subpart 1-1.10. The GSA Centralized Bidders Mailing List may be use for competitive ADPE and software procurement as established in ADTS procedures (see § 1-4.1109-3).

§ 5-3.5004 Recording of bids.

Bids shall be abstracted in accordance with § 5-2.403.

(End of Part)

CHAPTER 5A—OFFICE OF ACQUISITION POLICY, GENERAL SERVICES ADMINISTRATION

[APD 2800.3 CHGE 33]

PART 5A-3 [REMOVED]

1. 41 CFR is amended by removing in its entirety Part 5A-3.

CHAPTER 5B—OFFICE OF ACQUISITION POLICY, GENERAL SERVICES, ADMINISTRATION

[APD 2800.4 CHGE 14]

PART 5B-3 [REMOVED]

1. 41 CFR is amended by removing in its entirety Part 5B-3.

Dated: June 15, 1982.

William B. Ferguson,

Acting Assistant Administrator for Acquisition Policy.

[FR Doc. 82-18034 Filed 7-1-82; 8:45 am]

BILLING CODE 6820-61-M

DEPARTMENT OF ENERGY

41 CFR Parts 9-5, 9-7, 9-23 and 9-50

Amendments to the DOE Procurement Regulations

AGENCY: Department of Energy.

ACTION: Final rule.

SUMMARY: This final rule revises the DOE Procurement Regulations. The revisions will simplify the procurement process by allowing certain decisions to be made at a lower level. Some sections are updated to conform to amendments to the Federal Property Management Regulations and changes in DOE's assignments for management of certain property categories. Also, certain procedures and definitions are clarified. A detailed listing of specific revisions is given below under the section entitled "Supplementary Information."

EFFECTIVE DATE: August 31, 1982.

FOR FURTHER INFORMATION CONTACT:

Richard Langston, Procurement Policy Branch (MA931.1), Policy and Procedures Division, Procurement and Assistance Management Directorate, Department of Energy, (202) 252-8188

Elliot Winnick, Office of General Counsel, AGC for Procurement and Financial Incentives (GC44), Department of Energy, (202) 252-6902.

SUPPLEMENTARY INFORMATION:

I. Background.

II. Statutory and Regulatory Requirements.

III. Public Comments.

Background

Under Section 644 of the Department of Energy Organization Act (hereinafter referred to as "the Act") (Pub. L. 95-91, 91 Stat. 565 (41 U.S.C. 7254)), the Secretary of the Department is authorized to prescribe such procedural rules and regulations as he may deem necessary or appropriate to effectuate the functions vested in him. Accordingly, the Department of Energy Procurement Regulations (DOE-PR) were promulgated with an effective date of June 30, 1979 (see 44 FR 34424).

The specific changes being made are as follows: *Change 6.1* amends § 9-3.807-50, "Approvals and waiver," at paragraph (a) in order to simplify and streamline the procurement process by allowing delegation below the Head of the Procuring Activity of the authority to approve the findings required by FPR § 1-3.807-1(b)(1)(ii)(C) and § 1-3.807-3(f)(1); *Change 6.2* amends § 9-5.5206 in order to delete §§ 9-5.5206-6 and 9-5.5206-7 to assure consistency with amendments to the Federal Property Management Regulations and to delete § 9-5.5206-13 as a result of a change being made at § 9-5.5207; *Change 6.3* amends § 9-5.5207-2 to establish a new property category to be titled "Precious Metals" which will include the previous categories of gold and platinum and will be managed by the Oak Ridge Operations Office; *Change 6.4* amends the Classification and Security clauses at § 9-7.103-50 and § 9-7.103-53; *Change 6.5* adds a new paragraph to § 9-7.104-50, "Priorities, Allocations, and Allotments," informing DOE contractors that they may be eligible for priorities and allocations support in ordering necessary materials and equipment for their contracts, if the purpose of such contracts is to maximize domestic energy supplies; *Change 6.6* amends § 9-7.302-57, "Printing," to clarify the definition of printing and the procedures to be followed regarding printing; *Change 6.7* adds a new § 9-15.205-61 entitled "Printing costs" to note the limitation contained at § 9-7.302-57; *Change 6.8* amends Part 9-23, "Subcontracting Policies and Procedures," to relax the Headquarters review prerequisites, increase emphasis on surveillance, extend the cycle of subsequent reviews, and delegate increased approval authority to the Heads of the Procuring Activities; *Change 6.9* amends § 9-50.5206-6, "Miscellaneous items," to change a citation at paragraph (e), to change the reference at paragraph (1) from the Chicago Operations Office to the Oak Ridge Operations Office, and to remove from paragraph (m) the references to appliances and water coolers inasmuch as Amendment E-247 of the Federal Property Management Regulations (46 FR 34643, July 10, 1981) has changed the procedures for ordering these items; *Change 6.10* amends the "Security" and "Classification" clauses at § 9-50.704-1 and § 9-50.704-4; *Change 6.11* amends § 9-50.704-33, "Priorities, Allocations and Allotments," to reflect the change made at § 9-7.104-5 above; and *Change 6.12* adds a new clause entitled "Printing" at § 9-50.704.49. These changes are designed to provide greater discretion to the Heads of the Procuring Activities in the use of their delegated authority, to provide new guidance and to update the regulations. It is anticipated that these changes will simplify the procurement process and increase the clarity of the regulations.

II. Statutory and Regulatory Requirements

A. Review Under Executive Order 12291

Inasmuch as this final rule relates to agency management of the procurement function, the OMB clearance procedures set forth in Executive Order 12291 (February 17, 1981) are not applicable.

B. Review Under the Regulatory Flexibility Act

This final rule was reviewed under the Regulatory Flexibility Act of 1980, Pub. L. 96-354, 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. DOE certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities and, therefore, no regulatory flexibility analysis has been prepared.

C. Review Under the Paperwork Reduction Plan Act

DOE has determined that this rulemaking imposes no information collection and reporting requirements on

organizations and individuals external to DOE that may be subject to this regulation in accordance with the Paperwork Reduction Plan Act (44 U.S.C. 3501 *et. seq.*).

D. Review Under the National Environmental Policy Act

DOE has concluded that promulgation of this final rule clearly would not represent a major Federal action having significant impact on the human environment under the National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. 432 *et. seq.*), the Council on Environmental Quality Regulations (40 CFR Parts 1500–1508), and the DOE guidelines (10 CFR 1020), and therefore does not require an environmental impact statement pursuant to NEPA.

III. Public Comment

The changes being made by this final rule were published as a notice of proposed rulemaking on May 3, 1982, 47 FR 18923. That notice invited public comments for a 30 day period ending June 2, 1982. A correction notice was published on June 1, 1982, 47 FR 23780, extending the comment period through June 9, 1982. No comments were received. The revisions contained in this final rule are the same as those contained in the notice of proposed rulemaking except that the changes to the clauses entitled "Security," "Classification," and "Printing" shown at § 9–7.103 and § 9–7.302 (Changes 6.4 and 6.6) are repeated at § 9–50.704 (Changes 6.10 and 6.12). This corrects an oversight in the notice of proposed rulemaking.

List of Subjects in 41 CFR Parts 9–3, 9–5, 9–7, 9–15, 9–23, and 9–50

Government procurement.

For the reasons set forth in the preamble, Chapter 9 of Title 41 of the Code of Federal Regulations is amended as set forth below.

Issued in Washington, D.C. on June 28, 1982.

Hilary J. Rauch,

Director, Procurement and Assistance Management Directorate.

The regulations in 41 CFR Chapter 9 are amended as set forth below.

Authority: Section 644 of the Department of Energy Organization Act, Pub. L. 95–91, 91 Stat. 599, (42 U.S.C. 7254).

Note.—As an aid in identifying specific changes to the DOE Procurement Regulations, a two-digit identification number is assigned to each specific change. The first digit represents the numerical sequence of changes; thus, this is Change 6 to indicate that this is the sixth time that DOE has issued a final rule for the purpose of amending 41 CFR Chapter 9. The second digit is the numerical sequence of specific changes within a particular rule; the first change within the sixth rule is identified as Change 6.1

Change 6.1 Section 9–3.807–50, "Approvals and waiver," is amended by deleting the words, "without power of redelegation" from paragraph (a) regarding the authority to approve the findings required by FPR 1–3.807–1(b)(1)(ii)(C) and 1–3.807–3(f)(1). These findings involve determining that a price is not reasonable even though based on adequate price competition or a catalog or market price. The revised text will read:

§ 9–3.807–50 Approvals and waiver.

(a) Heads of Procuring Activities, or their delegees, may approve the findings required by FPR 1–3.807–1(b)(1)(ii)(C) and 1–3.807–3(f)(1) for contracts estimated to be within the limits of the authority delegated to them. In making such delegations, the Heads of the Procuring Activities shall require that either of these approvals be made at a level above the Contracting Officer as is required by FPR 1–3.807–1(b)(ii)(C).

Change 6.2 Section 9–5.5206, "Miscellaneous items," is amended by removing and reserving § 9–5.5206–6, "New electric water coolers," and § 9–5.5206–7, "Appliances." This revision is necessary as Amendment E–247, of the Federal Property Management Regulations (46 FR 34643, July 10, 1981) changed the manner in which these supply items could be procured. Section 9–5.5206–13, "Gold," is also removed and reserved as a result of the change at 6.3 below. The revised text will read:

§ 9–5.5206 Miscellaneous items.

§ 9–5.5206–6 [Reserved]

§ 9–5.5206–7 [Reserved]

§ 9–5.5206–13 [Reserved]

Change 6.3 Section 9–5.5207–2, "Platinum," is amended at both the Table of Contents and the text, to change its title to "Precious Metals," to change the assignment for this item from the Chicago Operations Office to the Oak Ridge Operations Office, and to expand this assignment to include other elements in the platinum family of metals as well as gold and silver. The revised text will read:

§ 9–5.5207–2 Precious metals.

The Oak Ridge Operations Office is responsible for maintaining the DOE supply of precious metals. These metals are platinum, palladium, iridium, osmium, rhodium, ruthenium, gold and silver. Oak Ridge Operations has assigned management of these metals to N.L.O., Inc., P.O. Box 39158, Cincinnati, Ohio 45239. Telephone numbers are (513) 738–1151, extension 228 or F.T.S. 774–8228. DOE Offices and cost-type contractors shall coordinate with N.L.O., Inc. regarding the availability of the above metals prior to the purchase of these metals on the open market.

Change 6.4 The clauses set forth at § 9–7.103–50, "Classification," and 9–7.103–53, "Security," are deleted and replaced by new clauses of the same title. This is necessary to assure compliance with Executive Order 12065, as amended by Executive Orders 12148 and 12163. The nature of the change in the Classification clause is to provide that only an Authorized Classifier may classify documents and to provide that in instances where such authority is delegated to a contractor, it cannot be redelegated or transferred to others. The changes to the Security clause involve specifying "of 1954" after the reference to the "Atomic Energy Act" in the preamble to the clause, adding the definitions of "Classified Information" and "National Security Information," and adding references to the newly defined category. The text of the new clauses is as follows:

§ 9–7.103–50 Classification.

* * * * *

Classification

In the performance of the work under this contract, the contractor shall ensure that an Authorized Original Classifier or Derivative Classifier shall assign classifications to all documents, material, and equipment originated or generated under the contract in accordance with classification regulations and guidance furnished to the contractor by the DOE. Every subcontract and purchase order issued hereunder involving the origination or generation of classified documents, material, or equipment shall include a provision to the effect that in the performance of such subcontract or purchase order, the subcontractor or supplier shall ensure that an Authorized Original Classifier or Derivative Classifier shall assign classifications to all such documents, materials, and equipment in accordance with classification regulations and guidance furnished to such subcontractor or supplier by the contractor.

* * * * *

§ 9–7.103–53 Security.

The following clause is required in contracts entered into under section 31 (research assistance) or 41 (ownership and operation of production facilities) of the Atomic Energy Act of 1954, as amended, and in other contracts and subcontracts, the performance of which involves or is likely to involve classified information.

Security

(a) Contractor's duty to safeguard all classified information. The contractor shall, in accordance with DOE security regulations and requirements, be responsible for safeguarding all classified information, and protecting against sabotage, espionage, loss and theft, the classified documents and material in the contractor's possession in connection with the performance of work under this contract. Except as otherwise expressly provided in this contract, the contractor shall, upon completion or termination of this contract, transmit to DOE any classified matter in the possession of the contractor or any person under the contractor's control in connection with performance of this contract. If retention by the Contractor of any classified matter is required after the completion or termination of the contract and such retention is approved by the Contracting Officer, the contractor will complete a certificate of possession to be furnished to DOE specifying the classified matter to be retained. The certification shall identify the items and types or categories of matter retained, the conditions governing the retention of the matter, and the period of retention, if known. If the retention is approved by the Contracting Officer, the security provisions of the contract will continue to be applicable to the matter retained.

(b) Regulations. The contractor agrees to conform to all security regulations and requirements of DOE.

(c) Definition of classified information. The term "classified information" means Restricted Data, Formerly Restricted Data, and National Security Information.

(d) Definition of Restricted Data. The term "Restricted Data" means all data concerning (1) design, manufacture, or utilization of atomic weapons; (2) the production of special nuclear material; or (3) the use of special nuclear material in the production of energy, but shall not include data declassified or removed from the Restricted Data category pursuant to Section 142 of the Atomic Energy Act of 1954, as amended.

(e) Definition of Formerly Restricted Data. The term "Formerly Restricted Data" means all data removed from the Restricted Data category under section 142 d. of the Atomic Energy Act of 1954, as amended.

(f) Definition of National Security Information. The term "National Security Information" means information or material which is owned by, produced for or by, or under the control of the United States Government, which has been determined pursuant to Executive Order 12065 or prior Orders to require protection against unauthorized disclosure, and which is so designated.

(g) Security clearance of personnel. The contractor shall not permit any individual to have access to any classified information, except in accordance with the Atomic Energy Act of 1954, as amended, Executive Order 12065, and the DOE's regulations or requirements applicable to the particular level and category of classified information to which access is required.

(h) Criminal liability. It is understood that disclosure of any classified information relating to the work or services ordered hereunder to any person not entitled to receive it, or failure to safeguard any classified information that may come to the contractor or any person under the contractor's control in connection with work under this contract, may subject the contractor, its agents, employees, or subcontractors to criminal liability under the laws of the United States. (See the Atomic Energy Act of 1954, as amended, 42 U.S.C. 2100 et seq.; 18 U.S.C. 793 and 794; and Executive Order 12065).

(i) Subcontracts and purchase orders. Except as otherwise authorized in writing by the contracting officer, the contractor shall insert provisions similar to the foregoing in all subcontracts and purchase orders under this contract.

Change 6.5 Section 9–7.104–50. "Priorities, allocations, and allotments," is amended by placing a prefix (a) before the existing text, correcting the name of the Department of Commerce group administering this program, and adding a new paragraph (b) to explain that priorities and allocations support may be available to DOE contractors if the purpose of their contract is to maximize domestic energy supplies. The revised text will read:

§ 9–7.104–50 Priorities, allocations, and allotments.

(a) The following clause may be used only in contracts and orders for military and atomic energy production and directly related activity, and supply contracts directly related thereto, where the programs have been authorized pursuant to the Atomic Energy Act of 1954, as amended.

Priorities, Allocations, and Allotments

The contractor shall follow the rules, regulations, and procedures of the Defense Priorities System and the Defense Materials System, Regulation I, and all other applicable regulations and orders of the International Trade Administration, Department of Commerce, in obtaining controlled materials and other products and materials needed to fill this order.

(b) Other contracts may be eligible for priorities and allocations support if their purpose is to maximize domestic energy supplies. Eligibility is dependent on an executive decision on a case by case basis. Guidance is provided by DOE Publication PR–0042, "Priorities and Allocations Support for Energy: Keeping Energy Programs on Schedule," dated August 1980, as it may from time to time be revised. If the purpose of the contract is to maximize domestic energy resources, include the following clause:

Priorities, Allocations, and Allotments—Special Clause

This contract may be eligible for priorities and allocations support, as provided for by Section 101(c) of the Defense Production Act of 1950, as amended by the Energy Policy and Conservation Act (Pub. L. 94–163, 42 U.S.C. 6201 *et seq.*) if its purpose is to maximize domestic energy supplies. Eligibility is dependent on an executive decision on a case by case basis with the decision being jointly made by the Departments of Commerce and Energy. DOE Regulations regarding Material Allocation and Priority Performance under Contracts or Orders to Maximize Domestic Energy Supplies can be found at Part 216 of Title 10 of the Code of Federal Regulations (10 CFR 216). Additional guidance is provided by DOE Publication PR–0042, "Priorities and Allocations Support for Energy: Keeping Energy Programs on Schedule," dated August 1980, as it may from time to time be revised. Copies may be obtained by written request to: Department of Energy, Technical Information Center (TIC), Post Office Box 62, Oak Ridge, Tennessee 37830.

Change 6.6 The present § 9–7.302–57, "Printing," is deleted and replaced with new coverage of the same topic. The change is being made to clarify the definition of printing and to provide procedures to be followed by contractor and Government personnel. The revised text will read:

§ 9–7.302–57 Printing.

Title 44, United States Code, "Public Printing and Documents," establishes policies regarding public printing and documents within the Federal Government. It provides that public printing will be accomplished by the Government Printing Office, its regional offices or authorized departmental printing plants. It provides a limited exemption for contractors. Requirements exceeding that limitation are to be accomplished utilizing Government resources. To facilitate this, Contracting Officers shall furnish the necessary forms and instructions to contractors, as called for by DOE Order 1340.1, and include the following clause in all contracts:

Printing

The contractor shall not engage in, nor subcontract for, any printing (as that term is defined in Title I of the Government Printing and Binding Regulations in effect on the effective date of this contract) in connection with the performance of work under this

contract: Provided, however, that performance of a requirement under this contract involving the duplication of less than 5,000 copies of a single page, or not more than 25,000 units in the aggregate of multiple pages, will not be deemed to be printing. A unit is defined as one sheet, size 8½ by 11 inches, one side only, one color.

a. The term "printing" includes the following processes: composition, platemaking, presswork, binding, microform publishing or the end items produced by such processes.

b. If fulfillment of the contract will necessitate reproduction in excess of the limits set forth above, contractors shall provide the Contracting Officer with camera ready copy as may be required elsewhere in the contract. The Contracting Officer will arrange for the production, acquisition, and dissemination of printed matter.

c. Printing services not obtained in compliance with this guidance will result in the cost of such printing being disallowed.

* * * * *

Change 6.7 New §§ 9–15.205–61, 9–15.303–J.45, and 9–15.603–2.B–61 entitled "Printing costs" are added. The text will read as follows:

§ 9–15.205–61 Printing costs

The costs of printing as defined at 9–7.302–57 are allowable only to the extent that they are allowed under the limited exemption provided therein.

* * * * *

§ 9–15.303–J.45 Printing costs

See the limitation at 9–15.205–61.

* * * * *

§ 9–15.603–2.B–61 Printing costs

See the limitation at 9–15.302–57.

Change 6.8 The existing Table of Contents and text of Part 9–23, "Subcontracting Policies and Procedures," is removed and replaced by the revised Part 9–23 of the same title. This revision is the result of a reassessment of the Contractor Procurement System Review program, which suggested a reduced Headquarters involvement in such reviews. The more significant changes in the revised coverage include (1) relaxing Headquarters review prerequisites, (2) increasing emphasis on surveillance and extending the cycle of subsequent reviews, and (3) delegating increased authority to cognizant HPAs to grant, withhold, or withdraw system approval. The proposed rule contains a number of other less significant changes designed to improve the overall continuity and clarity of the part. The revised text reads:

PART 9–23—SUBCONTRACTING POLICIES AND PROCEDURES

Sec.

9–23.0 Scope of part.

Subpart—9–23.1 Review of contractor procurement systems

Sec.

9–23.100 Scope of subpart.
9–23.101 Objectives.
9–23.102 Responsibilities.
9–23.103 Definitions.
9–23.104 Review criteria.
9–23.105 Types of reviews.
9–23.106 Extent of review.
9–23.107 Review of CPSR Reports.
9–23.108 Granting, continuing, withholding, and withdrawing approval.
9–23.109 Disclosure of approval status of a contractor's procurement system.
9–23.110 Surveillance of the contractor's approved procurement system.

§ 9–23.0 Scope of part.

This part sets forth policies and procedures for evaluation, review, and approval of contractor procurement systems. Reliance upon a contractor's approved procurement system will usually eliminate the need for reviewing and approving or consenting to most individual subcontracts. However, programmatic and other considerations will still require Government involvement at an early stage in procurement action planning and some subcontract approvals.

Subpart 9–23.1—Review of Contractor Procurement Systems

§ 9–23.100 Scope of subpart.

This subpart sets forth requirements for conducting contractor procurement system reviews (CPSRs).

§ 9–23.101 Objectives.

The objectives of the reviews are to provide:

(a) A means for evaluating the efficiency and effectiveness with which the contractor manages the procurement function in spending Government funds;

(b) The basis for the Contracting Officer to grant, continue, withhold, or withdraw approval of the contractor's procurement system;

(c) Reliable current information on contractor procurement systems for use in source selection, determining the appropriate type of contract, estimating contract costs, and establishing profit or fee objectives; and

(d) Current procurement system information for appropriate DOE activities.

§ 9–23.102 Responsibilities.

(a) DOE Contracting Officers, or designees, will conduct CPSRs of DOE cognizant contractors.

(b) Other Federal Agencies/Departments may be requested to conduct CPSRs, as appropriate, for other than DOE cognizant contractors. DOE Contracting Officers shall normally recognize other Federal Agency/Department approvals of contractors' procurement systems within the limitations identified by approving officials of such agencies.

(c) The Senior Procurement Official, Headquarters, is reponsible for overall conduct of the DOE-wide CPSR program.

§ 9–23.103 Definitions.

(a) The term "contractor", as used in this Subpart, refers to a "prime contractor" or "subcontractor" and means a separate entity of a contractor, such as an affiliate, division, or plant, which performs its own purchasing.

(b) The term "DOE cognizant contractors" refers to those contractors over which DOE has cognizance as identified in OMB Circular A–88, or those with which DOE has the preponderance of Government business. The term includes operating contractors, and pilot and demonstration plant contractors.

§ 9–23.104 Review criteria.

(a) A Contractor Procurement System Review (CPSR) is an evaluation of a contractor's procurement system and the effectiveness with which procurements are placed in performance of Government contracts. It is not limited to a specific Government contract.

(b) The Contracting Officer will initiate a CPSR after determining a review is warranted by the nature or extent of subcontracting. Generally, a CPSR shall be performed if the contractor is expected, within the next 12 months, to have in excess of $5,000,000 of Government-funded subcontracting under other than fixed-price contracts awarded on the basis of adequate price competition as defined in FPR 1–3.807(b)(1). (For the purpose of this paragraph, contract modifications are not considered to be competitively awarded). CPSRs should not ordinarily be performed on subcontractors unless, in addition to the criteria for conducting a CPSR on a prime contractor, the following criteria are also satisfied: (1) the preponderance of subcontractor sales is to prime contractors under the Federal Government, and (2) both the prime contractor and the subcontractor agree to performance of a CPSR.

(c) Contractor procurement systems meeting the criteria in paragraph (b) of this section shall not be reviewed if the Contracting Officer determines in writing, with Head of Procuring Activity concurrence, that the extent or nature of the subcontracting will not justify CPSR costs. In exceptional cases, a contractor not meeting the criteria in paragraph (b) of this section, may be reviewed if the

Contracting Officer determines that facts warrant such action.

(d) CPSRs will be conducted in accordance with appropriate agency directives and guidance.

(e) Initial, subsequent, and followup review teams should include appropriate representatives from DOE field offices; other Federal Agency participation may be additionally requested as appropriate. Generally, team composition should not consist exclusively of those who have a day-to-day relationship with the contractor regarding subcontract consent or approval.

§ 9-23.105 Types of reviews.

§ 9-23.105-1 Initial reviews.

An initial review shall be conducted when the contractor meets criteria in § 9-23.104. The review shall be a complete evaluation as described in § 9-23.106.

§ 9-23.105-2 Subsequent reviews.

If a contractor's procurement system is approved, the Contracting Officer shall annually determine the need for a subsequent review if the system still meets the criteria in § 9-23.104. The maximum length of time between subsequent reviews shall be determined by the Head of Procuring Activity based on Contracting Officer's ability to accomplish adequate surveillance of the contractor's procurement system as described in § 9-23.110. A subsequent review may be limited to specific areas, but shall include sufficient consideration of each factor listed in § 9-23-106(a) to establish current adequacy or inadequacy of the entire system. Such review shall generally be conducted to:

(a) Examine changes instituted since the previous review;

(b) Ascertain the status of prior recommendations upon which action has not been completed; and

(c) Determine whether the contractor's procurement system warrants continued approval.

§ 9-23.105-3 Special reviews.

After approval of the contractor's procurement system, the Contracting Officer may initiate special reviews in connection with identified weaknesses resulting from:

(a) Initial, follow-up, or subsequent review;

(b) Review of subcontracts submitted under the notification requirement of contract clauses;

(c) Changes in the contractor's procurement policies, procedures, or personnel;

(d) Changes in plant workload or type of work; or

(e) Information provided by Government personnel.

In conducting such reviews, the same effectiveness criteria used in previous reviews shall be applied to areas being examined.

§ 9-23.105-4 Follow-up reviews.

If approval of a contractor's procurement system is withheld or withdrawn, a follow-up review shall be made as soon as evidence is received from the contractor that factors leading to such action have been corrected. Whether this review consists of complete reexamination of the contractor's procurement system, or is confined to areas found deficient, is a matter of judgment and will depend on the time lapse between notice to the contractor of withholding or withdrawal of approval, and follow-up review.

§ 9-23.106 Extent of review.

(a) Generally, a review shall consist of a complete evaluation of the contractor's procurement system. The review shall be made in accordance with appropriate DOE directives and guidance, and shall give attention to:

(1) Degree of competition obtained;

(2) Pricing policies and techniques, including methods of obtaining accurate, complete, and current cost or pricing data, and certification as required;

(3) Methods of evaluating subcontractors' capabilities and financial responsibility;

(4) Treatment accorded affiliates and other concerns having close working arrangements with the contractor;

(5) Extent to which assurance is obtained that principal subcontractors apply sound pricing practices and have a satisfactory procurement system in dealing with lower-tier subcontractors;

(6) Appropriateness of the types of subcontracts used;

(7) Practices pertaining to small and socially and economically disadvantaged businesses, labor surplus areas, and other socio-economic provisions;

(8) Management surveillance of significant subcontract programs;

(9) Contractor procurement policies and procedures pertaining to such items as "make-or-buy" program, property control, obtaining warranties, and organizational conflicts of interest;

(10) Compliance with cost accounting standards in subcontract award and administration;

(11) Effectiveness of subcontracting policies and procedures;

(12) Effectiveness of policies and procedures for subcontract close-out actions;

(13) Adequacy of sole source justifications;

(14) Conformance of subcontracting terms and conditions with requirements of the prime contract;

(15) Acceptability and completeness of subcontractor representations and certifications;

(16) Adequacy of subcontracting negotiations and documentation; and

(17) Whether required DOE approval or consent has been obtained for subcontracts and deviations from required terms and conditions.

(b) In reviewing the contractor's procurement system, a determination shall be made as to whether subcontracting is competitively accomplished to the maximum practicable extent. This requires ascertaining whether:

(1) A sufficient number of sources are solicited; and

(2) Subcontracting procedures provide other essential elements needed for adequate and effective competition, including:

(i) Adequate description of any factors to be evaluated; and

(ii) Evaluation of all offers on a common basis.

(c) Decisions as to whether commercial items conform to the purpose and intent of the exemption from the requirement to submit and certify current cost or pricing data shall be analyzed.

§ 9-23.107 Review of CPSR Reports.

(a) Review team findings and recommendations contained in the CPSR Report shall be approved by the Head of Procuring Activity before the Contracting Officer makes a determination to continue, grant, withhold, or withdraw approval.

(b) If revisions are to be made to subcontract dollar thresholds or other limitations, the submittal to the HPA shall include:

(1) A stratification of the present subcontract review workload, including average workhours expended and lead times experienced in processing requests for subcontract consent and;

(2) An evaluation of anticipated benefits, including average workhours and lead times saved in processing requests for subcontract consent.

§ 9-23.108 Granting, continuing, withholding, and withdrawing approval.

(a) The Contracting Officer is responsible for granting, continuing, withholding, or withdrawing approval of a contractor's procurement system subject to the requirements of § 9-23.107(a). The Contracting Officer shall

approve a procurement system only after a CPSR discloses that the contractor's procurement policies and practices are effective and provide adequate protection of the Government's interests. Approval of a system shall be withheld if there are major weaknesses, if the contractor is unable to provide sufficient information upon which to base an affirmative determination that its procurement system is adequate and effective or if withholding of approval is otherwise deemed appropriate to protect the Government's interests.

(b) The Contracting Officer shall give the contractor written notice granting, continuing, withholding, or withdrawing approval of the procurement system. If the contractor's system is approved, the notification of approval shall include:

(1) The effective date of the approval;

(2) Approved plant(s), division(s), or facility of the company;

(3) Approval period (usually one year, maximum three years);

(4) Extent of applicability (usually all DOE contracts with the approved facility administered by the involved procurement office, and all such DOE contracts administered by other DOE procurement offices when the cognizant Contracting Officer concurs);

(5) Any special conditions which the contractor must follow in notifying the Contracting Officer or in obtaining Contracting Officer consent or approval (such as intracompany transfers, critical or programmatically important subcontracts, or awards of a noncompetitive subcontract);

(6) Other conditions such as:

(i) Contract terms that need to be changed; and

(ii) Advice that termination of approval will occur upon a change in the procurement system unless approved by the Contracting Officer; and

(7) A statement that approval may be withdrawn at any time at the Government's discretion.

(c) The approval (and any change in dollar thresholds or other limitations) will be based upon the degree of confidence in the contractor's procurement system as determined through the review and the need to maintain a review of the most significant subcontracts, subject to the limitations in § 9–50.302–5(b).

(d) Approval of a contractor's procurement system does not negate the requirement for advance notification except as set forth in § 9–3.901. Advance notification for information purposes is required in the following instances:

(1) Noncompetitive procurement over $25,000;

(2) Intracompany transfers or payment over $10,000; and

(3) Direct reimbursement of costs over $500.

The advance notice shall contain, as a minimum, a description of work, estimated costs, type of contract or reimbursement provisions, and extent of anticipated competition or justification for noncompetitive procurement. The Contracting Officer may at any time request additional information that must be furnished promptly and prior to award of the subcontract.

When approval of the contractor's procurement system is withheld or withdrawn, recommendations for correction of those deficiencies which will permit (after correction and assuming that other areas previously found to be satisfactory are not deficient) the granting or reinstatement of approval should be furnished to the contractor in writing. The contractor shall be requested to furnish as soon as possible (normally within two weeks) a time-phased plan for correction of deficiencies. Submission of periodic status reports to the Contracting Officer shall be required. Contents of contractor procurement systems review reports, and other information disclosed by the contractor during the review shall be divulged only to Government personnel having a need to know. However, the Contracting Officer will furnish three copies of the approved review report (less the contractor's recommendations to the Government) to the contractor for information purposes.

(f) When recommendations are made for improvement of an approved system, the contractor shall be requested to reply as soon as possible (normally within two weeks) as to its concurrence or position with respect to the recommendations.

(g) Copies of CPSR reports, copies of notifications granting, continuing, withholding, or withdrawing approval of a contractor's procurement system, copies of recommendations for improvement of an approved system, copies of notifications (or contract modifications) altering the subcontract consent dollar thresholds, and information received from the contractor pursuant to paragraphs (d) and (e) of this section, shall be transmitted to the Director, Policy and Procedures Division, (Attention MA931), Headquarters.

§ 9–23.109 Disclosure of approval status of a contractor's procurement system.

Upon request, a prime contractor may be informed that the procurement system of a proposed subcontractor has been approved under Government prime contracts, if such is the case. The prime contractor shall be cautioned that approval status is furnished only as of the date of notification and the Government does not assume the responsibility to keep the prime contractor advised of any change in approval status of the proposed subcontractor's procurement system.

§ 9–23.110 Surveillance of the contractor's approved procurement system.

(a) The Contracting Officer must maintain a sufficient level of surveillance to assure that the contractor continues to effectively manage the procurement program. The Contracting Officer shall develop a surveillance plan and submit it to the Head of the Procuring Activity for approval. The surveillance plan shall encompass all phases of the system (pre-award and post-award performance, contract completion, and close-out) and all operations affecting procurement and subcontracting. Surveillance shall consider all elements of the contractor's procurement system including, but not limited to, those items evaluated in the initial review. The surveillance plan must provide for review and consent to placement of a representative sample of subcontracts, including the largest and most complex subcontracts being issued each year.

(b) Certain subcontractors may require additional surveillance based on flowdown of policies concerning cost, schedule, and technical performance.

Change 6.9 Section 9–50.506–6, "Miscellaneous items," is amended at paragraph (e) to change the reference § 9–5,5206–13 to § 9–5.5207–2; is amended at paragraph (1) to indicate that the Oak Ridge Operations Office rather than the Chicago Operations Office is the manager for DOE supplies of the newly designated "Precious Metals" property category; and is amended at paragraph (m), subparagraphs (1) and (2) to delete the references to appliances and new electric water coolers as this guidance has been superseded by Amendment E–247 of the Federal Property Management Regulations, (46 FR 35643, July 10, 1981). Subparagraphs (7) and (8) of paragraph (m) are also revised to correct erroneous references to sections of the Federal Property Management Regulations. The revised text will read:

§ 9–50.506–6 Miscellaneous items (9–5.5206)

* * * * *

(e) Gold (See 9–5.5207–2)

* * * * *

(1) Prior to purchase of any of the precious metals (these are platinum, palladium, iridum, osmium, rhodium, ruthenium, gold and silver) on the open market, contractors shall clear the availability of such metals with N.L.O., Inc. as required by § 9–5.5207–2.

(m) * * *

(1) Reserved

(2) Reserved

* * * * *

(7) Materials handling equipment § 101–25.405 (9–5.5206–15)

(8) Coal § 101.26.602–4 (9–5.5206–18)

Change 6.10 The clauses set forth at § 9–50.704–1, "Security," and § 9–50.704–4, "Classification," are deleted and replaced by new clauses of the same title. This is necessary to assure compliance with Executive Order 12065, as amended by Executive Orders 12148 and 12163. The nature of the change in the Classification clause is to provide that only an Authorized Classifier may classify documents and to provide that in instances where such authority is delegated to a contractor, it cannot be redelegated or transferred to others. The changes to the Security clause involve specifying "of 1954" after the reference to the "Atomic Energy Act" in the preamble to the clause, adding the definitions of "Classified Information" and "National Security Information," and adding references to the newly defined category. The text of the new clauses is as follows:

§ 9–50.704–1 Security.

The following clause is required in contracts entered into under section 31 (research assistance) or 41 (ownership and operation of production facilities) of the Atomic Energy Act of 1954, as amended, and in other contracts and subcontracts, the performance of which involves or is likely to involve classified information.

Security

(a) Contractor's duty to safeguard all classified information. The contractor shall, in accordance with DOE security regulations and requirements, be responsible for safeguarding all classified information, and protecting against sabotage, espionage, loss and theft, the classified documents and material in the contractor's possession in connection with the performance of work under this contract. Except as otherwise expressly provided in this contract, the contractor shall, upon completion or termination of this contract, transmit to DOE any classified matter in the possession of the contractor or any person under the contractor's control in connection with performance of this contract. If retention by the Contractor of any classified matter is required after the completion or termination of the contract and such retention is approved by the Contracting Officer, the contractor will complete a certificate of possession to be furnished to DOE specifying the classified matter to be retained. The certification shall identify the items and types or categories of matter retained, the conditions governing the retention of the matter, and the period of retention, if known. If the retention is approved by the Contracting Officer, the security provisions of the contract will continue to be applicable to the matter retained.

(b) Regulations. The contractor agrees to conform to all security regulations and requirements of DOE.

(c) Definition of classified information. The term "classified information" means Restricted Data, Formerly Restricted Data, and National Security Information.

(d) Definition of Restricted Data. The term "Restricted Data" means all data concerning (1) design, manufacture, or utilization of atomic weapons; (2) the production of special nuclear material; or (3) the use of special nuclear material in the production of energy, but shall not include data declassified or removed from the Restricted Data category pursuant to Section 142 of the Atomic Energy Act of 1954, as amended.

(e) Definition of Formerly Restricted Data. The term "Formerly Restricted Data" means all data removed from the Restricted Data category under section 142d. of the Atomic Energy Act of 1954, as amended.

(f) Definition of National Security Information. The term "National Security Information" means information or material which is owned by, produced for or by, or under the control of the United States Government, which has been determined pursuant to Executive Order 12065 or prior Orders to require protection against unauthorized disclosure, and which is so designated.

(g) Security clearance of personnel. The contractor shall not permit any individual to have access to any classified information, except in accordance with the Atomic Energy Act of 1954, as amended, Executive Order 12065, and the DOE's regulations or requirements applicable to the particular level and category of classified information to which access is required.

(h) Criminal liability. It is understood that disclosure of any classified information relating to the work or services ordered hereunder to any person not entitled to receive it, or failure to safeguard any classified information that may come to the contractor or any person under the contractor's control in connection with work under this contract, may subject the contractor, its agents, employees, or subcontractors to criminal liability under the laws of the United States. (See the Atomic Energy Act of 1954, as amended, 42 U.S.C. 2100 et seq.; 18 U.S.C. 793 and 794; and Executive Order 12065).

(i) Subcontracts and purchase orders. Except as otherwise authorized in writing by the contracting officer, the contractor shall insert provisions similar to the foregoing in all subcontracts and purchase orders under this contract.

§ 9–50.704–4 Classification.

This clause is required in contracts involving classified information.

Classification

In the performance of the work under this contract, the contractor shall ensure that an Authorized Original Classifier or Derivative Classifier shall assign classifications to all documents, material, and equipment originated or generated under the contract in accordance with classification regulations and guidance furnished to the contractor by the DOE. Every subcontract and purchase order issued hereunder involving the origination or generation of classified documents, material, or equipment shall include a provision to the effect that in the performance of such subcontract or purchase order, the subcontractor or supplier shall ensure that an Authorized Original Classifier or Derivative Classifier shall assign classifications to all such documents, materials, and equipment in accordance with classification regulations and guidance furnished to such subcontractor or supplier by the contractor.

* * * * *

Change 6.11 Section 9–50.704–33, "Priorities, allocations, and allotments," is revised by (1) adding a new introductory sentence with the prefix "(a)" before the present text, (2) correcting the reference to the Department of Commerce, International Trade Administration, and (3) by adding a new paragraph (b) to explain that priorities and allocations support may be available to DOE contractors if the purpose of their contract is to maximize domestic energy supplies. The revised text will read:

§ 9–50.704–33 Priorities, allocations, and allotments.

(a) If the contract is for military or atomic energy production use the following clause:

Priorities, Allocations, and Allotments

The contractor shall follow the rules, regulations, and procedures of the Defense Priorities System and the Defense Materials System Regulation I and all other applicable regulations and orders of the International Trade Administration, Department of Commerce, in obtaining controlled materials and other products and materials needed to fill this order.

(b) Other contracts may be eligible for priorities and allocations support if their purpose is to maximize domestic energy supplies. Eligibility is dependent on an executive decision on a case by case basis. Guidance is provided by DOE Publication PR–0042, "Priorities and Allocations Support for Energy: Keeping Energy Programs on Schedule," dated August 1980, as it may from time to time be revised. If the purpose of the contract is to maximize domestic energy resources, include the following clause:

Priorities and Allocations—Special Clause

This contract may be eligible for priorities and allocations support, as provided for by Section 101(c) of the Defense Production Act of 1950, as amended by the Energy Policy and Conservation Act of 1975 if its purpose is to maximize domestic energy supplies. Eligibility is dependent on an executive decision on a case by case basis with the decision being jointly made by the Departments of Commerce and Energy.

DOE Regulations regarding Materials Allocation and Priority Performance under Contracts or Orders to Maximize Domestic Energy Supplies can be found at Part 216 of Title 10 of the Code of Federal Regulations (10 CFR 216). Additional guidance is provided by DOE Publication PR–0042, entitled "Priorities and Allocations Support for Energy: Keeping Energy Programs on Schedule," dated August 1980, as may from time to time be revised. Copies may be obtained by written request to: Department of Energy, Technical Information Cenfer (TIC), Post Office Box 62, Oak Ridge, Tennessee 37830.

Change 6.12 A new clause entitled "Printing" is added as Section 9–50.704–49. The new clause clarifies the procedures to be followed by DOE operating and on-site contractors in the area of printing services. The text will read as follows:

§ 9–50.704.49 Printing.

To the extent that duplicating or printing services may be required elsewhere in this contract, the contractor shall provide or secure such services in accordance with the Government Printing and Binding Regulations, Title 44 of the U.S. Code, and DOE Directives relative thereto.

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BILLING CODE 6450–01–M

FEDERAL EMERGENCY MANAGEMENT AGENCY

44 CFR Part 64

[Docket No. FEMA 6352]

Suspension of Community Eligibility Under the National Flood Insurance Program

AGENCY: Federal Emergency Management Agency.

ACTION: Final rule.

SUMMARY: This rule lists communities, where the sale of flood insurance has been authorized under the National Flood Insurance Program (NFIP), that are suspended effective the dates listed within this rule because of noncompliance with the flood plain management requirements of the program.

EFFECTIVE DATE: The third date ("Susp.") listed in the fifth column.

FOR FURTHER INFORMATION CONTACT: Mr. Richard E. Sanderson, Chief, Natural Hazards Division, (202) 287–0270, 500 C Street Southwest, Donohoe Building, Room 505, Washington, DC 20472.

SUPPLEMENTARY INFORMATION: The National Flood Insurance Program (NFIP), enables property owners to purchase flood insurance at rates made reasonable through a Federal subsidy. In return, communities agree to adopt and administer local flood plain management measures aimed at protecting lives and new construction from future flooding. Section 1315 of the National Flood Insurance Act of 1968, as amended (42 U.S.C. 4022) prohibits flood insurance coverage as authorized under the National Flood Insurance Program (42 U.S.C. 4001–4128) unless an appropriate public body shall have adopted adequate flood plain management measures with effective enforcement measures. The communities listed in this notice no longer meet that statutory requirement for compliance with program regulations (44 CFR Part 59 et seq.). Accordingly, the communities are suspended on the effective date in the fifth column, so that as of that date flood insurance is no longer available in the community.

In addition, the Director of Federal Emergency Management Agency has identified the special flood hazard areas in these communities by publishing a Flood Hazard Boundary Map. The date of the flood map, if one has been published, is indicated in the sixth column of the table. Section 202(a) of the Flood Disaster Protection Act of 1973 (Pub. L. 93–234), as amended, provides that no direct Federal financial assistance (except assistance pursuant to the Disaster Relief Act of 1974 not in connection with a flood) may legally be provided for construction or acquisition of buildings in the identified special flood hazard area of communities not participating in the NFIP, with respect to which a year has elasped since identification of the community as having flood prone areas, as shown on the Federal Emergency Management Agency's initial flood insurance map of the community. This prohibition against certain types of Federal assistance becomes effective for the communities listed on the date shown in the last column.

The Director finds that delayed effective dates would be contrary to the public interest. The Director also finds that notice and public procedure under 5 U.S.C. 533(b) are impracticable and unnecessary.

The Catalog of Domestic Assistance Number for this program is 83.100 "Flood Insurance." This program is subject to procedures set out in OMB Circular A–95.

Pursuant to the provision of 5 USC 605(b), the Associate Director of State and Local Programs and Support, to whom authority has been delegated by the Director, Federal Emergency Management Agency, hereby certifies that this rule if promulgated will not have a significant economic impact on a substantial number of small entities. As stated in section 2 of the Flood Disaster Protection Act of 1973, the establishment of local flood plain management together with the availability of flood insurance decreases the economic impact of future flood losses to both the particular community and the nation as a whole. This rule in and of itself does not have a significant economic impact. Any economic impact results from the community's decision not to (adopt) (enforce) adequate flood plain management, thus placing itself in non-compliance of the Federal standards required for community participation.

In each entry, a complete chronology of effective dates appears for each listed community.

List of Subjects in 44 CFR Part 64

Flood insurance, Flood plains.

Section 64.6 is amended by adding in alphabetical sequence new entries to the table.

§ 64.6 List of eligible communities.

State and county	Location	Community No.	Effective dates of authorization/cancellation of sale of flood insurance in community	Special flood hazard area identified	Date [1]
Alabama:					
Choctaw	Butler, city of	010033B	Aug. 7, 1975, emergency; July 5, 1982, regular; July 5, 1982, suspended.	Sept. 24, 1976, Oct. 26, 1979	July 5, 1982.
Cleburne	Heflin, city of	010043A	May 28, 1975, emergency; July 5, 1982, regular; July 5, 1982, suspended.	Nov. 1, 1974	Do.
Calhoun	Jacksonville, city of	010022B	Dec. 31, 1974, emergency; July 5, 1982, regular; July 5, 1982, suspended.	May 17, 1974, Jan. 9, 1976	Do.
Walker	Unincorporated areas	010301B	July 2, 1979 emergency; July 5, 1982, regular; July 5, 1982, suspended.	June 9, 1978	Do.
Arizona: Apache	Unincorporated areas	040001B	Apr. 11, 1975, emergency; July 5, 1982, regular; July 5, 1982, suspended.	Dec. 20, 1974, May 16, 1978	Do.
Connecticut:					
Litchfield	Thomaston, town of	090055B	July 16, 1975, emergency; July 5, 1982, regular; July 5, 1982, suspended.	May 31, 1984, Dec. 17, 1976	Do.
New Haven	Wolcott, town of	090093B	Aug. 6, 1975, emergency; July 5, 1982, regular; July 5, 1982, suspended.	May 3, 1974, Nov. 26, 1976	Do.
Iowa:					
Linn	Center Point, city of	190439A	Oct. 27, 1977, emergency; July 5, 1982, regular; July 5, 1982, suspended.	Oct. 29, 1976	Do.
Do	Marion, city of	190191B	June 30, 1975, emergency; July 5, 1982, regular; July 5, 1982, suspended.	Mar. 1, 1974, Dec. 10, 1976	Do.
Do	Robins, city of	190443A	Jan. 16, 1978, emergency; July 5, 1982, regular; July 5, 1982, suspended.	Mar. 26, 1976	Do.
Kentucky: Greenup	Greenup, city of	210088B	Dec. 15, 1975, emergency; July 5, 1982, regular; July 5, 1982, suspended.	Jan. 23, 1974, June 4, 1976	Do.
Maine: York	Buxton, town of	230146A	Apr. 1, 1976, emergency; July 5, 1982, regular; July 5, 1982, suspended.	Jan. 14, 1977	Do.
Massachusetts:					
Middlesex	Arlington, town of	250177B	Jan. 16, 1974, emergency; July 5, 1982, regular; July 5, 1982, suspended.	June 28, 1974, Jan. 14, 1977	Do.
Do	Cambridge, city of	250186B	July 24, 1975, emergency; July 5, 1982, regular; July 5, 1982, suspended.	June 21, 1974, Nov. 19, 1976	Do.
Berkshire	Clarksburg, town of	250020B	Aug. 11, 1975, emergency; July 5, 1982, regular; July 5, 1982, suspended.	July 26, 1974, Nov. 19, 1976	Do.
Do	Dalton, town of	250021B	Nov. 18, 1974, emergency; July 5, 1982, regular; July 5, 1982, suspended.	Sept. 20, 1974, Jan 21, 1977	Do.
Franklin	Erving, town of	250116B	Oct. 10, 1975, emergency; July 5, 1982, regular; July 5, 1982, suspended.	June 28, 1974, July 30, 1976	Do.
Middlesex	Groton, town of	250194B	Oct. 30, 1975, emergency; July 5, 1982, regular; July 5, 1982, suspended.	Sept. 6, 1974, Nov. 22, 1977	Do.
Do	Hopkinton, town of	250196B	Dec. 3, 1975, emergency; July 5, 1982, regular; July 5, 1982, suspended.	July 19, 1974, Oct. 8, 1976	Do.
Berkshire	Merrimac, town of	250092B	Feb. 7, 1975, emergency; July 5, 1982, regular; July 5, 1982, suspended.	Oct. 18, 1974, Sept. 3, 1976	Do.
Franklin	Orange, town of	250125B	Dec. 14, 1979, emergency; July 5, 1982, regular; July 5, 1982, suspended.	May 31, 1974, May 27, 1977	Do.
Plymouth	Rochester, town of	250280B	Sept. 8, 1975, emergency; July 5, 1982, regular; July 5, 1982, suspended.	July 19, 1974, Nov. 26, 1976	Do.
Worcester	Webster, town of	250343B	July 28, 1975, emergency; July 5, 1982, regular; July 5, 1982, suspended.	July 19, 1974, Mar. 4, 1977	Do.
Norfolk	Wrentham, town of	250258B	Dec. 10, 1974, emergency; July 5, 1982, regular; July 5, 1982, suspended.	July 19, 1974, Feb. 4, 1977	Do.
Missouri: Newton	Neosho, city of	290265B	Apr. 22, 1975, emergency; July 5, 1982, regular; July 5, 1982, suspended.	Jan. 16, 1974, Dec. 26, 1975	Do.
Montana:					
Beaverhead	Dillon, city of	300088B	Nov. 21, 1975, emergency; July 5, 1982, regular; July 5, 1982, suspended.	Nov. 8, 1974, July 30, 1976	Do.
Granite	Drummond, town of	300033B	Aug. 4, 1977, emergency; July 5, 1982, regular; July 5, 1982, suspended.	Mar. 18, 1977	Do.
Do	Unincorporated areas	300141A	Oct. 8, 1976, emergency; July 5, 1982, regular; July 5, 1982, suspended.	do	Do.
Beaverhead	Lima, town of	300177A	Oct. 22, 1975, emergency; July 5, 1982, regular; July 5, 1982, suspended.	do	Do.
Granite	Philipsburg, town of	300117A	Apr. 29, 1976, emergency; July 5, 1982, regular; July 5, 1982, suspended.	Sept. 26, 1975	Do.
New Jersey:					
Bergen	Leonia, borough of	340045A	Aug. 25, 1975, emergency; July 5, 1982, regular; July 5, 1982, suspended.	July 11, 1975	Do.
Morris	Mendham, township of	340511B	Apr. 22, 1975, emergency; July 5, 1982, regular; July 5, 1982, suspended.	Sept. 17, 1976, Dec. 15, 1978	Do.
Salem	Penns Grove, borough of	340419B	Aug. 7, 1975, emergency; July 5, 1982, regular; July 5, 1982, suspended.	June 28, 1974, Mar. 5, 1976	Do.
Gloucester	Swedesboro, borough of	340519B	July 23, 1975, emergency; July 5, 1982, regular; July 5, 1982, suspended.	Nov. 1, 1974, May 28, 1976	Do.
Cumberland	Vineland, city of	340176B	Dec. 17, 1971, emergency; July 5, 1982, regular; July 5, 1982, suspended.	May 4, 1973, July 22, 1977	Do.
Westchester	Ossining, village of	361021B	Oct. 18, 1974, emergency; July 5, 1982, regular; July 5, 1982, suspended.	July 19, 1974, Jan. 30, 1976	Do.
Ohio:					
Stark and Mahoning	Alliance, city of	390508B	July 31, 1975, emergency; July 5, 1982, regular; July 5, 1982, suspended.	June 7, 1974, June 18, 1976	Do.
Stark	Massillon, city of	390517C	Apr. 10, 1975, emergency; July 5, 1982, regular; July 5, 1982, suspended.	Aug. 22, 1975, May 18, 1979, and Jan. 9, 1974.	Do.
Stark, Carroll, Columbiana	Minerva, village of	390518B	May 12, 1975, emergency; July 5, 1982, regular; July 5, 1982, suspended.	July 23, 1976, Mar. 30, 1979	Do.
Stark	Waynesburg, village of	390667B	Apr. 22, 1982, emergency; July 5, 1982, regular; July 5, 1982, suspended.	Mar. 29, 1974, June 11, 1976	Do.
New Mexico:					
Valencia	Grants, city of	350090A	July 25, 1974, emergency; July 5, 1982, regular; July 5, 1982, suspended.	Nov. 12, 1976	Do.
Do	Milan, village of	350093B	Apr. 25, 1975, emergency; July 5, 1982, regular; July 5, 1982, suspended.	June 28, 1974, June 11, 1976	Do.

State and county	Location	Community No.	Effective dates of authorization/cancellation of sale of flood insurance in community	Special flood hazard area identified	Date [1]
Lincoln	Ruidoso Downs, village of	350034B	Feb. 18, 1975, emergency; July 5, 1982, regular; July 5, 1982, suspended.	May 3, 1974, June 11, 1976	Do.
North Carolina: Madison	Hot Springs, town of	370153A	Nov. 17, 1977, emergency; July 5, 1982, regular; July 5, 1982, suspended.	Sept. 17, 1976	Do.
South Carolina: Chester	Unincorporated areas	450047B	Aug. 20, 1975, emergency; July 5, 1982, regular; July 5, 1982, suspended.	Oct. 18, 1974, Nov. 25, 1977	Do.
Do.	Chester, city of	450048B	July 7, 1975, emergency; July 5, 1982, regular; July 5, 1982, suspended.	June 28, 1974, Apr. 2, 1976	Do.
Lancaster	Lancaster, city of	450121B	Dec. 7, 1973, emergency; July 5, 1982, regular; July 5, 1982, suspended.	May 24, 1974, Sept. 24, 1976	Do.
Tennessee: Fayette	Gallaway, town of	470048C	Jan. 28, 1976, emergency; July 5, 1982, regular; July 5, 1982, suspended.	Dec. 13, 1974	Do.
Do.	Somerville, town of	470051B	Aug. 27, 1975, emergency; July 5, 1982, regular; July 5, 1982, suspended.	May 17, 1974, Apr. 23, 1976	Do.
Texas: Bell	Belton, city of	480028B	July 2, 1974, emergency; July 5, 1982, regular; July 5, 1982, suspended.	Mar. 8, 1974, Jan. 23, 1976	Do.
Tarrant, Denton	South Lake, city of	480612B	Sept. 30, 1974, emergency; July 5, 1982, regular; July 5, 1982, suspended.	June 7, 1977, Feb. 15, 1974	Do.
Vermont: Chittenden	Richmond, town of	500040B	Nov. 8, 1974, emergency; July 5, 1982, regular; July 5, 1982, suspended.	June 4, 1976, Mar 22, 1974	Do.
Virginia: Southampton	Courtland, town of	510152B	Mar. 19, 1975, emergency; July 5, 1982, regular; July 5, 1982, suspended.	Mar. 15, 1974, May 7, 1976	Do.
Texas: Jackson	Edna, city of	485465C	Jan. 29, 1971, emergency; Nov. 12, 1971, regular; July 5, 1982, suspended.	Nov. 11, 1971, July 1, 1974, Apr. 18, 1975.	Do.
Washington: Skagit	Mount Vernon, city of	530158A	Jan. 21, 1975, emergency; May 17, 1982, regular; July 5, 1982, suspended.	May 7, 1976	Do.
Illinois: Scott	Village of Naples	170609B	Mar. 6, 1974, emergency; May 17, 1982, regular; July 5, 1982, suspended.	Apr. 2, 1976, Jan. 9, 1974	Do.
Indiana: Porter	Unincorporated areas	180425B	Sept. 5, 1975, emergency; Apr. 1, 1982, regular; July 5, 1982, suspended.	Apr. 14, 1978, Apr. 1, 1982	Do.

[1] Certain Federal assistance no longer available in special flood hazard area.

(National Flood Insurance Act of 1968 (title XIII of the Housing and Urban Development Act of 1968); effective Jan. 28, 1969 (33 F.R. 17804, Nov. 28, 1968), as amended, 42 U.S.C. 4001–4128; Executive Order 12127, 44 FR 19367; and delegation of authority to the Associate Director, State and Local Programs and Support)

Issued: June 21, 1982.

Lee M. Thomas,

Associate Director, State and Local Programs and Support.

[FR Doc. 82-17919 Filed 7-1-82; 8:45 am]

BILLING CODE 6718-03-M

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44 CFR Part 64

[Docket No. FEMA 6351]

List of Communities Eligible for the Sale of Insurance Under the National Flood Insurance Program

AGENCY: Federal Emergency Management Agency.

ACTION: Final rule.

SUMMARY: This rule lists communities participating in the National Flood Insurance Program (NFIP). These communities have applied to the program and have agreed to enact certain flood plain management measures. The communities' participation in the program authorizes the sale of flood insurance to owners of property located in the communities listed.

EFFECTIVE DATE: The date listed in the fifth column of the table.

ADDRESSES: Flood insurance policies for property located in the communities listed can be obtained from any licensed property insurance agent or broker serving the eligible community, or from the National Flood Insurance Program (NFIP) at: P.O. Box 3429, Bethesda, Maryland 20034, Phone: (800) 638–6620.

FOR FURTHER INFORMATION CONTACT: Mr. Richard E. Sanderson, Chief, Natural Hazards Division, (200) 287–0270, 500 C Street Southwest, Donohoe Building, Room 505, Washington, D.C. 20472.

SUPPLEMENTARY INFORMATION: The National Flood Insurance Program (NFIP), enables property owners to purchase flood insurance at rates made reasonable through a Federal subsidy. In return, communities agree to adopt and administer local flood plain management measures aimed at protecting lives and new construction from future flooding. Since the communities on the attached list have recently entered the NFIP, subsidized flood insurance is now available for property in the community.

In addition, the Director of the Federal Emergency Management Agency has identified the special flood hazard areas in some of these communities by publishing a Flood Hazard Boundary Map. The date of the flood map, if one has been published, is indicated in the sixth column of the table. In the communities listed where a flood map has been published, Section 102 of the Flood Disaster Protection Act of 1973, as amended, requires the purchase of flood insurance as a condition of Federal or federally related financial assistance for acquisition or construction of buildings in the special flood hazard area shown on the map.

The Director finds that delayed effective dates would be contrary to the public interest. The Director also finds that notice and public procedure under 5 U.S.C. 553(b) are impracticable and unnecessary.

The Catalog of Domestic Assistance Number for this program is 83.100 "Flood Insurance." This program is subject to procedures set out in OMB Circular A–95.

Pursuant to the provisions of 5 U.S.C. 605(b), the Associate Director, State and Local Programs and Support, to whom authority has been delegated by the Director, Federal Emergency Management Agency, hereby certifies that this rule, if promulgated will not have a significant economic impact on a substantial number of small entities. This rule provides routine legal notice stating the community's status in the NFIP and imposes no new requirements

or regulations on participating communities.

List of Subjects in 44 CFR Part 64

Flood insurance, Flood plains.

Section 64.6 is amended by adding in alphabetical sequence new entries to the table.

In each entry, a compete chronology of effective dates appears for each listed community. The entry reads as follows:

§ 64.6 List of eligible communities.

State and county	Location	Community No.	Effective dates of authorization/cancellation of sale of flood insurance in community	Special flood hazard area identified
Arizona: Navajo	Unincorporated areas	040066B	June 1, 1982, suspension withdrawn.	Aug. 23, 1974 and Jan. 30, 1979.
Alaska:				
Warangell Petersbrug Division.	Petersburg, city of	020074B	do.	June 14, 1974 and Feb. 4, 1977.
Sitka Division.	Sitka, city and borough of	020006B	do.	June 28, 1974 and Sept. 12, 1975.
California:				
Humboldt	Eureka, city of	060062B	do.	May 24, 1974 and Nov. 14, 1975.
Solano	Suisun City, city of	060372B	do.	Mar. 22, 1974 and June 11, 1976.
Tehama	Unincorporated areas	065064B	do.	Mar. 7, 1978.
Florida: Hernando	Brooksville, city of	120333B	do.	Feb. 21, 1975 and Nov. 21, 1975.
Illinois:				
Rock Island	Carbon Cliff, village of	170584B	do.	Apr. 12, 1974 and Apr. 16, 1976.
Kendall and LaSalle	Milligton, village of	170346B	do.	Dec. 28, 1973 and Mar. 5, 1976.
Kendall	Newark, village of	170344B	do.	Nov. 23, 1973 and Mar. 26, 1976.
Do.	Yorkville, city of	170347B	do.	Mar. 29, 1974 and Apr. 9, 1976.
Indiana:				
DuBois	Jasper, city of	180055B	do.	Oct. 26, 1973 and June 11, 1976.
Porter	Portage, city of	180202B	do.	July 26, 1974 and Oct. 31, 1975.
Iowa: Pottawattamie	Underwood, city of	190494A	do.	Mar. 26, 1976.
Kansas: Shawnee	Unincorporated areas	200331C	do.	Feb, 21, 1978 and Dec. 19, 1978.
Massachusetts:				
Berkshire	Hancock, town of	250025B	do.	June 28, 1974 and July 9, 1976.
Do	Lee, town of	250028B	do.	Mar. 22, 1974 and July 2, 1976.
Norfolk	Stoughton, town of	250253B	do.	Aug. 2, 1974 and June 21, 1977.
Middlesex	Sudbury, town of	250217B	do.	Aug. 23, 1974 and Dec. 10, 1976.
Do.	Wayland, town of	250224B	do.	July 26, 1974 and Dec. 24, 1976.
Worcester	West Brookfield, town of	250346B	do.	July 26, 1974 and Oct. 1, 1976.
Berkshire	West Stockbridge, town of	250045B	do.	July 26, 1974 and Aug. 22, 1978.
Plymouth	Mattapoisett, town of	255214A	do.	Jan. 9, 1976.
Michigan:				
Monroe	Luna Pier, city of	260150B	do.	June 28, 1974 and Apr. 2, 1976.
Lenawee	Tecumseh, city of	260117B	do.	May 24, 1974 and June 11, 1976.
Kent	Walker, city of	260110B	do.	Oct. 12, 1973 and June 18,1976.
Minnesota: Nobles	Adrian, city of	270318B	do.	May 3, 1974 and May 21, 1976.
Missouri:				
Jasper	Carl Junction, city of	290179B	do.	Feb. 8, 1974 and Aug 6, 1976.
Stoddard	Dexter, city of	290424B	do.	May 10, 1974 and Apr. 25, 1975.
Laclede	Lebanon, city of	290197B	do.	May 17, 1974 and Jan. 2, 1976.
Nevada: Lincoln	Caliente, city of	320015B	do.	Mar. 29, 1974 and May 2, 1975.
New Jersey:				
Salem	Carney's Point, township of	340424B	do.	Nov. 5, 1976.
Bergen	Palisades Park, borough of	340061	do.	Dec. 28, 1973 and June 18, 1976.
Gloucester	West Deptford, township of	340214B	do.	Mar. 8, 1974 and July 15, 1977.
New York:				
Oswego	Cleveland, village of	360998B	do.	May 31, 1974 and June 4, 1976.
Onondaga	Marcellus, village of	360586B	do.	Apr. 12, 1974.
Cayuga	Port Byron, village of	360121C	do.	May 3, 1974, June 11, 1976 and July 29, 1977.
Onondaga	Skaneateles, town of	360592A	do.	Nov. 8, 1974 and Oct. 31, 1975.
North Carolina: Wayne	Goldsboro, city of	370255B	do.	Dec. 24, 1976.
Ohio: Hamilton	Unincorporated areas.	390204B	do.	Apr. 14, 1978.
Oregon:				
Josephine	Cave Junction, city of	410107B	do.	NSFHA.
Yamhill	Dayton, city of	410252B	do.	Jan. 23, 1974 and Jan. 2, 1976.
Josephine	Unincorporated areas	415590B	do.	Aug. 16, 1977.
Pennsylvania:				
Beaver	Daugherty, township of	422313A	do.	Dec. 27, 1974.
Beaver and Lawrence	Ellwood City, borough of	420567B	do.	May 31, 1974 and May 7, 1976.
Blair	Hollidaysburg, borough of	420162B	do.	Oct. 12, 1973 and May 21, 1976.
Beaver	North Sewickley, township of	421161B	do.	Oct. 18, 1974 and May 7, 1976.
Do.	Pulaski, township of	422326A	do.	Dec. 20, 1974.
Juniata	Susquehanna, township of	421746A	do.	Jan. 24, 1975.
Texas:				
Angelina	Lufkin, city of	480009B	do.	Feb 22, 1974 and July 9, 1976.
Tarrant	Watauga, city of	480613B	do.	Mar. 8, 1974 and June 4, 1976.
Washington: King	Bothell, city of	530075B	do.	May 24, 1974 and June 20, 1975.
West Virginia:				
Kanawha	Cedar Grove, town of	540072B	do.	Mar. 8, 1974 and June 4, 1976.
Do.	East Bank, town of	540077B	do.	Mar. 22, 1974 and Sept. 26, 1975.
Wisconsin:				
Kenosha	Twin Lakes, village of	550211B	do.	June 7, 1974 and July 16, 1976.
Walworth	Whitewater, city of	550200B	do.	Jan. 9, 1974 and June 4, 1976.
Connecticut:				
New London	Colchester, town of	090095B	June 15, 1982, suspension withdrawn	Aug. 2, 1974 and Jan. 30, 1976.
Do	colchester, borough of	090192B	do.	June 28, 1974 and May 14, 1976.
Litchfield	Litchfield, town of	090047B	do.	June 21, 1974 and Dec. 17, 1976.
Florida: Pinellas	Pinellas Park, city of	120251C	do.	June 7, 1974, Mar. 28, 1975 and Aug. 15, 1977.
Illinois:				
Sangamon	Rochester, village of	170840A	do.	Mar. 21, 1975.
Kane	Sleepy Hollow, village of	170331B	do.	Apr. 12, 1974 and Apr. 9, 1976.
Massachusetts:				
Worcester	Barre, town of	250293B	do.	May 17, 1974 and Dec. 27, 1977.
Berkshire	Egremont, town of	250022B	do.	June 28, 1974 and Oct. 29, 1976.
Do.	Lanesborough, town of	250027B	do.	Mar. 29, 1974 and Dec. 10, 1976.

State and county	Location	Community No.	Effective dates of authorization/cancellation of sale of flood insurance in community	Special flood hazard area identified
Worcester	Lunenburg, town of	250315B	do	Sept. 6, 1974 and Dec. 10, 1976.
Do	Sterling, town of	250336B	do	July 19, 1974 and Dec. 17, 1976.
Do	Winchendon, town of	250348B	do	Aug. 3, 1974 and Sept. 10, 1976.
Plymouth	West Bridgewater, town of	250284B	do	Aug. 9, 1974 and July 30, 1976.
Michigan:				
Calhoun	Albion, city of	260050B	do	June 28, 1974 and July 11, 1975.
Washtenaw	Ann Arbor, city of	260213B	do	June 28, 1974 and Sept. 26, 1975.
Do	Manchester, village of	260316B	do	Feb. 22, 1974 and Apr. 11, 1975.
Minnesota: Winona	Goodview, city of	270528B	do	Mar. 19, 1976 and Mar. 16, 1979.
Missouri: St. Louis	Valley Park, city of	290391B	do	Dec. 17, 1973 and June 18, 1976.
New Hampshire: Coos	Berlin, city of	330029B	do	Aug. 27, 1976.
New Jersey:				
Passaic	Clifton, city of	340398B	do	May 31, 1974 and July 2, 1976.
Mercer	Hamilton, township of	340246B	do	Nov. 4, 1977 and Feb. 24, 1978.
Cumberland	Millville, city of	340173B	do	Jan. 14, 1977.
New York: Tioga	Barton, town of	360832B	do	June 21, 1974 and Oct. 31, 1975.
North Carolina: Lenoir	Kinston, city of	370145C	do	Mar. 15, 1974, Apr. 30, 1976 and July 25, 1980.
Oregon:				
Lane	Junction City, city of	410124B	do	May 10, 1974 and Aug 6, 1976.
Yamhill	Lafayette, city of	410254B	do	Nov. 30, 1973 and June 18, 1976.
Multnomah	Unincorporated areas	410179A	do	
Benton	Philomath, city of	410011B	do	Feb. 22, 1974 and Feb. 7, 1975.
Utah: Weber	Harrisville, city of	490208A	do	Aug. 8, 1975.
West Virginia: Kanawah	St. Albans, city of	540083B	do	Mar. 8, 1974 and Oct. 3, 1975.
Wisconsin: Waukesha	Pewaukee, village of	550468A	do	Mar. 3, 1976.
Texas:				
Fayette	Flatonia, town of	481102	June 3, 1982, emergency	July 30, 1976.
Howard	Unincorporated areas	481227	do	Dec. 13, 1977.
Wichita	do	481189	June 1, 1982, emergency	Aug. 1, 1978.
Tennessee: Morgan	do	470139	June 3, 1982, emergency	Jan. 17, 1975 and Sept. 1, 1978.
Virginia	Galax, city of	510066C	Sept. 29, 1978, emergency, June 1, 1982 withdrawn.	Aug. 2, 1974, Mar. 19, 1976 Dec. 25, 1981.
New Jersey: Hunterdon	Hampton, borough of	340236B	Oct. 9, 1975, emergency, Apr. 1, 1982, regular, Apr. 1, 1982, suspension, June 7, 1982, reinstated.	June 7, 1974.
Minnesota:				
Aitkin	Aitkin, city of	270001B	June 7, 1974, emergency, Mar. 15, 1982, regular, Mar. 15, 1982, suspension, June 7, 1982, reinstated.	Jan. 9, 1974, and Aug. 13, 1976.
Crow Wing	Riverton, city of	270100B	Jan. 21, 1974, emergency, Sept. 2, 1981, regular, Sept. 2, 1981, suspension, June 10, 1982, reinstated.	June 28, 1974, May 28, 1976.
Wisconsin: Calumet	Stockbridge, village of	550040B	Aug. 25, 1975, emergency, May 3, 1982, regular, May 3, 1982, suspension, June 10, 1982, reinstated.	Aug. 9, 1974 and Sept. 12, 1975.
Minnesota: Clay	Glyndon, city of	270083B	Sept. 26, 1975, emergency, Mar. 2, 1981, regular, Mar. 2, 1981, suspension, June 14, 1982, reinstated.	May 17, 1974 and July 16, 1976.
Illinois: Kendall	Lisbon, village of	170342A	June 11, 1982, emergency, June 11, 1982, regular.	Nov. 1, 1974 and Dec. 14, 1979.
Indiana: Marshall	Argos, town of	180489-New	June 14, 1982, emergency	
Ohio: Williams	Montpelier, village of	390581A	do	May 31, 1974 and May 21, 1976.
Pennsylvania:				
Clinton	West Keating, township of	421542A	June 15, 1982, emergency	Dec. 6, 1975 and Feb. 22, 1980.
Westmoreland	Export, borough of	420676B	April 17, 1975, emergency, Dec. 15, 1981, regular, Dec. 15, 1981, suspension, Mar. 31, 1982 reinstated.	June 28, 1974 and June 11, 1976.
Kansas: Jackson	Unincorporated areas	200619A	June 14, 1982, emergency, June 18, 1982, emergency.	May 31, 1977.
Missouri: Lewis	do	290844A	do	Sept. 22, 1981.
New York: Franklin	Franklin, town of	361397	do	July 18, 1975.
Tennessee: Dickson	Unincorporated areas	470046A	do	Dec. 6, 1974.
Wyoming: Lincoln	Afton, town of	560068	do	June 21, 1977.
Delaware: Sussex	Dewey Beach, town of [1]	100056	June 18, 1982, emergency, June 18, 1982, regular.	
Michigan: Jackson	Brooklyn, village of	260335	June 18, 1982, emergency, June 18, 1982 regular.	Oct. 8, 1976.
Virginia: Page	Stanley, town of	510255B	June 18, 1982, emergency, June 18, 1982, regular.	Feb. 4, 1977 and Feb. 3, 1982.

[1] The town of Dewey Beach, Sussex County, Del., has adopted an ordinance based on the Oct. 6, 1976, Sussex County Flood Insurance Study. This is a newly incorporated community shown on the Sussex County FIRM. (Comm. No. 100029A, I.D. Date Oct. 6, 1976, Emergency date, Apr. 16, 1971.)

(National Flood Insurance Act of 1968 (title XIII of the Housing and Urban Development Act of 1968); effective Jan. 28, 1969 (33 FR 17804, Nov. 28, 1968), as amended, 42 U.S.C. 4001–4128; Executive Order 12127, 44 FR 19367; and delegation of authority to the Associate Director, State and Local Programs and Support)

Issued: June 21, 1982.

Lee M. Thomas,

Associate Director, State and Local Programs and Support.

[FR Doc. 82-17920 Filed 7-1-82; 8:45 am]

BILLING CODE 6718-03-M

44 CFR Part 64

[Docket No. FEMA 6349]

List of Communities Eligible for the Sale of Insurance Under the National Flood Insurance Program

AGENCY: Federal Emergency Management Agency.

ACTION: Final rule.

SUMMARY: This rule lists communities participating in the National Flood Insurance Program (NFIP) and eligible for second layer insurance coverage. These communities have applied to the program and have agreed to enact certain flood plain management measures. The communities' participation in the regular program authorizes the sale of flood insurance to owners of property located in the communities listed.

EFFECTIVE DATES: The date listed in the fifth column of the table.

ADDRESSES: Flood insurance policies for property located in the communities listed can be obtained from any licensed property insurance agent or broker serving the eligible community, or from the National Flood Insurance Program (NFIP) at: P.O. Box 34294, Bethesda, Maryland 20034, Phone: (800) 638–6620.

FOR FURTHER INFORMATION CONTACT: Mr. Richard E. Sanderson, Chief, Natural Hazards Division, (200) 287–0270, 500 C Street Southwest, Donohoe Building—Room 505, Washington, DC 20472.

SUPPLEMENTARY INFORMATION: The National Flood Insurance Program (NFIP), enables property owners to purchase flood insurance at rates made reasonable through a Federal subsidy. In return, communities agree to adopt and administer local flood plain management measures aimed at protecting lives and new construction from future flooding. Since the communities on the attached list have recently entered the NFIP, subsidized flood insurance is now available for property in the community.

In addition, the Director of the Federal Emergency Management Agency has identified the special flood hazard areas in some of these communities by publishing a Flood Hazard Boundary Map. The date of the flood map, if one has been published, is indicated in the sixth column of the table. In the communities listed where a flood map has been published, Section 102 of the Flood Disaster Protection Act of 1973, as amended, requires the purchase of flood insurance as a condition of Federal or federally related financial assistance for acquisition or construction of buildings in the special flood hazard area shown on the map.

The Director finds that delayed effective dates would be contrary to the public interest. The Director also finds that notice and public procedure under 5 U.S.C. 553(b) are impracticable and unnecessary.

The Catalog of Domestic Assistance Number for this program is 83.100 "Flood Insurance." This program is subject to procedures set out in OMB Circular A–95.

Pursuant to the provisions of 5 U.S.C. 605(b), the Associate Director, State and Local Programs and Support, to whom authority has been delegated by the Director, Federal Emergency Management Agency, hereby certifies that this rule, if promulgated will not have a significant economic impact on a substantial number of small entities. This rule provides routine legal notice stating the community's status in the NFIP and imposes no new requirements or regulations on participating communities.

List of Subjects in 44 CFR Part 64

Flood insurance, Flood plains.

Section 64.6 is amended by adding in alphabetical sequence new entries to the table.

In each entry, a complete chronology of effective dates appears for each listed community. The entry reads as follows:

§ 64.6 List of eligible communities.

State and county	Location	Community No.	Effective date of authorization of sale of flood insurance for area[1]	Hazard area identified
Arkansas: Saline County	Shannon Hills, city of	050573	790306, emergency; 820517, regular	0
Arizona: Coconino County	Fredonia, town of	040021	750331, emergency; 820517, regular	740607
California:				
Tehama County	Red Bluff, city of	065053	710115, emergency; 820517, regular	740607
1017 Middlefield Rd.	Redwood City, city of	060325	750812, emergency; 820517, regular	740628
Siskiyou County	Siskiyou county[2]	060362	730223, emergency; 820517, regular	771115
Yuba County	Yuba county[2]	060427	740906, emergency; 820517, regular	770906
Connecticut: Hartford County	Marlborough, town of	090148	750205, emergency; 820517, regular	740719
Florida:				
Glades County	Glades county[2]	120095	750715, emergency; 820517, regular	780611
Hendry County	Hendry county[2]	120107	740827, emergency; 820517, regular	780721
Citrus County	Inverness, city of	120348	750715, emergency; 820517, regular	780113
Taylor County	Perry, city of	120303	750130, emergency; 820517, regular	740315
Gulf County	Wewahitchka, city of	120100	760519, emergency; 820517, regular	740809
Georgia: Liberty County	Flemington, city of	130124	741127, emergency; 820517, regular	741018
Iowa:				
Crawford County	Denison, city of	190096	750319, emergency; 820517, regular	740510
Mills County	Glenwood, city of	190203	741205, emergency; 820517, regular	740628
Shelby County	Kirkman, city of	190250	750609, emergency; 820517, regular	750822
Illinois:				
Whiteside County	Fulton, city of	170690	750702, emergency; 820517, regular	740531
Scott County	Naples, village of	170609	740306, emergency; 820517, regular	740109
Indiana:				
Johnson County	Greenwood, city of	180115	750519, emergency; 820517, regular	740109
Warrick County	Newburgh, town of	180276	730112, emergency; 820517, regular	731102
Massachusetts:				
Plymouth County	Bridgewater, town of	250260	751128, emergency; 820517, regular	740719
Worcester County	Templeton, town of	250339	750805, emergency; 820517, regular	740802
Michigan:				
Shiawassee County	Caledonia, township of	260300	740703, emergency; 820517, regular	750103
Clinton County	Watertown, charter township of	260291	740416, emergency; 820517, regular	741018
Minnesota:				
Hennepin County	Brooklyn Park, city of	270152	740205, emergency; 820517, regular	740412
Faribault County	Faribault county[2]	270669	741101, emergency; 820517, regular	770722
Anoka County	Lino Lakes, city of	270015	760430, emergency; 820517, regular	741213
Rock County	Luverne, city of	270411	740701, emergency; 820517, regular	740215
Washington County	Washington county[2]	270499	710430, emergency; 820517, regular	770603

State and county	Location	Community No.	Effective date of authorization of sale of flood insurance for area[1]	Hazard area identified
Missouri: Pemiscot County	Pemiscot county[2]	290779	750408, emergency; 820517, regular	810415
New Hampshire:				
Rockingham County	Exeter, town of	330130	750512, emergency; 820517, regular	740920
Rockingham County	Portsmouth, city of	330139	750710, emergency; 820517, regular	740719
New Jersey:				
Hunterdon County	Glen Gardner, borough of	340235	750708, emergency; 820517, regular	740628
Bergen County	Rockleigh, borough of	340071	750120, emergency; 820517, regular	770225
New York:				
Monroe County	Rush, town of	360432	730725, emergency; 820517, regular	740308
Tioga County	Tioga, town of	360842	750815, emergency; 820517, regular	740906
Ohio:				
Licking County	Alexandria, village of	390329	761126, emergency; 820517, regular	740531
Licking County	Granville, village of	390330	750606, emergency; 820517, regular	740607
Licking County	Johnstown, village of	390334	750624, emergency; 820517, regular	740412
Oregon:				
Lane County	Florence, city of	410123	750327, emergency; 820517, regular	740531
Washington County	Hillsboro, city of	410243	750120, emergency; 820517, regular	740412
Linn County	Tangent, city of	410147	750905, emergency; 820517, regular	760625
Pennsylvania:				
Beaver County	Beaver Falls, city of	420105	741212, emergency; 820517, regular	740222
Beaver County	Big Beaver, borough of	422307	750807, emergency; 820517, regular	750131
Chester County	Coatesville, city of	420274	741226, emergency; 820517, regular	740531
Lawrence County	Neshannock, township of	421794	741122, emergency; 820517, regular	741129
Montgomery County	Upper Salford, township of	421918	760524, emergency; 820517, regular	741206
Tennessee: Wilson County	Mount Juliet, city of	470290	760708, emergency; 820517, regular	750718
Texas:				
Tarrant County	Dalworthington Gardens, town of	481013	770721, emergency; 820517, regular	760806
Brazoria County	Iowa Colony, town of	481071	790808, emergency; 820517, regular	760702
Webb County	Laredo, city of	480651	750807, emergency; 820517, regular	770204
Wisconsin: Outagamie County	Kimberly, village of	550306	750523, emergency; 820517, regular	740614
Arkansas: Calhoun County	Hampton, city of	050023	750402, emergency; 820518, regular	740621
Texas:				
Henderson County	Murchison, city of	480330	810403, emergency; 820518, regular	760611
San Jacinto County	Shepherd, city of	480554	750818, emergency; 820518, regular	740823
Georgia:				
Dawson County	Dawsonville, city of	130064	770314, emergency; 820521, regular	750117
Jones County	Gray, city of	130237	750529, emergency; 820521, regular	740628
New York: Chautauqua County	Villenova, town of	361082	760922, emergency; 820521, regular	770225
Pennsylvania: Carbon County	Lansford, borough of	420250	750929, emergency; 820521, regular	740607
Louisiana: Grant Parish	Pollock, town of	220305	780814, emergency; 820525, regular	750815
Georgia: Franklin County	Franklin Springs, city of	130313	800311, emergency; 820528, regular	750404
New York: Wyoming County	Castile, village of	361563	780925, emergency; 820528, regular	750228
Pennsylvania: Monroe County	Mount Pocono, borough of	420692	761216, emergency; 820528, regular	750124
Total is: 63.				

[1] Key for reading 4th column (Effective Date): First two digits designate the year, the middle two digits designate the month, and the last two digits designate the day.
[2] Disaster community.

(National Flood Insurance Act of 1968 (title XIII of the Housing and Urban Development Act of 1968); effective Jan. 28, 1969 (33 FR 17804, Nov. 28, 1968), as amended, 42 U.S.C. 4001–4128; Executive Order 12127, 44 FR 19367; and delegation of authority to the Associate Director, State and Local Programs and Support)

Issued: June 16, 1982.

Lee M. Thomas,

Associate Director, State and Local Programs and Support.

[FR Doc. 82-17911 Filed 7-1-82; 8:45 am]

BILLING CODE 6718-03-M

44 CFR Part 67

National Flood Insurance Program; Final Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency.

ACTION: Final rule.

SUMMARY: Final base (100-year) flood elevations are listed below for selected locations in the nation.

These base (100-year) flood elevations are the basis for the flood plain management measures that the community is required to either adopt or show evidence of being already in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

EFFECTIVE DATE: The date of issuance of the Flood Insurance Rate Map (FIRM) showing base (100-year) flood elevations, for the community. This date may be obtained by contacting the office where the maps are available for inspection indicated on the table below.

ADDRESSES: See table below.

FOR FURTHER INFORMATION CONTACT: Mr. Robert G. Chappell, P.E., Federal Emergency Management Agency, National Flood Insurance Program, (202) 287–0230, Washington, D.C. 20472.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency gives notice of the final determinations of flood elevations for each community listed.

This final rule is issued in accordance with Section 110 of the Flood Disaster Protection Act of 1968 (Title XIII of the Housing and Urban Development Act of 1968 (Pub. L. 90–448)), 42 U.S.C. 4001–4128, and 44 CFR Part 67. An opportunity for the community or individuals to appeal this determination to or through the community for a period of ninety (90) days has been provided. No appeals of the proposed base flood elevations were received from the community or from individuals within the community.

The Agency has developed criteria for flood plain management in flood-prone areas in accordance with 44 CFR Part 60.

Pursuant to the provisions of 5 U.S.C. 605(b), the Associate Director, to whom the authority has been delegated by the Director, Federal Emergency Management Agency, hereby certifies that the final flood elevation determinations, if promulgated, will not have a significant economic impact on a substantial number of small entities. A flood elevation determination under section 1363 forms the basis for new local ordinances, which, if adopted by a local community, will govern future construction within the flood plain area. The elevation determinations, however,

impose no restriction unless and until the local community voluntarily adopts flood plain ordinances in accord with these elevations. Even if ordinances are adopted in compliance with Federal standards, the elevations prescribe how high to build in the flood plain and do not proscribe development. Thus, this action only forms the basis for future local actions. It imposes no new requirement; of itself it has no economic impact.

List of Subjects in 44 CFR Part 67

Flood insurance, Flood plains.

The final base (100-year) flood elevations for selected locations are:

FINAL BASE(100-YEAR) FLOOD ELEVATIONS

State	City/town/county	Source of flooding	Location	#Depth in feet above ground. *Elevation in feet (NGVD)
Arizona	Tucson (city), Pima County (FEMA-6218)	Airport Wash	Intersection of Drexel Road and Airport Wash	*2,477
			Intersection of Ginter Road and Euclid Avenue	*2,528
		Silvercroft Wash	Intersection of West Grant Road and Coyote Drive	*2,301
			25 feet downstream of the intersection of St. Marys Road and Silvercroft Wash.	*2,369
		Tucson Arroyo	Intersection of Brady Avenue and Davis Street	#2
			Intersection of East 6th Street and 9th Avenue	*2,366
			Intersection of North Cherry Avenue and 15th Street	*2,429
		Big Wash	10 feet upstream of the intersection of Mission Road and Big Wash.	*2,418
			Intersection of Placita Salitillo and Calle Del Ray	#1
		Santa Cruz River	Intersection of West Grant Road and Santa Cruz River	*2,302
			50 feet downstream of the intersection of Silvertake Road and Santa Cruz River.	*2,366
			Intersection of Valencia Road and Santa Cruz River	*2,456
		West Branch Santa Cruz River	Intersection of AJO Way and Phoebe Avenue	#2
		Rillito Creek	2,400 feet north along North Tucson Boulevard from its intersection with East Prince Road.	*2,353
		Pantano Wash	Intersection of East 22nd Street and Pantano Wash	*2,608
		Julian Wash	Intersection of Treat Avenue (extended) and Julian Wash.	*2,546
		Tanque Verde Creek	530 feet north along Arbor Circle from its intersection with Calle Eunice. Then 180 feet north.	*2,567
Maps available for inspection at Department of Engineering, 250 West Alameda, Tucson, Arizona.				
California	Dinuba (city), Tulare County (FEMA-6247)	Shallow Flooding	Intersection of Tulare Street and K Street	#1
			Intersection of P Street and Tulare Street	#2
Maps available for inspection at Department of Public Works, 405 East El Monte, Dinuba, California.				
Colorado	Canon City (city), Fremont County (FEMA-6247)	Arkansas River	Intersection of Riverside Avenue and Plum Street	*5,340
		Northeast Canon Drainage—East Branch.	Intersection of East Circle Drive and West Circle Drive	*5,335
		Northeast Canon Drainage—West Branch.	Intersection of Allison Avenue and Fifteenth Street	*5,340
		Southeast Canon Drainage	Intersection of Ninth Street and Griffin Avenue	*5,330
		Sand Creek	Intersection of U.S. Highway 50 and Canal Street	*5,370
		Forked Gulch	150 feet upstream from center of Pennsylvania Avenue.	*5,375
		West Forked Gulch	150 feet upstream from northernmost corporate limits	*5,330
Maps available for inspection at City Engineer's Office, 612 Royal Gorge Boulevard, Canon City, Colorado.				
Illinois	(V), Elwood, Will County (Docket No. FEMA-6247)	Jackson Creek	Just upstream of Brandon Road	*590
			About 1,200 feet downstream of Manhattan Road	*599
Maps available for inspection at the Village Hall, Mississippi Avenue, Elwood, Illinois.				
Illinois	(Unincorporated) Lake County (Docket No. FEMA-6247).	Des Plaines River	At southern county boundary	*642
			Just upstream of Buckley Road	*659
			At state boundary	*674
		Des Plaines River Tributary (at Russell).	At confluence with Des Plaines River	*673
			Just upstream of Kilbourne Road	*676
			Just upstream of State Highway 173	*692
			Just upstream of Stiehr Road	*703
			Just downstream of Wadsworth Road	*709
			Just upstream of Wadsworth Road	*713
		East Fork Des Plaines River Tributary (at Russell).	At confluence with Des Plaines River Tributary (at Russell).	*685
			Just downstream of State Highway 173	*701
			Just downstream of 21st Street	*709
			Just upstream of 21st Street	*713
			Just downstream of Waverly Street	*722
			Just upstream of Waverly Street	*727
		Skokie River	About 3,800 feet downstream of Elgin, Joliet and Eastern Railway.	*670
			Just upstream of Buckley Road	*684
			About 1,400 feet upstream of Buckley Road	*687
		Middle Fork North Branch Chicago River.	About 1,300 feet downstream of Half Day Road	*658
			About 1,200 feet upstream of Half Day Raod	*659
			About 2.7 miles downstream of State Highway 176	*668
			Just downstream of Elgin, Joliet and Eastern Railway	*674
			About 200 feet downstream of Buckley Road	*692
		West Fork North Branch Chicago River.	About 1,200 feet downstream of Montgomery Drive	*663
			About 200 feet downstream of Half Day Road	*667
			Just upstream of Half Day Road	*670

FINAL BASE(100-YEAR) FLOOD ELEVATIONS—Continued

State	City/town/county	Source of flooding	Location	#Depth in feet above ground. *Elevation in feet (NGVD)
		Hasting Creek	Just upstream of Unnamed Road (about 2,050 feet downstream of U.S. Highway 45).	*744
			About 1,000 feet downstream of State Highway 132	*766
			Just upstream of State Highway 132	*775
			About 1.6 miles upstream of State Highway 132	*782
		Mill Creek	Just upstream of U.S. Highway 41	*668
			Just downstream of spillway downstream of Stearns School Road.	*711
			Just upstream of spillway downstream of Stearns School Road.	*719
			Just downstream of spillway downstream of Grandwood Drive.	*750
			Just upstream of U.S. Highway 45	*763
			About 4,000 feet downstream of Center Street	*773
			About 2.5 miles upstream of Center Street	*787
		North Mill Creek	About 0.5 mile downstream of Millburn Road	*694
			Just downstream of Kelley Road	*724
			About 800 feet upstream of Kelley Road (upstream of dam).	*741
			At state boundary	*758
		Fox River	At confluence of Flint Creek	*737
			At state boundary	*743
		Buffalo Creek	Just upstream of Arlington Heights Road	*691
			Just upstream of Quentin Road	*784
			At downstream corporate limits of the Village of Lake Zurich.	*816
		Tributary to Buffalo Creek	About 550 feet downstream of Quentin Road	*772
			About 675 feet upstream of Quentin Road	*779
		Mutton Creek	About 1,050 feet downstream of Gravel Pit Road	*754
			Just downstream of Gravel Pit Road	*755
			Just downstream of Darrel Road	*759
		Indian Creek	Just downstream of footbridge (about 1,650 feet upstream of mouth at Des Plaines River).	*648
			About 200 feet upstream of confluence of Seavey Drainage Ditch.	*672
			About 500 feet downstream of confluence of West Branch Indian Creek.	*730
			About 100 feet downstream of spillway for Countryside Lake.	*776
			Just upstream of spillway for Countryside Lake	*786
			Just downstream of Chevy Chase Road	*790
			Just upstream of Chevy Chase Road	*795
			Just downstream of Gilmer Road	*808
			Just upstream of Gilmer Road	*819
			Just downstream of Schwerman Road	*838
		West Branch Indian Creek	About 3,325 feet downstream of Gilmer Road	*734
			Just downstream of spillway	*775
			Just upstream of spillway	*789
			Just downstream of Elgin, Joliet and Eastern railway	*796
		South Branch Indian Creek	At mouth at Indian Creek	*680
			Just downstream of State Highway 22	*691
			Just upstream of State Highway 83	*696
			About 1.1 miles upstream of Old McHenry Road	*748
			Just upstream of State Highway 22	*758
		Aptakisic Creek	Mouth at Des Plaines River	*643
			About 1.0 mile upstream of Pekara Road	*646
			Just downstream of Weiland Road	*671
			Just upstream of Busch Road (Vilage of Buffalo Grove corporate limit).	*678
			About 450 feet upstream of confluence of tributary to Aptakisic Creek.	*679
		Tributary to Aptakisic Creek	About 1,500 feet upstream of Aptakisic Road	*681
		Irondale Creek	Mouth at Meadow Haven Creek	*663
			Just downstream of Guerin Road	*663
		Meadow Haven Creek	Mouth at Tributary No. 1	*658
			Just downstream of Gerin Road	*679
			Just downstream of O'Plaine Road	*688
		Flint Creek	About 2,400 feet upstream of confluence with Fox River.	*737
			Just upstream of footbridge (about 3,000 feet upstream of mouth at Fox River).	*741
			Just downstream of U.S. Highway 14	*765
		Eagle Creek	About 0.9 mile downstream of Cedar Lake road	*772
			About 1,225 feed upstream of Cedar Lake Road	*784
		Bull Creek	About 1,300 feet upstream of mouth at Des Plaines River.	*659
			About 0.5 mile upstream of confluene of Bull Creek Tributary.	*686
			Just upstream of Midlothian Road	*780
			About 0.8 mile upstream of Midlothian Road	*798
		Bull Creek Tributary	About 250 feet upstream of mouth at Bull Creek	*678
			About 150 feet upstream of Countryside Drive	*719
			About 1,800 feet upstream of State Highway 137	*747
		North Branch Bull Creek Tributary	Mouth at Bull Creek Tributary	*723
			About 1,250 feet upstream of Bull Creek Drive	*733
		West Branch Bull Creek Tributary	Mouth at Bull Creek Tributary	*727
			Just upstream of Bull Creek Drive	*745

FINAL BASE(100-YEAR) FLOOD ELEVATIONS—Continued

State	City/town/county	Source of flooding	Location	#Depth in feet above ground. *Elevation in feet (NGVD)
		Greenleaf Creek	About 100 feet upstream of Washington Street	*688
			About 1,450 feet upstream of Washington Street	*691
			About 200 feet upstream of Greenleaf Street	*700
		Nippersink Creek	About 3,500 feet downstream of western county boundary.	*742
			At western county boundary	*744
		Sequoit Creek	About 300 fee downstream of Tiffany Road *.	751
			About 1,000 feet upstream of Soo Line Railroad	*765
			About 100 feet downstream of State Highway 173	*768
		Squaw Creek	Just upstream of State Highway 59	*742
			About 1.2 miles upstream of State Highway 134	*746
			Just upstream of Nippersink Road	*758
			Just upstream of Fairfield Road	*766
			About 1.2 miles upstream of Town Line Road	*784
		Willow Road Creek	About 1,500 feet upstream of confluence with Bangs Lake Drain.	*766
			About 3,800 feet upstream of confluence with Bangs Lake Drain.	*774
		Garland Road Tributary	Within unincorporated area	*776
		Suburban County Club Tributary	At mouth at Des Plaines River	*665
			Just upstream of Chicago and North Western railroad	*671
			Just downstream of Beach Road	*701
		South Fork Suburban Country Club Tributary.	At confluence with Suburban Country Club Tributary	*678
			Just upstream of Wall Avenue	*699
		Tower Lake Creek	Within unincorporated area	*737
		Tributary No. 1	About, 1,800 feet upstream of Buckley Road	*656
			About 3,000 feet upstream of Guerin Road	*676
		Kimball Avenue Tributary	Within unincorporated area	*776
		Farrington Ditch	Just upstream of Checker Road	*679
			About 2,650 feet upstream Checker Road	*681
		Seavey Drainage Ditch	Just downstream of U.S. Highway 45	*676
			Just upstream of Lake Charles spillway	*696
			About 2,500 feet upstream of Butterfield Road	*712
		Diamond Lake Drain	Just upstream of State Highway 83	*712
			About 1,200 feet upstream of Elgin, Joliet and Eastern railway.	*728
		Deer Lake Drain	At State boundary	*760
			Just upstream of Deer Lake Dam	*769
			Just upstream of Dam No. 2	*772
		Forest Lake Drain	About 1,200 feet upstream of mouth at Indian Creek	*727
			Just upstream of Gilmer Road	*737
			About 2,400 feet upstream of Gilmer Road	*742
		North Shore Drain	Within unincorporated area	*789
		Round Lake Drain	At mouth at Long Lake	*743
			Just upstream of confluence of Round Lake Drain Tributary.	*749
		Round Lake Drain Tributary	About 1,080 feet upstream of mouth at Round Lake Drain.	*751
		Bangs Lake Drain	Just downstream of County Highway 44	*744
			Just downstream of Mac Street	*752
			Just upstream of Mac Street	*757
			About 100 feet upstream of Brown Street	*771
			At confluence of Garland Road Tributary	*776
		Silver Lake Drain	At mouth at Sequoit Creek	*766
			About 2,300 feet upstream of mouth at Sequoit Creek	*767
		Kellogg Ravine	About 3,000 feet downstream of abandoned railroad	*644
			About 300 feet upstream of Kenosha Road	*691
		Slocum Lake Drain	Within community	*737
		North Shore Ditch	Just upstream of Blanchard Road	*651
			About 2,400 feet upstream of Blanchard Road	*654
		Bull Creek (near Waukegan)	Just upstream of Chicago and North Western Railroad	*607
			Just upstream of Sheridan Road	*614
			Just downstream of Talmadge Avenue	*620
			Just upstream of Talmadge Avenue	*627
			Just downstream of Beach Road	*632
			Just upstream of Beach Road	*638
			About 1,600 feet upstream of Dewoody Avenue	*670
		North Arm Flint Creek	Within unincorporated area	*756
		Lake Michigan	Shoreline	*584
		Round Lake	Shoreline	*765
		Diamond Lake	Shoreline	*742
		Sun Lake	Shoreline	*779
		Cedar Lake	Shoreline	*791
		Deep Lake	Shoreline	*780
		Cross Lake	Shoreline	*813
		Channel Lake	Shoreline	*742
		Lake Catherine	Shoreline	*742
		Lake Marie	Shoreline	*742
		Grass Lake	Shoreline	*742
		Bluff Lake	Shoreline	*742
		Petite Lake	Shoreline	*742
		Antioch Lake	Shoreline	*757
		Slocum Lake	Shoreline	*738
		Fox Lake	Shoreline	*742
		Nippersink Lake	Shoreline	*742
		Duck Lake	Shoreline	*742
		Pistakee Lake	Shoreline	*741

FINAL BASE(100-YEAR) FLOOD ELEVATIONS—Continued

State	City/town/county	Source of flooding	Location	#Depth in feet above ground. *Elevation in feet (NGVD)
		Brandenburg Lake	Shoreline	*741
		Redhead Lake	Shoreline	*741
		Shallow Flooding from Northwest Retention Basin.	About 1,000 feet south of intersection of Lake Shore Drive and Druce Lake Road.	*783
	Maps available for inspection at the Lake County Department of Planning, Zoning and Environmental Quality, County Building, Room A803, 18 N. County Street, Waukegan, Illinois.			
Illinois	(V), Romeoville, Will County (Docket No. FEMA-6247)	Des Plaines River	About 1,800 feet downstream of Romeo Road	*585
			About 1.2 miles upstream of Romeo Road	*588
	Maps available for inspection at the Village Hall, 13 Montrose Drive, Romeoville, Illinois.			
Indiana	(C), Rushville, Rush County (Docket No. FEMA-6247)	Flatrock River	At downstream corporate limits	*950
			Just upstream of Main Street	*955
			Just upstream of Chessie System	*957
		Hodges Branch	About 0.39 mile upstream of Chessie System	*958
			Just upstream of 9th Street	*967
			Just downstream of Main Street	*972
	Maps available for inspection at the City Building, Rushville, Indiana.			
Maryland	Millington, town, Kent and Queen Annes County (Docket No. FEMA-6247).	Chester River	Downstream corporate limits	*13
			Upstream corporate limits	*14
	Maps available for inspection at the Town Hall, Millington, Maryland.			
Michigan	(Township), Ash, Monroe County (Docket No. FEMA-6247).	Swan Creek	At Labo Road	*590
			Just upstream of Telegraph Road	*598
			At Carleton-Rockwood Road	*602
			Just upstream of Interstate 275	*606
			Just downstream of Grafton Road	*608
		North Branch Swan Creek	Mouth at Swan Creek	*605
			Just downstream of Interstate 275	*607
			At Will Carleton Drive	*612
	Maps available for inspection at the Town Hall, 1677 Ready Road, Carleton, Michigan.			
Michigan	(Township), Berlin, Monroe County (Docket No. FEMA-6247).	Huron River	Mouth at Lake Erie	*578
			About 3.5 miles downstream of Telegraph Road	*587
			Just upstream of Telegraph Road	*596
		Lake Erie	Shoreline	*578
		Swan Creek	Mouth at Lake Erie	*578
			Just downstream of Drew Road	*584
			Just upstream of Brandon Road	*586
			About 400 feet upstream of Interstate 75 Southbound	*588
		Mouille Creek	Mouth at Lake Erie	*578
			Just upstream of Hagerman Road	*579
		Laudenschlager Drain	About 3,300 feet downstream of Hagerman Road	*578
			Just downstream of Detroit and Toledo Shoreline Railroad.	*583
			Just upstream of Conrail	*586
			About 700 feet upstream of Ready Road	*586
	Maps available for inspection at the Town Hall, 5651 Trombley Road, Newport, Michigan.			
Minnesota	(C), Little Canada, Ramsey County (Docket No. FEMA-6247).	Gervais Lake	Shoreline	*862
		Round Lake	Shoreline	*905
		Savage Lake	Shoreline	*897
		Twin Lake	Shoreline	*872
	Maps available for inspection at the City Hall, 515 Little Canada Road, Little Canada, Minnesota.			
Missouri	(C), Washington, Franklin County (Docket No. FEMA-6247).	Busch Creek	At confluence with Dubois Creek	*486
			Just upstream of abandoned bridge	*492
			Just downstream of Madison Avenue	*496
			Just upstream of Madison Avenue	*503
			Just downstream of Locust Street	*510
			About 120 feet upstream of Jefferson Street	*515
			Just downstream of Private Road	*523
			Just upstream of Private Road	*531
			About 300 feet downstream of State Highway 100	*535
			Just upstream of State Highway 100	*547
		Southwest Branch Busch Creek	Mouth at Busch Creek	*486
			Just upstream of State Highway 100	*488
			About 1.58 miles upstream of State Highway 100	*507
		South Branch Busch Creek	Mouth at Busch Creek	*486
			At upstream corporate limits	*489
		St. Johns Creek	At Missouri Pacific Railroad	*494
			At upstream corporate limits	*494
		Missouri River	At downstream corporate limits	*486
			About 1.5 miles upstream of confluence of Saint Johns Creek.	*494
		Dubois Creek	At downstream corporate limits	*486
			At confluence of Busch Creek	*486
	Maps available for inspection at the City Hall, 4th and Jefferson Streets, Washington, Missouri.			
Nebraska	(C), Ashland, Saunders County (Docket No. FEMA-6247).	Salt Creek	Just upstream of U.S. Highway 6	*1,063
			About 200 feet upstream of the Burlington Northern Railroad (upstream of 13th Street).	*1,083
			At County Road 110	*1,085
		Wahoo Creek	At mouth	*1,068

FINAL BASE(100-YEAR) FLOOD ELEVATIONS—Continued

State	City/town/county	Source of flooding	Location	#Depth in feet above ground. *Elevation in feet (NGVD)
			About 400 feet upstream of the Burlington Northern Railroad near the northwest extraterritorial limit.	*1,078
		Clear Creek	Within extraterritorial limit	*1,071
		Silver Creek	Within extraterritorial limit	*1,071
Maps available for inspection at the City Hall, 1748 Silver Street, Ashland, Nebraska.				
Nebraska	(C), Wilber, Saline County (Docket No. FEMA-6247)	Big Blue River	About 3.3 miles downstream of State Highway 41	*1,310
			About 3.1 miles upstream of State Highway 41	*1,322
		Middle Unnamed Tributary of Big Blue River.	At mouth at Big Blue River	*1,312
			Just upstream of OK Street	*1,320
			About 0.75 mile upstream of Franklin Street	*1,368
		North Unnamed Tributary of Big Blue River.	At mouth at Big Blue River	*1,321
			Just upstream of State Highway 103	*1,325
			About 1.5 miles upstream of mouth (just upstream of County Road).	*1,355
Maps available for inspection at the City Hall, 101 West Third Street, Wilber, Nebraska.				
New Jersey	Mantua, township, Gloucester County (Docket No. FEMA-6247).	Mantua Creek	Downstream corporate limits	*10
			Upstream corporate limits	*11
Maps available for inspection at the Municipal Building, Main Street, Mantua, New Jersey.				
New York	Canajoharie, village, Montgomery County (Docket No. FEMA-6247).	Mohawk River	Downstream corporate limits	*300
			Upstream corporate limits	*302
Maps available for inspection at the Municipal Building, Erie Boulevard, Canajoharie, New York.				
New York	Constantia, town, (Oswego County (Docket No. FEMA-6247).	Oneida Lake	Entire shoreline	*373
		Panther Lake	Entire shoreline	*601
		Frederick Creek	Confluence with Scriba Creek	*373
			Upstream of Tannery Road Dam	*415
			Upstream of Knapp Road	*435
			Approximately 3,400' upstream of Kibbie Lake Road	*477
		Scriba Creek (Lake)	Confluence with Oneida Lake	*373
			Upstream of County Road No. 23 (downstream crossing).	*401
			Upstream of Parker Road	*448
			Upstream of Holley Hole Road	*505
			Upstream Corporate Limits	*548
		Dakins Creek	Confluence with Oneida Lake	*372
			Approximately 300' upstream of Johnson Road	*414
Maps available for inspection at the Town Hall, Frederick Street, Constantia, New York.				
New York	Fort Plain, village, Montgomery County (Docket No. FEMA-6247).	Mohawk River	Downstream corporate limits	*304
			Upstream corporate limits	*307
		Otsquago Creek	Confluence with Mohawk River	*305
			Upstream of South Street bridge	*322
			Upstream corporate limits	*352
Maps available for inspection at the Village Hall, 168 Canal Street, Fort Plain, New York.				
New York	Nelliston, village, Montgomery County (Docket No. FEMA-6247).	Mohawk River	Downstream corporate limits (extended)	*303
			Upstream corporate limits (extended)	*307
Maps available for inspection at the Village Hall, River Street, Nelliston, New York.				
New York	Patchogue, village, Suffolk County (Docket No. FEMA-6247).	Great South Bay	Entire shoreline within community	*6
			West Main Street to Crescent Street extended along southwestern corporate limits.	*5
			Crescent Street extended to Sunset Lane (Strand Drive) extended along southwestern corporate limits.	*6
Maps available for inspection at the Municipal Building, 14 Baker Street, Patchogue, New York.				
Ohio	(C), North Canton, Stark County (Docket No. FEMA-6247).	West Branch Nimishillen Creek	About 1,900 feet downstream of South Main Street	*1,065
			Just upstream of South Main Street	*1,074
			Just upstream of Dam	*1,085
			About 1,400 feet upstream of East Maple Street	*1,090
		Chatham Ditch	About 1,150 feet downstream of Marquardt Avenue	*1,090
			Just upstream of Marquardt Avenue	*1,100
			About 900 feet upstream of Marquardt Avenue	*1,101
		McDowell Ditch	About 2,050 feet downstream of Everhard Avenue	*1,056
			About 150 feet upstream of Everhard Avenue	*1,059
		Zimber Ditch	About 2,700 feet downstream of Glenwood Street Southwest.	*1,062
			About 2,400 feet upstream of Glenwood Street Southwest.	*1,064
Maps available for inspection at the Engineer's Office, City Hall, 145 North Main Street, North Canton, Ohio.				
Oklahoma	City of Oklahoma City, Oklahoma, Canadian, Cleveland, McClain, Pottawatomie Counties (FEMA-6254).	North Canadian River	Just upstream of St. Louis and San Francisco Railroad	*1,107
			Just upstream of Westminster Road	*1,124
			Just downstream of northeast 108th Street	*1,132
			Just downstream of Midwest Boulevard	*1,148
			Just downstream of I-35	*1,174
			Just downstream of Western Avenue	*1,185
			Just upstream of Portland Avenue	*1,196

FINAL BASE(100-YEAR) FLOOD ELEVATIONS—Continued

State	City/town/county	Source of flooding	Location	#Depth in feet above ground. *Elevation in feet (NGVD)
			Just upstream of Chicago Rock Island and Pacific Railroad.	*1,228
			Just upstream of U.S. Highway 66	*1,248
		North Canadian Tributary 8	Just upstream of northeast 93rd Street	*1,152
			Just upstream of Northeast 78th Street	*1,173
			Just downstream of northeast 63rd Street	*1,192
		North Canadian Tributary 9	Just downstream of St. Louis and San Francisco Railway.	*1,153
			Just upstream of Post Road	*1,186
		Crutcho Creek	Just downstream of Arnold Drive	*1,205
			Just downstream of southeast 59th Street	*1,225
			Just downstream of southeast 74th Street	*1,243
		Crutcho Creek Tributary E	Just upstream of southeast 44th Street	*1,210
			Just upstreamof Reserve Road	*1,228
		Crutcho Creek Tributary C	Just upstream of Twinning Drive	*1,213
			Just downstream of Epperly Drive	*1,246
		Crutcho Creek Tributary C–1	Approximately 400 feet downstream of southeast 59th Street.	*1,232
		Crutcho Creek Tributary F	Just upstream of Voorhees Road	*1,228
		Crutcho Creek Tributary G	Approximately 1,400 feet downstream of Atchison Topeka & Santa Fe Railway.	*1,240
		Cherry Creek	Just downstream of Parker Drive	*1,256
		Crooked Oak Creek	Just downstream of I–40	*1,175
			Just downstream of southeast 22nd Street	*1,194
			Just downstream of Grand Boulevard	*1,213
			Just upstream of southeast 44th Street	*1,221
			Just downstream of southeast 59th Street	*1,236
			Just upstream of Atchison Topeka and Santa Fe Railway.	*1,250
			Just upstream of southeast 74th Street (I–240)	*1,265
		Crooked Oak Creek Tributary A	Approximately 500 feet upstream of Eastern Avenue	*1,239
		Lightning Creek	Just upstream of southwest 29th Street	*1,192
			Just downstream of southwest 59th Street.	*1,213
			Just upstream of southwest 67th Street	*1,217
			Just upstream of I–240	*1,225
			Just downstream of Western Avenue	*1,247
			Just downstream of Walker Avenue	*1,264
		Lightning Creek Tributary-1	Just downstream of Southeast 59th Street	*1,224
			Just upstream of Santa Fe Avenue	*1,237
		Lightning Creek Tributary 3	Just upstream of South Walker	*1,231
		Lightning Creek Tributary 6	Approximately 1500 feet upstream of confluence with Lightning Creek.	*1,243
			Just downstream of Pennsylvania Avenue	*1,267
		Twin Creek	Just upstream of Western Avenue	*1,189
			Just upstream of Pennsylvania Avenue	*1,196
			Just upstream of St. Louis San Francisco Railway	*1,210
			Just downstream of southwest 29th Street	*1,221
			Just upstream of southwest 48th Street	*1,241
		Brock Creek	Just upstream of southeast 25th Street (Commerce Street).	*1,201
			Just upstream of southwest 44th Street	*1,223
			Just downstream of southwest 59th Street	*1,238
		North Canadian River Tributary 10	Just downstream of southwest 25th Street	*1,209
			Just upstream of South Portland Avenue	*1,227
		North Canadian River Tributary 12	Approximately 3,000 feet upstream of confluence of North Canadian Tributary 13.	*1,222
		North Canadian River Tributary 13	Just upstream of southwest 29th Street	*1,226
		Campbell Creek	Just upstream of southwest 29th Street	*1,234
		Campbell Creek East Branch	Just upstream of southwest 44th Street	*1,251
		Campbell Creek Middle Branch	Just upstream of Council Road	*1,264
			Just downstream of southwest 59th Street	*1,279
		North Canadian River Tributary 14	Just upstream of West Reno Avenue	*1,216
			Just downstream of Chicago, Rock Island, and Pacific Railroad.	*1,226
			Just upstream of 10th Street	*1,254
			Just downstream of N.W. 16th Street	*1,270
		Mustang Creek	Just upstream of southwest 15th Street	*1,236
			Just downstream of Morgan Road	*1,240
			Just downstream of Sara Road	*1,244
			Just downstream of southwest 29th Street	*1,280
			Just downstream of Czech Hall Road	*1,285
			Just downstream of Cemetary Road	*1,325
		Mustang Creek (New Channel)	Just downstream of Dam	*1,244
		Mustang Creek Tributary 1	Just downstream of southwest 29th Street	*1,241
			Just downstream of southwest 44th Street	*1,263
			Just downstream of southwest 59th Street	*1,288
		Mustang Creek Tributary 1 West Branch.	Just downstream of southwest 59th Street	*1,292
		Mustang Creek Tributary 2	Just downstream of southwest 29th Street	*1,255
			Just upstream of southwest 44th Street	*1,271
			Just upstream of Mustang Road	*1,279
			Just upstream of Czech Hall Road	*1,297
		Mustang Creek Tributary 2 South Branch.	Just downstream of southwest 59th Street	*1,287
		Mustang Creek Tributary 3	Just downstream of southwest 15th Street	*1,263

FINAL BASE(100-YEAR) FLOOD ELEVATIONS—Continued

State	City/town/county	Source of flooding	Location	#Depth in feet above ground. *Elevation in feet (NGVD)
			Just upstream of Mustang Road	*1,268
			Just upstream of Czech Hall Road	*1,289
			Just downstream of Reno Avenue	*1,320
		Mustang Creek Tributary 3 East Branch.	Just upstream of Mustang Road	*1,268
			Just upstream of Reno Avenue	1,281
		Mustang Creek Tributary 3 West Branch.	Just downstream of Wildwood Drive	*1,295
		Mustang Creek Tributary 4	Just downstream of Cemetary Road	*1,306
		Shell Creek	Just upstream of I-40	*1,279
			Just upstream of northwest 23rd Street	*1,285
			Just upstream of northwest 10th Street	*1,296
			Just upstream of West Reno Avenue	*1,305
			Just downstream of southwest 15th Street	*1,318
			Just upstream of southwest 29th Street	*1,332
		Shell Creek Tributary 1	Just downstream of Cimarron Road	*1,306
		Shell Creek Tributary 2	Just downstream of Richland Road	*1,290
		Shell Creek Tributary 3	Just downstream of northwest 10th Street	*1,295
			Just upstream of Richland Road	*1,304
			Just upstream of Frisco Road	*1,331
		Shell Creek Tributary 4	Just upstream of Cimarron Road	*1,306
			Just downstream of West Reno Avenue	*1,312
		Shell Creek Tributary 4 West Branch.	Just upstream of Cimarron Road	*1,299
		Shell Creek Tributary 5	Just upstream of Richland Road	*1,313
			Just upstream of southwest 15th Street	*1,324
			Just downstream of southwest 29th Street	*1,340
		Shell Creek Tributary 5 East Branch.	Approximately 1,000 feet upstream of confluence with Shell Creek-Tributary 5.	*1,316
		Shell Creek Tributary 6	Just upstream of southwest 29th Street	*1,333
		Canadian River	Just upstream of U.S. Highway 62	*1,162
		Canadian River Tributary 1	Just upstream of southwest 149th Street	*1,172
			Just upstream of southwest 134th Street	*1,183
			Just downstream of Pennsylvania Avenue	*1,186
			Just downstream of southwest 119th Street	*1,204
			Just downstream of southwest 104th Street	*1,232
		Tributary 1 of Canadian River Tributary 1.	Just upstream of southwest 149th Street	*1,175
		Tributary of Canadian River Tributary 1.	Just upstream of southwest 149th Street	*1,180
			Just upstream of Western Avenue	*1,191
		Tributary 0 of Canadian River Tributary 1.	Just downstream of southwest 134th Street	*1,190
			Just downstream of Western Avenue	*1,199
		Tributary 3 of Canadian River Tributary 1.	Just downstream of southwest 119th Street	*1,205
		Tributary 4 of Canadian River Tributary 1.	Just upstream of southwest 119th Street	*1,201
		Canadian River Tributary 2	Just upstream of southwest 149th Street	*1,162
			Just downstream of southwest 134th Street	*1,185
			Just upstream of southwest 119th Street	*1,210
		Cow Creek	Just downstream of southwest 134th Street	*1,185
			Just upstream of 119th Street	*1,196
			Just downstream of southwest 104th Street	*1,209
			Just upstream of southwest 89th Street	*1,232
		Cow Creek Tributary 1	Just downstream of southwest 119th Street	*1,202
			Just downstream of southwest 104th Street	*1,232
		Cow Creek Tributary 2	Just upstream of southwest 119th Street	*1,196
			Just upstream of Council Road	*1,237
			Just upstream of County Line Road	*1,259
			Just downstream of southwest 104th Street	*1,274
		North Branch of Cow Creek Tributary 2.	Just upstream of southwest 104th Street	*1,213
			Just downstream of Council Road	*1,257
		West Branch of Cow Creek Tributary 2.	Just upstream of southwest 104th Street	*1,240
		Cow Creek Tributary 3	Just upstream of southwest 104th Street	*1,213
		Deep Fork	Just downstream of Triple X Road	*916
			Just downstream of Choctaw Road	*932
			Just downstream of Memorial Road	*1,007
			Just upstream of northeast 122nd Street	*1,017
			Just downstream of northeast 108th Street	*1,028
			Just upstream of Britton Road	*1,043
			Just upstream of Wilshire Boulevard (78th Street)	*1,052
			Just upstream of northeast 63rd Street	*1,064
			Just upstream of Eastern Avenue	*1,077
			Just upstream of Keily Avenue	*1,088
			Just downstream of Lincoln Boulevard	*1,091
			Just upstream of Northeast Expressway	*1,111
			Just upstream of Mattern Drive	*1,138
			Just upstream of Young Boulevard	*1,152
			Just downstream of 36th Street	*1,164
			Just upstream of May Avenue	*1,181
			Just downstream of North Roff Street	*1,215
			Just downstream of Warren Avenue	*1,238
		Deep Fork Tributary 4	Approximately 2,500 feet upstream of confluence with Deep Fork.	*1,010
		Deep Fork Tributary 5	Just downstream of Turner Turnpike	*1,011
			Just downstream of northeast 122nd Street	*1,048
		Deep Fork Tributary 6	Just upstream of Interstate Highway 35	*1,046
		Deep Fork Tributary 7	Just upstream of Sooner Road	*1,031
			Just upstream of northeast 93rd Street	*1,070

FINAL BASE(100-YEAR) FLOOD ELEVATIONS—Continued

State	City/town/county	Source of flooding	Location	#Depth in feet above ground. *Elevation in feet (NGVD)
		Harrison Creek	Just downstream of Interstate Highway 35	*1,040
			Just downstream of Bryant Avenue	*1,053
			Just upstream of Eastern Avenue	*1,073
			Just downstream of Kelley Avenue	*1,105
			Just upstream of 108 Street	*1,127
		Harrison Creek Tributary 1	Approximately 1,500 feet upstream of confluence with Harrison Creek.	*1,051
		Harrison Creek Tributary 2	Just upstream of northeast 122nd Street	*1,063
			Just upstream of Eastern Avenue	*1,082
		West Branch of Harrison Creek Tributary 2.	Approximately 1,000 feet upstream of confluence with Harrison Creek Tributary 2.	*1,089
		Harrison Creek Tributary 3	Just downstream of Kelley Avenue	*1111
		Deep Fork Tributary 9	Just upstream of Missouri-Kansas-Texas Railroad	*1,050
			Just downstream of Wileshire Boulevard (78th Street)	*1,066
		Deep Fork Tributary 10	Just upstream of Interstate Highway 35	*1,052
			Just upstream of Eastern Avenue	*1,073
			Just upstream of Wilshire Boulevard (78th Street)	*1,097
		Deep Fork Tributary 11	Approximately 1,500 feet upstream of confluence with Deep Fork.	*1,072
		Deep Fork Tributary 12	Just upstream of 50th Street	*1,097
		Deep Fork Tributary 13	Just downstream of Grand Boulevard	*1,075
			Just downstream of Eastern Avenue	*1,110
			Just upstream of northeast 36th Street	*1,135
		Deep Fork Tributary 13A	Just upstream of Eastern Avenue	*1,115
		Deep Fork Tributary 13B	Just upstream of 36th Street	*1,127
		Deep Fork Tributary 16	Just downstream of 55th Street	*1,092
			Just upstream of northeast 50th Street	*1,119
			Just downstream of northeast 42nd Street	*1,121
		Deep Fork Tributary 16 West Branch.	Just upstream of northeast 50th Street	*1,112
			Just downstream of Lincoln Boulevard (U.S. Highway 77).	*1,118
		Deep Fork Tributary 17	Just upstream of northeast Expressway	*1,091
			Just downstream of Santa Fe Boulevard	*1,121
			Just downstream of northwest 71st Street	*1,130
		Deep Fork Tributary 18	Just downstream of Private Road	*1,137
			Just downstream of Northwest 35th Street	*1,148
		Deep Fork Tributary 19	Just upstream of North Walker	*1,144
			Just downstream of northwest 36th Street	*1,161
		Deep Fork Tributary 20	Just upstream of Western Avenue	*1,138
		Golf Course Creek	Just upstream of North Bellview Drive	*1,153
			Just downstream of northwest 63rd Street	*1,164
		Golf Course Creek West Branch	Just upstream of Rivera Drive	*1,163
		Cloverleaf Creek	Just downstream of Pennsylvania Avenue	*1,142
			Just downstream of Bellview Drive	*1,153
		Deep Fork Tributary 22	Approximately 1,000 feet upstream of confluence with Deep Fork.	*1,159
		Chisholm Creek	Just downstream of 192nd Street	*1,052
			Just upstream of 178th Street	*1,066
			Just downstream of Western Avenue	*1,096
			Just downstream of Memorial Road	*1,121
			Just downstream of 122nd Street	*1,143
			Just downstream of Pennsylvania Avenue	*1,164
		Chisholm Creek Tributary 3	Just downstream of 192nd Street	*1,067
		Chisholm Creek Tributary 4	Just downstream of Corporate Limits	*1,064
		Chisholm Creek Tributary 6	Just upstream of N.W. 164th Street	*1,085
		Chisholm Creek Tributary 8	Just upstream N.W. 150th Street	*1,098
			Just downstream of Memorial Road	*1,125
		Chisholm Creek Tributary 9	Just downstream of Hefner Road	*1,169
		Deer Creek	Just downstream of Morgan Road	*1,087
			Just downstream of Sara Road	*1,098
			Just upstream of Czech Hall Road	*1,127
			Just downstream of Frisco Road	*1,172
			Just downstream of Richland Road	*1,217
		Walnut Creek	Just upstream of N.W. 164th Street	*1,068
			Just downstream of N.W. 150th Street	*1,090
			Just downstream of N.W. 136th Street	*1,117
			Just upstream of Council Road	*1,167
			Just upstream of Hefner Road	*1,204
			Just upstream of Northwest Expressway	*1,230
		Deer Creek Tributary 3	Just downstream of N.W. 150th Street	*1,087
			Just upstream of Memorial Road	*1,125
			Just upstream of N.W. 122nd Street	*1,176
		Deer Creek Tributary 3 West Branch.	Just upstream of County Line Road	*1,152
		Deer Creek Tributary 4	Just downstream of N.W. 122nd Street	*1,167
		Deer Creek Tributary 5	Just upstream of Mustang Road	*1,121
		Deer Creek Tributary 6	Just downstream of Memorial Road	*1,134
		Deer Creek Tributary 7	Just upstream of Memorial Road	*1,125
			Just downstream of Northwest Expressway	*1,161
		Spring Creek of Deer Creek	Just downstream of Memorial Road	*1,129
			Just upstream of N.W. 122nd Street	*1,167
			Just downstream of Czech Hall Road	*1,211
		Deer Creek Tributary 8	Just downstream of Northwest Expressway	*1,149
			Just downstream of Cemetery Road	*1,185
		Deer Creek Tributary 11	Just downstream of Oak Hill Road	*1,178
		Deer Creek Tributary 12	Just downstream of Frisco Road	*1,170
		Deer Creek Tributary 13	Just upstream of Frisco Road	*1,220
		Deer Creek Tributary 14	Just upstream of Memorial Road	*1,225

FINAL BASE(100-YEAR) FLOOD ELEVATIONS—Continued

State	City/town/county	Source of flooding	Location	#Depth in feet above ground. *Elevation in feet (NGVD)
		Bluff Creek	Just downstream of N.W. 192nd Street	*1,036
			Just downstream of N.W. 122nd Street	*1,096
		Bluff Creek Tributary A	Just downstream of Portland Avenue	*1,082
		Bluff Creek Tributary A-1	Just downstream of Portland Avenue	*1,060
		Dry Creek of Bluff Creek	Just downstream of (West Bound) Memorial Road	*1,090
			Just downstream of Quail Creek Road	*1,139
		Brush Creek of Dry Creek	Just downstream of Oak Hollow Road	*1,132
		Spring Creek of Bluff Creek	Just upstream of MacArthur Boulevard	*1,108
			Just downstream of Britton Road	1,152
			Just downstream of N.W. 83rd Street	*1,180
			Just downstream of N.W. 63rd Street	*1,247
		Spring Creek West Branch	Just downstream of MacAuthur Boulevard	*1,102
			Just downstream of Hefner Road	*1,195
		Silver Creek of Spring Creek	Just downstream of Rockwell Avenue	*1,170
		Bluff Creek above Lake Hefner	Just downstream of Northwest Expressway	*1,215
			Just downstream of N.W. 63rd Street	*1,224
		Hog Creek	Just upstream of southeast 149th Street	*1,056
			Just upstream of southeast 119th Street	*1,072
			Just upstream of Choctaw Road	*1,086
			Just downstream of I-40	*1,116
			Just upstream of Hiwassee Road	*1,149
			Just upstream of Anderson Road	*1,179
			Just downstream of Westminister Road	*1,207
		Hog Creek Tributary 1	Just upstream of Choctaw Road	*1,084
		Hog Creek Tributary 2	Just upstream of Indian Meridian Road	*1,099
			Just upstream of S.E. 104th Street	*1,122
		Hog Creek East Branch	Just downstream Interstate Highway 40th Street	*1,114
			Just upstream of Interstate Highway 40	*1,124
			Just upstream of S.E. 59th Street	*1,149
		Hog Creek West Branch	Just upstream of Hiwassee Road	*1,124
			Just downstream of Anderson Road	*1,138
			Just upstream of Brook Haven Road	*1,185
		Hog Creek West Branch Tributary 1.	Approximately 400 feet upstream of confluence with Hog Creek West Branch.	*1,090
		Hog Creek West Branch Tributary 2.	Just downstream of Hiwassee Road	*1,222
		Hog Creek West Branch Tributary 3.	Just downstream of southeast 74th Street	*1,182
		Hog Creek Tributary 3	Just downstream southeast 59th Street	*1,146
			Just upstream southeast 59th Street	*1,152
		Hog Creek Tributary 5	Just downstream of southeast 44th Street	*1,172
		Hog Creek Tributary 6	Just downstream of southeast 44th Street	*1,155
Maps available for inspection at City Clerk's Office, Room 208, Municipal Building, 200 North Walker Street, Oklahoma City, Oklahoma 73102.				
Pennsylvania	Halifax, township, Dauphin County (Docket No. FEMA-6218).	Susquehanna River	Downstream Corporate Limits	*366
			Borough of Halifax downstream Corporate Limits	*371
			Confluence of Gurdy Run	*375
			Upstream Corporate Limits	*381
		Powell Creek	Downstream Corporate Limits	*396
			Approximately 730 feet upstream of Private Road extended.	*407
			Upstream of State Route 225	*423
			Upstream of Camp Hebron Road (downstream crossing).	*427
			Upstream of Konicks Road	*443
			Downstream of upstream crossing of Camp Hebron Road.	*478
		Armstrong Creek	Upstream of State Route 147	*374
			Confluence of New England Run	*385
			Downstream of 1st Dam	*395
			Upstream of State Route 225	*405
			Downstream Ridge Road	*420
			Approximately 2,275' upstream of Ridge Road	*429
		Gurdy Run	Upstream State Route 147	*375
			Upstream of downstream footbridge	*384
			Upstream Legislative Route 22029	*403
			Downstream of upstream footbridge	*427
Maps available for inspection by contacting Janet Noblit, at the Halifax Township Office, R.D. 3, Box T80, Halifax, Pennsylvania.				
Pennsylvania	Windsor, borough, York County (Docket No. FEMA-6181).	Fishing Creek	Downstream corporate limits	*622
			Penn Street (downstream)	*637
			Gay Street (upstream)	*650
			Upstream corporate limits	*678
Maps available for inspection at the Borough Office, Two West Main Street, Windsor, Pennsylvania.				
Washington	Cosmopolis (city), Grays Harbor County (FEMA-6247)	Grays Harbor	Intersection of Broadway Street (U.S. 101) and J Street.	*10
		Mill Creek	30 feet upstream of C Street	*21
Maps available for inspection at City Hall, 100 E. 1st., Cosmopolis, Washington.				
Washington	Lynden (city), Whatcom County (FEMA-6197)	Nooksack River	Area approximately 150 feet south of intersection of East Front Street and Hawley Street.	*57
Maps available for inspection at City Engineer's Office, 323 Front Street, Lynden, Washington.				

FINAL BASE(100-YEAR) FLOOD ELEVATIONS—Continued

State	City/town/county	Source of flooding	Location	#Depth in feet above ground. *Elevation in feet (NGVD)
Washington	Waitsburg (city), Walla Walla County (FEMA-6247)	Touchet River	Intersection of First Street and Jay Street	*1,247
			Intersection of Woods Street and U.S. Highway 12	*1,274
		Coppei Creek	Intersection of Arnold Street and Seventh Street	*1,243
			Intersection of Main Street and Sixth Street	#1

Maps available for inspection at City Hall, Waitsburg, Washington.

(National Flood Insurance Act of 1968 (Title XIII of Housing and Urban Development Act of 1968), effective January 28, 1969 (33 FR 17804, November 28, 1968), as amended; 42 U.S.C. 4001–4128; Executive Order 12127, 44 FR 19367; and delegation of authority to the Associate Director)

Issued: June 8, 1982.

Lee M. Thomas,

Associate Director, State and Local Programs and Support.

[FR Doc. 82-17624 Filed 7-1-82; 8:45 am]

BILLING CODE 6718-03-M

44 CFR Part 67

National Flood Insurance Program; Final Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency.

ACTION: Final rule.

SUMMARY: Final base (100-year) flood elevations are listed below for selected locations in the nation.

These base (100-year) flood elevations are the basis for the flood plain management measures that the community is required to either adopt or show evidence of being already in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

EFFECTIVE DATE: The date of issuance of the Flood Insurance Rate Map (FIRM) showing base (100-year) flood elevations, for the community. This date may be obtained by contacting the office where the maps are available for inspection indicated on the table below.

ADDRESSES: See table below.

FOR FURTHER INFORMATION CONTACT: Mr. Robert G. Chappell, P.E., Federal Emergency Management Agency, National Flood Insurance Program, (202) 287–0230, Washington, D.C. 20472.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency gives notice of the final determinations of flood elevations for each community listed.

This final rule is issued in accordance with Section 110 of the Flood Disaster Protection Act of 1968 (Title XIII of the Housing and Urban Development Act of 1968 (Pub. L. 90–448)), 42 U.S.C. 4001–4128, and 44 CFR Part 67. An opportunity for the community or individuals to appeal this determination to or through the community for a period of ninety (90) days has been provided, and the Agency has resolved the appeals presented by the community.

The Agency has developed criteria for flood plain management in flood-prone areas in accordance with 44 CFR part 60.

Pursuant to the provisions of 5 U.S.C. 605(b), the Associate Director, to whom authority has been delegated by the Director, Federal Emergency Management Agency, hereby certifies that the final flood elevation determinations, if promulgated, will not have a significant economic impact on a substantial number of small entities. A flood elevation determintation under section 1363 forms the basis for new local ordinances, which, if adopted by a local community, will govern future construction within the flood plain area. The elevation determinations, however, impose no restriction unless and until the local community voluntarily adopts flood plain ordinances in accord with these elevations. Even if ordinances are adopted in compliance with Federal standards, the elevations prescribed how high to build in the flood plain and do not proscribe development. Thus, this action only forms the basis for future local actions. It imposes no new requirement; of itself it has no economic impact.

List of Subjects in 44 CFR Part 67

Flood insurance, Flood plains.

The final base (100-year) flood elevations for selected locations are:

FINAL BASE (100-YEAR) FLOOD ELEVATIONS

State	City/town/county	Source of flooding	Location	#Depth in feet above ground. *Elevation in feet (NGVD)
Illinois	(C) O'Fallon St. Clair County (Docket No. FEMA-6224).	Ogles Creek	Just upstream of Interstate 64	*551
			Just downstream of Old Collinsville Road	*551
		Ogles Creek Tributary	About 200 feet downstream of Crestview Drive	*551
			Just downstream of West Highway Fifty	*552
		Engle Creek	About 370 feet upstream of O'Fallon-Troy Road	*504
			Just downstream of Illinois Terminal Railroad (near confluence of Engle Creek Ditch).	*515
			Just upstream of Illinois Terminal Railroad (near confluence of Engle Creek Ditch).	*520

FINAL BASE (100-YEAR) FLOOD ELEVATIONS—Continued

State	City/town/county	Source of flooding	Location	#Depth in feet above ground. *Elevation in feet (NGVD)
			Just downstream of Illinois Terminal Railroad (near divergence with Engle Creek Ditch.	*523
			Just downstream of West State Street	*533
			Just upstream of Chessie System	*542
			Just downstream of West Highway Fifty	*543
		Engle Creek Ditch	Just upstream of confluence with Engle Creek	*515
			Just downstream of divergence with Engle Creek	*525
Maps available for inspection at the City Hall, 200 North Lincoln Avenue, O'Fallon, Illinois.				
Oklahoma	City of Tulsa, Tulsa and Osage Counties (FEMA 6141).	Arkansas River	Just upstream of 51st Street (US Highway 66, Interstate 44).	*626
			Upstream of Texas and Pacific Railroad (near 31st Street).	*630
			Just upstream of 23rd Street bridge	*631
		Bird Creek	Just downstream of 56th Street North (upstream crossing).	*599
			Just downstream of US Highway 75	*603
		Bird Creek Tributary	Just downstream of Mohawk Park Road	*600
			Just downstream of 36th Street North	*611
		Coal Creek (North Tulsa)	Just downstream of Atchison Topeka and Santa-Fe Railway.	*600
			Just downstream of Apache Street	*618
			Just upstream Apache Street	*620
			Just downstream of Darlington Place	*638
		Coal Creek Tributary	Just upstream New Haven Avenue	*689
		Flat Rock Creek	Just upstream of Cherokee Expressway (US Highway 75).	*604
			Just upstream of Texas and Pacific Railroad	*622
		Flat Rock Creek Tributary	Just downstream of Cherokee Expressway (US Highway 75).	*603
		Dirty Butter Creek	Just downstream of 36th Street North	*621
			Just downstream of Texas and Pacific Railroad	*645
			Just downstream of Hartford Avenue	*652
		Dirty Butter Creek Tributary	Just downstream of Mohawk Boulevard	*631
			Just upstream of Mohawk Boulevard	*641
		Valley View Creek	Just downstream of 46th Street North	*625
			Just upstream of 54th Street North	*657
		Mingo Creek	Just upstream of 56th Street North	*591
			Just upstream of 46th Street North	*596
			Just upstream of 36th Street North	*611
			Just downstream of Apache Street	*613
			Just upstream of Interstate Highway 244	*618
			Just upstream of 11th Street South	*628
			Just upstream of 41st Street South	*652
			Just upstream of Broken Arrow Expressway	*657
			Just downstream of 51st Street South	*662
			Just upstream of 61st Street South	*690
		Douglas Creek	Upstream of 93rd East Avenue	*615
			Just upstream of St. Louis San Francisco Railroad Spur.	*618
		Mill Creek	Just upstream of Memorial Drive	*645
			Just upstream of 73rd Avenue East	*661
			Just downstream of 11th Street at upstream end of underground conduit.	*696
		Jones Creek	Just upstream of Memorial Drive	*647
			Just downstream 69th Avenue East	*686
		Audubon Creek	Just upstream of 90th Avenue East	*645
			Just upstream of Skelly Drive (Interstate Highway 44)	*668
		Bell Creek	Just upstream of 37th Street South	*650
			Just downstream of 93rd East Avenue	*653
			Just upstream of 90th East Avenue	*660
			Just upstream of Broken Arrow Expressway	*667
		Bell Creek Tributary	Just upstream of 41st Street South	*661
			Just upstream of Missouri, Kansas and Texas Railroad	*667
		Fulton Creek	Just upstream of 34th Street South	*654
			Just downstream of 39th Street South	*665
		Alsuma Creek	Just upstream of 46th Place South	*661
			Just downstream of Missouri, Kansas and Texas Railroad.	*670
		Little Creek	Just downstream of Mingo Valley Expressway service road south bound.	*615
			Just upstream of Garnett Road	*617
		Quarry Creek	Just upstream of Apache Street	*633
			Just upstream of 129th East Avenue	*648
		Eagle Creek	Just downstream of St. Louis and San Francisco Railroad.	*620
			Just upstream of St. Louis & San Francisco Railroad	*629
			Just downstream of Pine Street	*647
		Cooley Creek	Approximate 300 feet upstream of Mingo Valley Expressway.	*630
			Just upstream of Garnett Road	*642
			Just upstream of 129th East Avenue	*670
			Just downstream of Small Dam	*672
			Just upstream of Interstate Highway I-44	675
			Just upstream of Small Dam	*683
		Cooley Creek Tributary	Just upstream of Interstate Highway I-44	*678
			Just upstream of 4th Place South	*685

FINAL BASE (100-YEAR) FLOOD ELEVATIONS—Continued

State	City/town/county	Source of flooding	Location	#Depth in feet above ground. *Elevation in feet (NGVD)
			Just downstream of 11th Street South	*704
			Just upstream of 15th Street South	*730
		Tupelo Creek	Just downstream of 102nd East Avenue	*627
			Just upstream of Mingo Valley Expressway	*633
			Just upstream of 11th Street South	*645
			Just upstream of Interstate Highway I-44	*650
			Just upstream of 17th Street South	*661
		Tupelo Creek Tributary	Just upstream of 119th East Avenue	*665
			Just upstream of 121st East Avenue	*670
		Brook Hollow Creek	Just upstream of Mingo Valley Expressway	*652
			Just upstream of Garnett Road	*661
			Just upstream of 129th Avenue East	*694
			Just upstream of 28th Street South	*710
		Brook Hollow Creek Tributary	Just downstream of Garnett Road	*661
			Just upstream of 121st East Avenue	*679
		Sugar Creek	Just upstream of Mingo Valley Expressway	*651
			Just upstream of Garnett Road	*664
			Just downstream of 41st Street South	*670
		South Park Creek	Just upstream of Mingo Valley Expressway	*656
			Just upstream of Garnett Road	*666
		Ford Creek	Just downstream of intersection of Garnett Road and 51st Street South.	*668
			Just upstream of 129th East Avenue	*693
			Just upstream of Broken Arrow Expressway	*708
		Catfish Creek	Just downstream of 55th Street South	*670
		Spunky Creek Tributary A	Just upstream of 193rd East Avenue	*634
		Spunky Creek Tributary B	Just upstream of 193rd East Avenue	*628
			Just upstream of 177th East Avenue	*658
		Spunky Creek Tributary B-1	Just upstream of the downstream low water crossing	*652
		Harlow Creek	Just upstream of Keystone Expressway (U.S. Highway 64).	*661
		Harlow Creek Tributary	Just upstream of Edison Street	*665
		Blackboy Creek	At West 7th Street	*667
		Vensel Creek	Just downstream of 101st Street	*622
			Just upstream of Harvard Avenue	*647
			Approximately 100 feet upstream of 83rd Street	*677
		Fred Creek	Just downstream of 81st Street	*623
			Just upstream of Evanston Avenue	*655
			Just upstream of Harvard Avenue	*680
		Joe Creek	Just downstream of 71st Street	*622
			Just upstream of 61st Street	*634
			Just upstream of 51st Street	*655
		South Fork Joe Creek	Just upstream of Harvard Avenue	*664
			Just downstream of Marion Street	*682
			Just upstream of New Haven Avenue	*689
			Just downstream of Pittsburgh Avenue	*697
		Little Joe Creek	Just upstream of Harvard Avenue	*655
			Just upstream of New Haven Avenue	*663
			Just upstream of Yale Avenue	*689
			Just downstream of Hudson Avenue	*700
		South Fork Little Joe Creek	Just upstream of Yale Avenue	*695
		North Fork Little Joe Creek	Just upstream of Yale Avenue	*692
		East Branch Joe Creek	Just upstream of 41st Street South	*688
			Just upstream of 38th Street South	*694
		West Branch Joe Creek	Just upstream of 49th Street	*664
			Just downstream of 31st Street	*724
		Crow Creek	Just downstream of Peoria Avenue	*644
			Just upstream of 31st Avenue	*659
		Hager Creek	Just upstream of 91st Street	*628
			Just upstream of the Elwood Avenue crossing north of 81st Street.	*639
		Mooser Creek	Just upstream of Texas and Pacific Railroad	*627
			Just upstream of U.S. Highway 75 (Okmulgee Expressway).	*643
			Just upstream of 33rd West Avenue	*694
		Mooser Creek Tributary	Just upstream of 57th Street extended	*670
			Just downstream of 61st Street	*678
		Cherry Creek (West Tulsa)	Approximately 250 feet upstream of 37th Place	*633
		Red Fork Creek	Just upstream of Union Avenue	*642
			Just downstream of Yukon Avenue	*646
		Nickel Creek	Just upstream of 91st Street	*634
		West Branch Haikey Creek	Just upstream of Garnett Road	*674
			Just downstream of Mingo Road	*694
		Little Haikey Creek	Just upstream of Memorial Drive	*693
			Just upstream of Sewage Plant Access Road	*720
		Little Haikey Creek Tributary	Just downstream of 72nd East Avenue	*721
		Fry Ditch No. 2	Just upstream of 101st Street	*664
			Just downstream of Sheridan Avenue	*686
			Just upstream of 91st Street	*711
Maps available for inspection at City Engineer's Office, City Hall, 200 Civic Center, Room 514, Tulsa, Oklahoma 74103.				
Texas	City of El Paso, El Paso County (FEMA 5926)	Arroyo 1	Just upstream of Doniphan Road	*3,756
			Just downstream of Interstate Highway 10 (Southbound Lanes).	*3,822
			Just upstream of Interstate Highway 10 (Northbound Lanes.	*3,824
		Arroyo 2	Just upstream of Doniphan Road	*3,753

FINAL BASE (100-YEAR) FLOOD ELEVATIONS—Continued

State	City/town/county	Source of flooding	Location	#Depth in feet above ground. *Elevation in feet (NGVD)
			Just upstream of Service Road Interstate Highway 10 (Southbound).	*3,807
			Just upstream of Service Road Interstate Highway 10 (Northbound).	*3,814
			Just downstream of Thorn Dam	*3,848
			Just upstream of Thorn Dam	*3,891
			Just downstream of Lakehurst Road	*3,900
		Arroyo 2A	Just upstream of Lakehurst Road	*3,910
		Arroyo 3	Just downstream of Osborne Drive	*3,780
			Just upstream of Interstate Highway 10 (Northbound Lanes).	*3,804
		Arroyo 4	Just upstream of Doniphan Road	*3,745
			Just upstream of Interstate Highway 10 (Northbound Lanes).	*3,790
			Just downstream of Mesa Street	*3,880
			Just upstream of Mesa Street	*3,909
			Just downstream of North Wind Drive	*4,090
			Just upstream of North Wind Drive	*4,113
		Arroyo 5	Just downstream of Interstate Highway 10 (Southbound Lanes).	*3,765
			Just downstream of Mesa Street	*3,930
			Just downstream of Mesa Street	*3,971
		Arroyo 6	Just upstream of Doniphan Road	*3,745
			Just downstream of Delmar Avenue	*3,930
			Just upstream of Isabella Drive	*3,990
			Just upstream of Shadow Mountain Drive	*4,171
		Arroyo 6A	Just upstream of Thunderbird Drive	*4,382
		Arroyo 6B	Just upstream of Thunderbird Drive	*4,360
		Arroyo 7	Just downstream of Interstate Highway 10 (Southbound Lanes).	*3,789
			Just downstream of Mesa Street	*4,060
		Arroyo 8	Just upstream of Doniphan Road	*3,735
			Just downstream of Mesa Street	*4,040
			Just upstream of Mesa Street	*4,058
		Overland Flooding at Northwest of Arroyo 1—North of Mulberry Avenue.	At Achison Topeka and Santa Fe Railway	*3,749
		Ponding area West of Arroyo 1 Through Arroyo 8.	Just downstream of Frontera Road	*3,735
			Just upstream of Belva Road	*3,741
			Just downstream of Mulberry Avenue	*3,752
		Flow Path #11	Just downstream of East West Trail	*3,937
		Flow Path #13 (Drainage Channel #1).	Just upstream of U.S. Highway 54	*3,924
			Just upstream of McCombs Street	*3,957
			Just upstream of Rushing Drive	*3,990
			Just upstream of Kenworthy Drive	*4,037
		Flow Path #13A	Balinger Drive Extended	*4,003
		North East Pond	Donald Street	*3,919
		Flow Path #14 (Drainage Channel #2).	Just upstream of McCombs Street	*3,943
			Just upstream of McKinaw Drive	*3,965
			Just upstream of Rushing Drive	*3,970
			Just upstream of Sunvalley Drive	*4,077
		Flow Path #15	Hugg Street	#2
			Just upstream of Wren Avenue	*3,888
			Just upstream of Fairbank's Drive	*3,934
		Flow Path #16	Just upstream of Hercules Avenue	*3,880
			Just upstream of Hondo Pass Drive	*3,886
		Flow Path #17 (McKelligon Canyon).	At the road to the Concrete Batch Plant	*4,262
			Just downstream of McKelligon Canyon Road (uppermost crossing before the confluence of Flow Path #17A.	*4,580
		Flow Path #17A (McKelligon Canyon Tributary).	Just upstream of McKelligon Canyon Road	*4,648
		Flow Path #18	Just downstream of U.S. downstream of U.S. Highway 85 (Paisano Drive).	*3,735
			Just upstream of U.S. Highway 85 (Paisano Drive)	*3,743
		Flow Path #19	Just upstream of Atchison Topeka, and Santa Fe Railway.	*3,739
		Flow Path #20	Just upstream of Atchison, Topeka and Santa Fe Railway.	*3,732
			Just upstream of Mesa Street (U.S. Highway 80)	*4,088
		Flow Path #20A	Just downstream of Interstate Highway 10	*3,840
			Just upstream of Interstate Highway 10	*3,847
			Just upstream of Mesa Street (U.S. Highway 85, 185)	*4,131
		Flow Path #21	Just upstream Atchison Topeka and Santa Fe Railway	*3,740
			Just upstream of Southern Pacific Railroad (Easternmost Track).	*3,778
			Just downstream of Mesa Street	*3,880
			Just upstream of Mesa Street	*3,908
		Flow Path #21A	Just upstream of Southern Pacific Railroad	*3,778
			Just downstream of Interstate Highway 10	*3,800
			Just upstream of Stanton Street	*4,056
		Flow Path #22	Just upstream of Van Buren Dam (Reservoir No. 1)	*4,123
			Just downstream of Mall Dam (Approximately 1,550 feet upstream of Reservoir No. 1).	*4,182

FINAL BASE (100-YEAR) FLOOD ELEVATIONS—Continued

State	City/town/county	Source of flooding	Location	#Depth in feet above ground. *Elevation in feet (NGVD)
			Just upstream of Mall Dam (Approximately 1,550 feet upstream of Reservoir No. 1).	*4,202
		Flow Path #23	Just downstream of Residential Street	*3,724
			Just downstream of University Avenue	*3,846
			Just upstream of University Avenue	*3,860
		Flow Path #24	Just downstream of Scenic Drive	*4,112
			Just upstream of La Luz Avenue	*3,744
			Just upstream of Bliss Avenue	*3,759
		Flow Path #25	Just upstream of Hasting Avenue	*3,780
			Just upstream of Alameda Avenue	*3,702
			Just upstream of Durazno Avenue	*3,705
		Flow Path #26 (Phelps Dodge)	At Phelps Dodge Detention Basin	*3,750
			Just upstream of Hawkins Boulevard	*3,772
		Flow Path #27 Playa Drain	Just upstream of Americas Avenue (State Highway 375).	*3,666
			Just upstream of Knights Drive	*3,671
			Just upstream of George Orr Road	*3,686
			Just downstream of Ascarate Wasteway	*3,688
			Just upstream of Ascarate Street	*3,690
		Flow Path #27A (Left Bank Lateral Street, Flow of Flow Path #27).	North of Alameda Avenue	*3,697
		Flow Path #28 (Mesa Drain and Interceptor).	Just downstream of Carl Longuemari Road	*3,662
			Just upstream of Pendale Drive	*3,673
			Just upstream of Yarbrough Drive	*3,682
			Just upstream of Butcher Road	*3,691
		Flow Path #28A (Mesa Drain Below Interceptor).	Just upstream of Americas Avenue	*3,665
			Just upstream of Ivey Road	*3,668
		Flow Path #29	Shallow Flooding, Sheet Flow along Phoenix Drive	#2
			Just upstream of Interstate Highway 10	*3,835
			Just upstream of Jugarberry Drive	*3,860
		Flow Path #30	Just upstream of Mauer Drive	*3,693
		Flow Path #31 (Jesuit Draw)	Just upstream of Ryland Drive	*3,720
			Just upstream of Burnham Road	*3,771
		Flow Path #32	Just upstream of Geranium Drive	*3,683
			Just upstream of Northbound Frontage Road of Interstate Highway 10.	*3,760
		Flow Path #32A	Confluence of Flow Path #32 and Flow Path #32A	*3,766
		Flow Path #33 (Middle Drain)	Just upstream of North Carnes Road	*3,667
			Just upstream of Zaragosa Road	*3,670
		Middle Drain Below Interceptor	Just downstream of Inglewood Drive	*3,665
		Flow Path #36	Approximately 450 feet upstream of the confluence of Mesa Spur Drain and Flow Path #36.	*3,663
		Flow Path #37 (Franklin Drain)	Just upstream of Americas Avenue	*3,664
			Just upstream of Carl Longuemare Road	*3,665
		Shallow Flooding along Franklin Drain (Below Flow Path #28, Mesa Drain and Interceptor).	Just downstream Unnamed Road (At the end of Carl Longuemare Road).	*3,660
		Ponding Area P1	At the Dirt Road	*3,939
		Ponding Area P2	Entire Area	*3,938
		Ponding Area P3	At Montana Street	*3,937
		Ponding Area P4	Entire Area	*3,965
		Ponding Area P5	Entire Area	*3,966
		Ponding Area P6	At Album Road	*3,945
		Ponding Area P7	At Edgemere Boulevard	*3,965
		Ponding Area P8	At Hitchlock Road	*3,969
		Ponding Area P9	At East Glen Drive	*3,964
		Ponding Area P10	At Pico Norte	*3,945
		Ponding Area P11	Entire Area	*3,965
		Ponding Area P12	Entire Area	*3,967
		Shallow Flooding Sheet Flow	East of Lee Trevino Drive and Ponding Areas P11 and P12.	#2
		Ponding Area P13	Entire Area	*3,963
		Ponding Area P14	Entire Area	*3,983
		Ponding Area P15	Entire Area	*3,974
		Ponding Area P16	At Zaragosa Road	*4,003
		Lomaland Basin	Entire Area	*3,683
		*Overflow from Reservoir 1	At Mountain Avenue	#2
		Shallow Flooding, East Bank of Juan De Herrera Lateral Branch "B".	Entire	*3,668
		Shallow Flooding, West Bank of Ysleta Lateral.	At America's Avenue	*3,665
		Shallow Flooding, West of Flow Path #27 (Playa Drain).	Bernadine Avenue	*3,677
		Shallow Flooding, West of Flow Path, #28 (Mesa Drain and Interceptor).	At Oro Verde	*3,664
		Playa Lateral	Approximately 300 feet Southwest of Zaragosa Road	*3,662

Maps available for inspection at City Engineer's Office, City Hall, #2 Civic Center Plaza, El Paso, Texas 79901.

(National Flood Insurance Act of 1968 (Title XIII of Housing and Urban Development Act of 1968), effective January 28, 1969 (33 FR 17804, November 28, 1968), as amended; 42 U.S.C. 4001–4128; Executive Order 12127, 44 FR 19367; and delegation of authority to the Associate Director)

Issued: June 8, 1982.

Lee M. Thomas,

Associate Director, State and Local Programs and Support.

[FR Doc. 82-17625 Filed 7-1-82; 8:45 am]

BILLING CODE 6718-03-M

44 CFR Part 67

National Flood Insurance Program; Final Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency.

ACTION: Final rule.

SUMMARY: Final base (100-year) flood elevations are listed below for selected locations in the nation.

These base (100-year) flood elevations are the basis for the flood plain management measures that the community is required to either adopt or show evidence of being already in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

EFFECTIVE DATE: The date of issuance of the Flood Insurance Rate Map (FIRM) showing base (100-year) flood elevations, for the community. This date may be obtained by contacting the office where the maps are available for inspection indicated on the table below.

ADDRESSES: See table below.

FOR FURTHER INFORMATION CONTACT: Mr. Robert G. Chappell, P.E., Federal Emergency Management Agency, National Flood Insurance Program, (202) 287-0230, Washington, D.C. 20472.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency gives notice of the final determinations of flood elevations for each community listed.

This final rule is issued in accordance with Section 110 of the Flood Disaster Protection Act of 1968 (Title XIII of the Housing and Urban Development Act of 1968 (Pub. L. 90-448)), 42 U.S.C. 4001-4128, and 44 CFR Part 67. An opportunity for the community or individuals to appeal this determination to or through the community for a period of ninety (90) days has been provided. No appeals of the proposed base flood elevations were received from the community or from individuals within the community.

The Agency has developed criteria for flood plain management in flood-prone areas in accordance with 44 CFR Part 60.

Pursuant to the provisions of 5 U.S.C. 605(b), the Associate Director, to whom authority has been delegated by the Director, Federal Emergency Management Agency, hereby certifies that the final flood elevation determinations, if promulgated, will not have a significant economic impact on a substantial number of small entities. A flood elevation determination under section 1363 forms the basis for new local ordinances, which, if adopted by a local community, will govern future construction within the flood plain area. The elevation determinations, however, impose no restriction unless and until the local community voluntarily adopts flood plain ordinances in accord with these elevations. Even if ordinances are adopted in compliance with Federal standards, the elevations prescribe how high to build in the flood plain and do not proscribe development. Thus, this action only forms the basis for future local actions. It imposes no new requirement; of itself it has no economic impact.

List of Subjects in 44 CFR Part 67

Flood insurance, Flood plains.

The final base (100-year) flood elevations for selected locations are:

FINAL BASE (100-YEAR) FLOOD ELEVATIONS

State	City/town/county	Source of flooding	Location	‡Depth in feet above ground. *Elevation in feet (NGVD)
Connecticut	Plymouth, town, Litchfield County (Docket No. FEMA-6079).	Pequabuck River	Downstream corporate limits	*508
			Conrail (upstream)	*558
			U.S. Routes 6 and 202 (upstream)	*588
			Eagle Street (downstream)	*630
			Dam (upstream)	*669
			Preston Road (downstream)	*739
		Poland River	Confluence with Pequabuck River	*589
			North Main Street (upstream)	*603
			State Route 72 (upstream)	*662
			Dam (downstream)	*666
		Naugatuck River	Leadmine Road—extended (upstream)	*496
Maps available for inspection at the Plymouth Town Hall, Department of Planning, Zoning and Public Works, 19 East Main Street, Terryville, Connecticut.				
Florida	Lantana (town), Palm Beach County, FEMA-6247	Atlantic Ocean—open coast	Approxmately 520 feet east of the intersection of State Highway A1A and East Ocean Avenue.	*10
		Atlantic Ocean—Lake Worth	Eastern end of Naomi circle	*9
			Intersection of Prospect Road and Lakeside Place	*8
			Intersection of South Atlantic Drive West and South Atlantic Drive East.	*8
			Intersection of Atlantic Drive West and Barefoot Lane	*7
Maps available for inspection at Town Hall, Greynolds Circle, Lantana, Florida.				
Florida	Pahokee (city), Palm Beach County, FEMA-6247	Lake Okeechobee	Approximately 900 feet west of the intersection of 14th Terrace and State Highway 715.	*28
			Approximately 700 feet north of the intersection of Pahokee Road and Barfield Highway.	*28
Maps available for inspection at Building Department, 171 N. Lake Ave., Pahokee, Florida.				

FINAL BASE (100-YEAR) FLOOD ELEVATIONS—Continued

State	City/town/county	Source of flooding	Location	#Depth in feet above ground. *Elevation in feet (NGVD)
Florida	Palm Beach County (unincorporated areas),	Atlantic Ocean—open coast	Approximately 550 feet east of the intersection of Del Habour Drive and Ocean Boulevard.	*10
		Atlantic Ocean—Intracoastal Waterway.	Intersection of Harbor Road and Harbor Road South	*7
			Eastern end of Palm Court	*6
			Southern end of Waterway Road	*6
		Atlantic Ocean—Lake Worth and Little Lake Worth.	Intersection of Captains Landing and Captain's Key Drive.	*7
			Northern end of Lake Shore Place	*8
			Intersection of Lost Tree Way and Church Lane	*7
		Atlantic Ocean—Loxahatchee River (including north, northwest, and southwest forks).	Intersection of North Drive and Reverside Boulevard	*6
			Southern end of Holly Lane	*7
			Intersection of Woodridge Terrace and Center Street.	*6
		Lake Okeechobee	Approximately 2,000 feet west of intersection of Hooker Highway and Herbert Hoover Dike.	*30
	Maps available for inspection at Planning, Building & Zoning Department, 810 Datuna Street, West Palm Beach, Florida.			
Idaho	Idaho Falls (city), Bonneville County, FEMA-6247	Snake River	Crest of lower power dam	*4,677
	Maps available for inspection at Mayor's Office, 308 C Street, Idaho Falls, Idaho.			
Illinois	(V) Beecher, Will County (Docket No. FEMA-6243)	Trim Creek tributary	About 1,200 feet downstream of Indiana Avenue	*701
			Just upstream of Church Road.	*726
		Trim Creek	Within community	*696
	Maps available for inspection at the Clerk's Office, Municipal Building, 724 Penfield Street, Beecher, Illinois.			
Illinois	(C) East Moline, Rock Island County (Docket No. FEMA-6243)	Mississippi River	About 0.38 mile downstream of the downstream corporate limits.	*572
			At the upstream corporate limits	*574
		Rock River	Southeast of State Route 2	*577
		Shallow flooding (ponding due to rainfall).	An area within the Sugar Creek Levee from the 4th Avenue bridge to the mouth of the creek.	*569
			An area about 3,500 feet southwest of mouth of Sugar Creek, along Mississippi River levee.	*570
			An area northeast of 4th Avenue bridge over Sugar Creek.	*573
			An area southeast of the intersection of 7th Street and 5th Avenue.	*574
	Maps available for inspection at the Public Works Department, City Hall Annex, East Moline, Illinois.			
Illinois	(V) Manhattan, Will County (Docket No. FEMA-6247)	Manhattan Creek	Just downstream of Chicago, Milwaukee, St. Paul and Pacific Railroad.	*666
			Just downstream of Eastern Avenue	*680
	Map available for inspection at the Village Hall, 245 State Street, Manhattan, Illinois.			
Illinois	(V) McHenry Shores, McHenry County (Docket No. FEMA-6247)	Fox River	Within corporate limits	*740
	Maps available for inspection at the McHenry Shores Village Hall, 3215 West Beach Drive, McHenry, Illinois.			
Indiana	(T) Griffith, Lake County (Docket No. FEMA-6247)	Little Calumet River	Within corporate limits	*598
		Cady Marsh ditch	Just upstream of Cline Avenue	*614
			Just downstream of Colfax Street	*615
		Seberger ditch	Within corporate limits	*629
		Turkey Creek	Within corporate limits	*631
	Maps available for inspection at the Town Hall, 111 North Broad Street, Griffith, Indiana.			
Indiana	(Uninc.) Hancock County (Docket No. FEMA-6247)	Little Sugar Creek	About 2,500 feet downstream of County Road 600 South.	*800
			Just Upstream of County Road 600 South	*807
			Just upstream of U.S. Route 52	*822
		Sugar Creek	Just downstream of County Road 200 South	*847
			Just upstream of County Road 600 South	*794
			About 200 feet upstream of County Road 300 South	*812
			Just upstream of U.S. Route 40	*827
			Just upstream of State Route 13	*856
			Just downstream of State Route 234	*871
		Six Mile Creek	Mouth at Big Blue River	*844
			About 400 feet upstream of County Road 800 East	*846
			Just downstream of County Road 1,000 West (upstream crossing).	*880
		Buck Creek	Just upstream of County Line Road	*826
			Just downstream of Conrail	*827
			Just upstream of Conrail	*834
			Just upstream of State Route 234	*858
		Big Blue River	About 1.1 miles downstream of County Road 575 East	*831
		Brier Creek	Just downstream of County Road 1000 West	*851
			Just upstream of County Line Road	*827
		Doe Creek	About 2300 feet upstream of County Road 700 West	*846
			Just upstream of County Line Road	*806

FINAL BASE (100-YEAR) FLOOD ELEVATIONS—Continued

State	City/town/county	Source of flooding	Location	#Depth in feet above ground. *Elevation in feet (NGVD)
			Just upstream of County Road 700 West	*834
			About 2250 feet upstream of County Road 200 South	*844
Maps available for inspection at the Hancock County Courthouse, Surveyor's Office, Greenfield, Indiana.				
Indiana	(T) Highland, Lake County (Docket No. FEMA-6247)	Little Calumet River	Just upstream of Cline Avenue	*598
			At upstream corporate limits	*599
		Cady Marsh ditch	At confluence of Spring Street Ditch	*607
			Just downstream of Cline Avenue	*614
		Hart ditch	At mouth at Little Calumet River	*599
			At confluence of Cady Marsh ditch	*607
		Spring Street Ditch	About 200 feet upstream of mouth at Cady Marsh ditch.	*612
			Just downstream of Hart Road	*614
			Just downstream of Main Street	*622
Maps available for inspection at the Town Hall, 3333 Ridge Road, Highland, Indiana.				
Indiana	(T) Mooresville, Morgan County (Docket No. FEMA-6246)	White Lick Creek	At downsteam extraterritorial limits	*660
			Just upstream of State Highway 67	*667
			Just upstream of Greencastle Road	*671
			Just downstream of county line road	*678
		East fork White Lick Creek	At mouth	*661
			Just upstream of High Street	*666
			Just upstream of Bridge Street	*670
			At upstream county boundary	*679
Maps available for inspection at the Town Hall, 26 South Indiana, Mooresville, Indiana.				
Indiana	(T) Rome City, Noble County (Docket No. FEMA-6247)	Branch Creek	At western extraterritorial limits	*893
			At confluence of Little Lake	*895
		Little Lake	Shoreline	*895
		Sylvan Lake	Shoreline	*918
Maps available for inspection at the Town Hall, 123 Kerr Avenue, Rome City, Indiana.				
Indiana	(Uninc.) Shelby County (Docket No. FEMA-6247)	Little Sugar Creek	Mouth at Sugar Creek	*783
			Just downstream of County Road 1200	*805
			About 4,300 feet upstream of County Road 300 West	*813
		Snail Creek	Mouth at Sugar Creek	*738
			Just upstream of County Road 400 North	*763
			Just upstream of County Road 400 West	*784
			About 3,600 feet upstream of confluence of Sexton Ditch.	*790
		Sriodgrass ditch	Mouth at Snail Creek	*790
			About 1,500 feet upstream of confluence of Duckworth Ditch.	*799
		Dry fork	Mouth at Snail Creek	*743
			Just downstream of Conrail	*775
			Just upstream of Conrail	*781
			Just downstream of Frontage Road (downstream of Interstate 74).	*789
			About 0.19 mile upstream of County Road 800 North	*791
		Sugar Creek	About 1.9 miles downstream of Mill Dam	*734
			Just upstream of Interstate 74	*770
			Just downstream of County Road 1200 North	*794
		Brandywine Creek	About 0.3 mile downstream of County Road 300 North	*761
			Just upstream of Interstate 74	*775
			Just upstream of County Road 750 North	*803
			About 0.4 mile upstream of Chessie System	*831
		Big Blue River	About 1.0 mile upstream of State Route 44	*729
			About 1.0 mile upstream of Morristown Road	*779
			About 0.7 mile downstream of Freeport Dam	*814
			At upstream county boundary	*832
		Little Blue River	About 1.4 miles downstream of Interstate 74	*765
			Just downstream of Interstate 74	*775
Maps available for inspection at the Planning Commission Office, Shelby County Courthouse, Shelbyville, Indiana.				
Iowa	(C) Bellevue, Jackson County (Docket No. FEMA-6243)	Mississippi River	About 0.7 mile downstream of lock and dam No. 12	*602
			About 0.6 mile upstream of lock and dam No. 12	*603
		Mill Creek	About 150 feet upstream of the Chicago, Milwaukee, St. Paul and Pacific Railroad.	*602
			About 1,250 feet upstream of the Chicago, Milwaukee, St. Paul and Pacific Railroad.	*603
			About 2,400 feet downstream of State Highway 62	*616
			About 200 feet downstream of State Highway 62	*626
			About 1,300 feet upstream of State Highway 62	*629
Maps available for inspection at the City Hall, Bellevue, Iowa.				
Iowa	(C) Greene, Butler County (Docket No. FEMA-6243)	Shell Rock River	About 3,750 feet downstream of Traer Street dam	*955
			About 100 feet downstream of Traer Street dam	*956
			About 250 feet upstream of Traer Street dam	*958
			About 650 feet upstream of State Highway 14	*960
		Shell Rock River overflow channel	About 850 feet downstream of Main Street	*955
			About 400 feet upstream of Main Street	*958
			About 1,200 feet upstream of Iowa Street	*959

FINAL BASE (100-YEAR) FLOOD ELEVATIONS—Continued

State	City/town/county	Source of flooding	Location	#Depth in feet above ground. *Elevation in feet (NGVD)
Maps available for inspection at the City Hall, 123 North Second, Greene, Iowa.				
Iowa	(C) Manchester, Delaware County (Docket No. FEMA-6243)	Maquoketa River	At downstream corporate limits	*920
			Just upstream of West Marion Street	*932
			About 200 feet upstream of West Marion Street	*933
			About 1.9 miles upstream of West Marion Street	*936
		Tributary A	At mouth	*920
			Just upstream of South Brewer Street	*922
			Just upstream of East Main Street	*937
			Just downstream of East Union Street	*943
			About 1,900 feet upstream of East Acers Street	*952
Maps available for inspection at the City Hall, 208 East Main Street, Manchester, Iowa.				
Maryland	Highland Beach, town, Anne Arundel County (Docket No. FEMA-6247)	Chesapeake Bay	Entire shoreline within community	*10
Maps available for inspection by contacting Mr. Chester Pearson, Highland Beach Commissioner, at (202) 547-3742. Send comments to Honorable Chester Pearson.				
Maryland	Poolesville, town, Montgomery County (Docket No. FEMA-6243)	Dry Seneca Creek	Downstream corporate limits	*327
			Approximately 2,600' upstream of downstream corporate limits.	*337
			Upstream corporate limits	*367
Maps available for inspection at the Town Hall, Poolesville, Maryland.				
Michigan	(Twp.) Albion, Calhoun County (Docket No. FEMA-6247)	South branch Kalamazoo River	About 2.1 miles downstream of D Drive South	*946
			Just downstream of H Drive South	*955
			Just downstream of L Drive South	*962
		East branch Kalamazoo River	About 3,800 feet downstream of 29½ Mile Road	*943
			About 3,900 feet upstream of 29½ Mile Road	*948
		Unnamed creek	About 2,800 feet downstream of 29½ Mile Road	*948
			Just upstream of 29½ Mile Road	*954
			About 2,650 feet upstream of 29½ Mile Road	*958
Maps available for inspection at the Town Hall, Albion, Michigan.				
Michigan	(C) Eaton Rapids, Eaton County (Docket No. FEMA-6247)	Grand River	About 1.0 mile downstream of confluence of Grand River bypass.	*866
			Just downstream of State Street Dam	*870
			About 1,300 feet upstream of State Street Dam	*873
			At upstream southern corporate limit	*875
		Grand River bypass	Just upstream of Knight Street	*870
			Just upstream of Main Street	*872
		Spring Brook	About 1,500 feet upstream of footbridge	*871
			About 2,600 feet upstream of footbridge	*872
		Shallow flooding (overflow from Grand River and Grand River bypass).	Intersection of Main Street and Hamlin Street	*2
Maps available for inspection at the City Hall, 206 South Main Street, Eaton Rapids, Michigan.				
Michigan	(C) Mason, Ingham County (Docket No. FEMA-6247)	Sycamore Creek	About 1,200 feet downstream of Howell Road	*874
			Just upstream of Cemetery Drive	*879
			Just upstream of Maple Street	*888
			Just downstream of Kipp Road	*894
		Rayner Creek	At confluence with Sycamore Creek	*876
			Just upstream of Rogers Street	*880
			Just upstream of Columbia/Matthews Street	*884
			About 1,300 feet upstream of Matthews Street	*884
		Willow Creek	At confluence with Sycamore Creek	*891
			About 3,000 feet upstream of U.S. Highway 127	*893
Maps available for inspection at the City Hall, 201 West Ash Street, Mason, Michigan.				
Michigan	(Twp.) Pennfield, Calhoun County (Docket No. FEMA-6247)	Battle Creek River	About 850 feet upstream of Verona Dam	*830
			Just upstream of McAllister Road	*833
Maps available for inspection at the Town Hall, 20260 Capital Avenue, N.E., Battle Creek, Michigan.				
Michigan	(Twp.) Summit, Jackson County (Docket No. FEMA-6247)	McCain drain	About 1,800 feet downstream of State Highway 60	*956
			About 2,300 feet upstream of Spring Arbor Road	*963
		Grand River	About 2,100 feet upstream of Losey Avenue	*935
			About 4,600feet downstream of Stonewall Road	*940
			Just downstream of Stonewall Road	*945
			About 4,600 feet upstream of Glenshire Drive	*948
		Peterson Lake drain	Mouth at Grand River	*947
			Just upstream of Badgley Road	*950
			About 2,395 feet upstream of Horton Road	*952
			Just upstream of abandoned railroad bridge	*968
			About 1,600 feet upstream of Voorman Road	*970
		Finton Lake	Shoreline	*960
		Vandercook Lake	Shoreline	*949
		Brown Lake	Shoreline	*948
Maps available for inspection at the Town Hall, 2121 Ferguson Road, Jackson, Michigan.				
Nebraska	(C) Crete, Saline County (Docket No. FEMA-6243)	Big Blue River	About 2.5 miles downstream of State Highway 33	*1,346
			Just upstream of Burlington Northern Railroad	*1,357
			About 1.9 miles upstream of Tuxedo Park Road	*1,360

FINAL BASE (100-YEAR) FLOOD ELEVATIONS—Continued

State	City/town/county	Source of flooding	Location	#Depth in feet above ground. *Elevation in feet (NGVD)
		Walnut Creek	At mouth	*1,358
			Just downstream of Boswell Avenue	*1,358
			Just upstream of Boswell Avenue	*1,363
			About 7,500 feet upstream of Boswell Avenue	*1,377
Maps available for inspection at the City Hall, 243 East 13th, Crete, Nebraska.				
Nebraska	(V) DeWitt, Saline County (Docket No. FEMA-6247)	Big Blue River	About 5,000 feet downstream of Chicago, Rock Island and Pacific Railroad.	*1,286
			Just feet upstream of Chicago, Rock Island and Pacific Railroad.	*1,292
			About 15,700 feet upstream of Fillmore Avenue	*1,296
		Turkey Creek	About 4,200 feet downstream of Chicago, Rock Island and Pacific Railroad.	*1,288
			About 3,500 feet upstream of Burlington Northern Railroad.	*1,299
		Big Blue River overflow	At Chicago, Rock Island and Pacific Railroad	*1,290
			At Burlington Northern Railroad	*1,292
Maps available for inspection at the City Hall, 406 East Fillmore, DeWitt, Nebraska.				
Nebraska	(C) Omaha, Douglas County (Docket No. FEMA-6216)	Missouri River	At southern county boundary	*978
			About 0.4 mile downstream of Illinois Central Gulf Railroad.	*985
			At northern county boundary	*995
		Big Papillion Creek	About 200 feet downstream of Harrison Street	*1,001
			Just downstream of F Street	*1,015
			Just upstream of Interstate 80	*1,022
			Just downstream of 105th Street	*1,032
			Just downstream of Blondo Street	*1,045
			About 1.1 miles upstream of State Street	*1,082
		Rockbrook Creek	About 1,900 feet downstream of 105th Street	*1,030
			Just downstream of 105th Street	*1,042
			Just upstream of 105th Street	*1,051
			Just downstream of Interstate 680 Ramp	*1,069
		Little Papillion Creek	At mouth	*1,009
			About 175 feet downstream of Union Pacific Railroad	*1,013
			About 300 feet upstream of Union Pacific Railroad	*1,021
			Just upstream of Dodge Street	*1,040
			Just downstream of Fort Street	*1,075
			About 900 feet upstream of State Street	*1,088
		Cole Creek	At mouth	*1,041
			Just downstream of Western Avenue	*1,050
			Just upstream of Western Avenue	*1,055
			Just downstream of Blondo Street	*1,067
			Just upstream of Blondo Street	*1,074
			Just downstream of Maple Street	*1,075
			Just upstream of Maple Street	*1,083
			Just downstream of Military Avenue	*1,093
			Just upstream of Military Avenue	*1,102
			About 1,900 feet upstream of Ames Avenue	*1,110
			Just downstream of Redick Avenue	*1,143
		Thomas Creek	At mouth	*1,080
			Just downstream of Interstate 680	*1,098
			Just upstream of Interstate 680	*1,102
			Just upstream of Bennington Road	*1,151
			At northern county boundary	*1,194
		Hell Creek	Just upstream of Harrison Street	*1,055
			Just downstream of Interstate 80	*1,071
			Just upstream of Interstate 80	*1,080
			Just upstream of Q Street	*1,087
			Just downstream of L Street	*1,087
			Just upstream of L Street	*1,098
			Just downstream of West Center Road	*1,128
			Just upstream of West Center Road	*1,137
			Just downstream of Pacific Street	*1,161
		West Papillion Creek	Just upstream of Harrison Street	*1,044
			Just upstream of 156th Street	*1,077
			Just upstream of Pacific Street	*1,095
			About 1.0 mile upstream of 168th Street	*1,120
		Boxelder Creek	At mouth	*1,071
			Just downstream of 168th Street	*1,101
			About 0.5 mile downstream of 180th Street	*1,116
		North branch	At mouth	*1,110
		West Papillion Creek	Just downstream of 168th Street	*1,139
			About 0.34 mile upstream of State Street	*1,184
		Ponca Creek	At mouth	*994
			Just downstream of Pershing Drive	*1,002
			Just upstream of Pershing Drive	*1,007
			Just downstream of 36th Street	*1,022
			Just upstream of 36th Street	*1,032
			Just downstream of private drive (near Calhoun Road)	*1,051
			Just upstream of private drive (near Calhoun Road)	*1,061
			Just downstream of Calhoun Road	*1,062
Maps available for inspection at the City Planning Department, Omaha/Douglas Civic Center, 1819 Farnham Street, Omaha, Nebraska.				
New Jersey	Ridgefield Park, village, Bergen County (Docket No. FEMA-6243)	Hackensack River	Entire shoreline	*9
		Overpeck Creek	Entire shoreline	*9
Maps available for inspection at the Municipal Building, 234 Main Street, Ridgefield Park, New Jersey.				

FINAL BASE (100-YEAR) FLOOD ELEVATIONS—Continued

State	City/town/county	Source of flooding	Location	#Depth in feet above ground. *Elevation in feet (NGVD)
New Jersey	Stockton, borough, Hunterdon County (Docket No. FEMA-6246)	Delaware River	Downstream corporate limits	*78
			Bridge Street (upstream side)	*83
			Upstream corporate limits	*84
		Brookville Creek	Confluence with Delaware and Raritan Canal	*78
			Upstream of dam approximately 520' upstream of State Route 29.	*91
			Upstream corporate limits	*143
		Wickecheoke Creek	Confluence with Delaware and Raritan Canal	*84
			State Route 29 (upstream side)	*84
			Upstream corporate limits	*88
Maps available for inspection at the Municipal Building, Main Street, Stockton, New Jersey.				
New York	Bellport, village, Suffolk County (Docket No. FEMA-6247)	Great South Bay	Mott Drive extended to Brookside Avenue extended	*5
			Brookside Avenue extended to southwest corporate limits.	*6
Maps available for inspection at the Village Office, 144 South Conventry Road, Bellport, New York.				
New York	Fultonville, village, Montgomery County (Docket No. FEMA-6247)	Mohawk River	Downstream corporate limits (extended)	*287
			Upstream corporate limits (extended)	*291
Maps available for inspection at the Village Hall, Fultonville, New York.				
New York	Marathon, village, Cortland County (Docket No. FEMA-6224)	Tioughnioga River	Downstream corporate limits	*1,012
			Upstream corporate limits	*1,023
Maps available for inspection at the Village Office, Four Main Street, Marathon, New York.				
Ohio	(C) Cincinnati, Hamilton County (Docket No. FEMA-6243)	Ohio River	Just upstream of confluence of Muddy Creek	*493
			About 2.0 miles upstream of confluence of Little Miami River.	*502
		Little Miami River	Within community	*501
		Muddy Creek	Within community	*493
		Mill Creek	Just upstream of confluence with Ohio River	*497
			Just downstream of barrier dam (near Eighth Street)	*497
			Just upstream of barrier dam (near Eighth Street)	*481
			Just downstream of Old Ludlow Avenue	*491
		East fork Mill Creek	At confluence of East Fork Mill Creek	*539
		West fork	At upstream corporate limits	*540
			At confluence with Mill Creek (near Geringer Street)	*485
			About 450 feet upstream of Powers Street	*493
			Just upstream of southbound Beekman Avenue (near Colerain Avenue).	*508
			Just downstream of West Fork Road	*522
			At confluence of McFarland Creek	*565
		Clough Creek	At confluence with Little Miami River	*501
			About 1.75 miles upstream of Beechmont Avenue	*553
		Duck Creek	At confluence with Little Miami River	*501
			Just upstream of Conrail (about 0.8 mile upstream of Wooster Road).	*505
			Just downstream of Red Bank Road	*517
			Just upstream of Chessie System	*537
			About 450 feet downstream of Duck Creek Road	*549
		Congress Run	At confluence with Mill Creek	*520
			About 700 feet upstream of Ridgeway Avenue	*542
			About 620 feet downstream of Ridgeview Drive	*587
			About 100 feet upstream of Ridgeview Drive (at corporate limits).	*622
Maps available for inspection at the Division of Engineering, City Hall, 801 Plum Street, Cincinnati, Ohio.				
Ohio	(V) Empire, Jefferson County (Docket No. FEMA-6247)	Ohio River	Just downstream of confluence of Jeremy Run	*678
			At upstream corporate limits	*679
Maps available for inspection at the Mayor's Office, Town Hall, Empire, Ohio.				
Ohio	(V) Stratton, Jefferson County (Docket No. FEMA-6247)	Ohio River	At downstream corporate limit	*679
			At upstream corporate limit	*680
Maps available for inspection at the Mayor's Office, Town Hall, Third Street, Stratton, Ohio.				
Ohio	(V) Tiltonsville, Jefferson County (Docket No. FEMA-6247)	Ohio River	At downstream corporate limits	*663
			At upstream corporate limits	*663
Maps available for inspection at the Mayor's Office, Town Hall, Grandview and Market Streets, Tiltonsville, Ohio.				
Ohio	(V) Yorkville, Belmont and Jefferson Counties (Docket No. FEMA-6247)	Ohio River	Just downstream of confluence of Patton Run	*662
			About 0.8 mile upstream of Pike Island lock and dam	*663
		Deep Run	At mouth	*662
			Just downstream of State Route 7	*662
Maps available for inspection at the President's Office, Town Hall, 324 Market Street, Yorkville, Ohio.				
Utah	Utah County (unincorporated areas), FEMA-6247	Utah Lake	Intersection of 7300 North and 8000 West	*4,495
			Approximately 1,000 feet west of the intersection of Geneva Road and 5200 North.	*4,495
			Intersection of 4800 West and 5400 South	*4,495
			Intersection of Interstate Highway 15 and 2400 South	*4,495

FINAL BASE (100-YEAR) FLOOD ELEVATIONS—Continued

State	City/town/county	Source of flooding	Location	#Depth in feet above ground. *Elevation in feet (NGVD)
		Dry Creek	Eastern side of 8000 West over the channel	*4,622
			State Highway 80 over the channel	*4,770
		American Fork River	4800 West over the channel	*4,901
		Hobble Creek	Upstream side of Mapleton Drive over the channel	*4,816
		Jordan River	Approximately 1,000 feet east of the intersection of Cedar Fort Road and 10400 West.	*4,494
		Provo River	Downstream side of State Highway 78 over the channel.	*4,692
Maps available for inspection at Office of the County Engineer, County Building, 115 S. University Ave., Room 112, Provo, Utah.				
Virginia	Tangier, town, Accomack County (Docket No. FEMA-6247)	Chesapeake Bay	Entire shoreline within community	*6
		Tangier north channel	Entire shoreline within community	*6
		Tangier Sound	Entire shoreline within community	*6
Maps available for inspection at the Municipal Building, Tangier, Virginia.				
Wisconsin	(C) Chilton, Calumet County (Docket No. FEMA-6247)	South branch Manitowoc River	About 0.32 mile downstream of East Main Street	*842
			Just downstream of dam (about 0.02 mile downstream of State Street).	*880
			Just upstream of State Street	*887
			About 1.11 miles upstream of State Street	*890
Maps available for inspection at the Office of the City Clerk, City Hall, 42 School Street, Chilton, Wisconsin.				

(National Flood Insurance Act of 1968 (Title XIII of Housing and Urban Development Act of 1968), effective January 28, 1969 (33 FR 17804, November 28, 1968), as amended; 42 U.S.C. 4001–4128; Executive Order 12127, 44 FR 19367; and delegation of authority to the Associate Director)

Issued: June 8, 1982.

Lee M. Thomas,

Associate Director, State and Local Programs and Support.

[FR Doc. 82-17626 Filed 7-1-82; 8:45 am]

BILLING CODE 6718-03-M

44 CFR Part 67

National Flood Insurance Program; Final Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency.

ACTION: Final rule.

SUMMARY: Final base (100-year) flood elevations are listed below for selected locations in the nation.

These base (100-year) flood elevations are the basis for the flood plain management measures that the community is required to either adopt or show evidence of being already in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

EFFECTIVE DATE: The date of issuance of the Flood Insurance Rate Map (FIRM) showing base (100-year) flood elevations, for the community. This date may be obtained by contacting the office where the maps are available for inspection indicated on the table below.

ADDRESSES: See table below.

FOR FURTHER INFORMATION CONTACT:
Mr. Robert G. Chappell, P.E., Federal Emergency Management Agency, National Flood Insurance Program, (202) 287–0230, Washington, D.C. 20472.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency gives notice of the final determinations of flood elevations for each community listed.

This final rule is issued in accordance with Section 110 of the Flood Disaster Protection Act of 1968 (Title XIII of the Housing and Urban Development Act of 1968 (Pub. L. 90–448)), 42 U.S.C. 4001–4128, and 44 CFR Part 67. An opportunity for the community or individuals to appeal this determination to or through the community for a period of ninety (90) days has been provided. No appeals of the proposed base flood elevations were received from the community or from individuals within the community.

The Agency has developed criteria for flood plain management in floodprone areas in accordance with 44 CFR Part 60.

Pursuant to the provisions of 5 U.S.C. 605(b), the Associate Director, to whom authority has been delegated by the Director, Federal Emergency Management Agency, hereby certifies that the final flood elevation determinations, if promulgated, will not have a significant economic impact on a substantial number of small entities. A flood elevation determination under section 1363 forms the basis for new local ordinances, which, if adopted by a local community, will govern future construction within the flood plain area. The elevation determinations, however, impose no restriction unless and until the local community voluntarily adopts flood plain ordinances in accord with these elevations. Even if ordinances are adopted in compliance with Federal standards, the elevations prescribe how high to build in the flood plain and do not proscribe development. Thus, this action only forms the basis for future local actions. It imposes no new requirement; of itself it has no economic impact.

List of Subjects in 44 CFR Part 67

Flood insurance, Flood plains.

The final base (100-year) flood elevations for selected locations are:

FINAL BASE (100YEAR) FLOOD ELEVATIONS

State	City/town/county	Source of flooding	Location	#Depth in feet above ground. *Elevation in feet (NGVD)
California	Costa Mesa (city), Orange County (FEMA-5944)	Santa Ana River	Swan Drive between Sandpiper Drive and Albatross Drive.	*16
			Intersection of Albatross Drive and Adams Avenue	*19
			Intersection of South Coast Drive and Harbor Boulevard.	*32
			Begonia Avenue	*32
	Maps available for inspection at Planning Department, City Hall, Costa Mesa, California.			
California	Garden Grove (city), Orange County (FEMA-5944)	Santa Ana River	Intersection of Westminster Avenue and Taft Street	#3
			Intersection of Trask Avenue and Lilly Street	*104
			Intersection of Garden Grove Boulevard and Fairview Street.	#2
			Intersection of Oertly Drive and Willowood Avenue	*121
			Intersection of Trask Avenue and Havenwood Drive	#2
			Intersection of Harbor Boulevard and Flagstone Avenue.	#3
	Maps available for inspection at Public Works, 11391 Arcacia Parkway, Garden Grove, California.			
California	Hercules (city), Contra Costa County (FEMA-6143)	Refugio Creek	100 feet upstream from centerline of Southern Pacific Railroad.	*9
			Confluence with West Branch Refugio Creek	*18
			100 feet upstream from centerline of C Street	*61
			100 feet upstream from centerline of Redwood Road	*175
		West Branch Refugio Creek	100 feet downstream from centerline of San Pablo Avenue.	*32
			125 feet upstream from centerline of Interstate Highway 80.	*52
		East Branch Refugio Creek	350 feet downstream from centerline of Interstate Highway 80.	*30
			150 feet upstream from Interstate Highway 80 off ramp to Willow Avenue.	*38
		Pinole Creek	800 feet west from intersection of Hercules Avenue and Baccus Avenue.	*9
	Maps available for inspection at City Hall, 555 Railroad Avenue, Hercules, California.			
California	Westminster (city), Orange County (FEMA-5938)	Santa Ana River	Carnation Drive	#3
			Parkview Avenue	#3
			Carnegie Avenue	#3
	Maps available for inspection at City Hall, Westminster, California.			
Montana	Beaverhead County (unincorporated areas) (FEMA-6197).	Beaverhead River	Intersection of Beaverhead River and center of Interstate Highway 15.	*5,077
		Sheetflow	800 feet northwest from the confluence of Stodden Ditch and Beaverhead River.	#1
		Beaverhead River Overbank	50 feet upstream from center of Webster Lane	*5,034
		Blacktail Deer Creek	30 feet upstream from center of Interstate Highway 15 Access.	*5,072
		Junction Creek	Intersection of Junction Creek and center of Union Pacific Railroad.	*6,331
		Junction Creek Overbank	At the confluence of Junction Creek Overbank and Alder Creek.	*6,285
		Sheetflow	200 feet southwest from intersection of Union Pacific Railroad and Junction Creek.	#1
		Selway Slough	Intersection of Selway Slough and center of Schular Lane.	*5,044
		Stodden Slough	At the confluence of Stodden Slough and Stodden Ditch.	#1
	Maps available for inspection at Planning Department, Beaverhead County Courthouse, Dillon, Montana.			

(National Flood Insurance Act of 1968 (Title XIII of Housing and Urban Development Act of 1968), effective january 28, 1969 (33 FR 17804, November 28, 1968), as amended; 42 U.S.C. 4001–4128; Executive Order 12127, 44 FR 19367; and delegation of authority to the Associate Director)

Issued: June 7, 1982.

Lee M. Thomas,

Associate Director, State and Local Programs and Support.

[FR Doc. 82-17627 Filed 7-1-82; 8:45 am]

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 2, 83, and 87

[Gen. Docket No. 81-696; FCC 82-257]

Frequencies Available for Aeronautical Radionavigation and Maritime Mobile Communications

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: These rule changes allocate more spectrum space for the Aeronautical Radionavigation and Maritime Mobile services. The rules adopted permit assignment of frequencies in the band 435–490 kHz to Government aeronautical radiobeacon stations and the broadcast of urgent navigational and meteorological warnings by U.S. Coast Guard stations. The rapid increase in the number and greater distance offshore of the oil drilling rigs has placed a requirement for additional aeronautical radiobeacons for helicopter operations. The World Administrative Radio Conference, 1979, recommended that administrations select a frequency on a world-wide basis for transmission of navigational and meteorological warnings by coast stations. The United States designates the frequency 518 kHz for this purpose. These changes will improve the safety of aircraft and ships by improving the communications and the available aids to navigation.

EFFECTIVE DATE: July 19, 1982.

ADDRESS: Federal Communications Commission, Washington, D.C. 20554.

FOR FURTHER INFORMATION CONTACT: Nicholas G. Bagnato, Private Radio Bureau, (202) 632–7175.

SUPPLEMENTARY INFORMATION:

List of Subjects

47 CFR Part 2

Treaties, Allocations.

47 CFR Part 83

Ship stations, Telegraph.

47 CFR Part 87

Aeronautical stations.

In the matter of amendment of Parts 2, 83 and 87 to make frequencies in the band 415–435 kHz available for aeronautical radionavigation, to add a footnote permitting assignments to the aeronautical radionavigation service in the band 435–490 kHz, to designate 518 kHz for transmission of meteorological and navigational warnings, and to add Maritime Mobile (ships) as a primary service in the band 510–525 kHz.

Report and Order; Proceeding Terminated

Adopted: June 7, 1982.

Released: June 11, 1982.

1. In the Report and Order we are making more spectrum space available to aeronautical radiobeacons and providing a discrete frequency for broadcast of urgent navigational and meteorological warnings to ships.

Background

2. *Aeronautical Radiobeacons:* Radiobeacons in the band 190–525 kHz are normally operated by the U.S. Government. However, authorizations may be made by the Commission for non-Government operation of navigation aids in this band. Such authorizations are subject to coordination between the Commission and the Government agencies concerned. A special showing is required of need for service which the Government is not prepared to provide. For example, the Commission often licenses private radiobeacons at an offshore platform used by a private company.

3. *Warnings to ships:* The World Administrative Radio Conference, 1979, recommended that administrations consider designating one frequency in the bands 435–495 kHz or 505–525.5 kHz on a worldwide basis for narrow-band direct-printing telegraphy transmissions by coast stations of navigational and meteorological warnings to ships. Some administrations have designated 518 kHz for this purpose.[1] In the U.S. the band 510–525 kHz is currently used primarily for aeronautical radionavigation (radiobeacons).

4. *Government Request:* The Interdepartment Radio Advisory Committee (IRAC) of the National Telecommunications and Information Agency (NTIA) requested changes to the national Table of Allocations as follows:

a. In the band 415–435 kHz add Aeronautical Radionavigation as a primary service shared equally with Maritime Mobile as a primary service;

b. In the band 435–490 kHz add a US footnote permitting assignments to the Government Aeronautical Radionavigation service. This allocation will permit greater flexibility in the assignment of radiobeacons for Government stations where the Government station can accept the conditions specified in the footnote (secondary and no voice); and

c. In the band 510–525 kHz add Maritime Mobile as a primary service shared equally with Aeronautical Radionavigation as a primary service. Maritime Radionavigation (radiobeacons) as a secondary service is to be deleted since the maritime radionavigation would be incompatible with the proposed use of 518 kHz. A new US footnote is added to define the use of 518 kHz for U.S. Coast Guard stations to broadcast urgent navigational and meteorological warnings to ships using narrow-band direct-printing telegraphy.

Notice of Proposed Rule Making

5. In response to IRAC's request, the Commission released a Notice of Proposed Rule Making[2] proposing (1) to make more spectrum space available for aeronautical radionavigation beacons through sharing with maritime mobile in the existing bands, (2) to add new footnotes to the Table of Frequency Allocations which defines the use of 518 kHz for broadcast of urgent navigational and meteorological warnings and to define the procedures for making assignments to aeronautical radionavigation stations and (3) to amend the Table of Frequency Allocations to make maritime mobile a primary service and delete maritime radionavigation (radiobeacons) as a secondary service in the band 510–525 kHz.

Comments

6. Comments were filed by the following organizations:

a. The Aircraft Radio and Control Division of Cessna Aircraft Company;

b. The Southern Avionics Company; and

c. The Aircraft Owners and Pilots Associations.

All of the above organizations supported the Commission's proposal and urged its adoption.

Commission Action

7. The commenters affirmed the requirement for additional spectrum for radiobeacons in the aeronautical service and strongly endorsed the proposed rule changes. These changes would reduce frequency congestion, optimize the use of the frequencies available for aeronautical navigation and help meet the high demand for radiobeacon assignments at small airports. No opposition was received concerning the designation of 518 kHz as the single frequency in the MF band for the

[1] Docket No. 80–184, FCC 81–573, Released January 8, 1982, 47 FR 1022.

[2] Docket No. 81–696, FCC 81–432, released October 8, 1981, 46 FR 51784.

broadcast of urgent navigational and meteorological information.

8. We conclude it is in the public interest to provide additional spectrum for aeronautical radiobeacons and to designate the frequency 518 kHz for the broadcasting of urgent navigational and meteorological information. Therefore, we are amending §§ 2.106, 83.316 and 87.501 as proposed.

9. The adopted rules primarily pertain to the use of the spectrum for radionavigation and safety communications by ships and aircraft. In most cases, these rules will provide a marginal basis for improvement in the availability of navigation aids and meteorological information. Therefore, the Commission has determined that sections 603 and 604 of the Regulatory Flexibility Act of 1980 (Pub. L. 96–354) do not apply to this rulemaking proceeding, because the rules will not, if promulgated, have a significant economic impact on a substantial number of small entities.

10. Regarding questions on matters covered in this document contact Nicholas G. Bagnato at (202) 632–7175.

11. Accordingly, it is ordered, That pursuant to the authority contained in sections 4(i) and 303(r) of the Communications Act of 1934, as amended, Parts 2, 83 and 87 of the Commission's rules are amended, as set forth in the attached Appendix, effective July 19, 1982.

12. It is further ordered, That this proceeding is terminated.

(Secs. 4, 303, 48 Stat., as amended, 1066, 1082; 47 U.S.C. 154, 303)

Federal Communications Commission.

William J. Tricarico,

Secretary.

Appendix

Parts 2, 83 and 87 of Chapter I of Title 47 of the Code of Federal Regulations are amended as follows:

PART 2—FREQUENCY ALLOCATIONS AND RADIO TREATY MATTERS; GENERAL RULES AND REGULATIONS

Section 2.106, the Table of Frequency Allocations is revised and new footnotes US 231 and US 232 are added to read as follows:

§ 2.106 Table of frequency allocations.

* * * * *

FEDERAL COMMUNICATIONS COMMISSION

Band (kHz)	Service	Class of station	Frequency (kHz)	Nature of services of stations
7	8	9	10	11—
*	* *	* *	*	* *
415–435	AERONAUTICAL RADIO-NAVIGATION.	Radionavigation land		AERONAUTICAL RADIO-NAVIGATION.
	MARITIME MOBILE. (186)	Coast. Ship		MARITIME MOBILE. (telegraphy).
435–490 (US 231)	MARITIME MOBILE. (186)	Coast. Ship		MARITIME MOBILE. (telegraphy).
*	* *	* *	*	* *
510–525 (US 14) (US 18) (US 225) (US 232).	AERONAUTICAL RADIO-NAVIGATION.	Radionavigation land		AERONAUTICAL RADIO-NAVIGATION.
(US 232)	MARITIME MOBILE. (186)	Ship	510, 512, 518	MARITIME MOBILE. (telegraphy).

* * * * * * *

US 231: When an assignment cannot be obtained in the bands between 200 and 525 kHz, which are allocated to aeronautical radionavigation, assignments may be made to aeronautical radiobeacons in the maritime mobile band 435–490 kHz, on a secondary basis, subject to the coordination and agreement of those agencies having assignments within the maritime mobile band which may be affected. Assignments to aeronautical radionavigation radiobeacons in the band 435–490 kHz shall not be a bar to any required changes to the maritime mobile radio service and shall be limited to Government stations not employing voice emissions.

US 232: The frequency 518 kHz may be used by coast stations operated by the U.S. Coast Guard for the transmission of meteorological and navigational warnings to ships by means of narrow-band direct-printing telegraphy.

PART 83—STATIONS ON SHIPBOARD IN THE MARITIME SERVICES

In § 83.316, paragraphs (b) and (c) are revised to read as follows:

§ 83.316 Frequencies in the bands 90–160 kHz and 405–535 kHz available to ship stations for radiotelegraphy.

* * * * *

(b) 405–535 kHz:

kHz
410[1]
425
444[1]
454
468
480
500 calling and distress
512[1]
518[1]

[1] Subject to the special conditions and limitations set forth in paragraph (c) of this section.

(c)(1) Except for distress communications, the frequency 444 kHz is for communication with U.S. Government stations only. Its use is subject to the condition that harmful interference is not caused to the service of any coast station.

(2) The frequency 410 kHz may be used for radiodetermination and for communication by radiotelegraph with radio direction-finding stations concerning radiodetermination.

(3) The frequency 512 kHz may be used as a supplementary calling frequency when 500 kHz is being used for distress purposes and as a working frequency, except in those areas where it is in use as a supplementary calling frequency when 500 kHz is being used for distress purposes.

(4) The frequency 518 kHz is a receive only frequency by ship stations. It may be used by coast stations operated by the U.S. Coast Guard for the transmission of meteorological and navigational warnings to ships by means of narrow-band direct-printing telegraphy.

PART 87—AVIATION SERVICES

In § 87.501, paragraph (f) is revised to read as follows:

§ 87.501 Frequencies available.

* * * * *

(f) Radiobeacon stations: 190–285 kHz; 325–435 kHz; and 510–525 kHz.

* * * * *

[FR Doc. 82–17647 Filed 7–1–82; 8:45 am]

BILLING CODE 6210–01–M

Proposed Rules

Federal Register
Vol. 47, No. 128
Friday, July 2, 1982

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Parts 550 and 551

Pay Administration (General) and Federal Pay Administration Under the Fair Labor Standards Act; Computing Fractional Hours of Overtime Work

AGENCY: Office of Personnel Management.

ACTION: Proposed rulemaking, with comments requested.

SUMMARY: OMP is proposing to amend its general pay administration regulations to provide administrative procedures for crediting fractional hours of overtime work during which an employee performs the principal activities of his or her position. It is also proposing to amend both its general pay administration regulations and its regulations for pay administration under the Fair Labor Standards Act (FLSA) to provide consistent administrative procedures for the treatment of time spent in preshift and postshift activities. These actions are being proposed to simplify pay administration by providing the same procedures for crediting fractional hours of overtime work and for determining the creditability of time spent in preshift and postshift activities under the overtime provisions of title, 5 U.S. Code, and the FLSA.

DATE: Written comments will be considered if received no later than August 31, 1982.

ADDRESS: Send or deliver written comments to Craig B. Pettibone, Assistant Director for Pay and Benefits Policy, Compensation Group, P.O. Box 57, Room 4351, Office of Personnel Management, Washington, D.C. 20044.

FOR FURTHER INFORMATION CONTACT: Mary Angel, (202) 632–4684, or Dwight Brown, (202) 632–4634.

SUPPLEMENTARY INFORMATION: These proposed regulations provide formal instructions for the treatment of fractional hours of overtime work performed by employees subject to 5 CFR Part 550. The instructions parallel the instructions for the treatment of fractional hours of overtime work performed by employees covered by 5 CFR Part 551. (45 FR 85659). These regulations also propose to amend 5 CFR Parts and 551 to provide the same administrative procedures for the treatment of time spent in preshift and postshift activities under both Parts.

General Information

Work-related activities performed by an employee fall into two categories: First, the principal activities of an employee's position (these are the activities that the employee was hired to perform); and second, the preshift and postshift activities that may be associated with an employee's position (these are the activities that an employee performs in preparation for the beginning of the workday or after the conclusion of the workday).

All work, including overtime work, that an employee performs to accomplish the principal activities of his or her position is compensable. These proposed regulations provide administrative procedures for the treatment of fractional hours of overtime work, since overtime work may be performed in increments of time that are less than an hour and less than the fraction of an hour that the agency may use to account for such work. In addition, these proposed regulations differentiate between overtime work that is regularly scheduled and overtime work that is irregular or occasional. Time spent in preshift and postshift activities is also compensable (1) if the activities are, in fact, work, and (2) if the activities involve a substantial amount of time and effort on a daily basis. The proposed regulations provide administrative procedures for determining whether and how to credit time spent in preshift and postshift activities.

Principal Activities

All regulary scheduled overtime work is creditable in determining the amount of overtime pay to which an employee is entitled. An agency must compensate an employee for all regularly scheduled overtime work.

The proposed regulations provide that an agency shall compensate an employee for irregular or occasional overtime work by using one of the following four methods. An agency shall:

(1) Compensate the employee for every minute of irregular or occasional overtime work; or

(2) Limit the performance of irregular or occasional overtime work to the full increment used to credit that work; or

(3) Round irregular or occasional overtime work on a daily basis; or

(4) Round irregular or occasional overtime work on a weekly basis.

If an agency rounds irregular or occasional overtime work on a daily or weekly basis, it shall establish a fraction of an hour, equal to or less than a quarter of an hour, for crediting that work. The agency must round down to the next lower fraction of an hour those odd minutes of irregular or occasional overtime work that are less than 50 percent of the fraction used to compute that work and must round up to the next higher fraction of an hour those odd minutes of irregular or occasional overtime work that equal or exceed 50 percent of the fraction of an hour used to compute that work.

The Comptroller General has indicated that the General Accounting Office would have no objection if OPM were to provide by regulation for rounding odd minutes of irregular or occasional overtime work under 5 CFR Part 550.

Preshift and Postshift Activities

In determining whether preshift and postshift activities performed by an employee are compensable, an agency must first determine whether the activities are work. If the agency determines that they are work, it then must determine whether they require a substantial amount of time and effort.

If an employee performs preshift or postshift activities that are integral to the principal activity of his or her position, those preshift or postshift activities are work. However, if the employee performs preshift or postshift activities that are not closely related to the principal activity of his or her position, those preshift or postshift activities are not work.

If an agency determines that preshift or postshift activities are work, it must then determine whether the amount of time and effort involved in the performance of those activities is substantial. The courts and the

Comptroller General have generally held that more than ten minutes per day is a substantial amount of time and effort and that ten minutes or less per day is nominal and may be disregarded. These proposed regulations provide that if an employee spends more than ten minutes per day in preshift or postshift activities that are work, that time is compensable. The proposed regulations also provide that if an employee spends ten minutes or less per day in preshift or postshift activities that are work, that time is not compensable. This proposed change is, therefore, consistent with current procedures.

If an agency determines that preshift or postshift activities are not closely related to the principal activity or an employee's position and, therefore, are not work, those activities are generally noncompensable. However, there are two instances in which time spent in such activities is compensable: (1) When such nonwork activities immediately follow compensable preshift activities or (2) when they immediately precede compensable postshift activities. Whatever the amount of time involved, such activities are compensable because they are a part of the workday.

Preparatory and Concluding Activities Under FLSA

Finally, the proposed regulations will amend existing regulations that describe Federal Pay Administration Under the Fair Labor Standards Act (5 CFR Part 551).

Current regulations provide that a preparatory or concluding activity that is integral to the performance of a principal activity is part of the workday and is, therefore, compensable. They also provide a preparatory or concluding activity that is not integral to the performance of the principal activity is not part of the workday and is not compensable.

The proposed amendment to § 551.412, Title 5, CFR, would make preparatory and concluding activities that are integral to the performance of the principal activity(s) part of the workday if the aggregate time an employee spends in such activity(s) is more than ten minutes per day. It would also make preparatory and concluding activities that are not integral to the performance of the principal activity part of the workday only if they are performed after the commencement of the workday and before cessation of the workday. It would provide, therefore, the same treatment for time spent in preparatory and concluding activities under 5 CFR Part 551 and for time spent in preshift or postshift activities under 5 CFR Part 550.

Summary

The proposed amendments to 5 CFR Parts 550 and 551 would make it possible for agencies to simplify pay administration by using the same administrative procedures under both Parts to credit fractional hours of overtime work and to determine the creditability of time spent in preshift or postshift activities. OPM strongly encourages agencies to use the same administrative procedures under both Parts.

E.O. 12291, Federal Regulation

OPM has determined that this is not a major rule as defined under section 1(b) of E.O. 12291, Federal Regulation.

Regulatory Flexibility Act

I certify that, within the scope of the Regulatory Flexibility Act, this regulation will not have a significant economic impact on a substantial number of small entities as it provides procedures only for the computation of fractional hours of overtime work for Federal employees.

List of Subjects in 5 CFR 550 and 551

Government employees, Wages, Civil defense, Administrative practice and procedure, Fair Labor Standard Act, Travel, Manpower training programs.

Office of Personnel Management.

Donald J. Devine,

Director.

Accordingly, OPM proposes to amend Parts 550 and 551 of Title 5, Code of Federal Regulations, as shown below:

PART 550—PAY ADMINISTRATION (GENERAL)

§ 550.111 [Amended]

(1) Section 550.111 is amended by removing the words "each hour of" after the phrase "* * * overtime work means * * *" in paragraphs (a) and (d).

(2) Section 550.112 is amended by redesignating paragraphs (a) through (f) as paragraphs (d) through (i) respectively, and by adding new paragraphs (a) through (c) to read as follows:

§ 550.112 Computation of overtime work.

(a) *Regular overtime work.* An agency shall credit every minute of overtime work that is included in an employee's daily tour of duty.

(b) *Irregular or occasional overtime work.* (1) An agency shall use one of the following administrative procedures to credit irregular or occasional overtime work:

(i) Credit every minute of irregular or occasional overtime work.

(ii) Limit the performance of irregular or occasional overtime work to the full increment used to credit that work.

(iii) Round irregular or occasional overtime work on a daily basis.

(iv) Round irregular or occasional overtime work on a weekly basis.

(2) If an agency provides for rounding irregular or occasional overtime work, the following procedures shall apply:

(i) The agency shall establish a fraction of an hour, equal to or less than a quarter of an hour, for crediting that work. Agency policy or negotiated agreement may provide for fractions of less than a quarter hour.

(ii) The agency shall round down to the next lower increment those odd minutes of work that are less than 50 percent of the fraction used to compute that work and shall round up to the next higher increment those odd minutes of work that equal or exceed 50 percent of the fraction used to compute that work.

(c) *Preshift or postshift activities.* A preshift activity is and activity that an employee performs in preparation for commencement of his or her daily tour of duty and a postshift activity is a concluding activity that an employee performs after the completion of his or her daily tour of duty. Such activities are not principal activities of the employee's position. They are not within the purview of paragraphs (a) and (b) of this section.

(1) A preshift or postshift activity that is closely related to the principal activity(s) of the employee's position and is indispensable to its performance is an integral part of the principal activity. If the total time spent in that activity(s) is more than ten minutes per daily tour of duty, the agency shall credit it as hours of work.

(2) If a preshift or postshift activity is not an integral part of the principal activity(s), the agency shall credit the time spent in that activity as hours of work only if—

(i) The activity is performed immediately after a creditable preshift activity and before the daily tour of duty; or

(ii) The activity is performed immediately after the daily tour of duty and before a creditable postshift activity.

* * * * *

PART 551—PAY ADMINISTRATION UNDER THE FAIR LABOR STANDARDS ACT

Section 551.412 is revised to read as follows:

§ 551.412 Preparatory or concluding activities.

(a) A preparatory or concluding activity that is closely related to the principal activity(s) and is indispensable to its performance is an integral part of the principal activity(s). If the total time spent in that activity(s) is more than ten minutes per day, it is part of the workday and it shall be disregarded.

(b) A preparatory or concluding activity that is not an integral part of the principal activity(s) is not a part of the workday. Such an activity is a preliminary or postliminary activity and is not considered hours of work. However, any preliminary activity that is performed after the commencement of the workday or any postliminary activity that is performed prior to the cessation of the workday shall be included in hours of work.

(5 U.S.C. 5548(a); 29 U.S.C. 204(f))

[FR Doc. 82-18029 Filed 7-1-82; 8:45 am]

BILLING CODE 6325-01-M

MERIT SYSTEMS PROTECTION BOARD

5 CFR Parts 1204 and 1205

Freedom of Information Act; Privacy Act

AGENCY: Merit Systems Protection Board.

ACTION: Proposed amendment of rules.

SUMMARY: The merit Systems Protection Board proposes to amend its regulations to set forth realistic charges for photocopy and search fees incurred in granting Freedom of Information Act and Privacy Act requests; to limit the time period within which an initial denial may be appealed; and to reflect changes in titles of "Field Offices" and "Chief Appeals Officers" to "Regional Offices" and "Regional Directors," respectively.

DATE: Comments must be received on or before August 2, 1982.

ADDRESS: Comments should be addressed to Robert E. Taylor, Secretary, Merit Systems Protection Board, c/o Legal Publications Division, Suite 1404, 5205 Leesburg Pike, Falls Church, VA 22041.

FOR FURTHER INFORMATION CONTACT: Kathy Semone, (202) 653-7200.

SUPPLEMENTARY INFORMATION: Under the Freedom of Information Act and the Privacy Act, the Merit Systems Protection Board may establish fees for photocopying documents to be released, 5 U.S.C. 552(a)(4)(A), 552a(f)(5). Additionally, under the Freedom of Information Act, fees may be charged for the time expended searching for documents 5 U.S.C. 552(a)(4)(A). The current regulations need clarification regarding the calculation of fees for photocopying, duplication or audio and video tapes, and postage costs; to account for partial hours of search time; to differentiate between clerical and professional employees' search time; and to establish a time limit within which an appeal from an initial denial must be filed.

Regulatory Flexibility Act Statement

The Chairman, Merit Systems Protection Board, certifies that the Board is not required to prepare an initial or final regulatory analysis of this proposed rule change pursuant to section 603 or 604 of the Regulatory Flexibility Act, because of the determination that this rule would not have a significant economic impact on a substantial number of small entities, including business, small organizational units, and small governmental jurisdictions.

List of Subjects

5 CFR Part 1204

Freedom of Information Act.

5 CFR Part 1205

Privacy Act.

Pursuant to 5 U.S.C. 1205(g), it is proposed that Parts 1204 and 1205 of Subchapter A of Chapter II of Title 5, Code of Federal Regulations, be amended as follows:

PART 1204—FREEDOM OF INFORMATION ACT

1. Paragraphs (a) and (c) of § 1204.11 are revised to read as follows:

§ 1204.11 Submission of request.

(a) *Place.* Requests for copies of records shall be made to the appropriate regional office of the Board, or the Office of the Secretary, Merit Systems Protection Board, Washington, D.C. If the requestor has reason to believe the records in question are located in a regional office, it is appropriate to submit the request to that office. Requests to the region shall be addressed to the Regional Director at the appropriate regional office listed in appendix II of 5 CFR Part 1201. Requests shall be made during normal business hours, or submitted by mail. Requests shall be in writing.

* * * * *

(c) *Payment.* Records usually will not be released until fees have been received unless the fees are waived according to § 1204.13(a)(4) of this part. The Secretary of Regional Directors may release information before fee receipt when, in their judgment, the circumstances warrant such action.

2. Paragraph (d) of § 1204.12 is revised to read as follows:

§ 1204.12 Time limitations and determinations.

* * * * *

(d) *Determining Officials.* Determinations on requests shall be made by the Secretary of the Board or any Director of one of the MSPB regional offices.

3. The entire § 1204.13 fees is revised as follows:

§ 1204.13 Fees.

(a) Requests for records are subject to the following schedule of costs:

(1) *Duplication.* (i) The per page charge for photocopying is $.10.

(ii) Fees for duplication or transcription of audio or video tape recordings shall be charged at the actual cost to the MSPB.

(iii) Fees for search and duplication of automated records shall be charged at the actual cost to MSPB and will be provided upon request.

(2) *Manual Records Search.* $2.50 per quarter-hour if conducted by a clerical employee; $5.00 per quarter-hour if conducted by a professional or managerial employee.

(3) *Postage.* Fees for postage shall be charged at the actual cost to MSPB.

(b) *Waiver or Reduction of Fees.* The Secretary or Regional Director shall waive or reduce a fee when it is determined that furnishing the information will primarily benefit the general public. The existence of one or more of the five factors below will be considered in granting a waiver or reduction of the fee. However, the existence of one of the factors standing alone, shall not mean that the fee will be automatically waived or reduced.

(1) Whether the information is likely to result in the receipt of benefits by a larger number of persons;

(2) Whether waiver or reduction of the fee will result in the relief of a substantial personal hardship;

(3) Whether the MSPB costs for administrative processing of the fee will exceed the amount of the fee collected;

(4) Whether there is an indication that releasing the information is likely to benefit the commercial or other private interests of the requester rather than the general public;

(5) Whether the records requested are available from another source.

4. Paragraph (c) is added to § 1204.21 to read:

§ 1204.21 Submission.

* * * * *

(c) *Time Limit.* An appeal must be submitted within 30 days of the issuance of the denial.

PART 1205—PRIVACY ACT

5. Paragraph (a) of § 1205.11 is revised to read as follows:

§ 1205.11 Submission of request.

(a) *Place.* Inquiries or requests for access to records shall be made to the appropriate regional office of the Board, or the Office of the Secretary, Merit Systems Protection Board, Washington, D.C. 20419. If the requestor has reason to believe the records in question are located in a regional office, it is appropriate to submit the request to that office. Requests to the region shall be addressed to the Regional Director at the appropriate regional office listed in Appendix II of 5 CFR Part 1201.

* * * * *

6. Paragraph (d) is added to § 1205.11 to read:

* * * * *

(d) *Payment.* Records usually will not be released until fees have been received. The Secretary or the Regional Directors may release information before fee receipt when in their judgment, the circumstances warrant such action.

7. Paragraph (d) of § 1205.12 is revised to read as follows:

§ 1205.12 Time limitations and determinations.

(d) *Determining Officials.* Determinations on requests shall be made by the Secretary of the Board or by any Director of one of the MSPB regional offices.

8. Paragraph (b) of § 1205.16 is revised to read as follows:

§ 1205.16 Fees.

* * * * *

(b) *Duplication.* (1) The per page charge for photocopying is $.10.

(2) Fees for duplication or transcription of audio or video tape recordings shall be charged at the actual cost to the MSPB.

(3) Fees for duplication of automated records shall be charged at the actual cost to MSPB and will be provided upon request.

9. Paragraph (c) is added to § 1205.31 to read as follows:

§ 1205.31 Submission of appeals.

* * * * *

(c) *Time Limit.* An appeal must be submitted within 30 days of the issuance of a denial.

Dated: June 23, 1982.

Herbert E. Ellingwood,

Chairman.

[FR Doc. 82-17694 Filed 7-1-82; 8:45 am]

BILLING CODE 7400-01-M

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 101

Warehouse Charges, Proposed Rulemaking

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rulemaking.

SUMMARY: Section 101.29 of the Regulations for Cotton Warehouses issued under the U.S. Warehouse Act specifies that "For the purposes of this section the cotton season shall commerce, with respect to each warehouse, at such time not later than September 15 of each year, as the operator of the warehouse shall select, and he shall notify the Department in writing not less than five days next preceding the date selected."

The purpose of this action is to change the date "September 15" to "September 1," as suggested by the cotton trade.

DATE: Written comments should be filed not later than July 19, 1982.

ADDRESS: Comments should be filed in triplicate with the Hearing Clerk, U.S. Department of Agriculture, 14th & Independence Avenue, S.W., Washington, D.C. 20250, where they will be available for public inspection during regular business hours.

FOR FURTHER INFORMATION CONTACT: Dr. Orval Kerchner, Chief, Warehouse Development Branch, Warehouse Division, Agricultural Marketing Service, Department of Agriculture, Washington, D.C. 20250 (202-447-3616).

SUPPLEMENTARY INFORMATION: Notice is hereby given in accordance with the administrative procedure provisions in 5 U.S.C. 553, that the Agricultural Marketing Service (AMS), pursuant to the authority conferred by section 28 of the U.S. Warehouse Act (7 U.S.C. 268, hereinafter the "Warehouse Act"), is amending the warehouse regulations for the storage of cotton appearing in Part 101 of Subchapter E of Chapter 1 of Title 7 of the Code of Federal Regulations (7 CFR Part 101).

Section 101.29 of the Regulations for Cotton Warehouses issued under the Warehouse Act specifies in part that "For the purposes of this section the cotton season shall commerce, with respect to each warehouse, at such time not later than September 15 of each year, as the operator of the warehouse shall select, and he shall notify the Department in writing not less than five days next preceding the date selected." The purpose of this action is to change the date "September 15" to "September 1."

This same section provides in part that "A licensed warehouseman shall not make any unreasonable, exorbitant, or discriminatory charge for services rendered. Before a license to conduct a warehouse is granted under the Act, the warehouseman shall file with the Department a copy of his rules, if any, and a schedule of the charges to be made by him if licensed. Effective at the beginning of any cotton season, a licensed warehouseman may change his rate of charges for storage and other services, and the new rates may apply to all cotton then in storage as well as cotton received thereafter. At or before the beginning of each season every licensed warehouseman shall file with the Department a copy of his rules, if any, and of his schedule of charges for the ensuing season. Should a licensed warehouseman wish to make changes in his rates to become effective at any time other than at the beginning of a season, he shall file with the Department an amended schedule showing the contemplated changes, accompanied by a statement setting forth reasons therefor. No increase in the storage rate shown in such an amended schedule shall apply to cotton in storage at the time the change become effective. A licensed warehouseman may demand payment of all accrued charges at the close of each cotton season. If, upon demand, the owner of the cotton refuses to pay such charges at the end of a season, the warehouseman may take such action to enforce collection of his charges as is permitted by the laws of the State in which the warehouse is located. Each licensed warehouseman shall keep a copy of his current rules and schedule of charges exposed conspicuously in the place prescribed by § 101.6 and at such other place accessible to the public as the Secretary or his designated representative may from time to time designate."

Most cotton warehousemen licensed under provisions of the U.S. Warehouse Act also are approved under a Commodity Credit Corporation Cotton Storage Agreement. This agreement provides that "Subject to the provisions of the Cotton Storage Agreement, CCC-823 (10-1-75) and supplements or amendments thereto, entered into between the parties hereto, this Schedule of Rates shall become effective

as of October 1, 1981, and shall continue in effect unless superseded on October 1, 1982, or on a subsequent annual renewal date (October 1) of the agreement by the warehouseman submitting new rates at least 30 days prior to such annual renewal date of the agreement. The warehouseman warrants that the rates for services provided in Part A of this agreement will not be in excess of the rates charged other customers for the same services during the period this schedule is in effect."

Certain of the cotton trade have requested that the two governmental agencies correct what appears to be an inconsistency in otherwise similar requirements which can facilitate compliance by the trade. The Agricultural Marketing Service is willing to consider a change if such change will accomplish the avowed purpose. The propose action will do so and comments are elicited from all the cotton trade as to their feelings on this matter.

This action was reviewed under the USDA procedure established in accordance with Executive Order 12291 of February 7, 1981, and was classified "nonmajor" as it does not meet the criteria contained therein for major regulatory actions. William T. Manley, Deputy Administrator for Marketing Program Operations, determined that the action would not have a significant impact on a substantial number of small business entities because licensing is an elective of the applicant and use of the services is voluntary.

List of Subjects in 7 CFR Part 101

Administrative practice and procedure, Agriculture commodities, Cotton warehouses.

PART 101—COTTON WAREHOUSE

The regulations, therefore, are proposed to be amended as follows:

§ 101.29 [Amended]

1. Section 101.29 is amended by changing "September 15" to "September 1."

Done at Washington, D.C., June 28, 1982.

William T. Manley,

Deputy Administrator, Marketing Program Operations.

[FR Doc. 82-18030 Filed 7-1-82; 8:45 am]

BILLING CODE 3410-02-M

Food and Nutrition Service

7 CFR Part 210

National School Lunch Program; Meat Alternate Equivalencies

Cross Reference: For a document published by the food and Nutrition Service that delays the implemtation of a final rule relating to meat alternate equivalencies for cooked dry beans or peas and eggs published May 16, 1980 (45 FR 32502) until comments are analyzed and the proposed rulemaking process is complete on a document published June 29, 1982 (47 FR 28106) regarding a proposal that these equivalencies be returned to their lower pre-May 1980 levels, see the Final Rules section of this issue. Refer in the table of contents under "Food and Nutrition Service" to determine the appropriate page number.

BILLING CODE 3410-30-M

Food Safety and Inspection Service

9 CFR Parts 307 and 381

[Docket No. 82-007E]

Reimbursement for Preparation and Cleanup Time; Extension of Comment Period

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Proposed Rule; extension of comment period.

SUMMARY: On May 7, 1982, the Agency published a proposal to amend the overtime and holiday inspection service sections of the Federal meat and poultry products inspection regulations. The Agency has determined that it will extend the comment period an additional 30 days.

DATE: Comments must be received on or before August 5, 1982.

ADDRESS: Written comments to: Regulations Office, Attn: Annie Johnson, FSIS Hearing Clerk, Room 2637, South Agriculture Building, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, D.C. 20250. Oral comments to: Mark Manis, (202) 447-4820.

FOR FURTHER INFORMATION CONTACT: Mark Manis, Acting Director, Labor Management Relations Staff, Administrative Management, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, D.C. 20250, (202) 447-4820.

SUPPLEMENTARY INFORMATION: On May 7, 1982, the Agency published a proposed rule in the **Federal Register** (47 FR 19701) to amend Federal meat and poultry products inspection regulations relating to overtime and holiday inspection service. The Agency received a request dated June 24, 1982, from the National Broiler Council to extend the comment period to allow additional time to study the proposal and submit comments. The Agency is interested in receiving additional data on this proposal and has determined that there is sufficient justification for extending the comment period for 30 days.

Done at Washington, D.C., on: June 29, 1982.

Donald L. Houston,

Administrator, Food Safety and Inspection Service.

[FR Doc. 82-18134 Filed 7-1-82; 8:45 am]

BILLING CODE 3410-DM-M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Parts 154, 157, 375 and 381

[Docket No. RM82-25-000]

Fees Applicable to Producer Matters Under the Natural Gas Act; Extension of Time for Comments

June 28, 1982.

AGENCY: Federal Energy Regulatory Commission, DOE

ACTION: Notice of Proposed Rulemaking; extensions of comment period.

SUMMARY: On May 6, 1982, the Commission issued a Notice of Proposed Rulemaking involving fees applicable to producer matters under the Natural Gas Act (47 FR 20621, May 13, 1982). The comment period is being extended at the request of the Santa Fe Energy Company and Exxon Corporation.

DATE: Comments must be submitted on or before August 5, 1982.

ADDRESS: Submit comments to: Office of the Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, D.C. 20426.

FOR FURTHER INFORMATION CONTACT: Kenneth F. Plumb, Secretary, (202) 357-8400.

Kenneth F. Plumb,

Secretary.

On June 9, 1982, and June 14, 1982, Santa Fe Energy Company (Santa Fe) and Exxon Corporation (Exxon) filed respective motions for an extension of time to file comments in response to the Commission's Notice of Proposed Rulemaking issued May 6, 1982, in the above-docketed proceeding. Santa Fe's motion states that the company requires additional time in order to develop the

necessary facts to comment on this proposed rule. In its motion, Exxon requests that this extension be granted pending the Commission's placement of additional cost data in the public file, as indicated in the May 6, 1982, notice.

Because of the unanticipated delay in the placement of additional data in the public file of this proposed rule, notice is hereby given that an extension of time for the filing of comments is granted to an including August 5, 1982.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-18095 Filed 7-1-82; 8:45 am]

BILLING CODE 6717-01-M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Housing—Federal Housing Commissioner

24 CFR Part 201

[Docket No. R-82-980]

Property Improvement and Mobile Home Loans

Correction

In FR Doc. 82-17235 appearing on page 27867, in the issue of Monday, June 28, 1982, make the following corrections:

1. On page 27868, first column, the "DATE:" paragraph, the comment date should have read "August 27, 1982".

2. On page 27869, the figure in the column "Two or more" for "Washington, DC—MD—VA, SMSA" reading "52000" should read "52,500".

BILLING CODE 1505-01-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[A-4-FRL-2099-6]

Approval and Promulgation of Implementation Plan Mississippi; Revised Nonattainment Plan

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: On November 17, 1981, the State of Mississippi adopted a revision to the State Implementation Plan regarding nonattainment areas. This revision was submitted to EPA for approval on November 25, 1981. EPA has reviewed this submittal and found that it satisfies the requirements of 40 CFR 51.18 as amended on May 13 and August 7, 1980 and is therefore proposing to approve Mississippi's revised nonattainment plan. The public is invited to comment on this regulation.

DATE: To be considered, comments must be submitted on or before August 2, 1982.

ADDRESSES: Written comments should be addressed to Denise Pack of EPA Region IV's Air and Waste Management Division (see EPA Region IV address below). Copies of the materials submitted by Mississippi may be examined during normal business hours at the following locations:

Environmental Protection Agency, Region IV, Air Programs Branch, 345 Courtland Street, N.E., Atlanta, GA 30365

Mississippi Department of Natural Resources, Bureau of Pollution Control, P.O. Box 827, Jackson, MS 39205

FOR FURTHER INFORMATION CONTACT: Denise Pack of EPA Region IV, Air and Waste Management Division, at the above listed address and phone 404/881-3286 or FTS 257-3286.

SUPPLEMENTARY INFORMATION: On May 13, 1980 and on August 7, 1980 EPA promulgated amendments to the regulations for new source review in areas of nonattainment. The May 13, 1980, **Federal Register** notice (45 FR 31304) required States to modify their SIP to: (1) Require new sources locating in all portions of designated nonattainment areas to undergo nonattainment review; (2) preclude sources outside designated nonattainment areas from exacerbating violations; and (3) preclude sources from significantly impacting newly discovered non-attainment areas. The August 7, 1980, **Federal Register** notice (45 FR 52676) required Part D SIPs to be more stringent for modified sources in nonattainment areas.

On November 12, 1981, the Mississippi Commission on Natural Resources adopted an amendment to Mississippi Regulation APC-S-2. "Permit Regulations for Construction and/or Operation of Air Emission Equipment."

This regulation specifies the conditions that a new facility which is a major stationary source or major modification must satisfy in order to receive a permit to construct in a nonattainment area or in an area that impacts a nonattainment area. The regulation requires the facility to meet the lowest achievable emission rate (LAER) for the applicable air pollutant and when the nonattainment area implementation plan contains a reasonable further progress schedule (RFP), meet the schedule for compliance. The owner or operator of a source must also demonstrate that all major stationary sources owned or operated by such person in the State of Mississippi are in compliance or are on a schedule of compliance.

Additionally, the regulation affects sources locating in or near areas where an air quality standard is being or will be exceeded but for which no nonattainment area implementation plan has been adopted. The State of Mississippi has clarified the purpose of this portion (Section 2.4.8.3.) of its regulation. Section 2.5.8.3 applies only to: (1) Sources located in designated attainment areas where ambient monitoring indicates that the area is in fact nonattainment; (2) sources located in attainment areas that will cause violation of an ambient air quality standards and (3) sources located in nonattainment areas without approved Part D plans. After 18 months, a newly designated nonattainment area without an approved Part D plan is subject to the construction moratorium provisions of the Clean Air Act (40 CFR 52.24). The Mississippi regulation applies EPA's Emission Offset Ruling (40 CFR 51.18, Appendix S) to any facility that is a major source or major modification included in the above three categories.

Mississippi will be applying its new source review rules (APC-S-2 and the amended Appendix G-2) to the one designated nonattainment area in the State (Laurel, Mississippi). The Mississippi revisions are fully approvable as currently applied although several provisions of the state's rules do not fully conform with EPA's requirements.

Under section 171(2) of the Clean Air Act, state new source review rules must apply to all nonattainment areas that are designated as such under section 107(d) of the Act. Mississippi references its own nonattainment designations. At present, the federal and state nonattainment designations are identical (i.e., Laurel). If, in the future, EPA designates an area nonattainment and Mississippi does not, some new or modified major stationary sources could be inappropriately exempted from Part D requirements (e.g., LAER, offsets, statewide compliance). However, Mississippi is aware of this potential deficiency, does not anticipate any new designations by either EPA or the state, and has agreed to resolve any problems if and when they occur.

Further, the Mississippi rule authorizes exemptions from the offset requirements for resource recovery facilities, sources switching fuel due to lack of adequate fuel supplies and sources required to make changes

because of EPA regulations (refineries). These exemptions are not provided for in 40 CFR 51.18(j) and are allowed only insofar as they are consistent with the State's demonstration of reasonable further progress. These exemptions are insignificant as applied to Laurel because: (1) It is the only nonattainment area in the State and Masonite Corporation, the only major source in the area, currently burns woodwaste and heavy oil. Conversion from these fuels is unlikely; (2) the area has a relatively small population and does not generate enough waste to make the location of a resource recovery incinerator in the area feasible; and (3) there are no refineries located in the area.

EPA has reviewed the submitted material and found it has met the provisions of 40 CFR Part 51. Pursuant to EPA's rulemaking of October 14, 1981 (46 FR 50766), EPA has reviewed the Mississippi SIP and determined that the State's adoption of a plantwide definition of source in their New Source Review rules is consistent with the Mississippi control strategy demonstrating attainment and reasonable further progress for TSP in Laurel, the one TSP nonattainment area in the State. The State control strategy relies on a growth allowance to accommodate major new and modified sources, minor new and modified sources, and increases in secondary emissions. Laurel is currently operating under the growth allowance. As described above, Laurel is not a large industrial area and is anticipating little, if any, growth. Therefore, the State NSR rule is consistent with the attainment demonstration because it is unlikely that the growth allowance will be consumed.

Furthermore even if growth prospects increase and the growth allowance were to be consumed, the State can rely on its offset provision. The offset provision states that major new and modified sources must offset both their increase in emissions, and any increase in emissions resulting from minor source growth and new secondary emissions that is not otherwise accounted for in the State's attainment demonstration. The offset provision will be able to accommodate increases in emissions because the NSR rule will cover the same new "green field" plants (i.e., major new sources, as opposed to major modifications) under the plantwide definition as it does under the dual definition. Although the new plantwide definition could result in the issuance of fewer NSR permits for major modifications, and thus fewer opportunities for the State to require offsets, the difference between the plantwide definition and the dual definition is insignificant. Currently, there is only one major source in the area that could cause a major modification, and that source is not planning to "net" any major modifications out of NSR requirements. Therefore, even under the offset provision, the State NSR rule appears to be consistent with Mississippi's attainment demonstration.

Therefore, EPA is today proposing to approve the State's submittal as satisfying the requirements of an acceptable plan and is soliciting public comment on the regulation.

Pursuant to the provisions of 5 U.S.C. 605(b) the Administrator has certified (46 FR 8709) that the proposed rule will not if promulgated have a significant economic impact on a substantial number of small entities. This action only approves state actions. It imposes no new requirements.

The Office of Management and Budget has exempted this proposed rule from the requirements of section 3 of Executive Order 12291.

List of Subjects in 40 CFR Part 52

Air pollution control, Ozone, Sulfur oxides, Nitrogen dioxide, Lead, Particulate matter, Carbon monoxide, Hydrocarbons.

(Sec. 110 and 172 of the Clean Air Act (42 U.S.C. 7410 and 7502))

Dated: March 31, 1982.

Charles R. Jeter,

Regional Administrator.

[FR Doc. 82-18005 Filed 7-1-82; 8:45 am]

BILLING CODE 6560-50-M

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40 CFR Part 81

[A-5-FRL-2157-4]

Designation of Areas for Air Quality Planning Purposes Attainment Status Designations; Michigan

AGENCY: Environmental Protection Agency.

ACTION: Notice of proposed rulemaking.

SUMMARY: EPA is today proposing to change the designation for a portion of Midland County from non-attainment to attainment for the sulfur dioxide (SO_2) National Ambient Air Quality Standard (NAAQS). This revision to the Michigan State Implementation Plan (SIP) is based on a request from the State to redesignate this area.

DATE: Comments must be received on or before August 2, 1982.

ADDRESSES: Copies of the redesignation request and the supporting technical information are available at the following addresses:

Regulatory Analysis Section, Air Programs Branch, Region V, U.S. Environmental Protection Agency, 230 South Dearborn Street, Chicago, Illinois 60604

Michigan Department of Natural Resources, Air Quality Division, State Secondary Government Complex, General Office Building, 7150 Harris Drive, Lansing, Michigan 48917

Written comments on this action should be addressed to:

Gary Gulezian, Chief, Regulatory Analysis Section, Air Programs Branch, 230 South Dearborn Street, Chicago, Illinois 60604

FOR FURTHER INFORMATION CONTACT: Toni Lesser at the EPA, Region V, address listed above or call (312) 886-6037.

SUPPLEMENTARY INFORMATION: The Clean Air Act (Act) amendments of 1977 added section 107(d) to the Act. This section directed each State to submit to the Administrator of EPA a list of the NAAQS attainment status for all areas within the State. On March 3, 1978 (43 FR 8962), and on October 5, 1978 (43 FR 45993), pursuant to the requirements of section 107 of the Act. EPA designated certain areas in each state as nonattainment with respect to NAAQS for several pollutants including SO_2.

The primary SO_2 NAAQS is violated when either: (1) The annual arithmetic mean value of monitored SO_2 concentration exceeds 80 micrograms per cubic meter of air (80 $\mu g/m^3$) (the annual primary standard), or (2) the maximum 24-hour concentration of SO_2 at any site exceeds 365 $\mu g/m^3$ more than once per year (the 24-hour primary standard). The secondary SO_2 NAAQS is violated when the maximum 3-hour concentration at any site exceeds 1,300 $\mu g/m^3$ more than once per year.

A portion of Midland County, Michigan (36 square miles surrounding the Dow Chemical plant) was designated as a nonattainment area for the primary SO_2 NAAQS in the March 3, 1978 (43 FR 8964), **Federal Register** . This nonattainment designation was based on the fact that the Dow Chemical Midland plant operated a Supplementary Control System (SCS), in contravention to section 123 of the Act, in order to attain the SO_2 NAAQS. Dow Chemical's Midland plant is the major source of SO_2 emissions in Midland County.

On May 6, 1980 (45 FR 29790), EPA approved Michigan's SO_2 control strategy required by Part D of the Act for Midland County. The strategy

requires Dow Chemical to comply with the 1 percent sulfur content limitation contained in Michigan's Rule 336.1401. In that notice, EPA approved the Midland County strategy stating that the available information demonstrated that enforcement of those regulations will protect the ambient air quality in Midland County.

On September 28, 1981, the U.S. District Court for the Eastern District of Michigan in the case of the U.S.A. vs Dow Chemical Company, signed a consent decree which, among other items, committed Dow to comply with the requirements of R336.1401 by September 1, 1982.

On December 21, 1981, the State of Michigan requested that EPA designate Midland County as attainment for SO_2. Michigan indicated that, as of September 1, 1981, the Dow Chemical Company is no longer operating an SCS and that Dow Chemical is now burning compliance fuel (1 percent sulfur content). This switch to a lower sulfur content fuel has resulted in a significant reduction in sulfur dioxide emissions in the Midland area.

EPA has reviewed Michigan's request to redesignate a portion of Midland County from primary non-attainment to attainment for SO_2 and today is proposing to approve the State's request. As noted in EPA's rulemaking of May 6, 1980, EPA believes that Dow's compliance with the 1 percent sulfur limit in R336.1401 will assure attainment of the SO_2 NAAQS in Midland County. Therefore, EPA is proposing approval of the redesignation of Midland County as attainment for SO_2 based on Michigan's certification that Dow has been in compliance with R336.1401 since September 1, 1981.

A 30-day public comment period is being provided on this notice of proposed rulemaking. Public comment received on or before August 2, 1982 will be considered in EPA's final rulemaking. When possible, comments should be submitted in triplicate. All comments will be available for inspection during normal business hours at the Region V Office.

Under 5 U.S.C. 605(b), the Administrator has certified that redesignations do not have a significant economic impact on a substantial number of small entities (46 FR 8709). This action proposes to approve a revision to the attainment status designation within the terms of this certification and it imposes no additional regulatory requirements.

The Office of Management and Budget has exempted this rule from the requirements of section 3 of Executive Order 12291.

List of Subjects in 40 CFR Part 81

Air pollution control, National parks, Wilderness areas.

(Sec. 107(d) of the Clean Air Act, as amended (42 U.S.C. 7407))

Dated: June 16, 1982.

Valdas V. Adamkus,

Regional Administrator.

[FR Doc. 82-18049 Filed 7-1-82; 8:45 am]

BILLING CODE 6560-50-M

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40 CFR Part 720

[OPTS 50019A; (TSH-FRL 2121-8)]

Premanufacture Notices; Substantiation of Confidentiality Claims

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed Rule Related Notice.

SUMMARY: On November 7, 1980, EPA issued a Statement of Revised Interim Policy for submission of premanufacture notices (PMNs) under section 5 of the Toxic Substances Control Act in which the Agency encouraged PMNs submitters to substantiate claims of confidentiality at the time of submission. If confidentiality claims were not substantiated at the time of submission, EPA stated that it would send the submitter a letter requesting substantiation. EPA has reconsidered this policy and will no longer routinely request substantiation of confidentiality claims in PMNs. Substantiation will only be requested when EPA receives a request under the Freedom of Information Act or when, for some other reason, EPA decides that it must make a final confidentiality determination. However, the Agency will continue to require substantiation of chemical identity confidentiality claims made for PMNs for which EPA receives a notice of commencement of manufacture or import.

DATE: Written comments must be submitted by September 29, 1982. Procedures described in this notice will become effective upon publication of this notice.

ADDRESS: All comments should bear the identifying notation OPTS 50019A and be addressed to: Document Control Officer, Office of Toxic Substances (TS-793), Environmental Protection Agency, 401 M Street, SW., Washington, D.C. 20460.

FOR FURTHER INFORMATION CONTACT: Douglas G. Bannerman, Acting Director, Industry Assistance Office (TS-799), Environmental Protection Agency, 401 M St., SW., Washington, D.C. 20460, Toll Free: (800-424-9065), In Washington: (544-1404), Outside the USA: (Operator-202-544-1404).

SUPPLEMENTARY INFORMATION: Section 5 of the Toxic Substances Control Act (TSCA) requires any person who intends to manufacture or import a new chemical substance for a commercial purpose to submit a PMN to EPA at least 90 days before he commences manufacture or importation. A "new" chemical substance is one that is not included on the TSCA section 8(b) Inventory of Chemical Substances. At the end of the notice review period, the PMN submitter may manufacture or import the substance unless EPA has taken action to ban or otherwise regulate it. EPA proposed rules containing premanufacture notification and review procedures, 40 CFR Part 720, published in the **Federal Register** of January 10, 1979 (44 FR 2242), and published reproposals of certain provisions of the rules in the **Federal Register** of October 16, 1979 (44 FR 59764).

The premanufacture notification requirements of section 5 of TSCA went into effect on July 1, 1979. Since the proposed premanufacture notification rules had not been promulgated at that time, EPA issued a Statement of Interim Policy, published in the **Federal Register** of May 15, 1979 (44 FR 28564), which discussed the premanufacture notification requirements and the procedures EPA would follow in implementing those requirements pending promulgation of final rules. In the **Federal Register** of November 7, 1980 (45 FR 73478), EPA issued a Statement of Revised Interim Policy which expanded on the original May statement and discussed additional matters.

I. Substantiation of Confidentiality Claims

One of the matters discussed in the November Statement of Revised Interim Policy was substantiation of confidentiality claims. Under the Revised Interim Policy, submitters of PMNs are required to make any claims of confidentiality for information in the PMN at the time of submission. If submitters fail to make the claims at that time, EPA places the PMN in a public file and otherwise treats the notice as available to the public. The requirement to make all confidentiality claims at the time of submission remains unchanged.

The November statement also encouraged submitters of PMNs to substantiate their claims of confidentiality at the time of submission of the PMN. The submitters could use

the substantiation scheme in the EPA proposed PMN form. EPA also stated that, if the submitter failed to substantiate at the time of submission, EPA would send a letter to the submitter, shortly after receiving the PMN, requesting substantiation.

The decision to request substantiation of confidentiality claims for all PMNs shortly after submission was based on the Agency's desire to respond promptly to Freedom of Information Act (FOIA) requests for PMN information. The Agency, based on its experience up to that time, anticipated receiving large numbers of FOIA requests and wanted to be able to respond to those requests quickly so that FOIA requesters would receive a response within the 90-day PMN review period.

EPA has been operating under the Revised Interim Policy for a year and a half. In that time, EPA has not received large numbers of FOIA requests for confidential PMN information. At the same time, the substantiation requirement has not led to a reduction in the volume of information claimed confidential.

Based on this experience, EPA has reconsidered its policy of automatically requesting substantiation of all confidentiality claims in each PMN. Requiring substantiation of confidentiality claims can be an additional burden on submitters and the agency. If there are no FOIA requests for the information claimed confidential in a PMN, and EPA has no other reason to make a final confidentiality determination, EPA and the submitter have incurred that burden unnecessarily. The volume of FOIA requesters seeking confidential business information from PMNs has decreased since the substantiation requirement was imposed. Most requesters are satisfied with the sanitized copies of PMNs which submitters or EPA produce. At the same time, EPA has had little reason to initiate final confidentiality determinations for any other reason. In addition, when companies have been asked to substantiate claims, they have not withdrawn or limited their claims. Thus, requesting substantiation does not seem to have reduced the number of confidentiality claims.

As a result of these considerations, EPA has decided to no longer routinely request substantiation of confidentiality claims made in PMNs under the Interim Policy. Instead, EPA will request substantiation of confidentiality claims only when it receives an FOIA request for the information claimed as confidential or when EPA has its own reasons for making a final confidentiality determination, such as when regulatory action is contemplated for the PMN substance. In the proposed premanufacture notification rules, EPA proposed requiring substantiation of confidentiality claims at the time of submission. EPA has not decided whether this requirement will be part of the final rules. The policy announced today applies only to the interim period until the final rules are promulgated. During the interim period, EPA will continue to monitor the nature and volume of FOIA requests, the speed with which EPA is able to respond to FOIA requests, and the nature and extent of confidentiality claims made by submitters. EPA will consider this in deciding what substantiation requirements, if any, should appear in the final rule.

Claims will still be asserted by marking the appropriate box on the reporting form and signing the certification statement. If a submitter does not use the reporting form he should bracket or otherwise clearly identify the items of information claimed confidential. EPA still encourages submitters to use the EPA proposed PMN form for reporting.

EPA still believes that it is useful for PMN submitters to substantiate their confidentiality claims at the time of submission using the scheme contained in the EPA proposed form. Substantiating claims at the time of submission may be easier and less burdensome than having to do so at a later date. In addition, working through the substantiation responses can help a submitter determine whether certain confidentiality claims are the appropriate ones to make.

EPA's decision to remove the requirement that PMN confidentiality claims be substantiated at the time of their assertion does not modify the Agency's existing confidentiality requirements for PMN chemicals which are added to the TSCA Chemical Substances Inventory. After the end of the Notice review period and absent regulatory action by EPA, a PMN submitter may begin manufacture or import operations upon providing EPA a notice of commencement of manufacture or import. Substances for which EPA receives such a notice are thereafter listed by the Agency on the TSCA Chemical Substances Inventory.

Confidentiality claims made for PMN chemicals which are to be added to the Inventory must be asserted at the time of submission of a notice of commencement of manufacture or import. Failure to assert claims at that time will result in the publication of the relevant information on the Inventory. If a person asserts a claim of confidentiality for the specific chemical identity, he must substantiate that claim by providing EPA with detailed answers to the eleven questions which appear near the end of page 28569 of the Federal Register of May 15, 1979 (44 FR 28558). If this substantiation does not accompany the notice of commencement, the Agency sends the submitter a letter listing the substantiation questions which must be answered. If EPA does not receive a response within ten days, the Agency treats the claim as waived and publishes the chemical identity in the monthly Federal Register PMN report.

II. Submission of Sanitized PMN Forms

EPA's May 15, 1979, Statement of Interim Policy "strongly encourages" submitters to send both sanitized and unsanitized versions of their PMN's to the Agency.

EPA believes that the preparation of sanitized versions of PMNs by submitters improves the effectiveness of the PMN process in two ways. First, it results in a more efficient allocation of resources. The person asserting the confidentiality claim, who is more familiar with its nature, extent, and rationale, will in the same exercise sanitize the PMN, extracting any evidence of the confidential information. This frees the Agency's limited resources from the task of having to create a sanitized copy. Secondly, the submission of sanitized versions of PMNs by the manufacturers will reduce the chance of any error by EPA. Since EPA presently sanitizes hundreds of PMNs a year, it is possible, in spite of EPA's best efforts, that mistakes will be made. A submitter can minimize this risk by sanitizing its own PMN.

III. Regulatory Impact Requirements

Under Executive Order 12291, EPA must judge whether a "regulation" is "major" and therefore subject to the requirement of a Regulatory Impact Analysis. This "regulation" is not major because it is not expected to have an annual effect on the economy of $100 million or more, result in major cost or price increases to consumers, industry, government agencies, or geographic regions, or adversely affect competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

This "regulation" was submitted to the Office of Management and Budget for review as required by Executive Order 12291.

EPA has determined that this document does not come under the provisions of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.*, because less than ten parties are expected to be affected by any new information collection requirements in the notice.

(Sec. 5, Pub. L. 94-469, 90 Stat. 2013, [15 U.S.C. 2604])

List of Subjects in 40 CFR Part 720

Environmental protection, Chemicals, Premanufacture notifications, Hazardous materials, Recordkeeping and reporting requirements.

Dated: June 8, 1982.

John A. Todhunter,

Assistant Administrator for Pesticides and Toxic Substances.

[FR Doc. 82-17756 Filed 7-1 Filed 7-1-82; 8:45 am]

BILLING CODE 6560-50-M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

43 CFR Part 3140

Public Information Meeting on Competitive Tar Sand Leasing Program

AGENCY: Bureau of Land Management, Interior.

ACTION: Public Information Meeting on the Competitive Tar Sand Leasing Program proposed rulemaking.

SUMMARY: To announce a public information meeting on July 15, 1982, at 7:00 p.m., in Room 127, Salt Palace Convention Center, West Temple and First South Streets, Salt Lake City, Utah.

The purpose of this meeting is to discuss the proposed rulemaking (47 FR 25720; June 14, 1982) on the competitive tar sand leasing program as required by the Combined Hydrocarbon Leasing Act of 1981.

DATE: Additional written comments may be submitted before August 13, 1982.

ADDRESS: Comments on the proposed rulemaking should be sent to: Director (140), Bureau of Land Management, 18th & C Streets, N.W., Washington, D.C. 20240.

Comments will be available for public review in Room 5555 of the above address during regular working hours (7:45 a.m. to 4:15 p.m.), Monday through Friday, during office hours on regular working days.

FOR FURTHER INFORMATION CONTACT:

Edward E. Coggs (202) 343-3258.

James M. Parker,

Associate Director.

June 30, 1982.

[FR Doc. 82-18133 Filed 7-1-82; 8:45 am]

BILLING CODE 4310-84-M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 661

[Docket No. 2628-116]

Ocean Salmon Fisheries Off the Coasts of California, Oregon, and Washington

AGENCY: National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Proposed rule and availability of plan amendment.

SUMMARY: NOAA makes available copies of a Secretarial plan amendment and proposes implementing regulations for the ocean commercial salmon fisheries off the coasts of southern Oregon and California. Comments are requested on both the Secretarial plan amendment and these proposed rules. The regulations provide management measures identical to those implemented by emergency rule on June 1, 1982. The regulations are intended to prevent overfishing, to allow more salmon to survive the ocean fisheries and reach the Indian subsistence fisheries in internal waters, and to achieve spawning escapement requirements.

DATE: Comments on the Secretarial plan amendment and this proposed rule must be received by August 16, 1982.

ADDRESS: Submit comments to and copies of a Secretarial plan amendment, and a supplemental regulatory impact review/initial regulatory flexibility analysis for these regulations, are available from the Director, Northwest Region, National Marine Fisheries Service (NMFS), 7600 Sand Point Way N.E., BIN C15700, Seattle, WA 98115; or from the Director, Southwest Region, National Marine Fisheries Service, 300 South Ferry Street, Terminal Island, CA 90731.

FOR FURTHER INFORMATION CONTACT: H. A. Larkins (Regional Director, NMFS) 206-527-6150; or A. W. Ford (Regional Director, NMFS) 213-548-2575.

SUPPLEMENTARY INFORMATION: The fishery management plan (FMP) for the Commercial and Recreational Salmon Fisheries off the Coasts of Washington, Oregon, and California, prepared by the Pacific Fishery Management Council (Council), was approved by the Assistant Administrator for Fisheries, NOAA, (Assistant Administrator) on March 2, 1978. Regulations to implement the FMP were first published on April 14, 1978 (43 FR 15629), as emergency rules. Regulations to implement the 1981 amendment to the FMP were issued as final rules on September 9, 1981 (46 FR 44989), as corrected on September 16, 1981 (46 FR 45960), except off California where 1980 regulations were reinstated (published on January 29, 1982, 47 FR 4275).

The Council amended the FMP to improve management of the salmon fisheries in 1982. The 1982 amendment was intended to (1) provide adequate spawning escapements from ocean salmon fisheries for the various salmon runs; (2) meet treaty obligations to Indian fishermen; and (3) allow for a reasonable harvest for each segment of the salmon fishery, including the commercial and recreational ocean fisheries and the various internal water fisheries. The Council's 1982 FMP amendment, as it applies to the commercial salmon fishery north of Cape Blanco, Oregon, and to the recreational fisheries coastwide, was approved by the Assistant Administrator on May 6, 1982, under section 304 of the Magnuson Fishery Conservation and Management Act, 16 U.S.C. 1801 *et seq.* (Magnuson Act). Emergency interim rules to implement those portions of the Council's amendment were published on May 18, 1982 (47 FR 21256). The portion of the Council's recommended amendment for the commercial fisheries south of Cape Blanco was disapproved by the Assistant Administrator because it would not have allowed sufficient spawning escapement to the Klamath River and upper Sacramento River and would have unduly restricted the ocean harvest.

On April 23, 1982, the Council notified the Assistant Administrator that it did not intend to alter its 1982 recommendation for the management of the commercial ocean salmon fisheries south of Cape Blanco. Therefore, a Secretarial amendment was prepared to amend the FMP and implement appropriate management measures pertaining to the Klamath River and upper Sacramento River chinook stocks under section 304(c) of the Magnuson Act. That section authorizes the Secretary of Commerce (Secretary) to prepare FMPs or amendment to FMPs if the involved Council does not develop such FMP or amendment within a

reasonable period. The Council was apprised of the Secretary's intention to prepare a Secretarial amendment prior to publication of an emergency interim rule on June 1, 1982, under paragraph 305(e)(2) of the Magnuson Act. The Secretarial amendment was submitted to the Council for review and comment.

Current information on the abundance of major stocks of chinook and coho salmon available in 1982 to the commercial ocean fisheries south of Cape Blanco was summarized briefly in the preamble to the emergency interim rule that implemented the approved portions of the Council's 1982 amendment (47 FR 21256). Resource status information is also discussed in detail in Chapter IV of the report that accompanied the Council's FMP amendment. Status of stocks information and other factors were considered when the management measures that are contained within the Secretarial amendment were selected.

The preamble to the emergency interim rule for the commercial fisheries south of Cape Blanco, Oregon (47 FR 24134, June 3, 1982), thoroughly discussed the management measures contained in the Secretarial amendment and the regulations, which are identical to those being proposed herein. Comments on the proposed regulations and the Secretarial amendment will be accepted for 45 days from the publication date of this notice. Anyone interested in commenting on the proposed regulations should submit comments to the address shown above.

Classification

The Assistant Administrator has determined that these proposed regulations are necessary and appropriate for conservation of the salmon resources and management of the salmon fisheries off the coasts of Oregon and California and that they are consistent with the Magnuson Act, including the national standards, and other applicable law.

The NOAA Administrator has determined that these proposed rules are not "major" under Executive Order (E.O.) 12291 requiring a regulatory impact analysis. A supplement to the regulatory impact review/initial regulatory flexibility analysis (RIR/IRFA) has been prepared. This review contains an analysis of the expected impacts of the management measures and alternative management options. The review supports the determination that these rules are not "major" under E.O. 12291 criteria.

The NOAA Administrator has determined that an emergency situation exists for purposes of section 8(a)(1) of E.O. 12291 for the following reasons. As was stated in the preamble to the emergency interim rules that became effective on June 1, there is a critical need for specific regulations for the 1982 commercial salmon fisheries south of Cape Blanco, Oregon. This includes the need to have final regulations in place at the end of the period of emergency regulations (August 29), under section 305(e) of the Magnuson Act, since the season off southern Oregon runs through October 31, and the season off California runs through September 30. A reversion to prior regulations after August 29 (that is, to 1981 regulations off southern Oregon and to 1980 regulations off California) additionally would cause untoward confusion in the fisheries. Section 305(a) of the Magnuson Act requires that the public have an opportunity to comment on proposed regulations during a 45-day period. The duration of that comment period, together with periods specified for OMB review of the proposed and final versions of this rule, would not permit final rules to be promulgated by August 29. Thus it is impracticable to compy with section 3(c)(3) of E.O. 12291, which requires that NOAA transmit to the Director of the Office of Management and Budget (OMB) a copy of every nonmajor rule, at least 10 days prior to publication. However, a copy of these proposed regulations and a copy of the supplements RIR have been transmitted to the Director of OMB.

The NOAA Administrator also has determined that the emergency rules implementing the 1982 amended plan will have a significant economic impact on a substantial number of small entities for purposes of the Regulatory Flexibility Act, 5 U.S.C. 601–12. The supplement to the RIR/IRFA prepared for the Secretarial amendment, which comprises Appendix G of the FMP, indicates that the relatively less restrictive management measures imposed on the commercial ocean salmon fisheries south of Cape Blanco will have beneficial economic impacts on commercial fishermen and industries dependent on the ocean salmon fisheries. The estimate of exvessel revenue in 1982 compared to 1981 will be about the same for the troll fisheries between Cape Blanco and the California-Oregon border and will increase by about $1,500,000 for the troll fisheries off California.

A final supplement to the Environmental Impact Statement (FSEIS) for the 1982 FMP amendment was filed with the Environmental Protection Agency. A notice of availability of the FSEIS was published on April 30, 1982 (47 FR 18652). The action that is represented by these proposed regulations was within the range of alternatives analyzed in the FSEIS for the 1982 amendment. Therefore an additional supplement is not required.

These proposed regulations pertaining to the commercial fisheries south of Cape Blanco, Oregon, do not entail any Federal collection of information for purposes of the Paperwork Reduction Act, 44 U.S.C. 3507.

List of Subjects in 50 CFR Part 661

Fish, Fisheries, Fishing, Indians.

Dated: June 29, 1982

Robert K. Crowell,

Deputy Executive Director, National Marine Fisheries Service.

PART 661—OCEAN SALMON FISHERIES OFF THE COASTS OF CALIFORNIA OREGON AND WASHINGTON

For the reasons set out in the preamble, 50 CFR Part 661, is proposed to be amended as follows:

1. The authority citation for Part 661 reads as follows:

Authority: 16 U.S.C. 1801 *et seq.*

§ 661.3 [Amended]

2. In § 661.3, the definition of *Subarea* is amended by revising paragraph (e)(2), and paragraph (f)(1) to read as follows:

* * * * *

(e) Subarea E:

(1) * * *

(2) Southern boundary: a line extended due west from Point Arena, California, at 39°00′00″ N. latitude.

(f) Subarea F:

(1) Northern boundary: a line extended due west from Point Arena, California, at 39°00′00″ N. latitude.

* * * * *

3. In § 661.20, paragraphs (a)(4)(i) through (iv), (a)(5)(i) through (iii), and (a)(6)(i) through (iii); the seasons indicated for Subareas D through F in the table at paragraph (b)(2); and paragraph (b)(3) are revised to read as follows:

§ 661.20 Commercial fishing.

(a) * * *

(4) Subarea D (Cape Blanco, Oregon, to the Oregon-California border):

(i) The season for all salmon species, except coho, begins on May 1 and ends on May 31; during this season, only the gear specified in § 661.20(b)(2) may be used.

(ii) The season for all salmon species, except coho, reopens on June 1 and ends on June 8; during this season, only the

gear specified in § 661.20(b)(3) may be used.

(iii) The season for all salmon species, including coho, begins on July 1 and ends when the commercial coho quota is reached.

(iv) The season for all salmon species, except coho, continues from the date the commercial coho quota is reached and ends on October 31; during this season, only the gear specified in § 661.20(b)(3) may be used before September 6, and only the gear specified in § 661.20(b)(2) may be used after September 5.

(5) Subarea E (Oregon-California border to Point Arena, California):

(i) Subsequent to the 1982 season, the season for all salmon species, except coho, begins on May 1 and ends on May 24; during this season, only the gear specified in § 661.20(b)(2) may be used.

(ii) The season for all salmon species, including coho, begins on May 25 and ends on June 8.

(iii) The season for all salmon species, including coho, reopens on July 1 and ends on September 30.

(6) Subarea F (Point Arena, California, to U.S.-Mexico border):

(i) Subsequent to the 1982 season, the season for all salmon species, except coho, begins on April 22 and ends on May 24; during this season, only the gear specified in § 661.20(b)(2) may be used.

(ii) The season for all salmon species, including coho, begins on May 25 and ends on June 15.

(iii) The season for all salmon species, including coho, reopens on July 1 and ends on September 30.

(b) * * *

(2) * * *

Subarea and Season

A May 1–31
B May 1–31
C May 1–31 and after September 5 during the season specified in § 661.20(a)(3)(iv)
D May 1–31 and after September 5 during the season specified in § 661.20(a)(4)(iv)
E May 1–24 (subsequent to the 1982 season)
F April 22–May 24 (subsequent to the 1982 season)

* * * * *

(3) No person shall engage in commercial salmon fishing using other than hooks with whole natural bait or salmon plugs not less than five (5) inches long from June 1 to June 15 in subarea C, from June 1 to June 8 in subarea D, or from the date the coho commercial quota is reached to September 5 in subareas C and D. Gear commonly known as "spoons," "wobblers," "dodgers," and flexible plastic lures, are not considered salmon plugs, and are prohibited during the times specified in this § 661.20(b)(3).

* * * * *

[FR Doc. 82-18154 Filed 6-30-82; 11:46 am]
BILLING CODE 3510-22-M

Notices

Federal Register
Vol. 47, No. 128
Friday, July 2, 1982

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Office of the Secretary

Privacy Act of 1974; Systems of Records

Correction

In FR Doc. 82–16697, published at page 26680, on Monday, June 21, 1982, make the following corrections:

1. On page 26680, in the first column, in the "AGENCY" line, "Agricultural Department" should be corrected to read "Agricultural Marketing Service".

2. On page 26682, in the second column, under "USDA/P&SA–1", in the "System name" paragraph, in the second line "Administrative administration" should be corrected to read "Administration administrative".

BILLING CODE 1505–01–M

Rural Electrification Administration

East River Electric Power Cooperative, Inc.; Finding of No Significant Impact

AGENCY: Rural Electrification Administration, USDA.

ACTION: Notice of finding of no significant impact.

SUMMARY: REA has made a Finding of No Significant Impact concerning the proposed construction by the East River Electric Power Cooperative, Inc., (East River) of a 22.5 km (14 mi), 115 kV transmission line and a 115/69 kV substation. The line would connect the proposed East River, Ivanhoe Substation in Lincoln County, Minnesota, to the proposed Western Area Power Administration's (WAPA) Brookings to White, 21 km (13 mi), 230 kV transmission line in Brookings County, South Dakota.

FOR FURTHER INFORMATION CONTACT: REA's Finding of No Significant Impact and Environmental Assessment and East River's Borrower's Environmental Report (BER) may be obtained at the Office of the Director, Power Supply Division, Room 0230, South Agriculture Building, Rural Electrification Administration, Washington, D.C. 20250, telephone (202) 382–1400, or the East River Electric Cooperative, Inc., Drawer E, Madison, South Dakota 57042, telephone (605) 256–4536.

SUPPLEMENTARY INFORMATION: Since the East River and WAPA proposd lines cannot initially operate independently, REA considered both lines as a single project for the purpose of environmental review. REA has prepared an Environmental Assessment (EA) concerning the project which incorporated the East River BER and the WAPA EA. REA's independent evaluation of the combined project leads to the conclusion that approval of the project does not represent a major Federal action that would significantly affect the quality of the human environment.

Alternatives discussed in the EA are no action, an alternate type of construction and alternative line routing and substation sitings. The nature of the alternative routes and sites is that the alternatives are located in Lincoln County, Minnesota, and Brookings County, South Dakota, are of comparable size, and the terrain is similar. REA has determined the proposed project is an acceptable alternative because it would avoid, to the extent practicable, closed section lines, cultural resources, important farmland, endangered species habitat, wetlands and floodplains.

Approximately 0.13 km (0.08 mi) of wetlands and 1.1 km (0.7 mi) of floodplain would be crossed. REA has determined that there is no practicable alternative to crossing these areas and with single pole construction there should be no long term effects to the ecological functions of these areas. Further information concerning alternatives and environmental impacts is in the EA.

This program is listed in the Catalog of Federal Domestic Assistance as 10.850—Rural Electrification Loans and Loan Guarantees.

Dated: June 25, 1982.

Harold V. Hunter,

Administrator.

[FR Doc. 82–18064 Filed 7–1–82; 8:45 am]

BILLING CODE 3410–15–M

Soil Conservation Service

Ala-Tom Resource Conservation and Development Area, Alabama

AGENCY: Soil Conservation Service.

ACTION: Notice of a finding of no significant impact.

SUMMARY: Pursuant to Section 102(2)(C) of the National Environmental Policy Act of 1969; the Council on Environmental Quality Guidelines (40 CFR Part 1500); and the Soil Conservation Service Guidelines (7 CFR Part 650); the Soil Conservation Service, U.S. Department of Agriculture, gives notice that an environmental impact statement is not being prepared for the Ala-Tom RC&D Area, Perry, Dallas, Marengo, Choctaw, Clarke, Wilcox, Monroe, Washington, and Conecuh Counties, Alabama.

FOR FURTHER INFORMATION CONTACT: Ernest V. Todd, State Conservationist, Soil Conservation Service, P.O. Box 311, Auburn, Alabama 36830, telephone (205) 821–8070.

SUPPLEMENTARY INFORMATION: The environmental assessment of this federally assisted action indicates that the project will not cause significant local, regional, or national impacts on the environment. As a result of these findings, Ernest V. Todd, State Conversationist, has determined that the preparation and review of an environmental impact statement are not needed for this project.

The area measure concerns a plan for recreation facilities and critical area treatment. The planned works of improvement include picnic tables, grills and benches, picnic shelters, electric and water facilities, comfort station, boat launching, and parking areas. Conservation practices include subsurface drains, diversions, grading and shaping, critical area stabilization, and seeding.

The Notice of a Finding of No Significant Impact (FONSI) has been forwarded to the Environmental Protection Agency and to various Federal, State, and local agencies and

interested parties. A limited number of copies of the FONSI are available to fill single copy requests at the above address. Basic data developed during the environmental assessment are on file and may be reviewed by contacting Ernest V. Todd.

No administrative action on implementation of the proposal will be taken until August 2, 1982.

(Catalog of Federal Domestic Assistance Program No. 10.901, Resource Conservation and Development Program. Office of Management and Budget Circular A-95 regarding State and local clearinghouse review of Federal and federally assisted programs and projects is applicable)

Dated: June 25, 1982.

Ernest V. Todd,

State Conservationist.

[FR Doc. 82-17936 Filed 7-1-82; 8:45 am]

BILLING CODE 3410-16-M

CIVIL AERONAUTICS BOARD

Applications for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits; Week Ended: June 25, 1982

Subpart Q Applications

The due date for answers, conforming application, or motions to modify scope are set forth below for each application. Following the answer period the board may process the application by expedited procedures. Such procedures may consist of the adoption of a show-cause order, a tentative order, or in appropriate cases a final order without further proceedings.

Date filed	Docket No.	Description
June 21, 1982	40793	United Air Carriers, Inc. d/b/a Overseas National Airways, c/o Richard J. Kendall, Shaw, Pittman, Potts & Trowbridge, 1800 M Street, N.W., Washington, D.C. 20036. Application of United Air Carriers, Inc. d/b/a Overseas National Airways, pursuant to Section 401 of the Act and Subpart Q of the Board's Procedural Regulations requests authority to provide scheduled foreign air transportation of persons, property, and mail including combination passenger and cargo scheduled services, as follows: Between New York, New York, Amsterdam, The Netherlands, Beirut, Lebanon, Amman, Jordan, Kuwait, Abu Dhabi, and Dubai, United Arab Emirates. Conforming Applications, motions to modify scope and Answers may be filed by July 19, 1982.
June 23, 1982	40796	Capitol Air, Inc., P.O. Box 325, Smyrna, Tennessee 37167. Conforming Application of Capitol Air, Inc. pursuant to Section 401 of the Act and Subpart Q of the Board's Procedural Regulations requests issuance or amendment of a certificate of public convenience and necessity to engage in scheduled foreign air transportation of persons, property and mail between: A. "the terminal point Dallas/Fort Worth, Texas, on the one hand and the terminal point London, England on the other hand." B. "The terminal point Dallas/Fort Worth, Texas, the intermediate point London, England; and a terminal point or points in Belgium, The Netherlands, Luxembourg, the Federal Republic of Germany, Switzerland, Bahrain, Egypt, Kuwait, Oman, Qatar, the United Arab Emirates, and Athens, Greece." Answers may be filed by July 7, 1982.
June 24, 1982	40797	Air Florida, Inc., 3900 N.W. 79 Avenue, Miami, Florida 33166. Application of Air Florida, Inc. pursuant to Section 401 of the Act and Subpart Q of the Board's Procedural Regulations, requests an amendment of its certificate of public convenience and necessity for Route 197-F authorizing it to engage in air transportation with respect to persons, property and mail as follows: Between the terminal point Miami, Florida, via the intermediate point London, England and the coterminal points Copenhagen, Denmark; Oslo, Stavanger and Bergen, Norway; Stockholm and Gothenburg, Sweden and Helsinki, Finland. Conforming Applications, motions to modify scope and Answers may be filed by July 22, 1982.
June 25, 1982	40799	KLM Royal Dutch Airlines, c/o Paul V. Mifsud, 437 Madison Avenue, New York, New York 10022. Application of KLM Royal Dutch Airlines, pursuant to Section 402 of the Act and Subpart Q of the Board's Procedural Regulations, requests that its foreign air carrier permit be amended in the following respects: A. Delete route segment (2) and substitute therefor the following: (2) Between a point or points in The Netherlands and the intermediate point in Anchorage, Alaska, and between the point in Anchorage, Alaska and the points Tokyo, Japan; Seoul, Republic of Korea, Taipei, Taiwan, Republic of China. B. Wherever and whenever in the paragraphs following the route segments, the words "Tokyo, Japan" appear, the same shall be deleted and replaced by the following: "Tokyo, Japan; Seoul, Republic of Korea, Taipei, Taiwan, Republic of China." Answers may be filed by July 23, 1982.

Phyllis T. Kaylor,

Secretary.

[FR Doc. 82-18119 Filed 7-1-82; 8:45 am]

BILLING CODE 6320-01-M

CIVIL RIGHTS COMMISSION

Wyoming Advisory Committee; Agenda and Open Meeting

Notice is hereby given, pursuant to the provisions of the Rules and Regulations of the U.S. Commission on Civil Rights, that a meeting of the Wyoming Advisory Committee to the Commission will convene at 11:00 a.m. and will end at 2:00 p.m., on July 31, 1982, at the Hitching Post Inn, 1700 Lincolnway, in the Cheyenne Room, Cheyenne, Wyoming, 82001. The purpose of this meeting will be to review recent Commission activities, discuss followup activities to the report, *Workplace Conditions in Wyoming* and to plan for future Committee projects.

Persons desiring additional information or planning a presentation to the Committee, should contact the Chairperson, Jamie C. Ring, 520 Parkview Drive, Casper, Wyoming, 82601, (307) 268-2269 or the Rocky Mountain Regional Office, Brook Towers, 1020 Fifteenth Street, Suite 2235, Denver, Colorado, 80202, (303) 837-2211.

The meeting will be conducted pursuant to the provisions of the Rules and Regulations of the Commission.

Dated at Washington, D.C., June 29, 1982.

John I. Binkley,

Advisory Committee Management Officer.

[FR Doc. 82-18013 Filed 7-1-82; 8:45 am]

BILLING CODE 6335-01-M

DEPARTMENT OF COMMERCE

Bureau of Industrial Economics

[Docket No. 2654-115]

List of Names and Addresses of Bona Fide Motor-Vehicle Manufacturers

AGENCY: Bureau of Industrial Economics, Office of Producer Goods, Commerce.

ACTION: List of Names and Addresses of Bona Fide Motor-Vehicle Manufacturers.

SUMMARY: In accordance with headnote 2 to subpart B, Part 6, Schedule 6 of the Revised Tariff Schedules of the United States (19 U.S.C. 1202) and 15 CFR Chapter VI Part 615, the following is a list of the names and addresses of bona fide motor-vehicle manufacturers, as determined by the Director, Bureau of Industrial Economics, Department of Commerce, and the effective date for each such determination. Each determination shall be effective for the 12-month period beginning on the determination date shown following the name and address of each manufactuer. From time to time this list will be revised, as may be appropriate, to reflect additions, deletions, or other necessary changes.

EFFECTIVE DATE: May 1, 1982.

FOR FURTHER INFORMATION CONTACT: Joe Kellagher, Automotive Equipment Div., 566-7410.

Beatrice N. Vaccara,

Director, Bureau of Industrial Economics.

United States Bona Fide Motor Vehicle Manufacturers List May 1, 1982 With Date of Certification

Allentown Brake and Wheel Service, Inc., R.D. 3, P.O. Box 2088, Allentown, Pennsylvania 18001, October 19, 1981

American La France, Div. of A-T-O, Inc., 100 East LaFrance Street, Elmira, New York 14902, July 8, 1981

American Motors Corporation, 27777 Franklin Road, Southfield, Michigan 48034, January 1, 1982

American Trailer Service, Inc., 2814 North Cleveland Avenue, St. Paul, Minnesota 55113, January 1, 1982

American Transportation Corporation, Highway 65 South, Conway, Arkansas 72032, April 19, 1982

Amthor's Welding Service, Inc., 307 State Route 52 East, Walden, New York 12586, July 9, 1981

H.G. Anderson Equipment Corporation, 480 South Street, Rensselaer, N.Y. 12144, October 4, 1981

Antietam Equipment Corporation, P.O. Box 91, Hagerstown, Maryland 21740-0091, January 1, 1982

Arkansas Trailer Mfg., Inc., P.O. Box 4080, 32nd & Elm Street, Little Rock, Arkansas 72214, January 1, 1982

Arrow Trailer & Equipment Co., 140 North Dirksen Parkway, Springfield, Illinois 62702, March 31, 1982

Artic Enterprises, Inc., P.O. Box 635, Thief River Falls, Minnesota 56701, August 1, 1981

Attex International Inc., 6168 Woodbine Avenue, Ravenna, Ohio 44266, August 1, 1981

Automated Waste Equipment Company, Incorporated, 328 Fourth Street, Trenton, New Jersey 08638, September 1, 1981

Automotive Service Company, 111-113 North Waterloo, Jackson, Michigan 49204, January 18, 1982

Avanti Motor Corporation, P.O. Box 1916, South Bend, Indiana 46634, January 1, 1982

Aztec Products, P.O. Box 659, Mansfield, Texas 74808, December 1, 1981

Beam Truck and Body Inc., 433 Cumberland Hill Road, Woonsocket, Rhode Island 02895, September 1, 1981

Bender's Sales and Service Inc., 4805 Holland, Saginaw, Michigan 48601, November 15, 1981

Benson Truck Bodies, Inc., P.O. Box 49, Mineral Wells, W.V. 26150, August 1, 1981

Bernardo Truck Equipment Corp., 625 Main St. (Route 38), Wilmington, Mass. 01887, March 1, 1982

Bethlehem Fabricators, Inc., 1700 Riverside Drive, P.O. Box A, Bethlehem, Pennsylvania 18015, January 20, 1982

Allan U. Bevier, Inc., 1201 Ridgely Street, Baltimore, Maryland 21230, April 1, 1982

Bibeau Enterprises, Route 102, Londonderry, N.H. 03053, October 15, 1981

Blue Bird Body Company, P.O. Box 937, North Macon Road, Fort Valley, Georgia 31030, January 18, 1982

Boone Trailers, Inc., 154 Park Street, P.O. Box 109, Palmer, Massachusetts 01069, December 31, 1981

Boyertown Auto Body Works, Third and Walnut Streets, Boyertown, Pennsylvania 19512, September 1, 1981

Brake and Electric Sales Corp., 300 Mystic Avenue, Medford, Massachusetts 02155, December 1,1981

Brown Cargo Van, Inc., 807 East 29th Street, Lawrence, Kansas 66044, April 30, 1982

Bud Industries, Inc., 100 Pulaski Street, West Warwick, Rhode Island 02893, December 5, 1981

Bus Andrews Equipment Sales and Service, Inc., 2828 E. Kearney Street, Springfield, Missouri 65803, February 1, 1982

Bus Industries of America, Inc., Base Road, R.D. #1, Oriskany, N.Y. 13424, April 1, 1982

Caelter Industries, Inc., Purdy Avenue, Watertown, New York 13601, April 1, 1982

Capacity of Texas, Inc., P.O. Box 7848, Longview, Texas 75607, December 1, 1981

Capitol Trailer & Body Company, 3420 E. Broadway, P.O. Box 3191, North Little Rock, Arkansas 72117, December 1, 1981

The Carnegie Body Company, 9500 Brookpark Road, Cleveland, Ohio 44129, January 1, 1981

Carpenter Body Works, Inc., 1500 W. Main Street, Mitchell, Indiana 47446, January 1, 1982

Centennial Industries Div., Douglas & Lomason Co., P.O. Box 708, Columbus, Georgia 31993, June 1, 1981

Champion Home Builders Co., 5573 E. North Street, Dryden, Michigan 48428, August 1, 1981

Checker Motors Corporation, 2016 N. Pitcher Street, Kalamazoo, Michigan 49007, January 1, 1982

Cherry Valley Tank Div., Inc., 75 Cantiague Road, Westbury, New York 11590, April 1, 1982

Chrysler Corporation, CIMS 418-37-10, Chrysler Center, 12000 Lynn Townsend Drive, Highland Park, Michigan 48288, January 14, 1982

B.M. Clark Company, Inc., Route 17, P.O. Box 185, Union, Maine 04862, January 14, 1982

D. W. Clark Road Equipment, 448 East Brighton Avenue, Syracuse, New York 13205, May 1, 1982

Clark Enginering of Brownwood, Inc., P.O. Drawer 1386, Brownwood, Texas 76801, January 1, 1982

Clark Truck Equipment Company, 6821 Academy Parkway West, N.E., P.O. Box 3483, Albuquerque, New Mexico 87190, January 1, 1982

Clemett and Company, Inc., 2020 Lemoyne Street, Syracuse, New York 13211, September 1, 1981

Collins Industries, Inc., Box 58 H.A.B.I.T., Hutchinson, Kansas 67501, January 1, 1982

Commercial Truck & Trailer, Inc., 313 N. State Street, Girad, Ohio 44420, January 1, 1982

Cook Body Company, 3701 Harlee Avenue, Charlotte, North Carolina 28208, October 22, 1981

Correct Manufacturing Corporation, London Road Extension, Delaware, Ohio 43015, July 1, 1981

Crane Carrier Company, 1925 North Sheridan, Tulsa, Oklahoma 74151, January 1, 1982

Crenshaw Corporation, P.O. Box 24217, 1700 Commerce Road, Richmond, Virginia 23224, July 1, 1981

Crown Coach Corporation, 2428 East 12th Street, Los Angeles, California 90021, March 20, 1982

Dakota Manufacturing Co., Inc., 1910 South Rowley, Mitchell, South Dakota, 37301, November 1, 1981

Daleiden's, Inc., 425 E. Vine Street, Kalamazoo, Michigan 49001, January 31, 1982

Dealers Truck Equipment Inc., 2123 Fern Valley Road, P.O. Box 23224, Louisville, Kentucky 40213, March 1, 1982

Dealers Truck Equipment Co., Inc., 2460 Midway Street, P.O. Box 31435, Shreveport, Louisiana 71130, January 1, 1982

Decker Tank Company, 63 Royal Avenue, Hawthorne, New Jersey 07506, November 3, 1981

John Deere Horicon, Works of Deere and Company, 220 East Lake Street, Horicon, Wisconsin 53032, June 1, 1981

Delevan Industries, Inc., 1728 Walden Avenue, Buffalo, New York 14225, May 1, 1982

Dunham Manufacturing Co., Inc., P.O. Box 430, Minden, Louisiana 71055, January 1, 1982

Duralite Truck Body and Container Corporation, 1300 Bush Street, Baltimore, Maryland 21230, January 1, 1982

Eagle International, Inc., P.O. Box 4119, 2045 Les Mauldin Blvd., Brownsville, Texas 78520, January 1, 1982

Eastern Tank Corporation, 290 Pennsylvania Avenue, Paterson, New Jersey 07503, January 1, 1982
Eggiman Motor and Equipment Sales, Inc., 1813 West Beltline Highway, P.O. Box 9432, Madison, Wisconsin 53715, December 31, 1981
Eight Point Trailer Corporation, 6100 E. Washington Boulevard, Los Angeles, California 90040, January 18, 1982
Elder International, P.O. Box 2061, Houston, Texas 77001, August 1, 1981
Equipment Service, Inc., 40 Airport Road, Hartford, Connecticut 06114, April 1, 1982
E. & R. Trailer Sales, Inc., R.R. #1, Middle Point, Ohio 45863, January 1, 1982
Euclid, Incorporated, 22221 St. Clair Avenue, Cleveland, Ohio 44117, August 1, 1981
Ewell Equipment Company, 307 N. Timberland Drive, Lufkin, Texas 75901, February 2, 1982
Excalibur Automobile Corporation, 1735 South 106th Street, Milwaukee, Wisconsin 53214, May 22, 1981
Fontaine Truck Equipment Company, 653 Beale, P.O. Box 502, Memphis, Tennessee 38101, January 1, 1982
Ford Motor Company, The American Road, Dearborn, Michigan 48121, January 18, 1982
Freightliner Corporation, 4747 North Channel Avenue, Portland, Oregon 97217, December 14, 1981
French Tool & Manufacturing, 2501 Commerce Drive, Midland, Texas. 79703, July 1, 1981
Freuhauf Corporation, 10900 Harper Avenue, P.O. Box 238, Detroit, Michigan 48232, December 1, 1981
FWD Corporation, 105 East 12th Street, Clintonville, Wisconsin 54929, January 1, 1982
Peter Garafano & Son, Inc., 500 Marshall Street, Paterson, New Jersey 07503, June 5, 1981
Garnon Truck Equipment Company, 1617 Peninsula Drive, P.O. Box 1358, Erie, Pennsylvania 16505, January 1, 1982
General Motors Corporation, Room 12–136, 3044 West Grand Boulevard, Detroit, Michigan 48202, January 19, 1982
General Truck Equipment & Trailer Sales, P.O. Box 6954, 5310 Broadway Avenue, Jacksonville, Florida 32236–6954, January 1, 1982
Gillig Corporation, P.O. Box 3008, 25800 Clawiter Road, Hayward, California 94540, January 1, 1982
Gilson Brothers Company, P.O. Box 152, Plymouth, Wisconsin 53073, September 26, 1981
Gooch Brake & Equipment Company, 506 Grand Avenue, Kansas City, Missouri 64106, January 1, 1982
Granning Service Corporation, 3040 Wyoming Avenue, Dearborn, Michigan 48120, January 1, 1982
Gratiot Equipment Co., 1244 E. Center Street, P.O. Box 125, Ithaca, Michigan 48847, September 1, 1981
The Greyhound Corporation, Greyhound Tower, Phoenix, Arizona 85077 (doing business through) Motor Coach Industries, Inc., Pembina, North Dakota 58271, and Transportation Mfg. Corp., Roswell, New Mexico 88201, August 1, 1981
Grumman Flexible Corporation, 970 Pittsburgh Drive, Delaware, Ohio 43015, January 1, 1982
Grumman Olson Division, Grumman Allied Industries, 445 Broad Hollow Road, Melville, New York 11747, November 1, 1981
Hackney and Sons, 400 Hackney Avenue, P.O. Box 880, Washington, North Carolina 27889, January 1, 1982
Hackney & Sons (Midwest), Inc., West Laurel Street and Hackney Avenue, Independence, Kansas 67301, September 23, 1981
Hallenberger, Inc., 5716 Boonville Highway, P.O. Box 5085, Evansville, Indiana 47715, December 31, 1981
Harley-Davidson Motor Co., Inc., 3700 West Juneau Avenue, Milwaukee, Wisconsin 53201, April 1, 1982
Harris Truck and Trailer Sales, Incorporated, I–55 and Airport Exit, P.O. Box 619, Cape Girardeau, Missouri 63701, January 1, 1982
Heil Equipment Company of Philadelphia, Incorporated, 1223 Ridge Pike, Conshohocken, Pennsylvania 19428, January 1, 1982
Hendrickson Manufacturing Co., P.O. Box 249, Burr Ridge, Illinois 60521, January 1, 1982
The Hess & Eisenhardt Co., 8959 Blue Ash Road, Cincinnati, Ohio 45242, January 9, 1982
Hews Company, Inc., 190 Rumery Street, P.O. Box 2520, South Portland, Maine 04106, January 18, 1982
Hilbilt Mfg. Company, Division of Hill Equip. Co., Route 7, Box 5089, Benton, Arkansas 72015, January 1, 1982
Hutco of Oklahoma, 14001 East Admiral Place, Tulsa, Oklahoma 74116, January 1, 1982
IBEX Manufacturing, Inc., 2384 South Redwood Road, P.O. Box 25846, Salt Lake City, Utah 84125, August 1, 1981
Illinois Auto Central, Inc., 4750 S. Central Avenue, Chicago, Illinois 60638, October 1, 1981
International Harvester Co., 401 North Michigan Avenue, Chicago, Illinois 60611, January 18, 1982
Iroquois Mfg. Co., Inc., Richmond Road, Hinesburg, Vermont 05461 March 1, 1982
Isometrics, Inc., P.O. Box 660, 1402 N. Scales Street, Reidsville, North Carolina 27320, March 31, 1982
IVECO Trucks of North America, P.O. Box 1102, 1730 Walton Road, Blue Bell, Pennsylvania 19422, January 1, 1982
Jeep Corporation, 27777 Franklin Road, Southfield, Michigan 48034, January 1, 1982
Kaffenbarger Welding Company, 10100 Ballentine Pike, New Carlisle, Ohio 45344, January 1, 1982
Kawasaki Motors Corporation, 2009 E. Edinger Avenue, Santa Ana, California 92705, January 1, 1982
Kay Wheel Sales Co., Inc., 1771 Tomlinson Road, Philadelphia, Pennsylvania 19116, September 24, 1981
Kencar Equipment Company, 1906 Lakeview Avenue, Dayton, Ohio 45408–1398, January 1, 1982
Keystone Coach Manufacturing Co. of Florida, Inc., 501 Nova Road, P.O. Box 1055, Ormond Beach, Florida 32074, April 1, 1982
Leland Equipment Company, 5647 South 122 East Avenue, P.O. Box 45128, Tulsa, Oklahoma 74145, January 18, 1982
Loadcraft, Division of Allied Products Corporation, P.O. Box 431, Curtis Field, Brady, Texas 76825, November 1, 1981
Long Trailer Service, Inc., P.O. Box 5105, Greenville, South Carolina 29606, January 1, 1982
M & M Equipment, Inc., P.O. Box 152, Lebanon, New Hampshire 03766, March 14, 1982
Mack Trucks, Inc., P.O. Box M, Allentown, Pennsylvania 18105, January 1, 1982
Maday Body & Equipment Corp., 575 Howard Street, Buffalo, New York 14206, January 1, 1982
Madison Truck Equipment, Inc., 2410 South Stoughton Road, Madison, Wisconsin 53716, October 22, 1981
Manning Equipment, Inc., 12000 Westport Road, P.O. Box 23229, Louisville, Kentucky 40223, April 16, 1982
Marion Body Works, Inc., 211 W. Ramsdell Street, P.O. Box 500, Marion, WI. 54950–0500, January 1, 1982
Mark Body, Division Core Industries, P.O. Box 128, 50625 Richard W. Boulevard, Mt. Clemens, Michigan 48043–0128, March 31, 1982
Marmon Motor Co., P.O. Box 402009, Garland, Texas 75040, September 1, 1981
Maxon Industries, Inc., 5750 South Eastern Avenue, City of Commerce, California 90040, August 16, 1981
Meadows Hydraulics Sales and Service, Inc., U.S. 13 and S. Division St., Fruitland, Maryland 21826, September 23, 1981
Mercedes-Benz of North America, Inc., One Mercedes Drive, Montvale, New Jersey 07645, January 1, 1982
W.F. Mickey Body Co., Inc., P.O. Box 2044, 1505 Bethel Drive, High Point, North Carolina 27261, September 23, 1981
Mid West Truck Equipment Sales, Division of Electrographic Corp., 4041 No. Brush College Road, R.R. #7, Box 463F, Decatur, Illinois 62521, February 22, 1982
Middlekauff, Incorporated, 1615 Ketcham Avenue, Toledo, Ohio 43608, January 18, 1982
Mike & Joe Equipment Co., Inc., Rochester Road Equipment, Inc., 1240 Jefferson Road, Rochester, N.Y. 14623, June 1, 1981
Millington Truck Body Co., Inc., 8440 N. State Street, P.O. Box 281, Millington, Michigan 48746, December 1, 1981
Moline Body Company, 222 52nd Street, Moline, Illinois 61265, January 6, 1982
Moore and Sons, Inc., P.O. Box 30991, 2900 Airways Boulevard, Memphis, Tennessee 38130, December 31, 1981
Morgan Trailer Mfg. Co., t/a Morgan Corporation, Joanna Road, Box 258, Morgantown, Pennsylvania 19543, January 1, 1982
Motor Truck Equipment Corp., 2950 Irving Blvd., P.O. Box 47385, Dallas, Texas 75247, December 31, 1981
Multi Body & Hoist, 180 Varick Avenue, Brooklyn, N.Y. 11237, December 1, 1981
Nabors Trailer, Inc., P.O. Box 979, Mansfield, Louisiana 71052, January 1, 1982

Neil's Automotive Service, Inc., 167 E. Kalamazoo Avenue, Kalamazoo, Michigan 49007, January 1, 1982
Nelson Manufacturing Company, 6448 U.S. Route 224, R.R. #1, Ottawa, Ohio 45875, January 1, 1982
The Ness Company, Inc., P.O. Box 667, 270 N. Zarfoss Drive, York, Pennsylvania 17405, January 1, 1982
New Method Equipment Company, P.O. Box 4638, 707 27th Avenue, S.W., Cedar Rapids, Iowa 52404, December 31, 1981
Novi Manufacturing Company, 25701 Seeley Road, Novi, Michigan 48050, November 1, 1981
Ohio Truck Equipment, Inc., 4100 Rev Drive, Cincinnati, Ohio 45232, December 10, 1981
Omaha Standard, Inc., 2401 W. Broadway, Council Bluffs, Iowa 51501, January 1, 1982
Oshkosh Truck Corporation, 2307 Oregon Street, P.O. Box 2566, Oshkosh, Wisconsin 54903, January 18, 1982
Ottawa Truck Corporation, Gulf & Western Manufacturing Co., 415 East Dundee Street, Ottawa, Kansas 66067, December 10, 1981
Outboard Marine Corporation, 100 Sea Horse Drive, Waukegan, Illinois 60085, January 18 1982
PACCAR, Incorporated, d/b/a Kenworth Truck Company, Peterbilt Motors Company, P.O. Box 1518, Bellevue, Washington 98009, January 18, 1982
Palmer Spring Company, 355 Forest Avenue, Portland, Maine 04101, January 18, 1982
Peabody Galion, P.O. Box 607, 500 Sherman Street, Galion, Ohio 44833, October 31, 1981
Peerless Division, Lear Siegler, Incorporated, 18205 S. W. Boones Ferry Road, Tualatin, Oregon 97062 January 9, 1982
Perfection Equipment Company, P.O. Box 75540, 5100 West Reno, Oklahoma City, Oklahoma 73147, January 12, 1982
Petroleum Equipment and Supply Company, Inc., 34 Fulton Street, New Haven, Connecticut 06512, February 20, 1982
Phoenix Manufacturing, Inc., 375 West Union Street, Nanticoke, Pennsylvania 18634, February 20, 1982
Polaris Industries, Inc., 1225 North County Road 18, Minneapolis, Minnesota 55440, February 1, 1982
Power Brake Service & Equip. Co., Inc., 1022 Carnegie Avenue, Cleveland, Ohio 44115, December 31, 1981
Power Equipment Sales & Service, Inc., 2729 Agnes, P.O. Box 9156, Corpus Christi, TX 78403, June 1, 1981
Progress Industries, Inc., 400 East Progress Street, Arthur, Illinois 61911, October 1, 1981
PSI Mobile Products, Inc., 25 Eldridge, Mt. Clements, Michigan 48043, July 1, 1981
Quality Truck & Equipment Co., P.O. Box 102, I-55 Beltline and Mercer Avenue, Bloomington, Illinois 61701, November 15, 1981
R/S Truck Body Company, Inc., P.O. Box 420, Allen, Kentucky 41601, September 23, 1981
Recreative Industries, Inc., 60 Depot Street, Buffalo, Now York 14206, July 13, 1981
Rhode Island Petroleum Equipment, 464 Broadway, Pawtucket, R.I. 02860, July 31, 1981
Rowland Truck Equipment, Inc., 2900 N.W. 73rd Street, Miami, Florida 33147, November 19, 1980
Ryder Truck Rental, Inc., 4709 West 96th Street, P.O. Box 68490, Indianapolis, Indiana 46206, January 1, 1982
Scientific Brake and Equipment Co., P.O. Box 840, 314 W. Genesee Avenue, Saginaw, Michigan 48606, January 19, 1982
Sharpsville Steel Equip., Co., 6th & Main Streets, Sharpsville, Pennsylvania 16150, January 2, 1982
Shear Truck Mfg. Co., Inc., 2321 East Pioneer Drive, Irving, TX. 75601, October 20, 1981
Skillcraft Industries, Inc., 1270 Ogden Road, Venice, Florida 33595, September 1, 1981
Somerset Welding & Steel, Inc., P.O. Box 628, 773 S. Center Avenue, Somerset, Pennsylvania 15501, January 1, 1982
South Florida Engineers, Inc., 5911 E. Buffalo Avenue, P.O. Box 11927, Tampa, Florida 33680, July 2, 1981
Steffen, Incorporated, 623 West 7th Street, Sioux City, Iowa 51103, November 4, 1981
Taylor-Dunn Mfg. Company, 2114 West Ball Road, Anaheim, California 92804, October 3, 1981
Terex Corporation, State Route 91, Hudson, Ohio 44236, January 1, 1982
Thomas Built Buses, Inc., 1408 Courtesy Road, P.O. Box 2450, High Point, North Carolina 27261, March 1, 1982
Traffic Transport Engineering, Inc., 28900 Goddard Road, Romulus, Michigan 48174, July 1, 1981
Transport Equipment Company, 3400 6th Avenue, South, P.O. Box 3817, Seattle, Washington 98124, January 18, 1982
Triangle Fleet Service, 801 Coliseum Blvd. West, Fort Wayne, Indiana 46808, January 1, 1982
Truck Equipment, Inc., P.O. Box 3265, 1560 N.E. 44th Avenue, Des Moines, Iowa 50316, January 1, 1982
Truckers Equipment, Inc., P.O. Box 1086, 85 East Longfield Avenue, Mansfield, Ohio 44901, March 16, 1982
Truckers Equipment, Inc., 1501 N. Port Avenue, Corpus Christi, Texas 78408-0747, December 1, 1981
Truckers Equipment, Inc., 2022 N. 77 Sunshine Strip, Harlingen, Texas 78550, December 1, 1981
Truck Equipment, Inc., 680 Potts Avenue, Green Bay, Wisconsin 54304, January 1, 1982
Truck Equipment Service Company, 800 Oak Street, Lincoln, Nebraska 68521, January 1, 1982
Truck Parts and Equipment, Inc., 4501 West Esthner, Wichita, Kansas 67209, December 11, 1981
Twin Bay Industries, Inc., 8980 Cairn Highway, P.O. Box 37, Elk Rapids, Michigan 49629, April 30, 1981
Union City Body Company, Inc., 1015 West Pearl Street, Union City, Indiana 47390, September 1, 1981
Unit Rig & Equipment Co., 4110 S. 100th E. Avenue, Tulsa, Oklahoma 74145, January 1, 1982
Universal Go Tract of Georgia Ltd., 963 Industrial Park Drive, Marietta, Georgia 30062, June 1, 1981
Valley Truck and Equipment Company, Inc., P.O. Box 16, Trevett Road, Boston, New York 14025, October 15, 1981
Van Con, Incorporated, 123 Williams Street, Middlesex, New Jersey 08846, September 1, 1981
Volkswagen of America, Inc., 27621 Parkview Boulevard, Warren, Michigan 48092, October 11, 1981
Volvo White Truck Corporation, P.O. Box D-1, 1031 Summit Avenue, Greensboro, N.C. 27402, January 1, 1982
WABCO Construction & Mining Equipment, a Division of American Standard, Inc., 2300 N.E. Adams Street, P.O. Box 240, Peoria, Illinois 61639, February 1, 1982
Walter Equipment USA, Inc., Northeastern Industrial Park, P.O. Box 279, Guilderland Center, NY 12085, January 1, 1982
D. P. Way Corporation, 3822 W. Elm Street, P.O. Box 09336, Milwaukee, Wisconsin 53209, December 31, 1981
Wayne Corporation (an Indian Head Company), P.O. Box 1447, Industries Road, Richmond, Indiana 47374, October 31, 1981
Wayne Engineering Corporation, 2412 West 27th Street, Cedar Falls, Iowa 50613, October 31, 1981
Winnebago Industries, Inc., P.O. Box 152, Jct. Highways 9 and 69, Forest City, Iowa 50436, March 19, 1982
Wyman's, Incorporated, P.O. Box 541, Northfield Road, Montpelier, Vermont 05602, July 1, 1981

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International Trade Administration

Bicycle Speedometers From Japan; Final Results of Administrative Review of Antidumping Finding

AGENCY: International Trade Administration, Commerce.

ACTION: Notice of final results of administrative review of antidumping finding.

SUMMARY: On November 17, 1981, the Department of Commerce published the preliminary results of its administrative review of the antidumping finding on bicycle speedometers from Japan. This review covers 23 of the 25 known manufacturers, resellers and exporters of this merchandise to the United States and various time periods through October 31, 1981.

Interested parties were given an opportunity to submit oral or written comments, and a public hearing was conducted on January 12, 1982. Based on comments received, the Department has made adjustments to the margins for 14 firms. The margins in the preliminary results remain unchanged for all other firms.

EFFECTIVE DATE: July 2, 1982.

FOR FURTHER INFORMATION CONTACT: Betsy E. Stillman of David R. Chapman, Office of Compliance, International Trade Administration, U.S. Department of Commerce, Washington, D.C. (202-377-2923).

SUPPLEMENTARY INFORMATION

Background

On November 22, 1972, a dumping finding with respect to bicycle speedometers from Japan was published in the Federal Register as Treasury Decision 72–322 (37 FR 24826). On November 17, 1981, the Department of Commerce ("the Department") published in the Federal Register the preliminary results of its administrative review of the finding (46 FR 56486–88). The Department has now completed that administrative review.

Scope of the Review

Imports covered by this finding are shipments of bicycle speedometers including double gear hub drive and single gear hub drive speedometers used on exercisers. Such speedometers are currently classifiable under items 711.9300 and 711.9820 of the Tariff Schedules of the United States Anotated (TSUSA).

The preliminary results of review covered the 23 known firms engaged in the manufacture, sale, or export of bicycle speedometers for use on bicycles to the United States and various time periods from January 1, 1972 through October 31, 1980. While we have now concluded that the finding covers exerciser speedometers, we will examine sales of such speedometers in subsequent administrative reviews.

Analysis of Comments Received

Interested parties were invited to comment on our preliminary results. At the request of the petitioner, Stewart-Warner Corporation, and various respondents and importers, we held a hearing on January 12, 1982.

We received the following comments from the petitioner, Stewart-Warner.

(1) Comment

All speedometers suitable for use on exercisers, including double gear hub drive speedometers, are within the scope of the antidumping finding because such speedometers are of the class or kind of merchandise which the Treasury Department and the Tariff Commission investigated in 1972.

Position

In the notice of preliminary results of administrative review, we tentatively concluded that double gear hub drive speedometers are not within the scope of this antidumping finding, for the following reasons: (1) The finding was limited to "bicycle speedometers" classifiable under item 711.93 of the Tariff Schedules of the United States (TSUS), and (2) The U.S. Customs Service recently ruled that, because double gear hub drive speedometers are not chiefly used on bicycles, they are not classifiable as bicycle speedometers.

Subsequent to publication of our preliminary results, we received and considered comments from interested parties, physical exhibits, and the record of the Tariff Commission's original investigation of injury in this case. After further consideration of the issue, we have reached the final determination that double gear hub drive speedometers *are* included within the scope of the finding on bicycle speedometers.

Item 711.93 TSUS at the time of the fair value investigation covered single gear hub drive speedometers that were usable on both bicycles and exercisers. The Treasury Department's and the Tariff Commission's investigations both included single gear hub drive speedometers usable on both bicycles and exercisers. We conclude that the fair value investigation covered most, if not all, types of speedometers marketed at the time that were used on bicycles and exercisers.

Subsequent to the date of the finding, double gear hub drive speedometers were first developed and marketed. The differences in physical appearance, cost, and function between the double and single gear hub drive speedometers are minimal. Both types of speedometers are sold by wholesale distributors in kit form for use on either bicycles or exercisers. Both types are also sold to bicycle or exerciser original equipment manufacturers.

Merchandise of the same class or kind as single gear hub drive speedometers is included within this finding of dumping, regardless of its chief use and current classification. Accordingly, all bicycle speedometers suitable for use on exercisers, including double gear hub drive speedometers, are within the scope of the finding because such speedometers are of the class or kind of merchandise which the Treasury Department and the Tariff Commission investigated in 1972.

(2) Comment

The Department is required by statute to ascertain and verify the cost of production of bicycle speedometers sold by Sanyo Electric.

Position

The Department did not review or verify the cost of production for Sanyo in response to the petitioner's allegation. The Department received the petitioner's supporting documentation for the allegation too late to use in this administrative review, *i.e.*, after the hearing. The administrative burden on the Department to investigate, analyze, verify, and allow comment now on the possible existence of below cost sales would significantly delay the current administrative review. To be considered all allegations must be supported by some evidence and should have been submitted to the Department prior to the hearing. In future administrative reviews, such allegations and supporting documentation must be submitted prior to publication of the notice of preliminary results of review.

(3) Comment

The Department should reject all information regarding foreign market value submitted by Asahi in response to the Department's questionnaire as untimely and incomplete. The Department should instead use the best information otherwise available in making its final determination for Asahi in this review. The best information otherwise available is that based on another manufacturer's home market prices.

Position

The Department agrees that the responses by Asahi are incomplete or too late and will not consider them. Instead the Department is using the best information otherwise available.

Despite the Department's requests, Asahi omitted from its responses data which were critical to the Department's calculations for its notice of preliminary results of administrative review. Asahi submitted the requested information after the hearing. Consideration of Asahi's entirely new submission of data would have caused the Department to delay unduly the completion of this administrative review. Asahi's omissions from its responses to our questionnaires for this review have caused the Department to employ in the preliminary results an incorrect basis of calculation for foreign market value, that is, constructed value. The Department must, therefore, now resort to best information otherwise available.

As the Department concluded in the section 751 review of *Michelin X-Radial Steel Belted Tires from Canada* (46 FR 48737–41), the best information otherwise available is not the best information that a respondent is willing to produce. We scheduled verification of Asahi's constructed value data without knowing that the respondent had omitted significant and relevant facts from its responses which would have demonstrated, among other things, that Asahi had adequate home market sales. Therefore, the results of this verification are unacceptable.

Petitioner maintains that the best information otherwise available is

another firm's prices in the home market. The Department however believes that is is more reasonable to use as the best information otherwise available, for firms investigated at the fair value stage, the highest current rate for responding firms, since it is both higher than the most recent rate for Asahi and higher than its fair value rate. The highest current rate for responding firms is 26.44%

(4) Comment

The Department's adjustments to Sanyo's home market price for certain differences in circumstances of sale, *i.e.*, advertising, credit costs and inland freight, were not in accordance with law because there is no indication that any price differential is related to differences in these costs and because the expenses were not shown to be directly related to the sales under consideration.

Position

In making comparisons, the Department reduces the United States price and foreign market value to comparable terms. In its simplest form, the calculation compares ex-factory prices for sales to the U.S. and for sales to the home market. We made adjustments for advertising and credit costs in accordance with section 353.15(d) of the Commerce Regulations which states that reasonable allowances will be made for the *costs* to the seller of any differences in circumstances of sale. This regulation is consistent with section 773(a)(4) of the Tariff Act, which states that an allowance will be made for any price difference "wholly or partly" due to differences in circumstances of sale. We conclude that the differences in cost constitute a reasonable indication of the differences in price. Furthermore, the circumstances of sales adjustments were, when necessary, based on reasonable allocations of selling costs shown in product sales records of the narrowest corporate accounting unit. *See Brother Industries, Ltd., et al.* v. *United States*, 3 C.I.T. ——,Slip Op. 82–34 (April 30, 1982).

(5) Comment

The Department should have considered offers to sell in the home market before adopting third-country sales as a proxy for foregin market value in the case of Kaken Corporation.

Position

The Department knows of no *bona fide* offers for sale by Kaken Corporation in its home market and the petitioner has not provided any information regarding such offers. Therefore, we used third-country sales to establish foreign market value.

(6) Comment

The Department used the margins stated in Treasury master lists as best information available for deposit and assessment purposes. The petitioner contends that the Department should reevaluate the data underlying margins taken from previously issued Treasury master lists.

Position

As described in the Department's notice of final results for *Impression Fabric of Man-Made Fiber from Japan* (47 FR 17319–17321), as a general rule the Department presumes Treasury's master lists were correct.

(7) Comment

Sanyo excluded from its questionnaire responses most of its home market speedometer sales. The Department should require more complete information from Sanyo.

Position

Sanyo explained that the discrepancy arose because Sanyo reported sales of only those types of speedometers sold to the United States. The Department's questionnaire to manufacturers and sellers does request that total sales, both by quantity and by value, of similar as well as identifical merchandise be reported. Sanyo, however, did provide at our request and in a timely manner sufficient information to determine that the home market models chosen for comparison were the most similar, and that the quantity of these models sold in the home market was sufficient to establish that a viable home market existed for comparison to U.S. price.

(8) Comment

The Department should investigate the transshipment of Japanese bicycle speedometers through Canada to the U.S.

Position

The Department will investigate transshipments of Japanese bicycle speedometers through Canada should our records indicate that such transshipments are occurring. The Department's records do not indicate that such transshipments occurred during the period covered by this administrative review. The petitioner did not provide any information to the contrary for this period.

(9) Comment

The Department should monitor Japanese exports of bicycle and exerciser speedometers to the United States for possible diversion by manufacturers from trading companies with high estimated duty deposit rates to trading companies with no, or low, estimated duty deposit rates.

Position

The Department is aware of the potential for such diversion and believes that the section 751 review process provides adequate protection.

We received the following comments from Sanyo Electric.

(10) Comment

The petitioner has presented no evidence which would justify a cost of production inquiry as to Sanyo.

Position

See our position under Comment 2.

(11) Comment

Rather than compare Sanyo's sales to a large U.S. "mass merchandiser" with Sanyo's sales to dealers in the home market, the Department should compare Sanyo's U.S. sales to Sanyo's home market sales to its large distributor customer. This distributor customer buys Sanyo speedometers in quantities comparable to that of Sanyo's U.S. customer.

Position

The Department has reexamined its records and has determined that, in terms of function in the marketplace, both the home market dealers and Sanyo's large distributor customer are at a level of trade comparable to the U.S. "mass merchandiser" (retailer). Our calculation of foreign market value includes the sales to Sanyo's large distributor customer.

(12) Comment

The Department should not establish purchase price based on sales by Sanyo to trading companies since Sanyo had no definitive knowledge of the ultimate destination of the merchandise. The Department should use the F.O.B. Japan prices at which the trading companies sold to unrelated U.S. importers as a basis for purchase price.

Position

Records in the Department's possession indicate that Sanyo knew the destination of the merchandise when it sold to the trading companies. Therefore, the use of Sanyo's prices to

the trading companies conforms to section 772(b) of the Tariff Act.

(13) Comment

If the Department continues to adhere to its position that Sanyo's price to the trading companies should be the basis for calculating purchase price, the Department must ascertain the cost to the trading companies for all storage, transportation and repackaging costs incurred after purchase from Sanyo, and purchase prices must be increased by the amounts of such additional costs and expenses pursuant to section 772(d)(1)(A) of the Tariff Act.

Position

The Department maintains that the merchandise is packed, ready for shipment to the U.S., at the time of the sale to the trading companies. There is no indication that the trading companies added any charge for export packing. The Department would not allow addition for storage and transportation as described by Sanyo.

(14) Comment

Sanyo maintains that, since the Department calculated foreign market value on the basis of sales to distributors for comparison with Sanyo sales to trading companies, the Department incorrectly included sales to a bicycle manufacturer in its computation.

Position

Our aim was not to use sales to bicycle manufacturers in calculating foreign market value. We have rechecked our calculations and have eliminated any such sales.

(15) Comment

Sanyo claimed that the Department's use of packing costs on 1978 direct sales to the U.S. as best information available for a packing cost adjustment for 1976 sales to trading companies was improper. The Department should use as best information the packing cost information on the firm's 1977 sales to trading companies.

Position

The Department has decided that the best information available for the packing costs of home market and trading company sales prior to 1977 is actual data for sales which took place from 1977 through the end of the review period. We have calculated a weighted average packing cost for each market for the whole period and determined the relationship of that cost to the weighted average price in each market for the whole period. We then applied the ratio derived for each market to the actual unit price of each transaction in the U.S. and home market. We determined the derived difference in the packing costs between the two markets on each transaction and adjusted the foreign market value for these differences.

(16) Comment

The Department should include one specific 1979 home market sale in its calculation of foreign market value for Sanyo with respect to sales to a particular trading company.

Position

We agree and have adjusted our calculations accordingly.

We received the following comments from Asahi.

(17) Comment

Treasury, in its determination of sales at less than fair value, and the Tariff Commission, in its injury determination, did not include exerciser speedometers in their findings because: (1) the petitioner's original complaint and the Treasury fair value investigation referred only to bicycle speedometers; (2) at the time of the Treasury/Tariff Commission investigations, no exerciser speedometers were being produced in Japan for export to the United States; (3) none of the bicycle speedometers imported from Japan were marketed for use on exercisers. Furthermore, exerciser speedometers are not of the same class or kind of merchandise as bicycle speedometers under the Department's criteria.

Position

See our position under Comments 1 and 21.

(18) Comment

The Department's methodology in calculating constructed value and purchase price for Asahi is incorreot. Instead of using constructed value, the Department should accept new data submitted by Asahi after publication of the preliminary results notice which will eliminate the Department's need to use constructed value. With regard to purchase price, inland freight from Asahi to trading companies should not have been deducted.

Position

With regard to constructed value the Department considers the initial responses by Asahi to be incomplete and the new responses untimely and will not consider them. Instead the Department is using the best information otherwise available for cash deposit and assessment purposes. The best information otherwise available for Asahi is the highest current rate for responding firms. See our position under Comment 3. As for purchase price, deduction of inland freight is appropriate under section 772(d)(2)(A) of the Tariff Act.

(19) Comment

The petitioner has not presented any evidence to justify a cost of production investigation with respect to Asahi's bicycle speedometers. The Department's verification of Asahi's cost information rebuts petitioner's claim.

Position

See our position under Comment 3.

We received the following comments from various importers.

(20) Comment

Dorcy Cycle and Service Cycle Supply maintained that the Department's methodology for calculating constructed value for Asahi was incorrect. Furthermore, Dorcy maintained that petitioner's estimate of Japanese production costs was irrelevant in light of the Department's verification of Asahi's constructed value. Service Cycle argued, in addition, that the Department should make an upward adjustment to purchase price to account for defective merchandise.

Position

The Department does not intend to use any of the data regarding Asahi merchandise. The Department considers the initial information submitted by Asahi to be incomplete and the new responses untimely.

(21) Comment

Diversified Products argued that double gear hub drive speedometers classifiable under 711.98 TSUS were not included in the original antidumping investigation either by Treasury or the Tariff Commission. The petition, Treasury, and the Tariff Commission described the merchandise as classifiable under 711.93 TSUS. Only aftermarket/accessory type bicycle speedometers, not original equipment type speedometers, were the subject of the Tariff Commission investigation. Therefore, only those bicycle speedometers under 711.93 TSUS, which are attachable to bicycles or exercise machines, are subject to the finding. The Department cannot expand the scope of the original determination by now relying on the questionnaire of the Tariff Commission. Double gear hub drive speedometers used on exercisers are not

of the same class or kind as bicycle speedometers.

Position

See our position under Comment 1. The scope of the fair value investigation was defined to include all bicycle speedometers, not just those sold in the aftermarket. Therefore, the finding covered bicycle speedometers sold to original equipment manufacturers and aftermarket distributors.

(22) Comment

N.S. International argued that both double gear hub drive speedometers and single gear hub drive speedometers chiefly used with exercise cycles are not within the class or kind of merchandise included within the scope of the finding. N.S. International also argued that exerciser speedometers were not included in the original investigation because Treasury looked only at bicycle speedometers classifiable under 711.93 TSUS, not exerciser speedometers. Under the Antidumping Act of 1921 ("the 1921 Act"), the Tariff Commission could not expand the scope of Treasury's investigation.

Position

See our position under Comments 1 and 21. Even if we assume that, under the 1921 Act, Treasury had the exclusive responsibility for establishing the scope of the investigation, we maintain that the record of the Tariff Commission investigation properly reflected the scope of the investigation by Treasury.

Final results of the review

Based on our analysis of the comments received, we have changed the margins for 14 firms:

Manufacturer/exporter	Time period	Margin (percent)
A & A Japan Ltd. (mfr.—Kaken Corporation)	11/1/78–10/31/80	9.38
Royal Industries Limited (seller—Nihon Seiki Co., Ltd.) (mfr.—Asahi Keiki Seisakusho Co., Ltd.)	7/1/79–10/31/80	26.44
Yagami Corporation (mfr.—Asahi Keiki Seisakusho Co., Ltd.)	7/1/79–10/31/80	26.44
(mfr.—Taiyo Electric Co., Ltd.)[2]	1/1/72–5/31/73	7.0
	6/1/73–10/31/80	7.0
(seller—Sanyo Electric Company, Ltd.)	4/1/78–10/31/80	26.44
Ednar Inc.	1/1/75–10/31/80	[1]0.0
Shin-Ei Trading Co., Ltd.	1/1/75–10/31/80	[1]0.0
Hatsune Electric Industrial Co., Ltd.	1/1/75–10/31/80	[1]0.0
Honda Lock K.	2/1/79–10/31/80	[1]0.0
Kuwahara Co., Ltd.	8/1/79–10/31/80	[1]0.0
Maruka Machinery	4/1/78–10/31/80	[1]0.0
Sanyo Electric Trading Company, Ltd. (seller—Sanyo Electric Company, Ltd.)	4/1/78–10/31/80	5.76
Marui Ltd. (seller unknown)	2/1/77–10/31/80	26.44
(seller—Sanyo Electric Company, Ltd.)	6/1/78–10/31/80	24.16
Fujimoto Trading Co., Ltd. (seller—Sanyo Electric Company, Ltd.)	11/1/74–10/31/80	0.92
Toshoku, Ltd. (seller—Nicheboi Fuji Cycle Co., Ltd.) (seller—Sanyo Electric Company, Ltd.)	1/1/78–10/31/80	17.24
(seller—Sankyo International K.K.)	1/1/78–10/31/80	26.44
Inoue Trading Company (seller—Sanyo Electric Company, Ltd.)	7/1/76–10/31/80	15.18
Tokyo Pac Sales, Ltd.[2]	5/1/74–5/31/74	2.87
(seller—Sanyo Electric Company, Ltd.)	6/1/74–10/31/80	2.87
Sanyei Corporation (seller—Sankyo International K.K.)	1/1/75–10/31/80	26.44

[1] No shipments during period.
[2] Firm no longer exists.

The Department shall determine, and the U.S. Customs Service shall assess, antidumping duties on all appropriate entries with purchase dates during the periods of review. Individual differences between United States price and foreign market value may vary from the percentages stated above. The Department will separately issue appraisement instructions to the Customs Service.

Further, as provided by section 353.48(b) of the Commerce Regulations, a cash deposit of estimated antidumping duties based on the most recent of the margins calculated above shall be required on all shipments by these firms entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice. For any shipment from a new exporter not covered in this review, unrelated to any covered firm, a cash deposit shall be required at the highest rate for responding firms with shipments during the most recent period in which shipments occurred. These deposit requirements shall remain in effect until publication of the final results of the next administrative review. The Department intends to conduct the next administrative review by the end of November 1982. The Department encourages interested parties to review the public record and submit applications for protective orders, if desired, as early as possible during the next administrative review.

This administrative review and notice are in accordance with section 751(a)(1) of the Tariff Act (19 U.S.C. 1675(a)(1)) and section 353.53 of the Commerce Regulations (19 CFR 353.53).

Dated: June 28, 1982.

Judith Hippler Bello,

Deputy (for Policy) to the Deputy Assistant Secretary for Import Administration.

[FR Doc. 82-18076 Filed 7-1-82; 8:45 am]

BILLING CODE 3510-25-M

National Oceanic and Atmospheric Administration

National Marine Fisheries Service; Receipt of Application for Permit

Notice is hereby given that an Applicant has applied in due form for a Permit to take endangered species as authorized by the Endangered Species Act of 1973 (16 U.S.C. 1531–1543), the National Marine Fisheries Service regulations governing endangered fish and wildlife permits (50 CFR Parts 217–222).

1. Applicant:

a. Name: South Carolina Wildlife and Marine Resources Department (P307).

b. Address: P.O. Box 167, Columbia, South Carolina 29202.

2. Type of Permit: To enhance the propagation and survival.

3. Names and Number of Animals: Shortnose sturgeon (Acipenser brevirostrum), 1,200 per year.

4. Type of Take: The proposed research studies are to determine the occurrence, distribution, life history, and ecology of shortnose sturgeon in South Carolina. The research will involve the temporary maintenance of some adult specimens for propagation studies, tagging for population studies, radio tagging for distribution studies, and the collection of some specimens for biological data.

5. Location of Activity: All major lakes, river systems, and coastal areas of South Carolina.

6. Period of Activity: 5 years.

Written data or views, or requests for a public hearing on this application should be submitted to the Assistant Administrator for Fisheries, National Marine Fisheries Service, U.S. Department of Commerce, Washington, D.C. 20235, on or before August 2, 1982. Those individuals requesting a hearing should set forth the specific reasons why a hearing on this particular application would be appropriate. The holding of such hearing is at the discretion of the Assistant Administrator for Fisheries.

All statements and opinions contained in this application are summaries of those of the Applicant and do not necessarily reflect the views of the National Marine Fisheries Service.

Documents submitted in connection with the above application are available for review in the following offices:

Assistant Administrator for Fisheries, National Marine Fisheries Service, 300 Whitehaven Street, N.W., Washington, D.C.; and

Regional Director, National Marine Fisheries Service, Southeast Region,

9450 Koger Boulevard, St. Petersburg, Florida 33702.

Dated: June 28, 1982.

Richard B. Roe,

Acting Director, Office of Marine Mammals and Endangered Species, National Marine Fisheries Service.

[FR Doc. 82-18073 Filed 7-1-82; 8:45 am]

BILLING CODE 3510-22-M

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Adjusting the Import Restraint Level for Certain Cotton Apparel From Pakistan

June 29, 1982.

AGENCY: Committee for the Implementation of Textile Agreements.

ACTION: Adjusting the level of restraint established for cotton trousers in Category 347/348, produced or manufactured in Pakistan and exported during the twelve-month period which began on January 1, 1982, by the deduction of 6,017 dozen in overshipments from 1981 in Category 347. The adjusted level for 1982 will be 218,983 dozen.

(A detailed description of the textile categories in terms of T.S.U.S.A. numbers was published in the Federal Register on February 28, 1980 (45 FR 13172), as amended on April 23, 1980 (45 FR 27463), August 12, 1980 (45 FR 53506), December 24, 1980 (45 FR 85142), May 5, 1981 (46 FR 25121), October 5, 1981 (46 FR 48963), October 27, 1981 (46 FR 52409), February 9, 1982 (47 FR 5926), and May 13, 1982 (47 FR 20654)).

SUMMARY: Under the terms of the Bilateral Cotton Textile Agreement of March 9 and 11, 1982 between the Governments of the United States and Pakistan, the United States Government is adjusting the level of restraint for cotton textile products in Category 347/348 for 1982 to account for 1981 overshipments in Category 347 amounting to 6,017 dozen.

EFFECTIVE DATE: July 6, 1982.

FOR FURTHER INFORMATION CONTACT: Gordana Slijepcevic, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, Washington, D.C. 20230 (202/377-4212).

SUPPLEMENTARY INFORMATION: On March 26, 1982 there was published in the Federal Register (47 FR 13024) a letter dated March 22, 1982 from the Chairman of the Committee for the Implementation of Textile Agreements to the Commissioner of Customs which established levels of restraint for certain cotton textile products, including Category 347/348, produced or manufactured in Pakistan and exported during the twelve-month period which began on January 1, 1982. In the letter published below the Chairman of the Committee for the Implementation of Textile Agreements directs the Commissioner of Customs to reduce the level of restraint for Category 347/348 to 218,983 dozen.

Paul T. O'Day,

Chairman, Committee for the Implementation of Textile Agreements.

June 29, 1982.

Committee for the Implementation of Textile Agreements

Commissioner of Customs,
Department of the Treasury, Washington, D.C. 20229

Dear Mr. Commissioner: This letter amends, but does not cancel, the letter of March 22, 1981 which directed you to prohibit entry during the twleve-month period which began on January 1, 1982 and extends through December 31, 1982 of cotton textile products in certain specified categories, produced or manufactured in Pakistan.

Effective on July 6, 1982, the directive of March 22, 1981 is amended to reduce the level of restraint established for Category 347/348 to 218,983 dozen.[1]

The action taken with respect to the Government of Pakistan and with respect to imports of cotton textile products from Pakistan has been determined by the Committee for the Implementation of Textile Agreements to involve foreign affairs functions of the United States. Therefore, these directions to the Commissioner of Customs, which are necessary for the implementation of such actions, fall within the foreign affairs exception to the rule-making provisions of 5 U.S.C. 553. This letter will be published in the Federal Register.

Sincerely,

Paul T. O'Day,

Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 82-18074 Filed 7-1-82; 8:45 am]

BILLING CODE 3510-25-M

COMMODITY CREDIT CORPORATION

1982 Crop Price Support Rates—Flue Cured Tobacco

Correction

In FR Doc. 82-16558, published at page 26418, on Friday, June 18, 1982, make the following corrections:

1. On page 26419, in th second column, in the twentieth line "b¢fr" should be corrected to read "B6FR"; in the twenty-first line "B6FR" should be corrected to read "B4R".

2. Also on page 26419, in the third column, in the twelfth line "B5GK" should be corrected to read "B6GK"; in the thirteenth line "B6GG" should be corrected to read "B5GG".

BILLING CODE 1505-01-M

[1] The level of restraint has not been adjusted to account for any imports after December 31, 1981.

COMMODITY FUTURES TRADING COMMISSION

Proposed Collections of Information

In compliance with the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35), the Commodity Futures Trading Commission has submitted to the Office of Management and Budget for its review a series of proposed regulations that would expand the Commission's commodity options pilot program to include the trading of options on physical commodities. Interested members of the public may obtain a complete copy of these information collection proposals by contacting Joseph Salazar at (202) 254-9735. Persons wishing to comment on the Paperwork Reduction Act implications of these proposals are asked to send a copy of their comments to Mr. Salazar at the Commodity Futures Trading Commission, 2033 K Street, N.W., Washington, DC. 20581, and to the OMB Desk Officer for the agency, Robert Veeder, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, D.C. 20503.

Dated: June 28, 1982.

Jane K. Stucky,

Secretary of the Commission.

[FR Doc. 82-18015 Filed 7-1-82; 8:45 am]

BILLING CODE 6341-01-M

DEPARTMENT OF DEFENSE

Department of the Army

Army Science Board, 1982 Summer Study Group on Chemcial Warfare; Closed Meeting

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), announcement is made of the following Committee Meeting:

Name of the committee: Army Science Board (ASB).

Dates of meeting: Tuesday, 20 July 1982; Wednesday, 21 July 1982.

Times: 0830-1700 hours on 20 July (Closed); 0830-1600 hours on 21 July (Closed).

Place: The U.S. Army Nuclear and Chemical Agency, 7500 Backlick Road, Springfield, Virginia.

Agenda: The Army Science Board 1982 Summer Study Group on Chemcial Warfare will meet for a final coordination meeting and update on special topics and other Service RDTE programs prior to the writing session in August. This meeting will be closed to the public in accordance with Section 552b(c) of Title 5, U.S.C., specifically subparagraph (1) thereof, and Title 5, U.S.C. App. 1, subsection 10(d). The classified and nonclassified matters to be discussed are so inextricably intertwined so as to preclude opening any portion of the meeting. The ASB Administrative Officer, Helen M. Bowen, may be contacted for further information at (202) 695–3039 or 697–9703.

Helen M. Bowen,

Administrative Officer.

[FR Doc. 82–18060 Filed 7–1–82; 8:45 am]

BILLING CODE 3710–08–M

Army Science Board, Ad Hoc Subgroup on Robotics/Artificial Intelligence; Closed Meeting

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), announcement is made of the following Committee Meeting:

Name of the committee: Army Science Board (ASB)

Dates of meeting: Tuesday, 27 July 1982; Wednesday, 28 July 1982

Times: 0630–1700 hours on 27 July (Closed); 0830–1600 hours on 28 July (Closed)

Place: The BDM Corporation, 7915 Jones Branch Drive, McLean, Virginia

Agenda: The Army Science Board Ad Hoc Subgroup on Robotics/Artificial Intelligence will be meeting to review previous inputs, receive and present briefings, hold discussions, and do preliminary report writing on applications of this technology for the Army. This meeting will be closed to the public in accordance with Section 552b(c) of Title 5, U.S.C., specifically subparagraph (1) thereof, and Title 5, U.S.C. App. 1, subsection 10(d). The classified and nonclassified matters to be discussed are so inextricably intertwined so as to preclude opening any portion of the meeting. The ASB Administrative Officer, Helen M. Bowen, may be contacted for further information at (202) 695–3039 or 697–9703.

Helen M. Bowen,

Administrative Officer.

[FR Doc. 82–18061 Filed 7–1–82; 8:45 am]

BILLING CODE 3710–08–M

Army Science Board, Specialty Subgroup on Human Resources; Open Meeting

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (P.L. 92–463), announcement is made of the following Committee Meeting:

Name of the committee: Army Science Board (ASB)

Dates of meeting: Thursday, 29 July 1982; Friday, 30 July 1982

Times: 0630–1700 hours, 29 July (Open); 0830–1600 hours, 30 July (Open)

PLACE: The Pentagon, Conference Room 2E715B, Washington, D.C. 20310

AGENDA: The Army Science Board Specialty Subgroup on Human Resources will meet to receive briefings and hold discussions in that specific area of Army research, development, and acquisition with respect to the major issues, developments and opportunities. Among the briefers will be the Deputy Chief of Staff for Personnel and representatives from the U.S. Army Soldier Support Center. This meeting is open to the public. Any interested person may attend, appear before, or file statements with the committee at the time and in the manner permitted by the committee. In order to be able to accommodate prospective attendees, the Army Science Board Administrative Officer, Helen M. Bowen, must be notified no later than 26 July 1982. For further information call the ASB at (202) 695–3039 or 697–9703.

Helen M. Bowen,

Administrative Office.

[FR Doc. 82–18062 Filed 7–1–82; 8:45 am]

BILLING CODE 3710–08–M

Army Science Board, Ballastic Missile Defense Study Subgroup; Closed Meeting

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (P.L. 92–463), announcement is made of the following Committee Meeting:

Name of the committee: Army Science Board (ASB)

Date of meeting: Thursday, 29 July 1982

Time: 0830–1700 hours on 29 July (Closed)

Place: Denver, Colorado (Exact location to be determined.)

Agenda: The Army Science Board Subgroup conducting a study on Ballistic Missile Defense will meet to receive classified briefings, present progress briefings, and hold discussions of same. This meeting will be closed to the public in accordance with Section 552b(c) of Title 5, U.S.C., specifically subparagraph (1) thereof, and Title 5, U.S.C. App. 1, subsection 10(d). The classified and non-classified matters to be discussed are so inextricably interwined so as to preclude opening any portion of the meeting. The ASB Administrative Officer, Helen M. Bowen, may be contacted for further information at (202) 695–3039 or 697–9703.

Helen M. Bowen,

Administrative Officer.

[FR Doc. 82–18063 Filed 7–1–82; 8:45 am]

BILLING CODE 3710–08–M

Department of the Navy

Privacy Act of 1974; Amendments to Systems of Records

AGENCY: Department of the Navy, DOD.

ACTION: Amendments to Systems of Records.

SUMMARY: The U.S. Marine Corps proposes to amend 2 systems of records in its inventory of systems of records subject to the Privacy Act of 1974. The proposed changes to these systems notices are set forth below followed by the notices as amended.

DATE: The proposed action will be effective without further notice on August 2, 1982, unless comments are received which would result in a contrary determination.

ADDRESS: Send any comments to the system manager identified in the system notice.

FOR FURTHER INFORMATION CONTACT: Mrs. B. L. Thompson, Privacy Act Coordinator, Headquarters, U.S. Marine Corps, Washington, D.C. 20380, telephone: (202) 694–1452.

SUPPLEMENTARY INFORMATION: The U.S. Marine Corps systems notices for records systems subject to the Privacy Act of 1974 (5 U.S.C. 552a) Pub. L. 93–579 were published in the **Federal Register** as follows:

FR Doc. 81–897 (46 FR 6639) January 21, 1981

FR Doc. 82–674 (47 FR 2629) January 18, 1982

FR Doc. 82–2408 (47 FR 4328) January 29, 1982

FR Doc. 82–9405 (47 FR 14939) April 7, 1982

These changes do not require an altered system report as prescribed in 5 U.S.C. 552a(o).

M. S. Healy,

OSD Federal Register Liaison Officer, Department of Defense.

June 28, 1982.

Amendments

MFD00003

System name: Joint Uniform Military Pay System/Manpower Management System (JUMPS/MMS) (46 FR 6643) January 21, 1981

Changes:

Categories of records in the system: Beginning in line 10, delete the words "Federal Indemnity Compensation Act" and substitute the words "Federal Insurance Contributions Act." Add to end of paragraph the words "weight control/military appearance data."

Retention and disposal: In line 3, delete the words "6 months" and substitute "11 months."

MFD00005

System name: Retired Pay/Personnel System (RPPS) (47 FR 2629) January 18, 1982

Changes:

Categories of records in the system: In line 42, delete the words "Fiscal Year and Month" and substitute "Physical Exam (Year and Month)." Add following words to the end of the paragraph: "Premobilization Flag; Preassigned Monitored Command Code; Civil Reform Act of 1978 (PAYCAP)."

MFD00003

SYSTEM NAME:

Joint Uniform Military Pay System/ Manpower Management System (JUMPS/MMS)

* * * * *

CATEGORIES OF RECORDS IN THE SYSTEM:

File contains personnel and pay data which includes: Name, grade, SSN, date of birth, citizenship, marital status, home of record, dependents information, record of emergency data, enlistment contract or officer acceptance form identification, duty status, population group, sex, ethnic group, duty information, duty station/personnel assignment and unit information, security investigation, military pay record data such as information contained on the Leave and Earnings Statement which may include base pay/ allowances/allotments/bond authorization, health care coverage, special pay and bonus data, Federal and State Withholding/Income Tax Data, Federal Insurance Contributions Act Tax Withholding Data, Serviceman's Group Life Insurance Deductions, leave account, wage and tax summaries, separation document code, test scores/ information, language proficiency, military/civilian/off-duty education, training information, awards, combat tour information, aviation/pilot/flying time data, lineal precedence number, limited duty officer/warrant officer footnote, TAD data, power of attorney, moral code, conduct and proficiency marks, years in service, promotional data, weight control/military appearance data.

* * * * *

RETENTION AND DISPOSAL:

Magnetic records are maintained on all military personnel and certain civilians while they are in service or employed by the service and for a period of 11 months after separation. Paper and film records are maintained for a period of 10 years after the final transaction, then they are destroyed. End calendar and fiscal year "snapshots" of the MMS data base are maintained indefinitely in magnetic form at Headquarters, U.S. Marine Corps.

* * * * *

MFD00005

SYSTEM NAME:

Retired Pay/Personnel System (RPPS)

* * * * *

CATEGORIES OF RECORDS IN THE SYSTEM:

The RPPS automated system of records contains the following fields (data elements and data sets): Retired/ Retainer Date; Retainer Date; Pay Change; Information Status; Social Security Numbert (SSN) and Last, First, and Middle Initial (Key); Deletion Date; SSN; Retired Category Code; Member's Name; Pay Entry Base Date; Service for Pay; Active Service; Other Military Service Number (MSN); Prior MSN/ SSN/Key; Rank Code; Race Code; Sex Code; Disability Percent; Heroism Pay; Pay Table Code; Recomputation Age; Retirement Laws; Functional Account Number; Ranks; Birthdates; Pay Delete/ Suspense Code; Retired Serviceman's Family Protection Pay; Reserve Retirement Credit Points; Allotment Data; Withhlding Tax Data; Wage and Tax Summaries; Gross Pay; Taxable Pay; Withholding Tax; Dependency Indemnity Compensation; Pension Act of 1944 (Veterans Administration (VA) Wavier); Pension Act of 1964 (Dual Compensation GI); Retired Serviceman's Family Protection Plan; Survivor Benefit Plan; Social Security; Scheduled Collections; Net Pay; Special Handling Code (Check Delivery); Accumulated Summaries; Home Mailing Address; Check Mailing Address; Pay Distribution; Last Change Posted; Date Member Eligible to Retire; Date Arrived Continental United States Without Dependents; Primary Military Occupational Specialty; Districts; Highest Rank Held Satisfactorily; Service Prior to 1 July 1949; Service After 1 July 1949; Active Duty After Transfer to Fleet/Retired Rolls; Date Next Physical Exam (Year and Month); VA Disease Codes; Department of Defense Disease Codes; Nearest Hospital (See Table 9); Personnel Accounting Separation Designator; Earnings Statement Flag; Disability Pay; Change of Address Flag; Last Time Processed by Update-Extractor; SSN Validation; Remarks Area; One-Time Credit-Checkage; Scheduled Collection; Veterans Administration Claim Number; Tower Amendment Code; Premobilization Flag; Preassigned Monitored Command Code; Civil Service Reform Act of 1978 (PAYCAP).

[FR Doc. 82-18092 Filed 7-1-82; 8:45 am]

BILLING CODE 3810-C1-M

Office of the Secretary of Defense

Defense Intelligence Agency Advisory Committee; Closed Meeting

Pursuant to the provisions of Subsection (d) of Section 10 of Pub. L. 92-463, as amended by Section 5 of Pub. L. 94-409, notice is hereby given that a closed meeting of a Panel of the DIA Advisory Committee has been scheduled as follows: September 1, 1982, Wednesday, Plaza West, Rosslyn, Va.

The entire meeting, commencing at 0900 hours is devoted to the discussion of classified information as defind in Section 552b(c)(1), Title 5 of the U.S. Code and therefore will be closed to the public. Subject matter will be used in a special study on intelligence support to tactical commanders.

M. S. Healy,

OSD Federal Register Liaison Officer, Department of Defense.

June 28, 1982.

[FR Doc. 82-18001 Filed 7-1-82; 8:45 am]

BILLING CODE 3810-01-M

DEPARTMENT OF EDUCATION

National Advisory Council on Women's Educational Programs; Tentative Meeting

AGENCY: National Advisory Council on Women's Educational Programs.

ACTION: Notice of tentative meeting.

SUMMARY: This notice sets forth the schedule and proposed agenda of a meeting of the National Advisory Council on Women's Educational Programs, tentatively scheduled pending confirmation of the new appointees. This notice also describes the functions of the Council. Notice of this meeting is required under section 10(a)(2) of the Federal Advisory Committee Act. This document is intended to notify the general public of their opportunity to attend.

DATES: July 19, 1982, 9:00 a.m. to 4:00 p.m. and July 20, 1982, 9:00 a.m. to 5:00 p.m.

ADDRESS: The meeting will be held in the Council offices at 1832 M Street, N.W., Suite 821, Washington, D.C.

FOR FURTHER INFORMATION CONTACT: Kathleen Dauito, Administrative Officer, National Advisory Council on Women's Educational Programs, 1832 M Street

NW., Suite 821, Washington, D.C., 20036, (202) 653–5846.

SUPPLEMENTARY INFORMATION: The National Advisory Council on Women's Educational Programs is established pursuant to Pub. L. 95–561. The Council is mandated to (a) advise the Secretary on matters relating to equal education opportunities for women and policy matters relating to the administration of the Women's Educational Equity Act of 1978; (b) make recommendations to the Secretary with respect to the allocation of any funds pursuant to the Act, including criteria developed to insure an appropriate geographical distribution of approved programs and projects throughout the Nation; (c) recommend criteria for the establishment of program priorities; (d) make such reports as the Council determines appropriate to the President and Congress on the activities of the Council; and (e) disseminate information concerning the activities of the Council.

The National Advisory Council on Women's Educational Programs plans to meet from 9:00 a.m. to 4:00 p.m. on July 19, 1982, and from 9:00 a.m. to 5:00 p.m. on July 20, 1982 in the Council offices at 1832 M Street, N.W., Suite 821, Washington, D.C.

The proposed agenda for July 19, 1982 includes: general orientation information for new members; an overview of the Counctil's history, mandate, activities, and relationship to the Education Department and Congress; discussion of the economic and academic status of women today, with presentations by representatives of government agencies and the educational community.

On July 20, 1982, the agenda includes: the viewing of two films developed by projects funded under the Women's Educational Equity Act; discussions on Title IX, sexual harassment in academe, and adult women's educational needs; review of the Council's Policies and Procedures; election of Chair and Vice Chair; and plans for future meetings and activities.

The meeting of the Council will be open to the public. Records will be kept of the proceedings and will be available for public inspection at the office of the National Advisory Council on Women's Educational Programs, 1832 M Street, N.W., Suite 821, Washington, D.C., 20036.

Signed at Washington, D.C., on June 29, 1982.

Joy R. Simonson,

Executive Director.

[FR Doc. 82-18043 Filed 7-1-82; 8:45 am]

BILLING CODE 4000-01-M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER82-605-000]

Arkansas Power & Light Co.; Filing

June 28, 1982.

The filing Company submits the following:

Take notice that on June 17, 1982, Arkansas Power & Light Company (AP&L) tendered for filing a letter Agreement dated May 4, 1982 between AP&L and the City of Ruston, Louisiana (Ruston) for transmission service through the system of AP&L to the system of Louisiana Power & Light Company to permit a sale by Arkansas Electric Cooperative Corporation to Ruston of 27 MW capacity and associated energy.

AP&L requests an effective date of May 15, 1982, and therefore requests waiver of the Commission's notice requirements.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426, in accordance with Sections 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before July 14, 1982. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-18098 Filed 7-1-82; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. ER82-606-000]

Arkansas Power & Light Co.; Filing

June 28, 1982.

The filing Company submits the following:

Take notice that on June 17, 1982, Arkansas Power & Light Company (AP&L) tendered for filing a letter Agreement dated May 4, 1982 between AP&L and the City of Ruston, Louisiana (Ruston) for transmission service through the system of AP&L to the system of Louisiana Power & Light Company to permit a sale by Southwestern Power Administration to Ruston of 6 MW capacity and associated energy.

AP&L requests an effective date of July 1, 1982, and therefore requests waiver of the Commission's notice requirements.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426, in accordance with Sections 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before July 14, 1982. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-18097 Filed 7-1-82; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. EL79-20-000]

Buckeye Power, Inc. v. Cincinnati Gas & Electric Co.; Refund Report

June 28, 1982.

Take notice that on April 22, 1982, the Cincinnati Gas & Electric Company filed a refund report. Such report is made pursuant to the Commission's order issued on January 25, 1982.

Any person desiring to be heard or to protest this filing should file comments with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, on or before July 12, 1982. Comments will be considered by the Commission in determining the appropriate action to be taken. Copies of this filing are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-18099 Filed 7-1-82; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. ER82-603-000]

Cleveland Electric Illuminating Co.; Filing

June 28, 1982.

The filing company submits the following:

Take notice that on June 16, 1982, the Cleveland Electric Illuminating

Company (CEI) tendered for filing an executed Service Agreement and Exhibits A and B thereto, providing for transmission by CEI of approximately 50 MW of power from the 345-kv interconnection point on CEI's Juniper-Canton Line with the Ohio Power Company to the City of Cleveland, Ohio (City) in accordance with the terms and conditions of CEI's FERC Transmission Service Tariff.

CEI has requested waiver of the FERC's 60-day notice requirement in order to permit commencement of transmission service on June 1, 1982.

Any person desiring to be heard or to protest said application should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with §§ 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before July 14, 1982. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this application are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc 82-18100 Filed 7-1-82; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. RP82-111-000]

Commercial Pipeline Co., Inc.; Proposed Change in FERC Tariff

June 28, 1982.

Take notice that Commercial Pipeline Co., Inc. ("Commercial"), on June 22, 1982, tendered for filing proposed changes in its FERC Gas Tariff, Volume No. 1. Specifically, Commercial tendered for filing the following:

Thirty-Ninth Revised Sheet No. 3A Superseding Substitute Thirty-Eighth Revised Sheet No. 3A
Sixth Revised Sheet No. 7A Superseding Fifth Revised Sheet No. 7A
First Revised Sheet No. 7B Superseding Original Sheet No. 7B
Original Sheet No. 7C

The proposed changes revise the Purchased Gas Adjustment Clause ("PGA") of Commercial's FERC Gas Tariff to include the cost of company use and lost and unaccounted for gas. Commercial states that the effect of the proposed change is to calculate its PGA on the basis of the total sales methodology instead of the current total purchased volume method. Commercial requests that notice be waived to permit its filing herein to become effective June 23, 1982.

Copies of the filing were served on Commercial's FERC jurisdictional customers, the Kansas Corporation Commission and the Missouri Public Service Commission.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with sections 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8 and 1.10). All such petitions or protests should be filed on or before July 7, 1982. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

FR Doc. 82-18101 Filed 7-1-82; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. ER82-607-000]

Consolidated Edison Company of New York, Inc.; Filing

June 28, 1982.

The filing Company submits the following:

Take notice that on June 17, 1982, Consolidated Edison Company of New York, Inc. ("Con Edison") tendered for filing, as a supplement to a rate schedule an amendment to an exchange agreement with three companies of the Northeast Utilities system (the "NU Companies"): The Connecticut Light and Power Company, The Hartford Electric Light Company and Western Massachussetts Electric Company.

Con Edison states that the amendment makes only minor changes in Con Edison Rate Schedule FERC No. 48 (and by concurrence, The Connecticut Light and Power Company Rate Schedule FERC No. 175; The Hartford Electric Light Company Rate Schedule FERC No. 172; and Western Massachusetts Electric Company Rate Schedule FERC No. 148), as heretofore supplemented. Con Edison further states that the principal change brought about by the amendment would be the use of the most current Pumping-Generation Ratio used by the New England Power Exchange for the NU Companies' pumped storage project.

Con Edison requests an effective date of December 7, 1981, and therefore requests waiver of the Commission's notice requirements.

Con Edison states that a copy of its filing was served on the NU Companies.

Any person desiring to be heard or to protest said application should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with Sections 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before July 14, 1982. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-18102 Filed 7-1-82; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. ER82-604-000]

Florida Power & Light Co.; Filing

June 28, 1982.

The filing Company submits the following:

Take notice that Florida Power & Light Company (FPL), on June 16, 1982, tendered for filing document entitled Amendment Number Thirteen to Agreement to Provide Specified Transmission Service Between Flordia Power & Light Company and Fort Pierce Utilities Authority.

Amendment Number Thirteen updates the rates for transmission service provided by FPL, bringing them in accord with the increased rates filed by the Commission on July 1, 1981, in *Florida Power & Light Company* Docket No. ER81-588-000.

FPL requests that waiver of Section 35.3 of the Commission's Regulations be granted and that the proposed Amendment be made effective Immediately. FPL state that copies of the filing were served on the Director of Utilities, Fort Pierce Utilities Authority.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, DC 20426, in accordance with Section 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR

Section 1.8, 1.10). All such petitions or protest should be filed on or before July 14, 1982. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspect.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-18103 Filed 7-1-82; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. CP82-376-000]

Gas Company of New Mexico; Application

June 29, 1982.

Take notice that on June 15, 1982, Gas Company of New Mexico (Applicant), 1800 First International Building, Dallas, Texas 75270, filed in Docket No. CP82-376-000 an application pursuant to Section 7(c) of the Natural Gas Act and Sections 284.217 and 284.222 of the Commission's Regulations for authorization to transport natural gas for the account of Northwest Pipeline Corporation (Northwest), all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Applicant proposes to transport up to 10.5 billion Btu of natural gas per day for Northwest which gas would be part of an overall arrangement whereby natural gas would be transported to Phillips Pacific Chemical Company (Phillips Pacific), an agricultural end user. Phillips Pacific, it is asserted, would purchase natural gas from Southern Union Gathering Company (Gathering Company) at either the Kutz or Chaco delivery point in San Juan County, New Mexico. The gas sold at the Kutz delivery point, it is explained, would be delivered by Gathering Company into Applicant's pipeline system which would receive such gas for the account of Northwest and transport and redeliver such gas to Northwest in San Juan County, New Mexico. It is asserted that Northwest would then transport the gas to Phillips Pacific's Coulee plant.

Applicant states that if Northwest is unable to receive part or all of the deliveries from Applicant, Gathering Company would deliver and sell part or all of the volumes to Phillips Pacific at the Chaco delivery point. El Paso Natural Gas Company would then transport the volumes for the account of Northwest for redelivery of the volumes in La Plata County, Colorado. Applicant states that Northwest would thereafter transport the gas for ultimate delivery to Phillips Pacific's plant.

It is asserted that service would commence as soon as temporary authorization has been obtained and would continue for six months thereafter, and, possibly, for a longer period.

It is asserted that Applicant would charge a transportation rate equal to the approved rate contained in its Rate Schedule 61, on file with the New Mexico Public Service Commission.

Applicant asserts that it is unable to transport gas on a self-executing basis because Northwest would not hold title to the gas during transit nor would it be acquiring that gas for resale; rather, title to the gas would reside at all times with Phillips Pacific. It is further asserted that the subject gas would be used as feedstock and process fuel in the manufacture of fertilizer at the Coulee, Washington, plant; hence, would be classified as an essential agricultural use.

Any person desiring to be heard or to make any protest with reference to said application should on or before July 20, 1982, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's Rules.

Kenneth F. Plumb,

Secretary.

[FR Doc 82-18104 Filed 7-1-82 8:45 am]

BILLING CODE 6717-01-M

[Docket No. TA82-2-13-000]

Gas Gathering Corp.; Proposed PGA Rate Adjustment

June 25, 1982.

Take notice that on May 27, 1982, Gas Gathering Corporation (GGC) tendered for filing Thirteenth Revised Sheet No. 8 of 8, Supplement No. 24 to Rate Schedule No. 2, with an effective date of July 1, 1982. The filing amounts to a 35.68354¢ per Mcf in gas costs and a 26.48045 per Mcf reduction in the surcharge from 23.02676¢ to 3.45369¢ to amortize a credit balance of $31,040.70 in the defrerred purchased gas cost account.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426, in accordance with §§ 1.8 and 1.10 of the Commission's rules of practice and procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before July 2, 1982. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this file are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-18111 Filed 7-1-82; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. ER82-602-000]

The Hartford Electric Light Co.; Filing

June 28, 1982.

The filing Company submits the following:

Take notice that on June 16, 1982, The Hartford Electric Light Company (HELCO) tendered for filing as an initial rate schedule an agreement (the Exchange Agreement) between HELCO, The Connecticut Light and Power Company (CL&P), Western Massachusetts Electric Company (WMECO, and together with HELCO and CL&P, the NU Companies) and Fitchburg Gas and Electric Light Company (FG&E). The Exchange Agreement, dated as of October 10, 1981, provides for an exchange of excess capacity and associated energy from the Northeast Utilities system ("system power") for an equal amount of capacity from FG&E's gas turbine Unit No. 7 (the Exchange Unit). HELCO states that the timing of the exchanges cannot be accurately estimated but that the NU companies and FG&E enter into an exchange only when it was economic to do so.

FG&E will pay a capacity charge to the NU Companies for each exchange in an amount equal to the capacity exchange amount (expressed in kilowatts) for such exchange times $0.003 per kilowatt. FG&E will pay an energy charge to the NU Companies for each exchange in an amount equal to the kilowatthours provided by the NU Companies during such exchange times an energy charge rate. The energy

charge rate is based on the heat rate and the New England Power Exchange's replacement fuel price of the generating unit(s) which the NU Companies determine to be available to provide system power at the time of an exchange.

The NU Companies will pay FG&E an energy charge for each exchange in an amount equal to the kilowatthours provided by FG&E during such exchange times an energy charge rate. The energy charge rate is based on the heat rate and the New England Power Pool Exchange's replacement fuel price for the Exchange Unit. The NU Companies will pay a variable maintenance charge for each exchange equal to the product of the heat content of the fuel consumed (expressed in BTU's), the variable maintenance rate (expressed in $/BTU) and the NU Companies fractional entitlement in the Exchange Unit.

HELCO requests an effective date of October 10, 1981, and therefore requests waiver of the Commission's notice requirements.

Copies of this filing were mailed to CL&P, WMECO and FG&E

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426, in accordance with §§ 1.8 and 1.10 of the Commission's rules of practice and procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before July 13, 1982. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-18112 Filed 7-1-82; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. ER82-608-000]

Mississippi Power Co.; Filing

June 28, 1982.

The filing Company submits the following:

Take notice that on June 17, 1982, Mississippi Power Company (Mississippi) tendered for filing a Notice of Termination of the December 4, 1981, agreement effective May 30, 1982.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington D.C. 20426, in accordance with Sections 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before July 14, 1982. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protests parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

FR Doc. 82-18105 Filed 7-1-82; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. ER82-600-000]

New England Power Co., et al.; Filing

June 28, 1982.

The filing Company submits the following:

Take notice that New England Power Company (NEP), New England Electric Transmission Corporation (NEET), Vermont Electric Power Company (VELCO), and Vermont Electric Transmission Company (VETCO), on June 15, 1982, tendered for filing proposed new contracts which, when accepted, will permit the participating New England utilities to obtain access to and the benefits of hydroelectric energy from Hydro-Quebec. The filings are in furtherance of the interconnection of the facilities of the New England Power Pool (NEPOOL) with those of the Hydro-Quebec system by the construction of a high voltage direct current (dc) transmission line between a substation located in the vicinity of Sherbrooke, Quebec and a terminal facility at NEP's Comerford hydroelectric generation Station. Hydro-Quebec will construct and operate all facilities on the Canadian side of the border. In the United States the converter terminal facility will be constructed and operated by NEET, a wholly-owned subsidiary of the New England Electric System. The United States portion of the transmission line will be constructed either by NEET or by VETCO, a wholly-owned subsidiary of VELCO, depending upon whether the line is to be located in New Hampshire or in Vermont. Applications have been filed with state officials for the required state regulatory approvals and with the Economic Regulatory Administration of the Deparment of Energy which has jurisdiction over the required Presidential Permit.

The contracts filed with us for approval include: (1) Phase I Terminal Facility Support Agreement, as amended, between NEET and the participating New England Utilities; (2) Phase I New Hampshire Transmission Line Support Agreement between NEET and the participating New England Utilities; (3) Phase I Vermont Transmision Line Support Agreement, as amended, between VETCO and the participating New England Utilities; (4) Agreement with respect to Use of Quebec Interconnection, as amended, which sets forth the rights of the participating New England utilities to the benefits and savings associated with the Interconnection; (5) Agreements between VELCO and the participating Vermont utilities backing-up VELCO's obligations under the Line and Terminal Facility Support Agreements; (6) Agreement between VELCO and VETCO covering the operation of Vermont facilities; (7) Agreement between NEP and NEET providing for the lease of certain property and facilities; (8) Upper Development—Lower Development Transmission Line Support Agreement between NEP and NEET covering the operation of and support payments for the transmision facilities required by NEP to be performed by NEET.

The filing letter indicates that three agreements will be executed by Hydro-Quebec and the NEPOOL participants: an Interconnection Agreement, an Energy Banking Agreement and an Energy Contract. These agreements provide arrangements pursuant to which the participating New England utilities should be able to obtain surplus and pre-scheduled energy from Hydro-Quebec. In addition, they would allow the New England utilities to take advantage of the immense storage facilities available on the Hydro-Quebec system and thereby to transmit energy north for storage during NEPOOL's off-peak hours and receive energy back during on-peak hours. The filing indicates that the interconnection is cost justified even if the only benefits available to New England are as a result of energy banking. The pay-back period is accelerated if surplus energy is made available to the NEPOOL participants by Hydro-Quebec. In addition the filing indicates that the proposed arrangements will reduce significantly the present reliance of New England utilities on foreign oil, and would reduce as well the reserve margin required by the NEPOOL participants.

Copies of the filing were served on all affected utilities and on each of the six New England utility Commissions.

Any person desiring to be heard or to protest said applications should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with Section 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or befor July 20, 1982. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this application are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

FR Doc. 82-18106 Filed 7-1-82; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. ER82-599-000]

New England Power Pool; Filing

June 28, 1982.

The filing Company submits the following:

Take notice that on June 15, 1982, the New England Power Pool (NEPOOL) filed an Agreement Amending New England Power Pool Agreement (Amendment), dated as of December 1, 1981, which modifies the provisions of the New England Power Pool Agreement, dated as of September 1, 1971.

The NEPOOL Executive Committee states that NEPOOL participant utilities have entered into agreements covering the support and use of a proposed interconnection with Quebec. The Amendment revises Section 14.1 of the NEPOOL Agreement and adds a new Section 14.5 to the NEPOOL Agreement. These changes to the NEPOOL Agreement provide for administration of funds resulting from transactions over the proposed interconnection between Hydro-Quebec and NEPOOL participant utilities.

NEPOOL proposes that the Amendment become effective as of September 14, 1982, and has requested waiver of the Commission's customary notice rules to permit the Amendment to become effective more than on hundred and twenty days before service is first rendered over the planned interconnection facilities.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with Sections 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before July 20, 1982. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-18107 Filed 7-1-82; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. ER82-601-000]

Northern States Power Co.; Filing

June 28, 1982.

The filing Company submits the following:

Take notice that Northern States Power Company on June 16, 1982, tendered for filing Supplement No. 1, dated June 2, 1982, to the Interconnection and Interchange Agreement, dated June 23, 1978, with Interstate Power Company.

Supplement No. 1 amends the Interconnection and Interchange Agreement to add a second point of interconnection at New Prague, Minnesota.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protests with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with Sections 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before July 13, 1982. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-18108 Filed 7-1-82; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. CP82-365-000]

Northwest Pipeline Corp.; Application

June 29, 1982.

Take notice that on June 8, 1982, Northwest Pipeline Corporation (Applicant), P.O. Box 1526, Salt Lake City, Utah 84110, filed in Docket No. CP82-365-000 an application pursuant to Section 7 of the Natural Gas Act for a certificate of public convenience and necessity authorizing the construction and operation of certain natural gas facilities to expand an existing point of delivery for Cascade Natural Gas Corporation (Cascade) and the reallocation of natural gas service to Cascade and for permission and approval to abandon certain natural gas facilities presently utilized for the sale and delivery to Cascade, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

It is stated that by letter dated May 3, 1982, Cascade requested that Applicant increase the measuring and regulating capability of its Umatilla meter station facilities in Umatilla County, Oregon. It is further stated that Cascade informed Applicant that the modification of the existing delivery point would enable Cascade to provide firm natural gas service to an essential agricultural user located near Umatilla, Oregon, and that Cascade intends to provide proposed firm service by reallocating a portion of its currently authorized Rate Schedule ODL-1 service presently allocated to Longview-Kelso and environs to the proposed delivery point.

Specifically, Applicant proposes to construct and operate the following facilities:

(i) A metering and regulating station with appurtenances, to be designated the Umatilla meter station, located in Umatilla County, Oregon.

(ii) A 4-inch tap replacing the existing 2-inch tap on Northwest's 26-inch O.D. mainline located in Umatilla County, Oregon.

Applicant states that the maximum daily delivery obligation would be 5,444 Mcf of gas per day through the expanded Umatilla meter station.

It is stated that pursuant to a letter agreement dated May 3, 1982, Cascade has agreed to reimburse Applicant for all out-of-pocket costs incurred in constructing the proposed delivery point. The total cost of constructing the proposed facilities is estimated to be $139,450.

It is further stated that Cascade would install any additional downstream facilities necessary to effectuate the ultimate delivery of natural gas received

by Cascade through the Umatilla meter station.

Applicant also proposes to reallocate 55,000 therms equivalent from its existing Longview-Kelso and environs delivery point to the Umatilla meter station. The proposed reallocation of Applicant's maximum daily delivery obligation is as follows:

Delivery points	ODL-1 service agreement maximum daily delivery obligation (therms)	
	Presently effective	Proposed
Umatilla meter station	2,600	57,600
Longview-Kelso and environs	504,000	449,000
Total	506,600	506,600

Applicant states that the volumes of natural gas to be sold and delivered at the proposed meter station would be taken from volumes of natural gas which Applicant has heretofore been authorized to sell and deliver to Cascade under Applicant's existing Rate Schedule ODL-1 and that no increase in the daily contract quantity of natural gas which Applicant is authorized to sell and deliver to Cascade is proposed.

The facilities which Applicant hereby seeks permission and approval to abandon are specifically described as follows:

Umatilla Meter Station.

One positive displacement meter and 2-inch tap with the associated appurtenances located in Umatilla County, Oregon.

Any person desiring to be heard or to make any protest with reference to said application should on or before July 20, 1982, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to jurisdiction conferred upon the Federal Energy Regulatory Commission by Sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission or its designee on this application if no petition to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate and permission and approval for the proposed abandonment are required by the public convenience and necessity. If a petition for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Applicant to appear or be represented at the hearing.

Kenneth F. Plumb,

Secretary.

[FR Doc 82-18109 Filed 7-1-82; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. ER82-569-000]

Pacific Power & Light Co.; Filing

June 28, 1982.

The filing Company submits the following:

Take notice that Pacific Power & Light Company (Pacific) on June 2, 1982, tendered for filing, in accordance with Section 35.12 of the Commission 's Regulations, a Letter Agreement between Carbon Power & Light, Inc. (Carbon) and Pacific dated March 19, 1982 and executed by Carbon on April 21, 1982. The Letter Agreement provides for Pacific to provide Carbon with up to 3 MW of emergency service.

Pacific requests the rate schedule to become effective sixty days after the filing date.

Copies of the filing were supplied to Carbon.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with Sections 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before July 12, 1982. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-18110 Filed 7-1-82; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. CP81-438-002]

Texas Sea Rim Pipeline, Inc.; Amendment to Application

June 29, 1982.

Take notice that on May 28, 1982,[1] Texas Sea Rim Pipeline, Inc. (Applicant), P.O. Box 71, Conroe, Texas 77301, filed in Docket No. CP81-438-002 pursuant to Section 7(c) of the Natural Gas Act an amendment to its application filed November 25, 1981, in the instant docket so as to reflect removal of the volumetric limitation of 70,000 Mcf of natural gas per day which Applicant proposed to transport for Natural Gas Pipeline Company of America (Natural), all as more fully set forth in the amendment which is on file with the Commission and open to public inspection.

It is stated that Applicant proposed the transportation of up to 70,000 Mcf of natural gas per day from Outer Continental Shelf Block 9 and purchased by Natural. Applicant states that the volumes are delivered to Natural at the outlet side of field separation facilities located on The Superior Oil Company's existing Platform No. 2 in the Sabine Pass Area, offshore Texas, and then transported onshore through Applicant's existing point of interconnection in Jefferson County, Texas.

Applicant requests authority to transport any and all OCS Block 9 gas sold to Natural up to the maximum capacity of the 14-inch pipeline.

Applicant proposes a permanent rate for this additional transportation of 5.37 cents per Mcf.

Any person desiring to be heard or to make any protest with reference to said amendment should on or before July 20, 1982, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's rules of practice and procedure (18 CFR 1.8 or 1.10) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the

[1] The application was initially tendered for filing on May 28, 1982. However, the fee required by § 159.1 of the regulations under the Natural Gas Act (18 CFR 159.1) was not paid until June 3, 1982; thus, filing was not completed until the later date.

appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's Rules. All persons who have heretofore filed need not file again.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-18113 Filed 7-1-82; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. RP82-110-000]

Transcontinental Gas Pipe Line Corp.; Tariff Filing

June 28, 1982.

Take notice that Transcontinental Gas Pipe Line Corporation (Transco) on June 21, 1982 tendered for filing the following revised tariff sheets to the Purchased Gas Adjustment Clause (Section 22) contained in the General Terms and Conditions of Second Revised Volume No. 1 of its FERC Gas Tariff:

Fifth Revised Sheet No. 247
Third Revised Sheet No. 250
First Revised Sheet No. 250-A
Original Sheet No. 250-B

The revised tariff sheets are proposed to become effective on July 22, 1982.

Transco states that the purpose of this filing is to revise the procedure to reflect in Transco's rates any over or under recovered purchased gas costs pursuant to Section 22.5 of the PGA Clause, in order to reduce the fluctuations in recovery of the Deferred Account which exists under the method prescribed in the presently effective tariff. Transco proposes to change its procedure for determining the Deferred Adjustment by subdividing Account No. 191 so that the accumulated Unrecovered Purchased Gas Cost for each six month period and the amortization thereof through the Deferred Adjustment will be accounted for separately. Any balance, positive or negative, of Unrecovered Purchased Gas Costs remaining of the amortization will be transferred forward to the current accumulation period. In addition to this change, the method of determining carrying charges on Account No. 191 has been removed from the definition of Account (Section 22.3(h)) and placed in the section relating to the determination of the Deferred Adjustment (Section 22.5(a)).

Transco further states that copies of the instant filing have been sent to each of its customers and State Commissions.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protests with the Federal Energy Regulatory Commission, 825 North Capitol Street NE. Washington, D.C. 20426, in accordance with §§ 1.8 and 1.10 of the Commission's rules of practice and procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before July 7, 1982. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-18114 Filed 7-1-82; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. ER82-609-000]

Wisconsin Electric Power Co.; Filing

June 28, 1982.

The filing Company submits the following:

Take notice that Wisconsin Electric Power Company ("the Company") on *June 18, 1982,* tendered for filing executed service agreements with the City of Crystal Falls, Michigan ("Crystal Falls") and the City of Norway, Michigan ("Norway") to become effective May 14, 1982 and April 5, 1982 respectively.

The Company requests waiver of the Commission's 60-day notice requirement in order to allow the said effective dates.

Copies of this filing have been served on Crystal Falls, Norway and the Michigan Public Service Commission.

Any person desiring to be heard or to protest said application should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426, in accordance with §§ 1.8 and 1.10 of the Commission's rules of practice. All such protests should be filed on or before July 14, 1982. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of the application are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-18115 Filed 7-1-82; 8:45 am]

BILLING CODE 6717-01-M

Western Area Power Administration

Pick-Sloan Missouri Basin Program; Notice of a Rate Order

AGENCY: Western Area Power Administration, DOE.

ACTION: Notice of a rate order—Pick-Sloan Missouri Basin Program.

SUMMARY: Notice is given of Rate Order No. WAPA-12 of the Assistant Secretary for Conservation and Renewable Energy for placing increased power rates into effect on an interim basis for Pick-Sloan Missouri Basin Program (P-SMBP) power marketed by the Western Area Power Administration (Western).

The rate adjustment would increase average annual revenues from firm power sales in both the Eastern Division and the Western Division by a total of about $6 million to meet cost recovery criteria.

The proposed wholesale firm power rate for the Eastern Division of the P-SMBP consists of a capacity charge of $1.35 per kW-month plus a two step energy charge of 3.62 mills per kWh for all energy use up to and including that associated with a 60 percent monthly load factor and 7.00 mills per kWh for all additional energy use. This is expected to yield 5.80 mills per kWh, an increase of 0.65 mills per kWh over the 5.15 mills per kWh the existing rates were designed to yield. The Eastern Division peaking rate would also be increased to correspond with the proposed firm power capacity and energy rates. The charge for maintenance energy sales will be increased to 12 mills per kWh.

The proposed wholesale firm power rate for the Western Division consists of a capacity charge of $1.43 per kW-month plus 4.30 mills per kWh for energy associated with firms sales. This is expected to yield 7.20 mills per kWh, an increase of 0.65 mills per kWh over the 6.55 mills per kWh the existing rates were designed to yield. A new schedule for peaking power consistent with the firm power rate is proposed at $1.43 per kW-month with no energy being associated with the peaking service. In addition, a transmission service charge of 1.1 mills per kWh is proposed for both the Colorado River Storage Project and auxiliary wheeling over the Western Division transmission system.

The proposed wholesale composite firm power rate for both the Eastern and Western Divisions is expected to yield 6.10 mills per kWh, a 0.65 mills per kWh increase over the 5.45 mills per kWh the existing rate was designed to yield.

This rate order also contains discussion of the principal factors leading to the decisions on the rate increase and responses to the major comments, criticisms, and alternatives offered during the rate adjustment proceedings.

Effective date: The new rates would become effective on the first day of the first full billing period beginning on or after August 1, 1982.

FOR FURTHER INFORMATION CONTACT:

Mr. James D. Davies, Area Manager, Billings Area Office, Western Area Power Administration, P.O. Box EGY, Billings, MT 59101, (406) 657–6532

Mr. Conrad K. Miller, Chief, Rates and Statistics Branch, Western Area Power Administration, P.O. Box 3402, Golden, CO 80401, (303) 231–1535

Mr. James A. Braxdale, Office of Power Marketing Coordination, Mail Station 3344, Federal Building, 12th and Pennsylvania Avenue, NW., Washington, D.C. 20461, (202) 633–8338.

SUPPLEMENTARY INFORMATION: By Delegation Order No. 0204–33, effective January 1, 1979 (43 FR 60636, December 28, 1978), the Secretary of Energy delegated to the Assistant Secretary for Resource Applications the authority to develop power and transmission rates, acting by and through the Administrator, and to confirm, approve, and place in effect such rates on an interim basis. Department of Energy procedures for public participation in power and transmission rate adjustments issued on December 23, 1980 (45 FR 86976, December 31, 1980), were effective on December 31, 1980 with minor clarifying corrections on January 16, 1981 (46 FR 6864, January 22, 1981). The delegation order was amended effective March 19, 1981, and the procedures were further amended effective February 24, 1981 (46 FR 25426, May 7, 1981), in order to change all references from "Assistant Secretary for Resource Applications" to "Assistant Secretary for Conservation and Renewable Energy." The amendment was necessary as a result of the transfer on February 24, 1981, of the Office of Power Marketing Coordination and the power marketing administrations from the Assistant Secretary for Resource Applications to the Assistant Secretary for Conservation and Renewable Energy.

Proceedings on the proposed rate adjustment were initiated on December 29, 1981, with a mailing to all firm power customers and other interested persons of a draft customer brochure explaining the need for an increase and announcing a series of informal customer meetings. These meetings were conducted at four through January 21, 1982. At these preliminary meetings, Western's representatives explained the need for the increase and answered questions from interested persons.

On February 16, 1982, a 90-day customer consultation and comment period was initiated with an announcement of the proposed rate adjustment published in the Federal Register at 47 FR 6705. The February 16 notice also announced four public information forums conducted March 1 through March 4, 1982, and four public comment forums conducted April 5 through April 8, 1982. This announcement was later amended at 47 FR 10899 to add locations and telephone numbers where records could be examined. The information forums were further advertised with a February 16, 1982, press release and a February 18, 1982, customer mailing of a final customer brochure.

The comment forums were further advertised with a March 22, 1982, press release and customer mailing.

Public comments received have been considered in the preparation of this rate order.

Therefore, Rate Order No. WAPA–12 confirming and approving increased power rates on an interim basis is hereby issued, and the rates will be promptly submitted to the Federal Energy Regulatory Commission for confirmation and approval on a final basis.

Issued in Washington, D.C., June 28, 1982.

Joseph J. Tribble,

Assistant Secretary, Conservation and Renewable Energy.

[FR Doc. 82–18088 Filed 7–1–82; 8:45 am]

BILLING CODE 6450–01–M

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–2161–7]

Availability of Environmental Impact Statements Filed June 21 Through June 25, 1982 Pursuant to 40 CFR Part 1506.9

RESPONSIBLE AGENCY: Office of Federal Activities, General Information, 382–5075 or 382–5076.

Corps of Engineers:

EIS No. 820431, Final, COE, CA, North Bay Aqueduct Phase II, Construction, Permit, Solano County, Due: Aug. 2, 1982.

EIS No. 820424, Final, COE, LA, Deep Draft Access Improvements, New Orleans and Baton Rouge Ports, Due: Aug. 2, 1982.

EIS No. 820423, FSuppl, COE, PR, San Juan Harbor Navigational Improvements, Due: Aug. 2, 1982.

EIS No. 820414, Report, COE, MO, Stockton Lake, Sac River Downstream Flooding, Cedar County, Due: Aug. 2, 1982.

Department of Interior:

EIS No. 820422, Report, IBR, NB, Norden Dam, O'Neill Unit, Pick Sloan Missouri River Basin Program, Due: Aug. 27, 1982.

EIS No. 820425, Draft, BLM, CA, Clear Lake Resource Area, Wilderness Study, Napa, Lake and Yolo Cos. Due: Aug. 27, 1982.

EIS No. 820415, Draft, BLM, UT, Pinyon Planning Unit, Grazing Management Program, Due: Aug. 16, 1982.

Department of Transportation:

EIS No. 820428, Final, FHW, IL, US 51 Construction, Maroa to Bloomington, Macon and Dewitt Counties, Due: Aug. 2, 1982.

EIS No. 820417, Final, FHW, NB, NB–14 Improvements, Kansas/Nebraska Line, Superior, Nuckolls County, Due: Aug. 4, 1982.

EIS No. 820427, Final, FHW, NM, North-South Coors Boulevard and Coors Road Connection, Construction, Due: Aug. 2, 1982.

EIS No. 820416, Draft, CGD, FL, Garrison Channel Bridge Construction, Permit, Hillsborough County, Due: Aug. 16, 1982.

Environmental Protection Agency:

EIS No. 820429, Final, EPA, AR, Little Rock/Adams Field WWT Facilities, Grant, Pulaski County, Due: Aug. 2, 1982.

Department of Housing and Urban Development:

EIS No. 820419, Draft, HUD, CA, Canyon Lake Hills, Mortgage Insurance, Lake Elsinore, Riverside Co., Due: Aug. 16, 1982.

EIS No. 820426, Draft, HUD, CO, Grand Junction Areawide Study, Mesa County, Due: Aug. 16, 1982.

EIS No. 820430, Draft, HUD, IL, Butterfield Development, Mortgage Insurance, Aurora, DuPage County, Due: Aug. 16, 1982.

EIS No. 820420, Final, HUD, AL, Prattville East Development, Mortgage Insurance, Autauga County, Due: Aug. 2, 1982.

Nuclear Regulatory Commission:

EIS No. 820418, Final, NRC, KS, Wolf Creek Generating Station, Unit 1, License, Coffey County, Due: Aug. 2, 1982.

Department of Agriculture:

EIS No. 820413, Draft, SCS, NB, Wolf and Wildcat Creeks, Watershed Protection/Flood Prevention Plan, Due: Aug. 16, 1982.

EIS No. 820421, Final, SCS, TX, Pine Creek Watershed Protection/Flood Control Plan, Lamar County, Due: Aug. 2, 1982.

Amended Notices:

EIS No. 820341, Suppl, COE, CA, South Fork Flood Control Project, Santa Clara River, Los Angeles Co. *Published FR 06/04/82—Review extended, Due: July 30, 1982.

EIS No. 820378, Draft, BLM, UT, Ashley Creek Planning Area, Livestock Grazing Management Program *Published FR 06/18/82—Review extended, Due: Aug. 11, 1982.

EIS No. 820402, Draft, MMS, SEV, ATL 1983 OCS Oil/Gas Lease Sale #76 Offshore Mid-Atlantic States *Published FR 06/

25/82—Review extended. Due: Aug. 24, 1982.
EIS No. 820311, Final, USN, CA, fiscal year 1982–fiscal year 1986 Department of Defense Family Housing Project, San Diego Co. *Published FR 05/28/82—Review extended. Due: July 14, 1982.
EIS No. 820363, Draft, AFS, CA, Los Padres NF and Navajo Area Mineral Exploration Plan, Approval *Published FR 06/11/82—Officially withdrawn, Due:
Dated: June 29, 1982.

Paul C. Cahill,

Director, Office of Federal Activities.

[FR Doc. 82-18120 Filed 7-1-82; 8:45 am]

BILLING CODE 6560-50-M

[PF-276; PH-FRL 2160-4]

Certain Companies; Food and Feed Additive Petitions

AGENCIES: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA announces receipt of food and feed additive petitions proposing establishment of regulations permitting residues of certain pesticide chemicals in or on certain agricultural commodities.

ADDRESS: Written comments to: Franklin D. R. Gee, Product Manager (PM–17), Registration Division (TS–767C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

Written comments may be submitted while the petitions are pending before the agency. The comments are to be identified by the document control number "[PF–276]" and the specific petition number. All written comments filed in response to this notice will be available for public inspection in the product manager's office from 8:00 a.m. to 4:00 p.m., Monday through Friday, except legal holidays.

FOR FURTHER INFORMATION CONTACT: Franklin D. R. Gee, (703–557–2690).

SUPPLEMENTARY INFORMATION: EPA gives notice that the following food and feed additive petitions have been submitted to the Agency requesting establishment of regulations for pesticide chemicals in or on certain agricultural commodities in accordance with the Federal Food, Drug, and Cosmetic Act.

FAP 1H5312. Zoecon Corp., 975 California Ave., Palo Alto, CA 94304. Proposes amending 21 CFR Part 193 by establishing a regulation permitting residues of the insecticide insect growth regulator methoprene (isopropyl (*E,E*)-11-methoxy-3,7,11-trimethyl-2,4-dodecadienoate) in or on the commodities dried apples, dried apricots, dried peaches, dried prunes, raisins, wheat flour, macaroni (wheat), rice cereal, rye cereal, barley cereal, wheat cereal, corn cereal, corn meal, grits, hominy, oat cereal, spices, and dry dog food at 10.0 parts per million (ppm) in connection with an experimental use program.

FAP 1H5304. Zoecon Corp. Proposes amending 21 CFR Part 193 by establishing a regulation permitting residues of the insecticide *N*-[2-chloro-4-(trifluoromethyl)phenyl]-*D*-valine(+)-alpha-cyano(3-phenoxyphenyl)methyl ester in or on the commodity cottonseed oil at 1.0 ppm in connection with an experimental use program.

FAP 1H5304. Zoecon Corp. Proposes amending 21 CFR Part 561 by establishing a regulation permitting residues of the insecticide *N*-[2-chloro-4-(trifluoromethyl)phenyl]-*D*-valine(+)-alpha-cyano(3-phenoxyphenyl)methyl ester in or on the commodity cottonseed hulls at 0.3 ppm in connection with an experimental use program.

FAP 2H5338. Ciba-Geigy Corp., Agricultural Division, Greensboro, NC 27409. Proposes amending 21 CFR Part 561 by establishing a regulation permitting residues of the insecticide *N*-cyclopyl-1,3,5-triazine-2,4,6-triamine in or on the commodity poultry feeds at 5.0 ppm in connection with an experimental use program.

(Sec. 409(b)(5), 72 Stat. 1786, (21 U.S.C. 348))

Dated: June 22, 1982.

Douglas D. Campt,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 82-18007 Filed 7-1-82; 8:45 am]

BILLING CODE 6560-50-M

[OPTS-51420; TSH-FRL 2160-6]

Certain Chemicals; Premanufacture Notices

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Section 5(a)(1) of the Toxic Substances Control Act (TSCA) requires any person who intends to manufacture or import a new chemical substance to submit a premanufacture notice (PMN) to EPA at least 90 days before manufacture or import commences. Statutory requirements for section 5(a)(1) premanufacture notices are discussed in EPA statements of interim policy published in the **Federal Register** of May 15, 1979 (44 FR 28558) and November 7, 1980 (45 FR 74378). This notice announces receipt of seventeen PMNs and provides a summary of each.

DATES: Close of Review Period:

PMN 82–446, 82–447, and 82–448, September 16, 1982.
PMN 82–449, 82–450, 82–451, 82–452, and 82–453, September 19, 1982.
PMN 82–454, 82–455, 82–456, 82–457, 82–458, and 82–459, September 20, 1982.
PMN 82–460, September 21, 1982.
PMN 82–461 and 82–462, September 22, 1982.

Written comments by:

PMN 82–446, 82–447, and 82–448, August 17, 1982.
PMN 82–449, 82–450, 82–451, 82–452, and 82–453, August 20, 1982.
PMN 82–454, 82–455, 82–456, 82–457, 82–458, and 82–459, August 21, 1982.
PMN 82–460, August 22, 1982.
PMN 82–461 and 82–462, August 23, 1982.

ADDRESS: Written comments, identified by the document control number "[OPTS–51420]" and the specific PMN number should be sent to: Document Control Officer (TS–793), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Rm. E–409, 401 M St., SW., Washington, DC 20460, (202–382–3532).

FOR FURTHER INFORMATION CONTACT: David Dull, Acting Chief, Notice Review Branch, Chemical Control Division (TS–794), Office of Toxic Substances, Environmental Protection Agency, Rm. E–216, 401 M St., SW., Washington, DC 20460, (202–382–3729).

SUPPLEMENTARY INFORMATION: The following notice contains information extracted from the non-confidential version of the submission provided by the manufacturer on the PMNs received by EPA. The complete non-confidential document is available in the public reading room E–107.

PMN 82–446

Manufacturer. Confidential.

Chemical. (G) Substituted imidazolidinone.

Use/Production. Confidential. Prod. range: Confidential.

Toxicity Data. No data submitted.

Exposure. Manufacture, processing, use and disposal: dermal, a total of 20 workers, up to 1 hr/da, up to 250 da/yr.

Environmental Release/Disposal. 1,000–10,000 kg/yr released to land. Disposal by publicly owned treatment works (POTW) and approved landfill.

PMN 82–447

Manufacturer. Confidential.

Chemical. (G) Substituted imidazolidinone.

Use/Production. Confidential. Prod. range: Confidential.

Toxicity Data. No data submitted.

Exposure. Manufacture, processing, use and disposal: dermal, a total of 20 workers, up to 1 hr/da, up to 250 da/yr.
Environmental Release/Disposal. 1,000–10,000 kg/yr released to land. Disposal by POTW and approved landfill.

PMN 82–448

Importer. Confidential.
Chemical. (G) A reaction of phenylenebis [[[(butane derivative)-substituted]-phenyl]azo], compound with organic acids.
Use/Import. (S) Industrial colorant for paper. Import range: Confidential.
Toxicity Data. No data submitted.
Exposure. Negligible.
Environmental Release/Disposal. No release.

PMN 82–449

Manufacturer. The Upjohn Company.
Chemical. (S) 1-cyclohexen-1-amine, N,N-dibutyl.
Use/Production. (G) Intermediate chemical. Prod. range: Confidential.
Toxicity Data. No data submitted.
Exposure. Manufacture, processing, use and disposal: dermal and inhalation, a total of 12 workers, up to 8 hrs/da, up to 200 da/yr.
Environmental Release/Disposal. Less than 10 kg/yr released to water 8 hrs/da, 50 da/yr. Disposal by POTW, landfill and solidification.

PMN 82–450

Manufacturer. Confidential.
Chemical. (G) Amino alkyl alkoxy silanes.
Use/Production. (S) Additive in industrial maintenance and construction formulations. Prod. range: Confidential.
Toxicity Data. Acute oral: >16 ml/kg; Acute dermal: 16.0 ml/kg; Skin irritation: Moderate; Eye irritation: Severe; Inhalation: No deaths; Ames Test: Negative; COD: 2.0 mg/mg; BOD day 5: 32%.
Exposure. Manufacture and processing: dermal, inhalation and eye, a total of 20 workers, up to 3 hrs/da, up to 23 da/yr.
Environmental Release/Disposal. No release. Disposal by approved landfill.

PMN 82–451

Importer. Sandoz Colors and Chemicals Company.
Chemical. (G) Metal complexed disazo compound.
Use/Import. (S) Industrial textile fiber colorant. Import range: Confidential.
Toxicity Data. Acute oral: >5,000 mg/kg; Skin irritation: Non-irritant; Eye irrritation: Moderate irritant.
Exposure. Use: dermal and inhalation, 1 worker, 1 hr/da.
Environmental Release/Disposal. 10–100 kg/yr released to water 1 hr/da. Disposal by POTW and on site biological waste treatment.

PMN 82–452

Manufacturer. Confidential.
Chemical. (G) Benzoxazole oxazolidinone.
Use/Production. (G) Dye. Prod. range: Confidential.
Toxicity Data. Confidential.
Exposure. Manufacture and processing: dermal and inhalation, a total of 5 workers, up to 0–1 μgm/da, up to 365 da/yr.
Environmental Release/Disposal. 0–50 gms released to water.

PMN 82–453

Manufacturer. Confidential.
Chemical. (G) Benzoxazolium salt.
Use/Production. (G) Dye. Prod. range: Confidential.
Toxicity Data. Confidential.
Exposure. Confidential.
Environmental Release/Disposal. No release.

PMN 82–454

Manufacturer. Confidential.
Chemical. (G) Saturated polyester resin.
Use/Production. Confidential. Prod. range: Confidential.
Toxicity Data. No data submitted.
Exposure. Manufacture, processing and use: dermal, a total of 6 workers, up to 24 hrs/da, up to 250 da/yr.
Environmental Release/Disposal. Less than 10 kg/yr released to air. Disposal by incineration.

PMN 82–455

Manufacturer. Confidential.
Chemical. (G) Polyhaloalkoxyarylamide.
Use/Production. (S) Site-limited intermediate. Prod. range: Confidential.
Toxicity Data. Acute oral: >500 mg/kg; Acute dermal: > 500 mg/kg; Eye irritation: Slight irritant; Inhalation: >1.42 mg/L.
Exposure. Manufacture and processing: dermal and inhalation, a total of 2 workers, up to 24 hrs/da, up to 10 da/yr.
Environmental Release/Disposal. Negligible. Disposal by incineration.

PMN 82–456

Manufacturer. Uniroyal Chemical Company.
Chemical. (G) Isocyanate terminated polyether polyurethane prepolymer.
Use/Production. (S) Molded good applications. Prod. range: Confidential.
Toxicity Data. No data submitted.
Exposure. Manufacture and processing: 4 workers.
Environmental Release/Disposal. No release. Disposal by approved landfill.

PMN 82–457

Manufacturer. Confidential.
Chemical. (G) Alkyd derivative from fatty acids, substituted alkanoic acids, a carbomonocyclic anhydride, polyols and esters.
Use/Production. (G) Open use. Prod. range: 50,000–600,000 kg/yr.
Toxicity Data. No data submitted.
Exposure. Manufacture, processing and use: dermal and eye, a total of 142 workers, up to 6 hrs/da, up to 240 da/yr.
Environmental Release/Disposal. Less than 10 kg/yr released to air and water with 10–10,000 kg/yr to land. Disposal by incineration, landfill and sold as fuel.

PMN 82–458

Manufacturer. Confidential.
Chemical. (G) Polymer of a vegetable oil derivative, alkane diols and a carbomonocyclic anhydride.
Use/Production. (G) Open use. Prod. range: 30,000–450,000 kg/yr.
Toxicity Data. No data submitted.
Exposure. Manufacture, processing and use: dermal, a total of 111 workers, up to 6 hrs/da, up to 69 da/yr.
Environmental Release/Disposal. Less than 10 kg/yr released to air and water with 10–10,000 kg/yr to land. Disposal by incineration and landfill.

PMN 82–459

Manufacturer. Dow Corning Corporation.
Chemical. (G) Silicon substituted organic ester.
Use/Production. (G) Chemical intermediate. Prod. range: Confidential.
Toxicity Data. Acute oral: >5,000 mg/kg; Acute dermal: >2,000 mg/kg; Skin irritation: Non-irritant; Eye irritation: Non-irritant; E. Coli Assay: Non-mutagenic; Ames Test: Non-mutagenic; Fish 96 hr: >100 parts per million (ppm); Daphnia 48 hr: >100 ppm.
Exposure. Manufacture: 1 worker, 1 hr/da, 5 da/yr.
Environmental Release/Disposal. No release.

PMN 82–460

Manufacturer. Confidential.
Chemical. (G) Dialkyl amide of an alkenedioic acid.
Use/Production. (G) Open use. Prod. range: 20,000–200,000 kg/yr.
Toxicity Data. Acute oral: >5 g/kg; Skin irritation: Negative; Eye irritation: Positive.
Exposure. Manufacture, processing and use: dermal and inhalation, a total

of 10 workers, up to 8 hrs/da, up to 260 da/yr.

Environmental Release/Disposal. Release to water. Disposal by POTW.

PMN 82-461

Manufacturer. Confidential.

Chemical. (G) Diacyl peroxide.

Use/Production. (S) Polymerization initiator. Prod. range: Confidential.

Toxicity Data. Confidential.

Exposure. Processing (User): Dermal and inhalation.

Environmental Release/Disposal. No release.

PMN 82-462

Manufacturer. Confidential.

Chemical. (G) Trisubstituted benzoxazole.

Use/Production. (G) Site-limited intermediate. Prod. range: 60,000 kg/yr.

Toxicity Data. Acute oral: >3,000 mg/kg; Acute dermal: >1,000 mg/kg; Skin irritation: Slight; Eye irritation: Slight.

Exposure. Manufacture and use: minimal dermal and inhalation, a total of 80 workers, up to 2 hrs/da, up to 10 da/yr.

Environmental Release/Disposal. No release.

Dated: June 28, 1982.

Woodson W. Bercaw,

Acting Director, Management Support Division.

[FR Doc. 82-17764 Filed 7-1-82; 8:45 am]

BILLING CODE 6560-50-M

[OPTS-59093; TSH-FRL 2160-7]

Certain Chemicals; Premanufacture Exemption Applications

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA may upon application exempt any person from the premanufacturing notification requirements of section 5 (a) or (b) of the Toxic Substances Control Act (TSCA) to permit the person to manufacture or process a chemical for test marketing purposes under section 5(h)(1) of TSCA. Requirements for test marketing exemption (TME) applications, which must either be approved or denied within 45 days of receipt, are discussed in EPA's revised statement of interim policy published in the **Federal Register** of November 7, 1980 (45 FR 74378). This notice, issued under section 5(h)(6) of TSCA, announces receipt of two applications for exemptions, provides a summary, and requests comments on the appropriateness of granting each of the exemptions.

DATE: Written comments by July 19, 1982.

ADDRESS: Written comments, identified by the document control number "[OPTS-59093]" and the specific TME number should be sent to: Document Control Officer (TS-793), Office of Pesticides and Toxic Substances, Management Support Division, Environmental Protection Agency, Rm. E-401, 401 M Street, SW., Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: David Dull, Acting Chief, Notice Review Branch, Chemical Control Division (TS-794), Office of Toxic Substances, Environmental Protection Agency, Rm. E-216, 401 M Street, SW, Washington, DC 20460.

SUPPLEMENTARY INFORMATION: The following notice contains information extracted from the non-confidential version of the submission provided by the manufacturer on the TME received by EPA. The complete non-confidential document is available in the public reading room E-107.

TME 82-28

Close of Review Period. August 7, 1982.

Manufacturer. Confidential.

Chemical. (G) Modified acrylate ester.

Use/Production. (G) Specialty ink. Prod. range: 5,000 lbs for 1 yr.

Toxicity Data. No data submitted.

Exposure. 3 or 4 workers may have dermal exposure during processing and up to 6 may have dermal exposure during formulation.

Environmental Release/Disposal. No release.

TME 82-29

Close of Review Period. August 7, 1982.

Manufacturer. Confidential.

Chemical. (G) Modified acrylate ester.

Use/Production. (G) Specialty ink. Prod. range: 5,000 lbs for 1 yr.

Toxicity Data. No data submitted.

Exposure. 3 or 4 workers may have dermal exposure during processing and up to 6 may have dermal exposure during formulation.

Environmental Release/Disposal. No release.

Dated: June 28, 1982.

Woodson W. Bercaw,

Acting Director, Management Support Division.

[FR Doc. 82-17763 Filed 7-1-82; 8:45 am]

BILLING CODE 6560-50-M

[WH-FRL 2161-4]

State of Iowa; Water Programs: Determination of Primary Enforcement Responsibility

This public notice is issued pursuant to section 1413 of the Safe Drinking Water Act, as amended (42 U.S.C. 300f *et seq.*), and 40 CFR 142.10, published at 41 FR 2918 (January 20, 1976).

An application dated May 24, 1982, was received from the Executive Director of the Iowa Department of Environmental Quality, requesting that the State of Iowa be granted primary enforcement responsibility for public water systems in the State of Iowa, in accordance with the provisions of the Safe Drinking Water Act.

I have determined that the State of Iowa currently meets the conditions of the Safe Drinking Water Act and regulations for the assumption of primary enforcement responsibility for public water systems in the State of Iowa. The State—

1. Has adopted drinking water regulations which are no less stringent than the National Interim Primary Drinking Water Regulations;

2. Has adopted and will implement adequate procedures for the enforcement of such State regulations; including adequate monitoring and inspections;

3. Will keep such records and make such reports as required;

4. If it permits variances or exemptions from the requirements of its regulations, will issue such variances and exemptions in accordance with the provisions of the National Primary Drinking Water Regulations;

5. Has adopted and can implement an adequate plan for the provision of safe drinking water under emergency conditions.

While the State currently meets the requirements for primary enforcement responsibility, the Iowa General Assembly in May 1982, enacted a new law that amends the definition of "public water supply system" in the Iowa Department of Environmental Quality Act. The Act currently defines "public water supply system" as including systems that serve at least "fifteen service connections" or "twenty-five individuals." This definition is consistent with section 1401(4) of the Safe Drinking Water Act and 40 CFR 141.2(c) of the National Primary Drinking Water Regulations. The new law would amend the definition in the Iowa Department of Environmental Quality Act, limiting its coverage to systems that serve at least "twenty service connections" and "one

hundred individuals." The effective date of the new law is July 1, 1983.

The new definition of "public water supply system" is inconsistent with the Safe Drinking Water Act and the National Primary Drinking Water Regulations. The new definition would remove all systems serving less than one hundred individuals from the jurisdiction of the Iowa Department of Environmental Quality Act. A State may exercise primary enforcement responsibility pursuant to the Safe Drinking Water Act only during those periods that the Administrator of EPA determines the State has regulations "no less stringent than" the National Primary Drinking Water Regulations. Section 1413(a)(1). The National Primary Drinking Water Regulations provide that a State may exercise primary enforcement jurisdiction during any period for which the Administrator determines that the State has statutory authority to apply State regulations "to all public water systems in the State covered by the national primary drinking water regulations." 40 CFR 142.10(b)(6)(i).

If the new Iowa law redefining "public water supply system" becomes effective as scheduled on July 1, 1983, the State of Iowa will no longer meet the requirements for primacy in the Safe Drinking Water Act or the National Primary Drinking Water Regulations. Therefore, I am providing that my determination that the State of Iowa meets the requirements for primary enforcement responsibility will automatically terminate on July 1, 1983, if the new definition becomes effective. However, if the current definition of "public water supply system" in the Iowa Department Environmental Quality Act (fifteen service connections and twenty-five individuals) is not amended and, therefore, the new definition does not take effect, my determination will not terminate on July 1, 1983. This extraordinary action of granting primary enforcement responsibility with an automatic termination date is warranted in view of the fact that the Iowa Department of Environmental Quality Act has already been amended making the Act's coverage substantially less inclusive than the Safe Drinking Water Act. It is fundamental to any State's assumption of primary enforcement responsibility that the State law not be less inclusive than the Safe Drinking Water Act as to the universe of systems subject to that law. While Iowa's current drinking water program is approvable, that program, through the amended law to become effective on July 1, 1983, will be modified to a form that will no longer be approvable. Iowa's approvable program is scheduled to terminate on July 1, 1983. Therefore, my determination that Iowa meets the requirement for primary enforcement responsibility also must terminate on July 1, 1983, unless the currently effective program is not modified to make its coverage less inclusive than that of the Safe Drinking Water Act.

All interested parties are invited to submit written comments on this determination and and may request a public hearing. Written comments and/or a request for a public hearing must be submitted on or before August 2, 1982. A request for a public hearing shall include the following information:

1. The name, address and telephone number of the individual, organization or other entity requesting a hearing.

2. A brief statement of the requesting person's interest in the Regional Administrator's determination and information that the requesting person intends to submit at such hearing.

3. The signature of the individual making the request; or, if the request is made on behalf of an organization or other entity, the signature of a responsible official of the organization or other entity.

Frivolous or insubstantial requests for a hearing may be denied by the Regional Administrator. If is determined that a public hearing is appropriate said hearing will be held at 10 a.m. on Monday, August 2, 1982, in the Main Auditorium located in the Henry A. Wallace Building, 900 East Grand Avenue, Des Moines, Iowa 50319. If no timely and appropriate request for a hearing is received and the Regional Administrator does not elect to hold a hearing on his own motion, the scheduled hearing will not be held and this determination shall become effective thirty (30) days after issuance of this initial notice.

Commenters requesting a public hearing will be notified. Other interested parties should contact the Environmental Protection Agency or the Iowa Department of Environmental Quality for additional information.

The Office of Management and Budget has exempted this rule from the requirements of section 3 of Executive Order 12291.

A complete copy of the Iowa application for redelegation of primary enforcement responsibility is available for public inspection during normal business hours at the Office of the Regional Administrator, Environmental Protection Agency, 324 East 11th Street, Kansas City, Missouri 64106, and at the following location in Iowa:

The Iowa Department of Environmental Quality, Henry A. Wallace Building, 900 East Grand Avenue, Des Moines, Iowa 50319.

John J. Franke, Jr.,

Regional Administrator, Region VII.

June 29, 1982.

[FR Doc. 82-18050 Filed 7-1-82; 8:45 am]

BILLING CODE 6560-50-M

FEDERAL MARITIME COMMISSION

[Agreement No. 10453]

Availability of Finding of No Significant Impact

Upon completion of an environmental assessment, the Federal Maritime Commission's Office of Energy and Environmental Impact has determined that the Commission's decision on Agreement No. 10453 will not constitute a major Federal action significantly affecting the quality of the human environment within the meaning of the National Environmental Policy Act of 1969, 42 U.S.C. 4321 *et seq.*, and that preparation of an environmental impact statement is not required.

The agreement is between Empresa Lineas Maritimas Argentinas (ELMA) and Bottacchi, S.A. de Navegacion C.F.I.I. (Bottacchi) operating Argentine flag common carrier vessels between U.S. Atlantic ports and ports in Brazil, Uruguay, Argentina and Paraguay. Under the terms of the agreement, each party will, from time to time, charter space on vessels operated by it to the other party, and the parties will cooperate with each other to rationalize sailings in the trade.

This Finding of No Significant Impact (FONSI) will become final within 20 days of publication of this notice in the **Federal Register** unless a petition for review is filed pursuant to 46 CFR 547.6(b).

The FONSI and related environmental assessment are available for inspection on request from the Office of the Secretary, Room 11101, Federal Maritime Commission, Washington, D.C. 20573, telephone (202) 523-5725.

Francis C. Hurney,

Secretary.

[FR Doc. 82-18002 Filed 7-1-82; 8:45 am]

BILLING CODE 6730-01-M

Security for the Protection of the Public Financial Responsibility To Meet Liability Incurred for Death or Injury to Passengers or Other Persons on Voyages; Issuance of Certificate (Casualty)

Notice is hereby given that the following have been issued a Certificate of Financial Responsibility to Meet Liability Incurred for Death or Injury to Passengers or Other Persons on Voyages pursuant to the provisions of Section 2, Pub. L. 89–777 (80 Stat. 1356, 1357) and Federal Maritime Commission General Order 20, as amended (46 CFR 540): The Black Sea Shipping Company, c/o March Shipping Passenger Services, 1001 Franklin Ave., Garden City, New York 11530.

Dated: June 29, 1982.

Francis C. Hurney,

Secretary.

[FR Doc. 82–18003 Filed 7–1–82; 8:45 am]

BILLING CODE 6730–01–M

Security for the Protection of the Public Indemnification of Passengers for Nonperformance of Transportation; Issuance of Certificate (Performance)

Notice is hereby given that the following have been issued a Certificate of Financial Responsibility for Indemnification of Passengers for Nonperformance of Transportation pursuant to the provisions of Section 3, Pub. L. 89–777 (80 Stat. 1357, 1358) and Federal Maritime Commission General Order 20, as amended (46 CFR Part 540): The Black Sea Shipping Company, c/o March Shipping Passenger Services, 1001 Franklin Ave., Garden City, New York 11530.

This Certificate expires August 22, 1982.

Dated: June 29, 1982.

Francis C. Hurney,

Secretary.

[FR Doc. 82–18004 Filed 7–1–82; 8:45 am]

BILLING CODE 6730–01–M

FEDERAL PREVAILING RATE ADVISORY COMMITTEE

Annual Report; Availability

Pursuant to the provisions of section 10(d) of the Federal Advisory Committee Act (Pub. L. 92–463) and Circular A–63, revised, of the Office of Management and Budget—notice is hereby given to the availability of the Federal Prevailing Rate Advisory Committee 1981 Annual Report.

The report summarizes the activities and recommendations of the Committee to the Director, Office of Personnel Management in dealing with the Federal prevailing rate systems for craft, trade, and labor employees paid from either appropriated or nonappropriated funds during calendar year 1981.

Single copies of the report will be furnished without charge. Multiple copies can be furnished at a fair and equitable fee upon written request addressed to the Chairman, Federal Prevailing Rate Advisory Committee, Office of Personnel Management, Room 1340, 1900 E Street, N.W., Washington, D.C. 20415.

The report may be otherwise examined and/or copies obtained at the above office and address between the hours of 8:15 a.m. and 4:45 p.m. Monday through Friday, legal holidays excluded.

William B. Davidson, Jr.,

Chairman, Federal Prevailing Rate Advisory Committee.

June 28, 1981.

[FR Doc. 82–18048 Filed 7–1–82; 8:45 am]

BILLING CODE 6325–01–M

FEDERAL RESERVE SYSTEM

Bank Holding Companies; Proposed de Novo Nonbank Activities

The bank holding companies listed in this notice have applied, pursuant to section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and section 225.4(b)(1) of the Board's Regulation Y (12 CFR 225.4(b)(1)), for permission to engage *de novo* (or continue to engage in an activity earlier commenced *de novo*), directly or indirectly, solely in the activities indicated, which have been determined by the Board of Governors to be closely related to banking.

With respect to each application, interested persons may express their views on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interest, or unsound banking practices." Any comment on an application that requests a hearing must include a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of that proposal.

Each application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank indicated for that application. Comments and requests for hearings should identify clearly the specific application to which they relate, and should be submitted in writing and received by the appropriate Federal Reserve Bank not later than July 28, 1982.

A. **Federal Reserve Bank of Kansas City** (Thomas M. Hoenig, Assistant Vice President) 925 Grand Avenue, Kansas City, Missouri 55480:

1. *AmeriCorp,* Shawnee, Oklahoma, (insurance activities; Oklahoma): To engage indirectly through a subsidiary, Banker's Insurance Agency of Shawnee, Inc., Shawnee, Oklahoma, in the sale of life, accident and health, and mortgage cancellation insurance directly related to extensions of credit by AmeriCorp's subsidiary bank, American National Bank and Trust Company of Shawnee, Shawnee, Oklahoma. These activities would be conducted from an office in Shawnee, Oklahoma, serving Pottawatomie County, Oklahoma.

2. *Morrow & Keeling, Inc.,* Chanute, Kansas, (insurance activities; Kansas): To engage in the sale of credit life, accident and health insurance related to extensions of credit by its subsidiary bank. These activities would be conducted in Chanute, Kansas, serving Chanute and the surrounding area.

Board of Governors of the Federal Reserve System, June 28, 1982.

Dolores S. Smith,

Assistant Secretary of the Board.

[FR Doc. 82–18009 Filed 7–1–82; 8:45 am]

BILLING CODE 6210–01–M

Formation of Bank Holding Companies

The companies listed in this notice have applied for the Board's approval under section 3(a)(1) of the Bank Holding Company Act (12 U.S.C. 1842(a)(1)) to become bank holding companies by acquiring voting shares and/or assets of a bank. The factors that are considered in acting on the applications are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

Each application may be inspected at the offices of the Board of Governors, or at the Federal Reserve Bank indicated for that application. With respect to each application, interested persons may express their views in writing to the address indicated for that application. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of

fact that are in dispute and summarizing the evidence that would be presented at a hearing.

A. **Federal Reserve Bank of Atlanta** (Robert E. Heck, Vice President) 104 Marietta Street, NW., Atlanta, Georgia 30303:

1. *Central Bancshares, Inc.*, Glenmora, Louisiana; to become a bank holding company by acquiring 80 percent of the voting shares of Central Bank & Trust Company, Glenmora, Louisiana. Comments on this application must be received not later than July 28, 1982.

B. **Federal Reserve Bank of Chicago** (Franklin D. Dreyer, Vice President) 230 South LaSalle Street, Chicago, Illinois 60690:

1. *Savanna Bancorp., Inc.*, Savanna, Illinois; to become a bank holding company by acquiring 80 percent of the voting shares of Savanna State Bank, Savanna, Illinois. Comments on this application must be received not later than July 28, 1982.

C. **Federal Reserve Bank of Kansas City** (Thomas M. Hoenig, Assistant Vice President) 925 Grand Avenue, Kansas City, Missouri 55480:

1. *Docking Bank Consulting Company*, Arkansas City, Kansas; to become a bank holding company by acquiring 50 percent or more of the voting shares of The Union State Bank, Arkansas City, Kansas. Comments on this application must be received not later than July 28, 1982.

D. **Federal Reserve Bank of Dallas** (Anthony J. Montelaro, Assistant Vice President) 400 South Akard Street, Dallas, Texas 75222:

1. *The Banc of San Jacinto County Bancshares, Inc.*, Coldspring, Texas; to become a bank holding company by acquiring 100 percent of the voting shares of The Bank of San Jacinto County, Coldspring, Texas. Comments on this application must be received not later than July 28, 1982.

Board of Governors of the Federal Reserve System, June 28, 1982.

Dolores S. Smith,

Assistant Secretary of the Board.

[FR Doc. 82-18010 Filed 7-1-82; 8:45 am]

BILLING CODE 6210-01-M

First National Corp. of Jacksonville; Formation of Bank Holding Company

First National Corporation of Jacksonville, Jacksonville, Alabama, has applied for the Board's approval under section 3(a)(1) of the Bank Holding Company Act (12 U.S.C. 1842(a)(1)) to become a bank holding company by acquiring 80 per cent or more of the voting shares of The First National Bank of Jacksonville, Jacksonville, Alabama. The factors that are considered in acting on the application are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

First National Corporation of Jacksonville, Alabama, has also applied, pursuant to section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and section 225.4(b)(2) of the Board's Regulation Y (12 CFR 225.4(b)(2)), for permission to engage in the activities of acting as agent or broker for the sale of credit life and health and accident insurance. These activities would be performed from offices of Applicant's subsidiary in Jacksonville and Anniston, Alabama, and the geographic area to be served is Calhoun County, Alabama. Such activities have been specified by the Board in section 225.4(a) of Regulation Y as permissible for bank holding companies, subject to Board approval of individual proposals in accordance with the procedures of section 225.4(b).

Interested persons may express their views on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Atlanta.

Any views or requests for hearing should be submitted in writing and received by the Reserve Bank not later than July 28, 1982.

Board of Governors of the Federal Reserve System, June 28, 1982.

Dolores S. Smith,

Assistant Secretary of the Board.

[FR Doc. 82-18012 Filed 7-1-82; 8:45 am]

BILLING CODE 6210-01-M

Acquisition of Bank Shares by Bank Holding Companies

The companies listed in this notice have applied for the Board's approval under section 3(a)(3) of the Bank Holding Company Act (12 U.S.C. 1842(a)(3)) to acquire voting shares or assets of a bank. The factors that are considered in acting on the applications are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

Each application may be inspected at the offices of the Board of Governors, or at the Federal Reserve Bank indicated for that application. With respect to each application, interested persons may express their views in wiritng to the address indicated for that application. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

A. **Federal Reserve Bank of St. Louis** (Delmer P. Weisz, Vice President) 411 Locust Street, St. Louis, Missouri 63166:

1. *First Bancrop of Belleville, Inc.*, Belleville, Illinois; to acquire at least 80 percent of the voting shares or assets of Dupo State Savings Bank, Dupo, Illinois. Comments on this application must be received not later than July 28, 1982.

B. **Federal Reserve Bank of Kansas City** (Thomas M. Hoenig, Assistant Vice President) 925 Grand Avenue, Kansas City, Missouri 64198:

1. *Guardian Banshares, Inc.*, Alliance, Nebraska; to acquire 19.975 percent of the voting shares of Bridgeport State Company, Bridgeport, Nebraska. Comment on this application must be received not later than July 28, 1982.

2. *Hemingford Banshares, Inc.*, Hemingford, Nebraska; to acquire 19.975 percent of the voting shares of Bridgeport State Company, Bridgeport, Nebraska. Comments on this application must be received not later than July 28, 1982.

3. *Hyannis Banshares, Inc.*, Hyannis, Nebraska; to acquire 24.9 percent of the voting shares of Bridgeport State Company, Bridgeport, Nebraska. Comments on this application must be received not later than July 28, 1982.

4. *Mullen Banshares, Inc.*, Mullen, Nebraska; to acquire 24.9 percent of the voting shares of Bridgeport State Company, Bridgeport, Nebraska. Comments on this application must be received not later than July 28, 1982.

5. *Thedford Banshares, Inc.*, Thedford, Nebraska; to acquire 10.25 percent of the voting shares of Bridgeport State Company, Bridgeport, Nebraska. Comments on this application must be received not later than July 28, 1982.

C. **Federal Reserve Bank of Dallas** (Anthony J. Montelaro, Assistant Vice President) 400 South Akard Street, Dallas, Texas 75222:

1. *Carthage Bancshares, Inc.*, Carthage, Texas; to acquire 100 percent of the voting shares of assets of First National Bank of Beckville, Beckville, Texas, a proposed new bank. Comments on this application must be received not later than July 28, 1982.

2. *National Bancshares Corporation of Texas*, San Antonio, Texas; to acquire 100 percent of the voting shares or assets of Peoples Bank, Houston, Texas. Comments on this application must be received not later than July 28, 1982.

Board of Governors of the Federal Reserve System, June 28, 1982.

Dolores S. Smith,

Assistant Secretary of the Board.

[FR Doc. 82-18011 Filed 7-1-82; 8:45 am]

BILLING CODE 6210-01-M

FEDERAL TRADE COMMISSION

Early Termination of the Waiting Period of the Premerger Notification Rules; Marjorie S. Gray

AGENCY: Federal Trade Commission.

ACTION: Granting of request for early termination of the waiting period of the premerger notification rules.

SUMMARY: Marjorie S. Gray is granted early termination of the waiting period provided by law and the premerger notification rules with respect to the proposed acquisition of certain voting securities of Bill S. Saxon. The grant was made by the Federal Trade Commission and the Assistant Attorney General in charge of the Antitrust Division of the Department of Justice in response to a request for early termination submitted by both parties. Neither agency intends to take any action with respect to this acquisition during the waiting period.

EFFECTIVE DATE: June 4, 1982.

FOR FURTHER INFORMATION CONTACT: Roberta Baruch, Senior Attorney, Premerger Notification Office, Bureau of Competition, Room 303, Federal Trade Commission, Washington, D.C. 20580 (202) 523-3894.

SUPPLEMENTARY INFORMATION: Section 7A of the Clayton Act, 15 U.S.C. 18a, as added by Title II of the Hart-Scott-Rodino Antitrust Improvements Act of 1976, requires persons contemplating certain mergers or acquisitions to give the Commission and Assistant Attorney General advance notice and to wait designated periods before consummation of such plans. Section 7A(b)(2) of the Act permits the agencies, in individual cases, to terminate this waiting period prior to its expiration and requires that notice of this action be published in the **Federal Register.**

By direction of the Commission.

Carol M. Thomas,

Secretary.

[FR Doc. 82-18040 Filed 7-1-82; 8:45 am]

BILLING CODE 6750-01-M

Early Termination of the Waiting Period of the Premerger Notification Rules; Louis A. Farris

AGENCY: Federal Trade Commission.

ACTION: Granting of request for early termination of the waiting period of the premerger notification rules.

SUMMARY: Louis A. Farris is granted early termination of the waiting period provided by law and the premerger notification rules with respect to the proposed acquisition of certain voting securities of The Retirement Research Foundation. The grant was made by the Federal Trade Commission and the Assistant Attorney General in charge of the Antitrust Division of the Department of Justice in response to a request for early termination submitted by Louis A. Farris. Neither agency intends to take any action with respect to this acquisition during the waiting period.

EFFECTIVE DATE: June 4, 1982.

FOR FURTHER INFORMATION CONTACT: Roberta Baruch, Senior Attorney, Premerger Notification Office, Bureau of Competition, Room 303, Federal Trade Commission, Washington, D.C. 20580 (202) 523-3894.

SUPPLEMENTARY INFORMATION: Section 7A of the Clayton Act, 15 U.S.C. 18a, as added by Title II of the Hart-Scott-Rodino Antitrust Improvements Act of 1976, requires persons contemplating certain mergers or acquisitions to give the Commission and Assistant Attorney General advance notice and to wait designated periods before consummation of such plans. Section 7A(b)(2) of the Act permits the agencies, in individual cases, to terminate this waiting period prior to its expiration and requires that notice of this action be published in the **Federal Register.**

By direction of the Commission.

Carol M. Thomas,

Secretary.

[FR Doc. 82-18041 Filed 7-1-82; 8:45 am]

BILLING CODE 6750-01-M

Early Termination of the Waiting Period of the Premerger Notification Rules; Investors Management Corporation

AGENCY: Federal Trade Commission.

ACTION: Granting of request for early termination of the waiting period of the premerger notification rules.

SUMMARY: Investors Management Corporation is granted early termination of the waiting period provided by law and the premerger notification rules with respect to the proposed acquisition of certain voting securities of Sirloin Stockade, Inc., a subsidiary of Lucky Stores, Inc. The grant was made by the Federal Trade Commission and the Assistant Attorney General in charge of the Antitrust Division of the Department of Justice in response to a request for early termination submitted by both parties. Neither agency intends to take any action with respect to this acquisition during the waiting period.

EFFECTIVE DATE: June 4, 1982.

FOR FURTHER INFORMATION CONTACT: Roberta Baruch, Senior Attorney, Premerger Notification Office, Bureau of Competition, Room 303, Federal Trade Commission, Washington, D.C. 20580 (202) 523-3894.

SUPPLEMENTARY INFORMATION: Section 7A of the Clayton Act, 15 U.S.C. 18a, as added by Title II of the Hart-Scott-Rodino Antitrust Improvements Act of 1976, requires persons contemplating certain mergers or acquisitions to give the Commission and Assistant Attorney General advance notice and to wait designated periods before consummation of such plans. Section 7A(b)(2) of the Act permits the agencies, in individual cases, to terminate this waiting period prior to its expiration and requires that notice of this action be published in the **Federal Register.**

By direction of the Commission.

Carol M. Thomas,

Secretary.

[FR Doc. 82-18037 Filed 7-1-82; 8:45 am]

BILLING CODE 6750-01-M

Early Termination of the Waiting Period of the Premerger Notification Rules; James P. Linn

AGENCY: Federal Trade Commission.

ACTION: Granting of request for early termination of the waiting period of the premerger notification rules.

SUMMARY: James P. Linn is granted early termination of the waiting period provided by law and the premerger notification rules with respect to the proposed acquisition of certain voting securities of Bill D. Saxon. The grant was made by the Federal Trade Commission and the Assistant Attorney General in charge of the Antitrust Division of the Department of Justice in

response to a request for early termination submitted by both parties. Neither agency intends to take any action with respect to this acquisition during the waiting period.

EFFECTIVE DATE: June 4, 1982.

FOR FURTHER INFORMATION CONTACT: Roberta Baruch, Senior Attorney, Premerger Notification Office, Bureau of Competition, Room 303, Federal Trade Commission, Washington, D.C. 20580 (202) 523–3894.

SUPPLEMENTARY INFORMATION: Section 7A of the Clayton Act, 15 U.S.C. 18a, as added by Title II of the Hart-Scott-Rodino Antitrust Improvements Act of 1976, requires persons contemplating certain mergers or acquisitions to give the Commission and Assistant Attorney General advance notice and to wait designated periods before consummation of such plans. Section 7A(b)(2) of the Act permits the agencies, in individual cases, to terminate this waiting period prior to its expiration and requires that notice of this action be published in the **Federal Register.**

By direction of the Commission.

Carol M. Thomas,

Secretary.

[FR Doc. 82–18036 Filed 7–1–82; 8:45 am]

BILLING CODE 6750–01–M

Early Termination of the Waiting Period of the Premerger Notification Rules; Kerr-McGee Corp.

AGENCY: Federal Trade Commission.

ACTION: Granting of request for early termination of the waiting period of the premerger notification rules.

SUMMARY: Kerr-McGee Corp. is granted early termination of the waiting period provided by law and the premerger notification rules with respect to the proposed acquisition of all voting securities of Coquina Oil Corp. and Coquina Petroleum Inc., from Fluor Corp. The grant was made by the Federal Trade Commission and the Assistant Attorney General in charge of the Antitrust Division of the Department of Justice in response to a request for early termination submitted by Fluor Corp. Neither agency intends to take any action with respect to this acquisition during the waiting period.

EFFECTIVE DATE: June 11 1982.

FOR FURTHER INFORMATION CONTACT: Roberta Baruch, Senior Attorney, Premerger Notification Office, Bureau of Competition, Room 303, Federal Trade Commission, Washington, D.C. 20580 (202) 523–3894.

SUPPLEMENTARY INFORMATION: Section 7A of the Clayton Act, 15 U.S.C. 18a, as added by Title II of the Hart-Scott-Rodino Antitrust Improvements Act of 1976, requires persons contemplating certain mergers or acquisitions to give the Commission and Assistant Attorney General advance notice and to wait designated periods before consummation of such plans. Section 7A(b)(2) of the Act permits the agencies, in individual cases, to terminate this waiting period prior to its expiration and requires that notice of this action be published in the **Federal Register.**

By direction of the Commission.

Carol M. Thomas,

Secretary.

[FR Doc. 82–18039 Filed 7–1–82; 8:45 am]

BILLING CODE 6750–01–M

Early Termination of the Waiting Period of the Premerger Notification Rules; WICOR, Inc.

AGENCY: Federal Trade Commission.

ACTION: Granting of request for early termination of the waiting period of the premerger notification rules.

SUMMARY: WICOR, Inc. is granted early termination of the waiting period provided by law and the premerger notification rules with respect to the proposed acquisition of certain voting securities of Sta-Rite Industries, Inc. The grant was made by the Federal Trade Commission and the Assistant Attorney General in charge of the Antitrust Division of the Department of Justice in response to a request for early termination submitted by both parties. Neither agency intends to take any action with respect to this acquisition during the waiting period.

EFFECTIVE DATE: June 4, 1982.

FOR FURTHER INFORMATION CONTACT: Roberta Baruch, Senior Attorney, Premerger Notification Office, Bureau of Competition, Room 303, Federal Trade Commission, Washington, D.C. 20580 (202) 523–3894.

SUPPLEMENTARY INFORMATION: Section 7A of the Clayton Act, 15 U.S.C. 18a, as added by Title II of the Hart-Scott-Rodino Antitrust Improvements Act of 1976, requires persons contemplating certain mergers or acquisitions to give the Commission and Assistant Attorney General advance notice and to wait designated periods before consummation of such plans. Section 7A(b)(2) of the Act permits the agencies, in individual cases, to terminate this waiting period prior to its expiration and requires that notice of this action be published in the **Federal Register.**

By direction of the Commission.

Carol M. Thomas,

Secretary.

[FR Doc. 82–18038 Filed 7–1–82; 8:45 am]

BILLING CODE 6750–01–M

GENERAL SERVICES ADMINISTRATION

[F–82–21]

Delegation of Authority to the Secretary of Defense

1. *Purpose.* This delegation authorizes the Secretary of Defense to represent the consumer interests of the executive agencies of the Federal Government in proceedings before the Louisiana Public Service Commission involving intrastate telecommunications service rates.

2. *Effective date.* This delegation is effective immediately.

3. *Delegation.*

a. Pursuant to the authority contained in the Federal Property and Administrative Services Act of 1949, 63 Stat. 377, as amended, particularly Sections 201(a)(4) and 205(d) (40 U.S.C. 481(a)(4) and 486(d)), authority is delegated to the Secretary of Defense to represent the consumer interests of the Federal executive agencies before the Louisiana Public Service Commission involving the application of the South Central Bell Telephone Company in Docket No. U–15445 for an increase in rates for telecommunications services.

b. The Secretary of Defense may redelegate this authority to any officer, official, or employee of the Department of Defense.

c. This authority shall be exercised in accordance with the policies, procedures, and controls prescribed by the General Services Administration, and shall be exercised in cooperation with the responsible officers, officials, and employees thereof.

d. The Department of Defense shall add the General Services Administration to its service list in this case so that GSA will receive copies of

testimony, briefs, and other Department of Defense filings.

Dated: June 21, 1982.

Francis A. McDonough,

Deputy Commissioner for Government-wide Management, Automated Data and Telecommunications Service.

[FR Doc. 82-18069 Filed 7-1-82; 8:45 am]

BILLING CODE 6820-25-M

[F-82-20]

Delegation of Authority to the Secretary of Defense

1. *Purpose.* This delegation authorizes the Secretary of Defense to represent the consumer interests of the executive agencies of the Federal Government in proceedings before the Minnesota Public Utilities Commission involving intrastate telecommunications service rates.

2. *Effective date.* This delegation is effective immediately.

3. *Delegation.*

a. Pursuant to the authority contained in the Federal Property and Administrative Services Act of 1949, 63 Stat. 377, as amended, particularly Sections 201(a)(4) and 205(d) (40 U.S.C. 481(a)(4) and 486(d)), authority is delegated to the Secretary of Defense to represent the consumer interests of the Federal executive agencies before the Minnesota Public Utilities Commission involving the application of the Northwestern Bell Telephone Company in Docket No. P-421/GR-82-203 for an increase in rates for telecommunications services. The authority delegated to the Secretary of Defense shall be exercised concurrently with the Administrator of General Services.

b. The Secretary of Defense may redelegate this authority to any officer, official, or employee of the Department of Defense.

c. This authority shall be exercised in accordance with the policies, procedures, and controls prescribed by the General Services Administration, and shall be exercised in cooperation with the responsible officers, officials, and employees thereof.

d. The Department of Defense shall add the General Services Administration to its service list in this case so that GSA will receive copies of testimony, briefs and other Department of Defense filings.

Dated: June 21, 1982.

Francis A. McDonough,

Deputy Commissioner for Government-wide Management, Automated Data and Telecommunications Service.

[FR Doc. 82-18068 Filed 7-1-82; 8:45 am]

BILLING CODE 6820-25-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 82N-0154]

FDA Policy Relating to Limitations of Labeling Terminology in Over-the-Counter Drug Monographs; Public Hearing

AGENCY: Food and Drug Administration.

ACTION: Notice of public hearing.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a public hearing will be held on the agency's policy of limiting the terms that may be used in over-the-counter (OTC) drug product's label to the specific terminology included in the applicable final OTC drug monograph. This policy, known as the "exclusivity" policy, has been challenged throughout the OTC drug review process, and the agency has been petitioned for a hearing respecting the policy's implementation in the context of the nighttime sleep-aid and stimulant drug products monographs. Although interested persons are invited to submit comments on any aspect of the exclusivity policy regarding any OTC drug product, the Commissioner of Food and Drugs will structure the hearing to seek answers to the specific questions listed below in this notice.

DATES: Written notices of participation must be filed by August 13, 1982. The public hearing will be held on September 29, 1982, beginning at 9 a.m.

ADDRESSES: The hearing will be held in conference rooms D, E, and F, Parklawn Building, 5600 Fishers Lane, Rockville, MD. Written notices of participation should be sent to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, National Center for Drugs and Biologics (HFD-510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, (301) 443-4960.

SUPPLEMENTARY INFORMATION: The Commissioner will hold a public hearing on the agency's policy relating to limitations on labeling terminology in OTC drug monographs. The hearing will be held on September 29, 1982, beginning at 9 a.m., in conference rooms D, E, and F, Parklawn Building, 5600 Fishers Lane, Rockville, MD.

FDA published the tentative final monographs (proposed regulations) for OTC nighttime sleep-aid and stimulant drug products in the **Federal Register** of June 13, 1978 (43 FR 25544). The tentative final monograph for nighttime sleep-aid drug products stated that the labeled indications for such products "shall be limited to one or more of the following phrases: 'Helps fall asleep', 'For relief of occasional sleeplessness', 'Helps to reduce difficulty in falling asleep.' " The tentative final monograph for stimulant drug products stated that the labeled indication for such products "shall be limited to the following phrase: 'Helps restore mental alertness or wakefulness when experiencing fatigue or drowsiness.' " In accordance with FDA policy, all other claims or representations of indications would be excluded from the monograph. Thus, any nighttime sleep-aid or stimulant drug product containing labeling that included claims or representations other than those phrases listed above would be a new drug and/or misbranded under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(p) and 352). A hearing has been requested to challenge the proposed limitations of labeling terminolgy.

The policy of limiting monograph labeling terminology to specific words and phrases considered and approved by FDA is known as the "exclusivity" policy. It has been the subject of comment throughout the OTC drug review process. With the publication of the tentative final monograph for OTC antacid drug products in the **Federal Register** of November 12, 1973 (38 FR 31260), FDA responded to comments proposing that terms other than those specified in the monograph should be allowed in the product labeling. The agency concluded that the terms recommended by the panel fully met the intent of the regulation. The agency further explained that allowing each manufacturer to select words other than those set forth in the monograph would result in continued consumer confusion and deception (38 FR 31264).

With the publication of the final monograph for OTC antiacid drug products in the **Federal Register** of June 4, 1974 (39 FR 19862), the agency addressed a comment that the language required for a labeling warning should not be mandatory because a manufacturer may wish to use minor variations in words to provide clearer understanding by consumers. The agency responded as follows (39 FR 19868):

> The Commissioner believes that uniformity in labeling language is essential to consumers. For this reason, the combining of warnings is permitted only where it will retain uniform terminology. Allowing minor word variations, or rearrangement of the same words, would result in similar or

confusing warnings which would not be in the best interest of the public.

In the **Federal Register** of March 13, 1975 (40 FR 11718), FDA announced an amendment to the monographs for OTC antacid and antiflatulent drug products. Those monographs previously required that such products have labeling that "represents or suggests" the product as therapy for certain conditions set forth in quotation marks. A comment stated that the phrase "represents or suggests" raised the question whether terms analogous or similar to the quoted conditions could be used. The agency restated the position that allowing each manufacturer to select its own terminology would result in continued consumer confusion and deception. To clarify the effect of the exclusivity policy, FDA amended the monographs by deleting the phrase "represents or suggests" and substituting the requirement that the labeling of the product "identify" the product with only the specified terms. The controversy concerning exclusivity was not, however, abated, even though in subsequent tentative final monographs FDA has consistently expanded the labeling recommended by the panels to include alternative terminology suggested in comments.

Subsequently, comments both supporting and objecting to the exclusivity policy were submitted to a number of OTC drug rulemaking proceedings, including the proposed monograph for OTC nighttime sleep-aid and stimulant drug products. The comments objecting to the limitation on labeling terminology charged that it is unduly restrictive, unconstitutional, and contrary to the purpose of the Federal Food, Drug, and Cosmetic Act in that it prevents manufacturers from using truthful alternative wording. FDA responded to these comments in the tentative final monographs for OTC nighttime sleep-aid and stimulant drug products as follows (43 FR 25554):

> The Commissioner believes that labeling terminology relating to indications for use is inseparable from the scientific and medical determinations made by the panel and by FDA concerning the conditions under which a drug ingredient is safe and effective. If a manufacturer varies the terminology approved in the monograph, it is representing its product as safe and effective for a condition for which the product's ingredients have not been found to be safe and effective, or else it is assuming that the variant terminology means the same thing as the terminology approved in the monograph. To permit this practice would defeat the purpose of the OTC Drug Review. The Commissioner believes that the listed indications provide a concise description of those therapeutic effects that scientists recognize OTC nighttime sleep-aids to have, in language that is clear, accurate, and meaningful to the layman. If alternative wording or synonyms are desired, the agency may be petitioned for their inclusion in the monograph.
>
> The Commissioner rejects the contention that limiting permissible labeling claims to those approved in the monograph is unlawful and unconstitutional because it prohibits use of truthful alternative wording. The purpose of the OTC Drug Review is to determine which claims are truthful and which are not, and ample opportunity is provided to settle the question through the OTC Drug Review and monograph amendment procedures.

The agency further noted, in a response to a comment on the exclusivity policy as it relates to both nighttime sleep-aid and stimulant drug products, that the agency would permit alternative terminology only after approval of an appropriate petition to the agency under § 330.10(a)(12) (21 CFR 330.10(a)(12)) and publication of an amendment to an appropriate monograph (43 FR 25545).

The objections to the exclusivity policy were resubmitted with respect to nighttime sleep-aid and stimulant drug products after publication of the tentative final monographs, and an oral hearing was requested. Because of the frequency with which the issue of exclusivity has been raised and is likely to be raised again with respect to future monographs, FDA is granting the request for a hearing to consider whether the agency's long-stated policy on labeling exclusivity for OTC drugs should be retained, modified, or eliminated. The OTC drug review regulations at § 330.10(a)(8) provide that after reviewing objections filed in response to a tentative final monograph, the Commissioner may, by notice in the **Federal Register**, grant an oral hearing. The procedures for such a hearing are set forth in 21 CFR Part 15; the hearing on exclusivity is granted in accordance with these regulations. The agency has also received a number of requests for hearings on other issues in the nighttime sleep-aid and stimulant drug products rulemaking. Those other hearing requests have not as yet been granted or denied, but are still under consideration.

The scope of the hearing now being granted broadly encompasses all aspects, both practical and legal, of the exclusively policy and its possible alternatives, and participants are invited to comment on any matter related to that policy. The inquiry will be structured, however, to seek answers to the following questions:

(1) Does the government have a substantial interest in restricting the terminology used in the labeling of OTC drug products?

(2) If the government's interest is substantial, does restricting labeling to terminology approved by FDA in a final monograph directly advance this interest?

(3) Is the restriction imposed by the exclusivity policy more extensive than is necessary to serve that interest?

(4) By imposing such a restriction, does the agency exceed its authority under the Federal Food, Drug, and Cosmetic Act?

(5) Is the restriction a prior restraint on free speech that is prohibited by the Constitution?

(6) Should there be limitations on terminology used in the labeling of OTC drug products? If the current policy of exclusivity of labeling should be changed, what changes would be desirable from the standpoints of consumers and marketers? The following alternatives have been identified:

(a) Provide a separate list of approved synonyms maintained on file in the Dockets Management Branch. This alternative would retain the exclusivity policy but provide a simplier and more expeditious means of obtaining additional acceptable language for use in labeling.

(b) Require specific information to be included in a designated area of a product's labeling without deviation from the approved language, but permit manufacturers to use their own synonymous language outside the designated area. This alternative would preserve the exclusivity policy with respect to claims made in the designated area, thus providing consumers with an FDA-approved source of information on the label itself, while at the same time allowing manufacturers the flexibility to employ reasonable interpretive language elsewhere in the product's labeling. The agency believes that this alternative represents a compromise that may incorporate the advantages of the exclusivity policy while avoiding some of its perceived rigidity.

(c) Allow manufacturers to interpret the claims included in a monograph in synonymous language. This alternative would abandon the exclusivity policy. Manufacturers would still be required to employ accurate, nonmisleading terminology, but would not have to obtain FDA's prior approval for the language chosen.

The agency is interested in hearing comments on each of these alternatives.

Interested persons who wish to participate must send a notice of participation on or before August 13, 1982, to the Dockets Management Branch, Food and Drug Administration,

Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857. All notices submitted should be identified with the docket number found in brackets in the heading of this notice and should contain the following information: name; address; telephone number; business affiliation, if any, of the person desiring to make a presentation; and the approximate amount of time requested for the presentation.

Groups having similar interests are requested to consolidate their comments and present them through a single representative. FDA may require joint presentations by persons with common interests. After reviewing the notices of participation, FDA will notify each participant of the schedule and time allotted to each person.

The administrative record will remain open for 15 days after the hearing to allow comment on matters raised at the hearing.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 201, 502, 505, 701(a), 52 Stat. 1040–42 as amended, 1050–53 as amended, 1055 (21 U.S.C. 321, 352, 355, 371(a))) and under authority delegated to the Commissioner (21 CFR 5.10).

Dated: June 25, 1982.

Mark Novitch,

Acting Commissioner of Food and Drugs.

[FR Doc. 82–18016 Filed 7–1–82; 8:45 am]

BILLING CODE 4160–01–M

[Docket Nos. 80P–0501 and 81P–0115]

Coherent, Inc., and Cooper Medical Devices Corp., Microsurgical Argon Laser Intended for Use in Otology; Panel Recommendations on Petitions for Reclassification; Extension of Comment Period

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is extending the time for submitting comments on the notice of panel recommendations on the petitions submitted by Coherent, Inc., and Cooper Medical Devices Corp., to reclassify from class III (premarket approval) into class II (performance standards) the microsurgical argon laser intended for use in otology and for use in otoloaryngology. FDA is taking this action in response to a request for an extension of the comment period.

DATE: Comments by July 10, 1982.

ADDRESS: Written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Denis L. McCarthy, Bureau of Radiological Health (HFX–460), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–3426.

SUPPLEMENTARY INFORMATION: In the Federal Register of May 11, 1982 (47 FR 20188), FDA issued for public comment a notice of panel recommendations on petitions submitted by Coherent, Inc., and Cooper Medical Devices Corp. to reclassify from class III into class II the microsurgical argon laser intended respectively for use in otology and in otolaryngology. The notice provides a 30-day comment period which ends on June 10, 1982. On May 27, 1982, FDA received from Cooper Medical Devices Corp. a request for an extension of the comment period. Cooper states that it is now gathering and evaluating information and clinical data directly relevant to its reclassification petition, but will be unable to complete its evaluation and submit it with the company's comments in the comment period specified in the notice.

FDA agrees that additional time for the preparation and submission of meaningful information and clinical data is in the public interest. Therefore, FDA is granting a 30-day extension of the comment period to July 10, 1982.

Interested persons may, on or before July 10, 1982, submit to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding the notice. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the generic name of the device and the docket numbers 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: June 28, 1982.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 82–17995 Filed 6–29–82; 10:01 am]

BILLING CODE 4160–01–M

[Docket No. 81N–0200]

Review of Agency Rules

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its current priorities for reviewing the agency's existing rules under the Regulatory Flexibility Act (Pub. L. 96–354) and Executive Order 12291. FDA has undertaken a systematic review of its existing rules for the purpose of identifying and eliminating any unnecessary regulatory burdens on the public.

FOR FURTHER INFORMATION CONTACT: Richard T. Hunt, Regulations Policy Staff (HFC–10), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–3480.

SUPPLEMENTARY INFORMATION:

Background

FDA is committed to eliminating unnecessary regulatory burdens while maintaining appropriate public protection. In the Federal Register of July 14, 1981 (46 FR 36333), FDA published a notice announcing its plan for undertaking a systematic review of its existing rules in accordance with requirements of the Regulatory Flexibility Act and Executive Order 12291. The review is designed to identify rules that ought to be revised or revoked because they impose unnecessary burdens on the public generally or on specific segments of the public such as small business. The notice identified FDA's principal criteria to be used in establishing review priorities—the greatest opportunity for cost reduction and the availability of data. Because FDA believes it important that those affected by its regulations have an opportunity to participate in the review, notice also solicited data, information, and views form the public to assist the agency in identifying unduly burdensome regulations and in establishing an appropriate review schedule.

Public Comments

In response to the July 14, 1981 notice, the agency received comments from 125 individuals and organizations concerning over 100 regulations, some of which were the subject of multiple comments. These comments represented a broad spectrum of interests including individual firms, trade associations, health professionals, consumer groups, and academic institutions.

A substantial portion of the comments were concentrated in a few regulatory areas. The targets of greatest public interest were regulations dealing with investigational new drug and new drug applications, food labeling, bioresearch monitoring, and current good manufacturing practice. These regulatory areas accounted for more than 30 percent of the comments received. The majority of comments on these and other regulations recommended revision rather than

revocation of the regulations. Some of the difficulties described by the comments included duplication of regulations, possible mismatches between the level of regulatory effort and the degree of risk associated with product usage, and obsolescence of regulations because of new technological developments.

Review Priorities

FDA has selected the regulations listed below as its highest review priorities at this time. By September 1983, FDA expects to review each of these reglations and decide whether to retain it unchanged or to initiate rulemaking to revise or revoke it. These priorities are the result of a systematic, agencywide assessment of public comments as well as other available information. Several consideration went into developing the priorities, including the level of public interest, the potential for a major reduction of economic impact, and the ability to distribute the review workload among available FDA staff. In selected instances, however, regulations have been included on this initial priority list even though FDA received few comments concerning them and the economic impact of the regulations is minor. These latter regulations are included because reviews have been underway, revisions are now being recommended, and the unnecessary regulatory burden can be removed soon.

21 CFR	Regulation
Sections: 102.30 to 102.33.	Common or usual names for nonstandardized foods—juice beverages.
Part:	
110	Current good manufacturing practice in manufacturing, processing, packing, or holding human food.
203	Patient package inserts for prescription drug products.
211	Current good manufacturing practice for finished pharmaceuticals.
Parts 310 and 314	New drug applications.
Part 312	New drugs for investigational use.
Parts 430 to 460	Antibiotic certification.
Part:	
606	Current good manufacturing practice for human blood and blood products.
640	Additional standards for human blood and blood products.
660	Additional standards for diagnostic substances for laboratory tests.
Section: 740.17	Bubble bath products.
Part:	
813	Investigational exemptions for intraocular lenses.
1002	Records and reports (radiological health).

Three of the regulations listed deal with current good manufacturing practice. Although all current good manufacturing practice and current good laboratory practice regulations will be scheduled for review, the substantial size of the effort restricts the agency's immediate attention to those current good manufacturing practice regulations included in the priority list.

The agency will select future priorities as reviews are completed and additional information on economic impact is received. From time to time, the agency expects to solicit information from the public to help select these priorities and conduct reviews.

Burden Assessment

In the process of reviewing an existing regulation, FDA will first ascertain if the regulation imposes a burden that would necessitate substantial economic analysis. If so, the agency will take prompt action to collect, analyze, and interpret the required information. Any regulation suspected of having a substantial impact will be assessed to determine how the costs and benefits would change if the regulation were rescinded or modified. This approach will not seek to estimate the historical impact of a regulation; i.e., the accumulated burden and benefit of the requirement from its inception. Rather, the agency will determine what current costs may be avoided if a requirement is rescinded or modified. It is anticipated that this analysis will frequently require assistance from the persons affected by the regulation in question.

When each review is completed, the agency will take appropriate action to achieve regulatory objectives with the least cost burden. Any proposed revisions or revocations of regulations that result from these reviews will be listed in future semiannual agendas of regulations and will be published in the **Federal Register** for public comment.

Dated: June 25, 1982.

Mark Novitch,

Acting Commissioner of Food and Drugs.

[FR Doc. 82-18017 Filed 7-1-82; 8:45 am]

BILLING CODE 4160-01-M

Health Resources Administration

Grants to State Health Planning and Development Agencies Determination of Population of the States

This notice provides the population figures the Department will use when it determines the amount of grants to State Health Planning and Development Agencies (State Agencies).

Section 1525 of the Public Health Service Act (added by the National Health Planning and Resources Development Act of 1974, Public Law 93-641 and the Health Planning and Resources Development Amendments of 1979, P.L. 96-79), authorized the Secretary of Health and Human Services to make grants (hereinafter referred to as "planning grants") to State Agencies to assist them to meet their operating costs. The amount of the planning grant is determined in accordance with a formula and is based in part on a determination by the Secretary of the population of the States. The formula is provided in the regulations governing grants to State Agencies (42 CFR Part 123, Subpart C). Section 123.204(b) of these regulations provides that the Secretary will determine the population of each State based upon the latest available estimate from the Department of Commerce, and will publish annually in the **Federal Register** a list of all States and their populations. This list is based on the 1980 Census of Population and Housing, final report of the Bureau of Census, Publication PHC 80-V-1, and Executive Order 12256, (published in the **Federal Register** December 18, 1980).

Accordingly, the Secretary has made the following determination of populations of the States.

Dated: June 28, 1982.

Robert Graham,

Acting Administrator, Health Resources Administration.

POPULATION OF THE STATES FOR PURPOSES OF DETERMINATION OF PLANNING AND DEVELOPMENT GRANTS, FISCAL YEAR 1982

State	Population
Alabama	3,890,171
Alaska	400,481
American Samoa	32,395
Arizona	2,718,016
Arkansas	2,285,803
California	23,673,412
Colorado	2,888,934
Connecticut	3,107,906
Delaware	595,225
District of Columbia	637,981
Florida	9,839,602
Georgia	5,464,655
Guam	105,821
Hawaii	965,000
Idaho	943,935
Illinois	11,420,191
Indiana	5,490,299
Iowa	2,913,437
Kansas	2,363,358
Kentucky	3,661,433
Louisiana	4,204,742
Maine	1,124,660
Maryland	4,216,756
Massachusetts	5,737,717
Michigan	9,258,584
Minnesota	4,077,478
Mississippi	2,520,638
Missouri	4,917,584
Montana	786,690
Nebraska	1,570,096
Nevada	799,554
New Hampshire	920,610
New Jersey	7,372,018
New Mexico	1,300,188
New York	17,565,458
North Carolina	5,874,489
North Dakota	652,695
North Mariana Islands	16,758
Ohio	10,797,579
Oklahoma	3,025,566
Oregon	2,632,843
Pennsylvania	11,867,718

POPULATION OF THE STATES FOR PURPOSES OF DETERMINATION OF PLANNING AND DEVELOPMENT GRANTS, FISCAL YEAR 1982—Continued

State	Population
Puerto Rico	3,187,570
Rhode Island	947,154
South Carolina	3,119,208
South Dakota	690,178
Tennessee	4,590,870
Texas	14,229,793
Trust Territory	116,974
Utah	1,461,117
Vermont	511,456
Virginia	5,346,499
Virgin Islands	95,591
Washington	4,130,233
West Virginia	1,949,644
Wisconsin	4,706,195
Wyoming	470,816
Total	230,191,774

[FR Doc. 82-18056 Filed 7-1-82; 8:45 am]

BILLING CODE 4160-15-M

Determination of Population of Health Service Areas

Section 1516 of the Public Health Service Act (added by the National Health Planning and Resources Development Act of 1974, Pub. L. 93-641 and the Health Planning and Resources Development Amendments of 1979, P.L. 96-79), authorizes the Secretary of Health and Human Services to make grants (hereinafter referred to as "planning grants") to health systems agencies to assist them in meeting their costs of operation. The amount of the planning grant to each health systems agency is determined in accordance with a formula set forth in amended section 1516, and is based in part upon a determination by the Secretary of the population of the health service area to be served by each agency. The governing regulations, at 42 CFR 122.205, provide that the Secretary will determine the population of the areas based upon the latest available estimate from the Department of Commerce, and will publish annually in the **Federal Register** a list of all health service areas and their populations. The populations of the health service areas are to be published prior to the final allocation of funds in each fiscal year.

In accordance with the Omnibus Budget Reconciliation Act of 1981 (P.L. 97-35) the Governors of five States (Alabama, Louisiana, Missouri, Nebraska, and Ohio) have recently requested and received approval from the Secretary for their States to be designated under section 1536 of the Act. Therefore, the attached population figures exclude the HSAs in these States since they are being eliminated in accordance with section 1536. Additionally, pursuant to section 1536 of the Act, certain States (Hawaii and Rhode Island), do not have health service areas established within them or health systems agencies designated for them but are nonetheless eligible to receive planning grants under section 1516 based in part upon their population. This Notice sets forth their populations as of April 1, 1980, on the same basis as for health service areas.

The Secretary of Health and Human Services has determined, for purposes of the determination of planning grants for health systems agencies for Fiscal Year 1982, that the population of the health service areas and the areas designated under section 1536, based on the latest available estimate from the Department of Commerce, are to be derived from the April 1, 1980 population counts, issued by the Bureau of Census. These Series PHC 80-V, population reports furnish the latest available census population counts for the population of States by counties, incorporated places, and selected minor jurisdictions which are on a comparable, uniform, and consistent basis as needed for the derivation of population totals for health service areas. Data from the Department of Treasury, Office of Revenue Sharing, "Census Tribal Population List", were used to make adjustment of the population of health service areas in Arizona and the health service area that includes portions of Arizona, New Mexico, and Utah.

The population of the health service and other areas as described above are, except for adjustments made to those areas as required by Executive Order 12256, (published in the **Federal Register**, December 18, 1980), which deals with the census estimates of Cuban and Haitian entrants to the United States between April 1, 1980 and September 30, 1980, the same as those published in the **Federal Register**, March 3, 1982. The population figures used in making the adjustments were published by the Census Bureau in the **Federal Register**, June 24, 1981.

Accordingly, the Secretary has made the following determination of the populations of the health service areas and areas designated under section 1536 as described above.

Dated: June 28, 1982.

Robert Graham,

Acting Administrator, Health Resources Administration.

HEALTH SERVICE AREA POPULATIONS FOR PURPOSES OF DETERMINATION OF PLANNING GRANTS IN FISCAL YEAR 1982[1]

State	Health service areas	Population
Alaska	1	49,660
	2	269,123
	3	81,698
Arizona	1	1,636,501
	2	671,159
	3	191,962
	4, including Utah No. 2—4,560 and New Mexico No. 2—47,868.	124,575
	5	146,247
Arkansas	1	718,790
	2	575,596
	3	498,396
	4	492,891
California	1	661,141
	2	1,256,581
	3	634,229
	4	1,490,380
	5	1,762,751
	6	822,845
	7	1,295,231
	8	658,935
	9	1,311,815
	10	828,559
	11	7,480,927
	12	1,583,712
	13	1,931,890
	14	1,954,146
Colorado	1	1,986,273
	2	612,200
	3	290,411
Connecticut	1	626,563
	2	597,180
	3	497,893
	4	895,246
	5	490,894
Delaware	1	595,225
Florida	1	862,457
	2	686,758
	3	748,532
	4	1,719,604
	5	1,232,860
	6	984,920
	7	808,571
	8	1,015,823
	9	1,781,647
Georgia	(1), see Tennessee, No. 3	
	2	562,323
	3	2,298,313
	4, including South Carolina No. 5—105,625.	658,204
	5	822,557
	6	566,677
	7	603,673
Hawaii	Sec. 1536	965,000
Idaho	1	943,935
Illinois	1	594,609
	2	715,657
	3	586,564
	4	799,384
	5	640,113
	6	3,006,461
	7	2,906,536
	8	866,501
	9	495,170
	10, including Iowa No. 3—200,458.	443,680
Indiana	1	1,972,537
	2	2,162,653
	3	1,355,109
Iowa	1	2,542,294
	2	
	(3), see Illinois No. 10	
Kansas	1	
	2	596,423
	3	850,853
Kentucky	1	1,823,584
	2	1,571,632
Maine	1	1,124,660
Maryland	1	334,395
	2	579,203
	3	832,425
	4	2,174,023
	5	296,620

HEALTH SERVICE AREA POPULATIONS FOR PURPOSES OF DETERMINATION OF PLANNING GRANTS IN FISCAL YEAR 1982[1]—Continued

State	Health service areas	Population
Massachusetts	1	603,517
	2	680,521
	3	487,934
	4	2,110,619
	5	1,023,073
	6	631,903
Michigan	1	4,682,201
	2	700,181
	3	783,576
	4	1,087,078
	5	591,627
	6	769,929
	7	324,065
	8	319,757
Minnesota	(1), see North Dakota No. 2.	
	2, including Wisconsin No. 7—135,901.	479,182
	(3), see North Dakota No. 3.	
	4	453,263
	5	1,985,925
	6	526,256
	7	405,765
Mississippi	1	2,520,638
Montana	1	786,690
Nevada	1	337,368
	2	462,176
New Hampshire	1	920,610
New Jersey	1	1,293,500
	2	1,964,923
	3	561,492
	4	2,043,957
	5	1,508,036
New Mexico	1	1,252,250
	(2), see Arizona No 4	
New York	1	1,664,728
	2	1,203,152
	3	1,405,794
	4, including Pennsylvania No. 8—107,144.	419,948
	5	1,362,774
	6	1,931,663
	7	7,078,200
	8	2,606,083
North Carolina	1	1,017,120
	2	1,114,710
	3	995,736
	4	817,609
	5	897,615
	6	1,031,699
North Dakota	1	299,396
	2, including Minnesota No. 1—160,365.	305,879
	3, including Minnesota No. 3—202, 513.	410,298
Oklahoma	1	3,025,416
Oregon	1	1,139,399
	2	1,139,486
	3	353,918
Pennsylvania	1	3,682,899
	2	934,313
	3	811,558
	4	1,413,581
	5	754,574
	6	2,889,755
	7	770,648
	(8), see New York No. 4	
	9	503,006
Rhode Island	Sec. 1536	947,154
South Carolina	1	822,338
	2	863,394
	3	624,679
	4	703,172
	(5), see Georgia No. 4	
South Dakota	1	690,178
Tennessee	1, including Virginia No. 6—90,597.	508,676
	2	845,039
	3, including Georgia No. 1—105,779.	604,498
	4	1,516,692
	5	452,561
	6	859,720
Texas	1	370,174
	2	365,563
	3	500,350
	4	659,715
	5	3,258,412
	6	1,353,640
	7	806,568
	8	1,288,036
	9	1,349,485
	10	654,874
	11	3,276,636
	12	345,900
Utah	1	1,456,557
	(2), see Arizona No. 4	
Vermont	1	511,456
Virginia	1	695,768
	2	1,105,834
	3	1,159,681
	4	960,110
	5	1,334,409
	(6), see Tennessee No. 1	
Washington	1	2,529,374
	2	593,643
	3	488,237
	4	518,979
West Virginia	1	1,949,644
Wisconsin	1	827,173
	2	1,765,089
	3	471,676
	4	511,263
	5	592,695
	6	402,058
	(7), see Minnesota No. 2	
Wyoming	1	470,816
Total	178	198,743,450

[1] Population based on Bureau of the Census population counts as of April 1, 1980 and Executive Order 12256 (published in the FEDERAL REGISTER, December 18, 1980) as noted in the accompanying text of this Notice.

[FR Doc. 81-18057 Filed 7-1-82; 8:45 am]

BILLING CODE 4160-15-M

Office of Refugee Resettlement

Demonstration Projects To Involve Community and Corporate Business Leadership Effectively in Refugee Job Development and Job Placement Programs; Announcement of the Availability of Grant Funds

Closing Date: August 20, 1982. An application must be mailed or hand-delivered by the closing date.

The Director invites applications for demonstration projects to involve community and corporate business leadership in refugee job development and job placement programs.

Authorization

Authority for this activity is contained in the Immigration and Nationality Act (8 U.S.C. 1522) as amended by the Refugee Act of 1980, Section 412, Pub. L. 96-212. No Catalogue of Federal Domestic Assistance Number has been issued.

Available Funds

It is expected that approximately $250,000 will be available for new grants in fiscal year 1982. The Director estimates that these funds could support three (3) projects. The anticipated award for a project is between $60,000 and $100,000.

However, these estimates do not bind the Office of Refugee Resettlement to a specific number of grants or to the amount of any grant unless the amount is otherwise specified by statute or regulations.

Awards will be for one year with no further funding anticipated.

Summary

This announcement governs the award of grants to public entities and non-profit organizations for the development of new and innovative methods to involve community and business leadership effectively in refugee job development and job placement programs. These projects include provision for the dissemination of these methods to employment service providers serving the refugee population.

Applications Delivered by Mail

An application sent by mail must be addressed to the U.S. Department of Health and Human Services, Social Security Administration, Office of Refugee Resettlement, Grants Management Branch, Room 1332, Switzer Building, 330 C Street, S.W., Washington, D.C. 20201. An applicant must show proof of mailing consisting of one of the following:

(1) A legible dated U.S. Postal Service postmark;

(2) A legible mail receipt with the date of mailing stamped by the U.S. Postal Service;

(3) A dated shipping label, invoice or receipt from a commercial carrier.

If an application is sent through the U.S. Postal Service, the Director does not accept either of the following as prof of mailing: (1) A private metered postmark, or (2) a mail receipt that is not dated by the U.S. Postal Service.

Applicants should note that the U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, the applicant should check with its local post office.

Applicants are encouraged to use registered or at least first class mail. Each late applicant will be notified that its application will not be considered.

Applications Delivered by Hand

An application that is hand delivered must be taken to the U.S. Department of Health and Human Services, Social Security Administration, Office of Refugee Resettlement, Grants Management Branch, Room 1332, Switzer Building, 330 C Street, S.W., Washington, D.C. 20201.

The Grants Management Branch will accept a hand-delivered application

between 8:30 am and 5:00 pm Eastern Daylight Time daily, except Saturdays, Sundays, and Federal holidays.

An application that is hand-delivered will not be accepted after 5:00 pm on the closing date.

FOR FURTHER INFORMATION CONTACT: U.S. Department of Health and Human Services, Social Security Administration, Office of Refugee Resettlement, Program Services Branch, Room 1332, Switzer Building, 330 C Street, S.W., Washington, D.C. 20201, telephone (202) 245–0403.

SUPPLEMENTARY INFORMATION:

I. Program Objectives

This announcement describes the availability of funding for national projects to demonstrate new and innovative methods to involve community and business leadership effectively in developing job opportunities for refugees and in managing job placement programs that respond to the needs of employers and contribute to the economic self-sufficiency of refugees. Grant awards under this announcement will be for a twelve-month period following the date of award.

The objectives of these projects are to develop new sources of employment for refugees, to heighten the awareness of the business community of the refugee work force, and to increase refugee employment. Employment service providers in the field have indicated that employers whh are familiar with refugees found them to be industrious and dependable. Yet, some sources have also indicated that the corporate world is not fully aware of refugees' potential contributions, and that many service providers are not adequately accessing community and corporate leadership. This grant program is designed to facilitate the development of processes that reduce refugee dependency and increase self-sufficiency.

More effective involvement of the community and corporate business leaders would address the problem of refugee unemployment. Providing employment for refugees will not only reduce the cost of public assistance but also preserve the limited social services resources for the truly needy. Refugees who work contribute to the society and lessen the burden of local communities. Futhermore, mental health experts have also found that refugees who work are adjusting to their new life more quickly.

Projects funded under this grant announcement will focus upon the development, testing and dissemination of methods of accessing "gatekeepers" in various types of businesses and corporations in order to increase their employment of refugees. These methods must be applicable to existing employment service programs and must fall within the scope of the ORR social services program. They must provide for the development of more effective linkages between business and corporate leaders and job development staff in refugee social service agencies.

II. Eligible Grantees

Eligible grantees are public entities and organizations incorporated as non-profit under the laws of their State. Private for profit agencies or firms are not eligible.

III. Activities

The grantees shall be required to carry out the following tasks:

Task 1: Develop methods to improve the delivery of employment services through more effective involvement of community and corporate business leaders. Grantees shall identify the barriers and deficiencies in the present system of job development for refugees and develop methods to eliminate those barriers and increase the accessibility of the corporate sector. The proposed methods should be designed to:

(a) access the gatekeepers of national corporations, or corporations with facilities in several communities and of local businesses; (b) increase the cooperation of the corporate sector through its own institutions such as the Chamber of Commerce, the Private Industry Council or the National Alliance of Business; and (c) use the resources untapped within a community such as the Senior Corps of Retired Executives (SCORE), the Rotary Club, etc. Tasks 1b and 1c could be substituted in the proposal by any appropriate creative methodology that results in the expansion of job opportunities for refugees.

Task 2: Produce and field test materials and instructions to be used by refugee employment service providers to implement the methodology proposed. At a minimum, these materials must include: description of the innovative concepts and evaluation instrument; description of the infrastructure of the community with particular emphasis upon the business sector; identification of the target group of employers and community organizations as well collateral materials to be used by service providers. These materials may include printed materials such as posters and pamphlets, direct mail materials, slides, video or other visual aids and usage instructions.

Task 3: Implement the proposed concepts by systematic application and evaluation of the designed methods at a minimum of three demonstration sites. These sites must be representative of communities having the majority of refugees; in particular those communities that have a significant number of refugees. Cooperation and collaboration with all refugee employment services at the demonstration sites are required. One of the demonstrations in each approved grant must involve the headquarters of a national corporation and/or a company with facilities in more than one community. Demonstrations may include three or more different community sites of a single corporation as well as one or more locally based companies.

Task 4: Revised materials and evaluation instrument produced under Task 2 to reflect the results of the activities at the three demonstration sites. The final products should be organized into a technical assistance package.

Task 5: Design and implement a disssemination plan for the final products of the grant. The dissemination plan should be national in scope and must be coordinated with the Office of Refugee Resettlement. Implementation may be in the form of workshops, training or on-site technical assistance, or other appropriate mechanisms.

Creation of advisory boards made up of representatives from the business community, the refugee employment services staff and other civic groups are strongly encouraged.

IV. A–95 Notification Process

OMB Circular A–95 is expected to be rescinded prior to the closing date for the receipt of applications, making the applicability of Circular A–95 to this program moot.

V. Application Submission and Approval Procedures

Applicants may request grant applications from the Department of Health and Human Services, Social Security Administration, Office of Refugee Resettlement, Grants Management Branch, Room 1332, Switzer Building, 330 C Street, S.W., Washington, D.C. 20201, 202–245–0403. Prospective grantees must submit an original application and two copies to the Grants Management Branch.

An independent panel will be convened to evaluate and rate applications. Final funding decisions will be made by the Director of the Office of Refugee Resettlement. Criteria for panel evaluation are listed in Section VII below. It is estimated that grant

awards will be issued on or about September 15, 1982.

VI. Applicable Regulations

The following HHS regulations apply to grants under this Notice:

45 CFR Part 16 Department Grant Appeals Process;

45 CFR Part 74 Administration of Grants;

45 CFR Part 75 Informal Grant Appeals Process;

45 CFR Part 80 Nondiscrimination Under Programs Receiving Federal Assistance Through the Department of Health and Human Services Effectuation of Title VI of the Civil Rights Act of 1964.

45 CFR Part 81 Practice and Procedures for Hearings Under Part 80 of this Title.

45 CFR Part 84 Nondiscrimination on the Basis of Handicap in Programs and Activities Benefitting from Federal Financial Assistance.

45 CFR Part 90 Nondiscrimination on the Basis of Age in Programs or Activities Receiving Federal Financial Assistance.

VII. Criteria for Evaluating Applications

Project grant applications will be evaluated and rated according to the following criteria:

A. Completeness and Responsiveness of the Proposed Program Design and Implementation Plan

- Identification and analysis of barriers and deficiencies in existing job development and job placement programs for refugees. (10 points)
- Presentation of a clear and comprehensive work plan to accomplish the task of (a) developing creative and cost-effective methods to involve community and business leadership in expanding job opportunities for refugees, (b) preparing materials to assist employment service providers in implementing the proposed methods; (c) implementing the conceptualized methods at demonstration sites; (d) producing the technical assistance materials and (e) designing and implementing the dissemination plan. (30 points)

B. Applicant Capacity

- Previous experience and success of the applicant organization in accessing major corporations and/or associations and organizations of the business community at national and local levels. (25 points)
- Evidence of the applicant organization's capacity for administrative management including organization chart for the proposed project. (5 points)
- Qualifications of individual professionals to administer the project. Appointment of key staff will be subject to ORR approval. (15 points)
- Adequacy and accessibility of facilities and other resources to implement the proposed project. (5 points)

C. Project Evaluation

- Plan for project self-evaluation including methodology for evaluating the proposed methods and for measuring outcomes. (5 points)

D. Financial Management

- Reasonableness of estimated costs in relation to anticipated results (cost/benefit ratio). (5 points)

VIII. Application Content

All applicants will use Standard Form SSA–96, "Federal Assistance" in submitting project proposals. Grant applications must also include the following:

1. Identification and description of the barriers and deficiencies of the refugee job development and job placement program;
2. A work plan to meet the project objectives, including identification of all services and materials to be developed and the dissemination plan. The work plan should describe in detail the proposed tasks and subtasks as indicated in Section V above;
3. A management plan for fiscal and program administration to accomplish the grant objectives including a project management chart, time line and staff assignments;
4. Detailed program budget;
5. Description of the applicant organization. If other than a public agency, description of its organizational mandate, funding sources, key staff and principal officers, organization address and telephone number;
6. Documentation of applicant's experience with the services proposed including description of other projects similar to the proposed activities; and
7. Documentation on non-profit status—IRS form 501 C3 or equivalent.

IX. Records and Reports

Grantees will be required to maintain such fiscal and operational records as are necessary for federal monitoring and auditing of the grants. This record keeping shall include but not be limited to:

(1) All materials to be disseminated; and

(2) Quarterly fiscal and program progress reports due 30 days after the last calendar day of each quarter following the effective date of the grant award.

Phillip N. Hawkes,

Director, Office of Refugee Resettlement.

June 29, 1982.

[FR Doc. 82–18087 Filed 7–1–82; 8:45 am]

BILLING CODE 4190–11–M

Technical Assistance to Mutual Assistance Associations in Business Development and Business Management; Announcement of the Availability of Grant Funds

Closing Date: August 20, 1982. An application must be mailed or hand-delivered by the closing date.

The Director invites applications for projects offering technical assistance to mutual assistance associations in business development and business management.

Authorization

Authority for this activity is contained in the Immigration and Nationality Act (8 U.S.C. 1522) as amended by the Refugee Act of 1980, Section 412, Public Law 96–212. No Catalog of Federal Domestic Assistance number has been issued.

Available Funds

It is expected that approximately $250,000 will be available for new grants in fiscal year 1982. The Director estimates that these funds could support three (3) projects. The anticipated award for a project is between $50,000 and $100,000.

However, these estimates do not bind the Office of Refugee Resettlement to a specific number of grants or to the amount of any grant unless that amount is otherwise specified by statute or regulations.

Awards will be for one year with no further funding anticipated.

Summary

This announcement governs the award of grants to provide funding for the delivery of technical assistance to Mutual Assistance Associations (MAAs) and refugee organizations in business development activities. Under this announcement, MAAs on behalf of their community and in cooperation with business experts will have access to technical assistance from experienced consultants and trainers. The grantee will develop a methodology and implementation process to attain maximum impact on MAA and refugee community business development, business management and training activities.

Applications Delivered by Mail

An application sent by mail must be addressed to the U.S. Department of Health and Human Services, Social Security Administration, Office of Refugee Resettlement, Grants Management Branch, Room 1332, Switzer Building, 330 C Street, S.W., Washington, D.C. 20201. An applicant must show proof of mailing consisting of one of the following:

(1) A legibly dated U.S. Postal Service postmark.

(2) A legible mail receipt with the date of mailing stamped by the U.S. Postal Service.

(3) A dated shipping label, invoice or receipt from a commercial carrier.

If an application is sent through the U.S. Postal Service, the Director does not accept either of the following as proof of mailing: (1) A private metered postmark, or (2) a mail receipt that is not dated by the U.S. Postal Service.

Applicants should note that the U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, the applicant should check with its local postal office.

Applicants are encouraged to use registered or at least first class mail. Each late applicant will be notified that its application will not be considered.

Applications Delivered by Hand

An application that is hand delivered must be taken to the U.S. Department of Health and Human Services, Social Security Administration, Office of Refugee Resettlement, Grants Management Branch, Room 1332, Switzer Building, 330 C Street, S.W., Washington, D.C. 20201.

The Grants Management Branch will accept a hand-delivered application between 8:30 am and 5:00 pm Eastern Daylight Time daily, except Saturdays, Sundays, and Federal holidays.

An application that is hand-delivered will not be accepted after 5:00 pm on the closing date.

FOR FURTHER INFORMATION CONTACT:

U.S. Department of Health & Human Services, Social Security Administration, Office of Refugee Resettlement, Room 1332, Switzer Building, 330 C Street, S.W., Washington, D.C. 20201, telephone (202) 245-0403.

SUPPLEMENTARY INFORMATION:

I. Program Objectives

This announcement describes the availability of funding for grants supporting the provision of technical assistance (T.A.) to Mutual Assistance Associations and refugee organizations involved in business development activities. It is anticipated that either an MAA with demonstrable business development experience and/or expert staff or a business organization working in close cooperation with an MAA, will be able to accomplish the objectives of this project. The successful grantee will develop a methodology for the delivery of T.A. to refugees in several communities. Grantees will be excepted to use local resources where available while providing business management training and on-site consultations to refugee organizations seeking business opportunities or refugee businesses already established, seeking T.A.

Many refugee groups have developed an interest and have become involved in various kinds of business and economic development activities as a means of achieving economic self-sufficiency and increasing job opportunities for refugees. Refugee businesses are seen as potential sources of employment, especially in areas where other job opportunities for refugees may be limited. Moreover, the presence of refugee businesses in a community can provide role models of effective refugee adaptation to their new environment.

As members of the refugee community have become increasingly interested in and able to assist their countrymen in business activity, MAAs have become directly involved in business development. Their leaders have recognized the need for business management training and direct consultation by persons experienced in American business practices. This program is directed at increasing refugee opportunities and successes in business through consultations with refugee businesses and refugee organizations exploring business ventures.

Proposals should detail substance, process, and format. Business development activities such as feasibility planning, "the business-package" preparation, and provision of information on business resources are potential topics for inclusion in this program. Additionally, such business services as assistance in marketing, bookkeeping, merchandising, inventory control, and referrals to professional resources for follow-up, may also be included.

It is important to the success of this program that the relationships between refugee community organizations and business organizations become explicit. Therefore, it is a requirement under this application notice, that the prospective grantee demonstrate an agreement for a specific amount of cash or a specific in-kind contribution from the business community or other non-public sources. In-kind contributions may involve specific assignments of significant staff resources or the loan of key personnel to the funded project.

The successful grantees under this announcement will provide detailed, hands-on instruction and consultation to MAAs, refugee organizations, and refugee businesses in business development activities.

II. Eligible Grantees

MAAs and other non-profit organizations with demonstrated experience in consulting and training in business development, and/or business management are eligible to apply for a grant under this program. MAAs or consortia of MAAs, or MAAs working with a specific agreement with a management/business consultant organization, are prospective applicants. An MAA is defined, for purposes of this grant, as an incorporated non-profit refugee organization.

III. Activities

Successful applicants under this announcement will have business development, management consultation and training expertise. It is anticipated that prospective grantees will demonstrate current contacts and experience in the business sector, knowledge of the refugee community, and skill in providing training and on-site technical assistance.

Applicants will be expected to design a methodology and time/task specification of how they plan to approach business development assistance and management training to refugees in several communities. It is anticipated that some combination of practitioner workshops, site visits, consultations and/or conferences may be included as part of a design for programs proposed under this announcement.

The applicant is required to document business development expertise, refugee-community access and a commitment of specific resources from the corporate sector or business community. It is expected that the applicant will clearly show how their proposal will result in an improved capacity for refugee involvement in business activity and a greater number of refugee-owned or operated business establishments which extend employment opportunities for refugees. The proposed program and its prospective accomplishments should all be stated in measurable terms.

Though initial needs assessments may be necessary, it is expected that prospective grantees will be familiar enough with the needs of refugee

community groups and business development opportunities that substantial business development and training needs assessments can be minimized. Target populations should be identified and justified in the proposal.

IV. A-95 Notification Process

OMB Circular A-95 is expected to be rescinded prior to the closing date for the receipt of applications, making the applicability of A-95 to this program moot.

V. Application Submission and Approval Procedures

Applicants may request grant applications from the Department of Health and Human Services, Social Security Administration, Office of Refugee Resettlement, Grants Management Branch, 330 C Street, SW., Washington, D.C. 20201, 202-245-0403. Prospective grantees must submit an original application and two copies to the Grants Management Branch.

An independent panel will be convened to evaluate and rate applications. Final funding decisions will be made by the Director of the Office of Refugee Resettlement. Criteria for panel evaluation are listed under IX below. It is estimated that grant awards will be issued on or about September 15, 1982.

VI. Applicable Regulations

The following HHS regulations apply to grants under this notice:

45 CFR Part 16 Department Grant Appeals Process;

45 CFR Part 74 Administration of Grants;

45 CFR Part 75 Informal Grant Appeals Procedures;

45 CFR Part 80 Nondiscrimination under programs receiving Federal Assistance through the Department of Health and Human Services Effectuation of Title VI of the Civil Rights Act of 1964.

45 CFR Part 81 Practice and Procedures for Hearings under Part 80 of this Title.

45 CFR Part 84 Nondiscrimination on the Basis of Handicap in Programs and Activities Benefitting from Federal Financial Assistance.

45 CFR Part 90 Nondiscrimination on the Basis of Age in Programs or Activities Receiving Federal Financial Assistance.

VII. Criteria for Evaluating Applications

Project grant applications will be evaluated and rated according to the following criteria:

1. The presentation of a clear, efficient, cost-effective plan for organizing, developing, and accomplishing the tasks and program outlined in the proposal. Demonstrated organizational capacity for overall administrative management. (15 points)

2. The extent to which the applicant can demonstrate through past experience in business development, the ability to deliver the proposed services including meeting program timelines. (25 points)

3. An operationally feasible plan for the establishment of an efficient, supportive and collaborative working relationship with the refugee community, and the business sector. The extent to which there is documentation for the relationships required for the success of the program. (20 points)

4. The extent and appropriateness of the cash or in-kind contribution (the non-federal match) from the business sector to the applicant. The applicant should be able to demonstrate a private-section commitment that will serve as a foundation for current and on-going activities. (20 points)

5. The extent to which activities can be evaluated quantitatively and qualitatively as demonstrated by a reasonable plan for project evaluation; and the extent to which program goals are being or can be met. (10 points)

6. The reasonableness of anticipated costs. (10 points)

VIII. Application Content

All applicants will use Standard Form SSA 96 in submitting project proposals. Grant applications must also include the following:

1. Description of the applicant organization including its organizational mandate, funding sources, principal officers, addresses, telephone number, and photo copies of the organization's certificate of non-profit status (501-C-3-papers).

2. A listing and explanation of any previous, relevant applicant experience related to this project. Appropriate projects may include (but are not limited to) small business development, organizing and developing management training programs, management consultation and/or economic development consultation; intensive work with refugees and/or other special populations; refugee resettlement activities; or other similar specialized projects.

3. Specification of project goals, objectives, and a work plan for their accomplishment. This plan should specifically include a task by task implementation and time schedule.

4. A description of arrangements and documentation showing how requirements for the non-federal match contribution will be met. Match-participation may be in the form of corporate cash or personnel loans, foundation support, and/or significant organizational staff support. The matching contribution should be described as follows:

(a) Amount of money;

(b) Percentage of staff time contributed;

(c) Description of relevant skills of loaned personnel;

(d) Sources of contribution.

5. Establishment of an advisory board reflecting experience and expertise relative to the project objectives must be detailed. It is expected that one or more refugee organizations will be represented on this board.

6. Position descriptions and qualifications for the project director and key staff. All staff must possess demonstrable relevant experience for the functions they are hired to perform.

7. Detailed Program Budget.

IX. Records and Reports

Grantees will be required to maintain such fiscal and operational records as are necessary for Federal monitoring and auditing of the grant. In addition to the fiscal reporting requirements delineated in 45 CFR Part 74, quarterly project program reports will be required—due 30 days after the last day of each quarter following the effective date of the grant. The format for these reports will be provided by the Office of Refugee Resettlement.

Phillip N. Hawkes,

Director, Office of Refugee Resettlement.

June 29, 1982.

[FR Doc. 82-18116 Filed 7-1-82; 8:45 am]

BILLING CODE 4190-11-M

Office of the Secretary

Agency Forms Submitted to the Office of Management and Budget for Clearance

Each Friday the Department of Health and Human Services (HHS) publishes a list of information collection packages it has submitted to the Office of Management and Budget (OMB) for clearance in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). The following are those packages submitted to OMB since the last list was published on June 18.

Public Health Service

National Institutes of Health

Subject: Guest Researcher Assignment Form (NIH-590)—New.

Respondents: Individuals.

Alcohol Drug Abuse and Mental Health Administration

Subject: Drug Abuse Warning Network (0930–0078)—Revision.

Respondents: Hospital emergency rooms and medical examiners/coroners.

Center for Disease Control

Subject: National Evaluation of School Health Curriculum—New.

Respondents: Individuals or households/state or local governments.

OMB Desk Officer: Richard Eisinger

Food and Drug Administration

Subject: Investigational Device Exemption Reports and Records (0910–0078)—Extension.

Respondents: Individuals or households/businesses or other institutions.

OMB Desk Officer: Fay S. Iudicello.

Social Security Administration

Subject: Request for Authorization to Report Annual Wage and Social Security Contributions on Magnetic Tape (SSA–2478, 2479, 2480, 2481, 2482)—New.

Respondents: State or local governments/businesses or other institutions.

OMB Desk Officer: Milo Sunderhauf.

Copies of the above information collection clearance packages can be obtained by calling the HHS Reports Clearance Officer on 202–245–6511.

Written comments and recommendations for the proposed information collections should be sent directly to both the HHS Reports Clearance Officer and the appropiate OMB Desk Officer designated above at the following addresses:

J. J. Strnad, HHS Reports Clearance Officer, Hubert H. Humphrey Building, Room 524.F, Washington, D.C. 20201.

OMB Reports Management Branch, New Executive Office Building, Room 3208, Washington, D.C. 20503, Attn: (name of OMB Desk Officer).

Dated: June 25, 1982.

Dale W. Sopper,

Assistant Secretary for Management and Budget.

[FR Doc. 82-17926 Filed 7-1-82; 8:45 am]

BILLING CODE 4150-04-M

Public Health Service

Privary Act of 1974; Waiver of Advance Notice Period for a New System of Records

AGENCY: Public Health Service, HHS.

ACTION: Waiver of advance notice period for a new system of records.

SUMMARY: **Federal Register** document 82–16416, appearing at page 26240 in the issue for Thursday, June 17, 1982, provided notification of a new system of records proposed by the Alcohol, Drug Abuse and Mental Health Administration. That system is 09–30–0041, "Subject-Participants in a Drug Abuse Research Study on Naltrexone," HHS/ADAMHA/NIDA. The document stated that the Public Health Service had requested that the Office of Management and Budget (OMB) grant a waiver of the usual requirements that a system of records not be put into effect until 60 days after the report is sent to OMB and the Congress.

OMB granted the requested waiver on June 11, 1982.

Accordingly, the new system of records, 09–30–0041, became effective upon the date of the waiver except for the routine uses established for the system. They will become effective July 19, 1982, following the public comment period.

Dated: June 24, 1982.

Wilford J. Forbush,

Deputy Assistant Secretary for Health Operations and Director, Office of Management.

[FR Doc. 82-18018 Filed 7-1-82; 8:45 am]

BILLING CODE 4160-20-M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[INT DEIS 82–41]

Availability of Draft Environmental Impact Statement and Notice of Public Hearing; Preliminary Wilderness Recommendations for the Clear Lake Resource Area, Ukiah District, California

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: Pursuant to Section 102(2)(C) of the National Environmental Policy Act of 1969, the Bureau of Land Management has prepared a draft environmental impact statement concerning preliminary wilderness recommendations for the Clear Lake Resource Area, Ukiah District, California. The proposed action is to designate the Cedar Roughs Wilderness Study Area (WSA) and the Rocky Creek-Cache Creek WSA as nonsuitable for wilderness. Alternatives considered include all wilderness, no wilderness, partial wilderness, and no action.

DATES: Comments on the draft environmental impact statement are being solicited from public agencies and interested inviduals and organizations. The Bureau of Land Management invites written comments on the statement to be submitted by September 1, 1982, to the District Manager, Ukiah District, P.O. Box 940, 555 Leslie Street, Ukiah, California 95482.

A public hearing on the wilderness study will be held from 7:00 p.m. to 10:00 p.m. on August 2, 1982, at 292 West Beamer Street, Woodland, California.

ADDRESSES: A limited number of copies of the draft environmental impact statement are available at the Ukiah District Office and at the following locations:

California State Office, Bureau of Land Management, 2800 Cottage Way, Sacramento, CA 95825, Telephone: (916) 484–4541

Washington Office, Bureau of Land Management, Interior Building, 18th and C Streets, N.W., Washington, D.C. 20240

FOR FURTHER INFORMATION CONTACT: Stanley R. Whitmarsh, Recreation Planner, Bureau of Land Management, Ukiah District Office, P.O. Box 940, 555 Leslie Street, Ukiah, California 95482, Telephone (707) 462–3873.

Dated: June 16, 1982.

Van W. Manning,

District Manager.

[FR Doc. 82-17566 Filed 7-1-82; 8:45 am]

BILLING CODE 4310-84-M

Issuance of Land Exchange Conveyance Document; Exchange of Public and Private Lands; Bear Lake County, Idaho

The United States has issued an Exchange Conveyance Document to Lazy C–H Ranch, Inc., Route 1, Montpelier, Idaho 83524, for the following described lands under Section 206 of the Federal Land Policy and Management Act of 1976.

Boise Meridian, Idaho

T. 14 S., R. 45 E.,
Sec. 23, NE¼NE¼.
Comprising 40.00 acres of public land.

In exchange for these lands, the United States acquired the following described lands:

Boise Meridian, Idaho

T. 14 S., R. 45 E.,
Sec. 13, SE¼SE¼.
Comprising 40.00 acres of private land.

The purpose of this exchange was to consolidate public land for better

management, authorize farming of the public land by transferring it to private ownership, and provide long-term benefits to the Government in livestock forage and wildlife habitat. The public interest was well served through completion of this exchange.

The values of the Federal public land and the non-Federal land in the exchange were appraised at $7,350.00 and $6,000.00 respectively. An equalization payment of $1,350.00 was paid to the United States by Lazy C–H Ranch, Inc.

Dated: June 25, 1982.

Louis B. Bellesi,

Chief, Division of Operations.

[FR Doc. 82-18066 Filed 7-1-82; 8:45 am]

BILLING CODE 4310-84-M

Minerals Management Service

Outer Continental Shelf Offshore the Middle Atlantic States; Availability of Draft Environmental Impact Statement and Location and Dates of Public Hearing Regarding Proposed Oil and Gas Lease Sale No. 76

Pursuant to section 102(2)(C) of the National Environmental Policy Act of 1969, the Minerals Management Service has prepared a draft environmental impact statement relating to a proposed oil and gas lease sale offering tracts consisting of 24.6 million acres of submerged lands on the Outer Continental Shelf offshore the Middle Atlantic States (OCS Sale No. 76).

Single copies of the draft environmental impact statement can be obtained from the Manager, Atlantic OCS Region, Minerals Management Service, 1951 Kidwell Drive, Suite 601, Vienna, VA 22180 and from the Offshore Environmental Assessment Division, Minerals Management Service, Washington, D.C. 20240.

Copies of the draft environmental impact statement will also be available for review in the following public libraries:

East Albermarle Regional Library, 205 E. Main Street, P.O. Box 303, Elizabeth City, NC 28560
New Bern-Craven County Public Library, 400 Johnson Street, New Bern, NC 27909
Olivia Raney Public Library, 104 Fayetteville Street, Raleigh, NC 27601
Wilmington Public Library, 409 Market Street, Wilmington, NC 28401
New York Public Library, 5th Avenue & 42nd Street, New York, NY 10018
Nassau Library System, Reference Division, 900 Jerusalem Avenue, Uniondale, NY 11553
Suffolk Cooperative Library, 627 N. Sunrise Service Road, P.O. Box 1872, Bellport, NY 11713
Trenton Free Public Library, 120 Academy Street, Trenton, NJ 08608
Atlantic City Free Library, Illinois & Pacific Avenues, Atlantic City, NJ 08401
Providence Public Library, 150 Empire Street, Providence, RI 02903
Newport Public Library, Aquidneck Park, Newport, RI 02840
Boston Public Library, Copley Square, Boston, MA 02117
Christian Science Monitor, 1 Norway Street, Boston, MA 02115
Free Library of Philadelphia, Logan Circle, Philadelphia, PA 19141
Rehoboth Beach Public Library, Municipal Center, Rehoboth Avenue, Rehoboth Beach, DE 19971
Ocean County Library, 15 Hooper Avenue, Toms River, NJ 08753
Atlantic County Library,Surrogate Building, Mays Landing, NJ 08330
Public Library, 105 45th Street, Sea Isle City NJ 08243
Public Library, 639 Washington Street, Cape May, NJ 08204
Enoch Pratt Free Library, 400 Catherdral Street, Baltimore, MD 21201
Norfolk Public Library System, 301 S. City Hall Avenue, Norfolk, VA 23510
Monmouth County Library, 25 Broad Street, Freehold, NJ 07728
East Bruswick Public Library, 2 Jean Walling Civic Center, East Brunswick, NJ 08816
New Jersey State Library, P.O. Box 1898, Trenton, NJ 08625
Eastern Shore Area Library, 122–126 South Division Salisbury, MD 21801
Wilmington Institute Free Library and Newcastle County Free Library, 10th & Market Street, Wilmington, DE 19801

In accordance with 43 CFR 3314.1, public hearings will be held on September 15, 1982, at the Omni International Hotel, Waterfront Drive and St. Paul Boulevard, Norfolk, Virginia for the purpose of receiving comments regarding the Middle Atlantic OCS leasing proposal. The hearings will begin at 10:00 a.m., E.D.T., and will conclude at 5:00 p.m., or earlier if all scheduled witnesses have testified.

The hearings will provide the Secretary of the Interior with additional information from both public and private sectors to help evaluate fully the potential effects of leasing oil and gas tracts offshore the Middle Atlantic States. In addition, the proceedings will give the Secretary the opportunity to receive further comments and views of concerned Federal, State, and local agencies.

Interested individuals, representatives of organizations, and public officials who wish to testify at the hearing are requested to contact the Manager, Atlantic OCS Region, Minerals Management Service, at the above address by 4:30 p.m., September 8, 1982. Written comments from those unable to attend the hearing also should be addressed to the Manager, Atlantic OCS Region, Minerals Management Service at the above address. The Minerals Management Service will accept written testimony and comments on the draft environmental impact statement until September 20, 1982. Time limitations make it necessary to limit the length of oral presentations to ten (10) minutes. An oral statement may be supplemented, however, by a more complete written statement which may be submitted to the hearing officer at the time of presentation of the oral statement. Written statements presented in person at the hearing will be considered as part of the hearing record. To the extent that time is available after presentation of oral statements by those who have given advance notice, the hearing officer will give others present an opportunity to be heard.

After testimony and comments have been received and analyzed, a final environmental impact statement will be prepared.

Dated: June 29, 1982.

David C. Russell,

Deputy Director, Minerals Management Service.

Approved:

Bruce Blanchard,

Director, Environmental Project Review.

[FR Doc. 82-18046 Filed 7-1-82; 8:45 am]

BILLING CODE 4310-84-M

National Park Service

Availability of Draft Development Concept Plan; Upper Frijoles and Back Gate Areas, Bandelier National Monument, Santa Fe, Sandoval and Los Alamos Counties, New Mexico

Pursuant to the National Environmental Policy Act of 1969, Title 40 of the Code of Federal Regulations, and Part 516 of the Departmental Manual, the National Park Service has prepared a Draft Development Concept Plan for the Upper Frijoles and Back Gate areas of Bandelier National Monument, Santa Fe, Sandoval and Los Alamos Counties, New Mexico.

The Draft Development Concept Plan for the Upper Frijoles and Back Gate areas has been prepared to provide

additional visitor use and improve and upgrade existing visitor facilities.

The Draft Development Concept Plan is available for review in the Office of the Superintendent, Bandelier National Monument, Los Alamos, New Mexico 87544; and the Southwest Regional Office, National Park Service, 1100 Old Santa Fe Trail, Santa Fe, New Mexico. Copies of the document may be obtained, upon request, from Bandelier National Monument, at the address provided above.

Anyone wishing to provide comments on the Draft Development Concept Plan should provide them to the Superintendent, Bandelier National Monument, Los Alamos, New Mexico 87544, by August 2, 1982.

Dated: June 23, 1982.

Robert Kerr,

Regional Director, Southwest Region.

[FR Doc. 82-18058 Filed 7-1-82; 8:45 am]

BILLING CODE 4310-70-M

Availability of Plan of Operations for the Purpose of Oil Drilling Operations; Big Cypress National Preserve

In accordance with § 9.52 of Title 36 of the Code of Federal Regulations, Big Cypress National Preserve has received from Clayton Williams, Jr., a Plan of Operations for a seismic survey in the Barnes Strand to Windmill Prairie area of the Preserve. The public is invited to review and comment on the Plan of Operations, copies of which are available for review during normal business hours at Everglades National Park, Route 27, 12 miles south of Homestead Florida; Big Cypress National Preserve, Ochopee, Florida; Miami-Dade Public Library System, Main Library, 1 Biscayne Boulevard, Miami, Florida; Collier County Public Library, 650 Central Avenue, Naples, Florida; and at the National Park Service, Southeast Regional Office, 75 Spring Street, S.W., Atlanta, Georgia. Comments received on or before August 2, 1982 will be entered into the official record. For further information, contact Pat Tolle, Management Assistant, Everglades National Park (305) 247-6211.

Dated: June 29, 1982.

Neal G. Guse,

Acting Regional Director, Southeast Region.

[FR Doc. 82-18186 Filed 7-1-82; 8:45 am]

BILLING CODE 4310-70-M

Office of Surface Mining Reclamation and Enforcement

Abandoned Mine Land Reclamation Program; Ohio

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

ACTION: Receipt of the Abandoned Mine Land Reclamation (AMLR) Grant Application from the State of Ohio.

SUMMARY: On June 2, 1982, the State of Ohio submitted to OSM its proposed AMLR grant application under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The grant will not be approved until the Secretary has approved the Title IV Reclamation Program.

ADDRESSES: Copies of the full text of the proposed Ohio grant application are available for review during regular business hours at the following locations:

Office of Surface Mining Reclamation and Enforcement, Ohio State Office, 2242 So. Hamilton Road, Columbus, Ohio 43227, and

Nina Rose Hatfield, State Office Director, Office of Surface Mining Reclamation and Enforcement, Ohio State Office, 2242 S. Hamilton Road, Columbus, Ohio 43227.

FOR FURTHER INFORMATION CONTACT: Nina Rose Hatfield, State Director, Ohio State Office, 614/469-2500.

SUPPLEMENTARY INFORMATION: On October 20, 1980, a State reclamation plan was submitted to the Secretary. The Ohio Plan has been reviewed by the Secretary and is presently awaiting approval. Under Section 405(f) of the SMCRA, the Secretary cannot approve a State AMLR program grant unless that State has an approved State AMLR program pursuant to Section 405(d) of the SMCRA.

On June 2, 1982, OSM received an AMLR grant application from the State of Ohio.

Title IV of the Surface Mining Control and Reclamation Act of 1977 (SMCRA), Public Law 95-87, 30 U.S.C. 1201 *et seq.*, establishes an AMLR program for the purposes of reclaiming and restoring land and water resources adversely affected by past mining. This program is funded by a reclamation fee imposed upon the production of coal. Lands and water eligible for reclamation under the program are those that were mined or affected by mining and abandoned or left in an inadequate reclamation status prior to August 3, 1977, and for which there is no continuing reclamation responsibility under State and Federal law.

Each State having within its borders coal mined lands eligible for reclamation under Title IV of SMCRA may submit to the Secretary a State reclamation grant application to implement the provisions of the approved State Reclamation Plan. However, grants for reclamation may be issued only to States with an approved Title V Regulatory Program for active mine reclamation and an approved Title IV Reclamation Program. The grant application received from the State of Ohio will be reviewed and held pending a final approval by the Secretary on the State's Title IV program in accordance with SMCRA.

This notice describes the nature of the proposed projects. This publication does not represent any decision by the Secretary on the Title IV Reclamation Program, but is published solely for the purpose of expediting the review process and the implementation of the reclamation program if the Title IV program of the State of Ohio is approved.

The Director has found that the State has given the public adequate notice and opportunity to comment in public hearings, and the record of such hearings does not reflect major unresolved controversies.

OSM intends to continue to discuss the State's application with representatives of the State throughout the review process.

In order to comply with the requirements of the National Environmental Policy Act, OSM will assess the environmental effects of all State reclamation projects. The primary basis for this assessment will be the environmental information provided in the project grant application.

The Ohio AMLR grant application can be approved if:

1. The Director finds that the public has been given adequate notice and opportunity to comment, and the record does not reflect major unresolved controversies.

2. Views of other Federal agencies have been solicited and considered.

3. The application meets all the requirements of the OSM, AMLR program provisions and the required Federal circulars.

4. The State has an approved regulatory program and an approved State reclamation plan.

The following constitutes a summary of the contents of the submission:

1. Designation of authorized State Agency to administer the program,

2. Objectives and need for the assistance,
3. Project ranking and selection,
4. Coordination with other reclamation programs,
5. Results and benefits expected,
6. Plan of action pertaining to the scope,
7. Monthly or quarterly projections of accomplishments to be achieved,
8. Kinds of data to be collected and maintained,
9. Criteria used to evaluate the results and success of the projects,
10. Key individuals to be employed,
11. Precise location of the project and area to be served,
12. Budgetary calculations for each project,
13. Description of the public's participation in planning and preparation of the grant application,
14. A complete environmental assessment for each project.

Reclamation projects included in application and location:

Athens County
- Nelsonville Mine Seeps (mine seeps)

Belmont County
- Barton (Village of) (mine drainage and gob pile)
- Belmont County Road 10 (landslide and mine seepage)
- Blaine School Subsidence (subsidence)
- Coe (subsidence)
- Glenns Run (gob pile)
- Goosetown (mine seepage)
- Holloway (strip mine and stream restoration)
- Indian Run (gob pile)
- Perko (mine seepage and landslide)
- Zemba (mine seepage)

Carroll County
- Holland (mine shafts)

Columbiana County
- Columbiana County Shafts (mine shafts)

Coshocton County
- Mills (subsidence)

Gallia County
- Africa Road (eroded strip mine, toxic spoil)

Harrison County
- Cavin (subsidence)
- Green Township Road 64 (pit seepage)
- Harrison County Road 2 (dangerous highwall)

Jackson County
- Jackson County Road 40 (landside)
- Walton Shaft (mine shaft)

Jefferson County
- Jefferson County Road 1 (landslide)
- Jefferson County Road 53 (Lake George) (road flooding, blocked drainage system)
- Jug Run II (mine drainage)
- Little Short Creek (gob pile, strip mine)
- Richmond (Village) (dangerous highwall and pit)
- Rivers (landslide)
- WTOV (mine shaft)

Mahoning County
- Mahoning County Shafts (mine shafts)
- Tecumseh Trailer Park (dangerous highwall)
- Youngstown Shafts (mine shafts)

Meigs County
- Lewis/Wolfe Drive (mine shafts)
- Little Leading Creek (strip mine, acid mine drainage, sedimentation, flooding)
- Meigs #2 (strip mine, sedimentation, flooding)
- Snowville (strip mine, sedimentation, acid water, flooding)

Noble County
- Whiskey Run (erosion, blocked drainage system, flooding)

Perry County
- Bond (subsidence)
- Fee-German (subsidence)
- New Lexington Subsidence (subsidence)
- New Lexington Reservoir II (mine drainage)

Summit County
- Barberton (subsidence)

Trumbull County
- Trumbull County Shafts II and III (mine shafts)

Tuscarawas County
- Martin-Velleca (mine seepage)
- Uhrichsville (mine seepage)
- Warwick Township Road 269 (mine seepage).

Dated: June 22, 1982.

J. Steven Griles,

Director, Office of Surface Mining.

[FR Doc. 82-18143 Filed 7-1-82; 8:45 am]

BILLING CODE 4310-05-M

Abandoned Mine Land Reclamation Program; Tennessee

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

ACTION: Receipt of the Abandoned Mine Land Reclamation (AMLR) Grant Application from the State of Tennessee.

SUMMARY: On April 18, 1982, the State of Tennessee submitted to OSM its proposed AMLR grant application under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The grant will not be approved until the Secretary has approved the Title V Regulatory Program and the Title IV Reclamation Program.

ADDRESSES: Copies of the full text of the proposed Tennessee grant application are available for review during regular business hours at the following locations:

Office of Surface Mining Reclamation and Enforcement, Region II, 530 Gay Street, Suite 500, Knoxville, Tennessee 37902 and

Tennessee Division of Surface Mining, Abandoned Lands Section, Dempster Building, 305 West Springdale, Knoxville, Tennessee 37917, Contact Person: Tim Eagle

FOR FURTHER INFORMATION CONTACT: W. Hord Tipton, Acting Regional Director, Office of Surface Mining Reclamation and Enforcement, 530 Gay Street, Suite 500, Knoxville, Tennessee 37902, (615) 971-5231.

SUPPLEMENTARY INFORMATION: On March 24, 1982, a State reclamation plan was submitted to the Secretary. Action by the Secretary on the plan has been delayed because Tennessee does not have an approved State regulatory program under Title V of SMCRA. Under Section 405(c) of the SMCRA, the Secretary cannot approve a State AMLR program unless that State has an approved State regulatory program pursuant to Section 503 of the SMCRA.

On April 18, 1982, OSM received an AMLR grant application from the State of Tennessee.

Title IV of the Surface Mining Control and Reclamation Act of 1977 (SMCRA), Pub. L. 95-87, 30 U.S.C. 1201 *et seq.*, establishes an AMLR program for the purposes of reclaiming and restoring land and water resources adversely affected by past mining. This program is funded by a reclamation fee imposed upon the production of coal. Lands and water eligible for reclamation under the program are those that were mined or affected by mining and abandoned or left in an inadequate reclamation status prior to August 3, 1977, and for which there is no continuing reclamation responsibility under State and Federal law.

Each State having within its borders coal mined lands eligible for reclamation under Title IV of SMCRA may submit to the Secretary a State reclamation grant application to implement the provisions of the approved State Reclamation Plan. However, grants for reclamation may be issued only to States with an approved Title V Regulatory Program for active mine reclamation and an approved Title IV Reclamation Program. The grant application received from the State of Tennessee will be reviewed and held pending a final approval by the Secretary on the State's Title V and Title IV programs in accordance with SMCRA.

This notice describes the nature of the proposed projects. This publication does

not represent any decision by the Secretary on the Title V Regulatory Program or the Title IV Reclamation Program, but is published solely for the purpose of expediting the review process and the implementation of the reclamation program, if the Title V and Title IV programs of the State of Tennessee are approved.

The Director has found that the State has given the public adequate notice and opportunity to comment in public hearings, and the record of such hearings does not reflect major unresolved controversies.

The Department intends to continue to discuss the State's application with representatives of the State throughout the review process.

In order to comply with the requirements of the National Environmental Policy Act, OSM will assess the environmental effects of all State reclamation projects. The primary basis for this assessment will be the environmental information provided in the project grant application.

The Tennessee AMLR grant application can be approved if:

1. The Director finds that the public has been given adequate notice and opportunity to comment, and the record does not reflect major unresolved controversies.
2. Views of other Federal agencies have been solicited and considered.
3. The application meets all the requirements of the OSM, AMLR program provisions and the required Federal circulars.
4. The State has an approved regulatory program and an approved State reclamation plan.

The following constitutes a summary of the contents of the submission:

1. Designation of authorized State Agency to administer the program,
2. Objectives and need for the assistance,
3. Project ranking and selection,
4. Coordination with other reclamation programs,
5. Results and benefits expected,
6. Plan of action pertaining to the scope,
7. Monthly or quarterly projections of accomplishments to be achieved,
8. Kinds of data to be collected and maintained,
9. Criteria used to evalute the results and success of the projects,
10. Key individuals to be employed,
11. Precise location of the project and area to be served,
12. Budgetary calculations for each project,
13. Description of the public's participation in planning and preparation of the grant application, and
14. A complete environmental assessment for each project.

Reclamation projects included in the application and their location:

1. Title: Royal Blue Mine Reclamation Project; Location: Western Campbell County; Description: Seal portals and eliminate hazardous structures.
2. Title: 19–B Garbage Dump Reclamation Project; Location: Northern Central Scott County; Description: Eliminate hazardous impoundments, highwalls, and garbage.
3. Title: Frozen Head Reclamation Project; Location: Eastern Morgan County; Description: Seal portals, eliminate hazardous structures, and stabilize disposal areas.
4. Title: Kent Hollow Landslide Reclamation Project; Location: Central Campbell County; Description: Stabilize landslide.
5. Title: Stinging Fork Reclamation Project; Location: Bledsoe County; Description: Eliminate hazardous highway and sources of poor water quality.
6. Title: Twinton Reclamation Project; Location: Western Fentress County; Description: Seal airshaft, eliminate hazardous structure, and reclaim gob material.
7. Title: Tennessee Big Creek Phase I Maintenance; Location: Grundy County; Description: Liming, fertilizing, revegetation; and reworking drain crossings.

Dated: June 23, 1982.

J. Steven Griles,

Director, Office of Surface Mining.

[FR Doc. 82–18144 Filed 7–1–82; 8:45 am]

BILLING CODE 4310–05–M

INTERSTATE COMMERCE COMMISSION

Motor Carriers; Intent To Engage In Compensated Intercorporate Hauling Operations

This is to provide notice as required by 49 U.S.C. 10524(b)(1) that the named corporations intend to provide or to use compensated intercorporate hauling operations as authorized in 49 U.S.C. 10524(b).

1. Parent corporation and address of principal office: Albertson's, Inc., P.O Box 20, 250 Parkcenter Blvd., Boise, ID 83726.

2. Wholly-owned subsidiary: Albertson's Trucking, Inc. (an Idaho corporation).

1. Parent corporation and address of principal office: Martin Gas Sales, Inc., P.O. Drawer 191, Kilgore, TX 75662.

2. Wholly-owned subsidiaries which will participate in the operations, and States of incorporation: A. Martin Gas Transport, Inc., Texas Corporation; B. Heavy Fuels, Inc., Texas Corporation; C. Martin Truck Leasing, Inc., Texas Corporation; and D. Transport, Inc., Mississippi Corporation.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 82–18024 Filed 7–1–82; 8:45 am]

BILLING CODE 7035–01–M

[Vol. No. 274]

Motor Carriers; Permanent Authority Decisions; Restriction Removals; Decision-Notice

Decided: June 28, 1982.

The following restriction removal applications, filed after December 28, 1980, are governed by 49 CFR Part 1137. Part 1137 was published in the **Federal Register** of December 31, 1980, at 45 FR 86747.

Persons wishing to file a comment to an application must follow the rules under 49 CFR 1137.12. A copy of any application can be obtained from any applicant upon request and payment to applicant of $10.00.

Amendments to the restriction removal applications are not allowed.

Some of the applications may have been modified prior to publication to conform to the special provisions applicable to restriction removal. Canadian Carrier Applicants: In the event an application to transport property, filed by a Canadian domiciled motor carrier, is unopposed, it will be reopened on the Commission's own motion for receipt of additional evidence and further consideration in light of the record developed in Ex Parte No. MC–157, *Investigation Into Canadian Law and Policy Regarding Applications of American Motor Carriers For Canadian Operating Authority.*

Findings

We find, preliminarily, that each applicant has demonstrated that its requested removal of restrictions or broadening of unduly narrow authority is consistent with the criteria set forth in 49 U.S.C. 10922(h).

In the absence of comments filed within 25 days of publication of this decision-notice, appropriate reformed authority will be issued to each applicant. Prior to beginning operations under the newly issued authority, compliance must be made with the normal statutory and regulatory requirements for common and contract carriers.

By the Commission, Restriction Removal Board, Members Shaffer, Ewing, and Williams.

Agatha L. Mergenovich,

Secretary.

MC 110686 (Sub-70)X, filed May 3, 1982 and previously noticed in **Federal Register** of June 9, 1982, republished as corrected this issue. Applicant: McCORMICK DRAY LINE, INC., Avis, PA 17721. Representative: David A. Sutherland, Suite 400, 1150 Connecticut Ave. NW., Washington, DC 20036. Lead aend Subs 5, 7, 8, 9, 10, 12, 13, 15, 16, 17, 19, 21, 22, 24, 25, 26, 28, 30, 32, 34, 35, 36, 39, 41, 42, 44, 47, 48, 49, 51F, 52, 54, 55F, 56F, 63F, 64F, 65F, 67F, and 69 certificates, broaden as previously published and, in addition, (A) broaden commodity descriptions as follows: Sub 52, to "transportation equipment, internal combustion engines, transportation equipment and internal combustion engine parts, and materials, equipment, and supplies used in the manufacture and distribution thereof," from aircraft and internal combustion engines and parts, and materials, equipment, and supplies; (B) broaden cities as follows: lead certificate, Schuylkill County, PA (Mahoney City and Pottsville); Clinton County, PA (Lock Haven, Woolrich, Beech Creek, and Renovo); Camden and Gloucester Counties, NJ and Philadelphia County, PA (Camden, NJ); Sub 32, Clinton County, PA (Avis) and Sub 36, Knox County, IL (Galesburg). The purpose of this republication is to correct inadvertent omissions and errors.

MC 121811 (Sub-10)X, filed June 22, 1982. Applicant: McCLELLAN ENTERPRISES, Inc., P.O. Box 1327, Tifton, GA 31794. Representative: J. L. Fant, P.O. Box 577, Jonesboro, GA 30237. Sub 3F, broaden lumber to "lumber and wood products."

MC 124170 (Sub-191)X, filed October 21, 1981 and previously noticed in **Federal Register** November 9, 1981, republished as corrected this issue. Applicant: FROSTWAYS, INC., 3000 Chrysler Service Drive, Detriot, MI 48207. Representative: William J. Boyd, Suite 205, 2021 Midwest Road, Oak Brook, IL 60521. Lead and Subs 3, 8, 12, 13, 14, 15, 19, 22, 23, 26, 31, 32, 33, 40, 48, 55, 64, 66, 68, 71, 72, 76, 82F, 89F, 90F, 92F, 95F, 103F, 106F, 107F, 110F, 111F, 113F, 120F, 121F, 122F, 125F, 129F, 130F, 146F, 147F, 150F, 152F, and 157 certificates and 159F permit, broaden as previously published and, in addition, in the lead and Sub-Nos. 76, 89, and 107, Philadephia, PA, to Bucks, Montgomery, Chester, Delaware, and Philadelphia Counties, PA, New Castle County, DE, and Salem, Gloucester, Camden, Burlington, Mercer, Hunterdon, and Monmouth Counties, NJ. The purpose of this republication is to allow broadening of Philadelphia under the standards enunciated in No. MC 87523 (Sub-No. 119)X, *Stewart Trucking Company—Administrative Appeal* (not printed), decided December 17, 1981.

MC 127955 (Sub-13)X, filed June 21, 1982. Applicant: RICCI TRANSPORTATION CO., INC., Odessa Ave. and Aloe St., Pomona, NJ 08240. Representative: Joseph A. Keating, Jr., 121 S. Main St., Taylor, PA 18517. Sub 4 certificate: broaden to (1) "food and related products" from malt beverages in containers; (2) county-wide authority: (a) Onondaga County, NY (Syracuse), (b) Forsyth County, NC (Winston-Salem), and (c) Atlantic County, NJ (Landisville); and (3) radial authority.

MC 146084 (Sub-4)X, filed June 21, 1982. Applicant: THOMAS R. GOLTZ, d.b.a. GOLTZ TRUCKING, Box 91 Young America, IN 46998. Representative: Robert W. Loser II, 1101 Chamber of Commerce Bldg., 320 N. Meridian St., Indianapolis, IN 46204. Sub 2, remove against commodities-in-bulk restrictions from salt/salt products and materials equipment and supplies used in manufacture/distribution thereof; and broaden territorial scope to between points in U.S., under continuing contract(s) with named shipper.

MC 156927 (Sub-1)X, filed June 21, 1982. Applicant: C & L TRUCKING COMPANY, 1827 Clement St., P.O. Box 2347, Alameda, CA 94501. Representative: Charles L. Coleman, III, Two Embarcadero Center, San Francisco, CA 94111. Lead certificate: (1) eliminate the restriction "to traffic having an immediately prior or subsequent movement by water;" and (2) broaden to countywide authority: San Francisco, Alameda, Contra Costa, San Mateo, Santa Clara and Marin Counties, CA (from points in the San Francisco, Alameda, Richmond, and Oakland, CA commercial zones).

[FR Doc. 82-18025 Filed 7-1-82; 8:45 am]

BILLING CODE 7035-01-M

Motor Carriers; Permanent Authority Decisions; Decision-Notice

The following applications, filed on or after February 9, 1981, are governed by Special Rule of the Commission's Rules of Practice, see 49 CFR 1100.251. Special Rule 251 was published in the **Federal Register** on December 31, 1980, at 45 FR 86771. For compliance procedures, refer to the **Federal Register** issue of December 3, 1980, at 45 FR 80109.

Persons wishing to oppose an application must follow the rules under 49 CFR 1100.252. Applications may be protested *only* on the grounds that applicant is not fit, willing, and able to provide the transportation service or to comply with the appropriate statutes and Commission regulations. A copy of any application, including all supporting evidence, can be obtained from applicant's representative upon request and payment to applicant's representative of $10.00.

Amendments to the request for authority are not allowed. Some of the applications may have been modified prior to publication to conform to the Commission's policy of simplifying grants of operating authority.

Findings

With the exception of those applications involving duly noted problems (e.g., unresolved common control, fitness, water carrier dual operations, or jurisdictional questions) we find, preliminarily, that each applicant has demonstrated a public need for the proposed operations and that it is fit, willing, and able to perform the service proposed, and to conform to the requirements of Title 49, Subtitle IV, United States Code, and the Commission's regulations. This presumption shall not be deemed to exist where the application is opposed. Except where noted, this decision is neither a major Federal action significantly affecting the quality of the human environment nor a major regulatory action under the Energy Policy and Conservation Act of 1975.

In the absence of legally sufficient opposition in the form of verified statements filed on or before 45 days from date of publication (or, if the application later become unopposed), appropriate authorizing documents will be issued to applicants with regulated operations (except those with duly noted problems) and will remain in full effect only as long as the applicant maintains appropriate compliance. The unopposed applications involving new entrants will be subject to the issuance of an effective notice setting forth the compliance requirements which must be satisfied before the authority will be issued. Once this compliance is met, the authority will be issued.

Within 60 days after publication an applicant may file a verified statement in rebuttal to any statement in opposition.

To the extent that any of the authority granted may duplicate an applicant's other authority, the duplication shall be construed as conferring only a single operating right.

Note.—All applications are for authority to operate as a motor common carrier in interstate or foreign commerce over irregular routes, unless noted otherwise. Applications for motor contract carrier authority are those where service is for a named shipper "under contract".

Please direct status inquiries to the Ombudsman's Office, (202) 275–7326.

Volume No. OP3–099

Decided: June 23, 1982.

By the Commission, Review Board No. 2, Members Carleton, Fisher, and Williams. (Member Williams not participating.)

MC 159655, filed June 15, 1982. Applicant: SHERRIN TRUCKING, INC., Route 1, Box 606, Wingate, NC 28174. Representative: David W. Erdman, 300 Law Bldg., Charlotte, NC 28202, (704) 372–7664. Transporting *food and other edible products and byproducts intended for human consumption* (except alcoholic beverages and drugs), *agricultural limestone and fertilizers, and other soil conditioners* by the owner of the motor vehicle in such vehicle, between points in the U.S. (except AK and HI).

MC 162484, filed June 11, 1982. Applicant: ROOSEVELT JOHNSON, d.b.a. R. JOHNSON REFRIGERATED TRUCKING SERVICE, P.O. Box 4232, Stockton, CA 95204. Representative: Arden Riess, P.O. Box 7965, Stockton, CA 95207, (209) 957–6128. Transporting *food and other edible products and byproducts intended for human consumption* (except alcoholic beverages and drugs), *agricultural limestone and fertilizers, and other soil conditioners* by the owner of the vehicle in such vehicle, between points in the U.S. (except AK and HI).

Volume No. OP4–232

Decided: June 28, 1982.

By the Commission, Review Board No. 2, Members Carleton, Fisher, and Williams.

MC 136816 (Sub–16), filed June 21, 1982. Applicant: THE UNIVERSE COMPANY, INC., 3523 L St., Omaha, NE 68107. Representative: Arlyn L. Westergren, 9202 W Dodge Rd., Suite 201, Omaha, NE 68114, (402) 397–7033. Transporting, for or on behalf of the United States Government, *general commodities* (except used household goods, hazardous or secret materials, and sensitive weapons and munitions), between points in the U.S. (except AK and HI).

MC 162476, filed June 14, 1982. Applicant: FREIGHT-RIGHT, 3941 Edge Rd., Pittsburgh, PA 15227. Representative: Edward M. Roberts, Sr. (same address as applicant), (412) 881–1146. As a *broker of general commodities* (except household goods), between points in the U.S. (except AK and HI).

MC 162536, filed May 27, 1982. Applicant: SWIFT INTERNATIONAL, INC., 7901 4th St., North, Suite 308, St. Petersburg, FL 33704. Representative: Robert J. Gallaher, 1000 Connecticut Ave., NW., Suite 1200, Washington, DC 20036, (202) 785–0024. As a broker of *general commodities* (except household goods), between points in the U.S. (except AK and HI).

Volume No. OP4–234

Decided: June 23, 1982.

By the Commission, Review Board No. 2, Members Carleton, Fisher, and Williams. (Member Williams not participating.)

MC 59117 (Sub-87), filed November 14, 1980. Applicant: ELLIOTT TRUCK LINE, INC., P.O. Box 1, Vinita, OK 74301. Representative: Tom B. Kretsinger, 20 East Franklin, Liberty, MO 64068, (816) 781–6000. Transporting *general commodities* (except classes A and B explosives, and household goods), between Excelsior Springs, Altamont, and Maysville, MO; Arriba, Burlington, Calhan, Flagler, Limon, Roman, Simla, and Stratton, CO; and Smith Center, Belleville, Mankato, Cuba, Norton, and Colby, KS, on the one hand, and, on the other, points in the U.S. (except AK and HI). Condition: Issuance of a certificate in this proceeding is conditioned upon applicant certifying to the Commission, prior to commencing operations, that all rail service has actually terminated at specified points. The certification should be sent to the Deputy Director, Section of Operating Rights, Interstate Commerce Commission, Washington, DC 20423.

MC 141197 (Sub-50), filed November 20, 1980. Applicant: FLEMING-BABCOCK, INC., 4106 Mattox Rd., Riverside, MO 64151. Representative: Tom B. Kretsinger, 20 East Franklin, Liberty, MO 64068, (816) 781–6000. Transporting *general commodities* (except classes A and B explosives and household goods), between Excelsior Springs, Altamont, and Maysville, MO; Arriba, Burlington, Calhan, Flagler, Limon, Roman, Simla, and Stratton, CO; and Smith Center, Belleville, Mankato, Cuba, Norton, and Colby, KS, on the one hand, and, on the other, points in the U.S. (except AK and HI). Condition: Issuance of a certificate in this proceeding is conditioned upon applicant certifying to the Commission, prior to commencing operations, that all rail service has actually terminated at specified points. The certification should be sent to the Deputy Director, Section of Operating Rights, Interstate Commerce Commission, Washington, DC 20423.

MC 162277, filed June 1, 1982. Applicant: QUICKY MESSENGER SERVICE, 160 Corabelle Ave., Lodi, NJ 07644. Representative: Donald M. Ferraiolo, 1040 Clifton Ave., Clifton, NJ 07013, (201) 777–6767. Transporting *shipments weighing 100 pounds or less* if transported in a motor vehicle in which no one package exceeds 100 pounds, between points in the U.S. (except AK and HI).

Volume No. OP4–238

Decided: June 25, 1982.

By the Commission, Review Board No. 2, Members Carleton, Fisher, and Williams.

MC 162527, filed June 17, 1982. Applicant: TERRY L. HODGE TRUCKING CO., 33312 29th Place S.W., Federal Way, WA 98003. Representative: Terry L. Hodge (same address as applicant), (206) 927–8137. Transporting *food and other edible products and byproducts for human consumption* (except alcoholic beverages and drugs), *agricultural limestone and fertilizers, and other soil conditioners* by the owner of the motor vehicle in such vehicle, between points in the U.S. (except AK and HI).

Agatha L. Mergenovich,

Secretary.

[FR Doc. 82–18026 Filed 7–1–82; 8:45 am]

BILLING CODE 7035–01–M

Motor Carriers; Permanent Authority Decisions; Decision-notice

The following applications, filed on or after February 9, 1981, are governed by Special Rule of the Commission's Rules of Practice, see 49 CFR 1100.251. Special Rule 251 was published in the **Federal Register** of December 31, 1980, at 45 FR 86771. For compliance procedures, refer to the **Federal Register** issue of December 3, 1980, at 45 FR 80109.

Persons wishing to oppose an application must follow the rules under 49 CFR 1100.252. A copy of any application, including all supporting evidence, can be obtained from applicant's representative upon request and payment to applicant's representative of $10.00.

Amendments to the request for authority are not allowed. Some of the applications may have been modified prior to publication to conform to the Commission's policy of simplifying grants of operating authority.

Findings

With the exception of those applicatins involving duly noted

problems (e.g., unresolved common control, fitness, water carrier dual operations, or jurisdictional questions) we find, preliminarily, that each applicant has demonstrated a public need for the proposed operations and that it is fit, willing, and able to perform the service proposed, and to conform to the requirements of Title 49, Subtitle IV, United States Code, and the Commission's regulations. This presumption shall not be deemed to exist where the application is opposed. Except where noted, this decision is neither a major Federal action significantly affecting the quality of the human environment nor a major regulatory action under the Energy Policy and Conservation Act of 1975.

In the absence of legally sufficient opposition in the form of verified statements filed on or before 45 days from date of publication, (or, if the application later becomes unopposed) appropriate authorizing documents will be issued to applicants with regulated operations (excepts those with duly noted problems) and will remain in full effect only as long as the applicant maintains appropriate compliance. The unopposed applications involving new entrants will be subject to the issuance of an effective notice setting forth the compliance requirements which must be satisfied before the authority will be issued. Once this compliance is met, the authority will be issued.

Within 60 days after publication an applicant may file a verified statement in rebuttal to any statement in opposition.

To the extent that any of the authority granted may duplicate an applicant's other authority, the duplication shall be construed as conferring only a single operating right.

Note.—All applications are for authority to operate as a motor common carrier in interstate or foreign commerce over irregular routes, unless noted otherwise. Applications for motor contract carrier authority are those where service is for a named shipper "under contract".

Please direct status inquiries to the Ombudsman's Office, (202) 275–7326.

Volume No. OP2–137

Decided: June 24, 1982.

By the Commission, Review Board No. 1, Members Parker, Chandler, and Fortier.

MC 98713 (Sub-9), filed June 16, 1982. Applicant: ORANGE BELT STAGES, 525 East Acequia St., Visalia, CA 93277. Representative: T. S. Haworth (same address as applicant), 415–393–9000. Transporting, over *Regular Routes, passengers and their baggage and express and newspapers,* in the same vehicle with passengers (1) between Fresno and Lemoore, CA: for Fresno over CA Hwy 99 to junction CA Hwy 43, then over CA Hwy 43 to Hanford, then over CA Hwy 198 to Lemoore, and return over the same route, (2) between Fresno, CA and junction CA Hwy 41 and CA Hwy 46, over CA Hwy 41, (3) between Fresno and Visalia, CA: from Fresno over CA Hwy 99 to Selma, then over unnumbered Hwys to Parlier, Reedley, and Dinuba, CA, to junction CA Hwy 63 at Orosi, then over CA Hwy 63 to Visalia, and return over the same route, and (4) serving all intermediate points in routes (1) through (3) above. Condition: Issuance of this certificate is subject to prior or coincidental cancellation of applicant's written request of Certificate of Registration No. MC–98713 (Sub-No. 5).

Note.—Applicant may track this authority with its existing authority.

MC 107012 (Sub-769), filed May 28, 1982. Applicant: NORTH AMERICAN VAN LINES, INC., 5001 U.S. Hwy. 30 West, Fort Wayne, IN 46818. Representative: Bruce W. Boyarko, (same address as applicant), 219–429–2224. Transporting *general commodities* (except classes A and B explosives, household goods, and commodities in bulk), between points in the U.S., under continuing contract(s) with Hart Stores, Inc., Division Big Bear Foods, Inc., of Columbus, OH.

MC 107012 (Sub-772), filed June 7, 1982. Applicant: NORTH AMERICAN VAN LINES, INC., 5001 U.S. Hwy. 30 West, Fort Wayne, IN 46818. Representative: Bruce W. Boyarko, (same address as applicant), 219–429–2224. Transporting *general commodities* (except classed A and B explosives, household goods, and commodities in bulk), between points in the U.S., under continuing contract(s) with Mobil Corporation, of Fairfax, VA.

MC 124692 (Sub-376), filed June 14, 1982. Applicant: SAMMONS TRUCKING, P.O. Box 4347, Missoula, MT 59806. Representative: James B. Hovland, 525 Lumber Exchange Building, Ten South Fifth St., Minneapolis, MN 55402, (612) 340–0808. Transporting *lumber and wood products,* between points in the U.S. (except AK and HI).

MC 127253 (Sub-56), filed May 10, 1982, published in the **Federal Register** issue of June 2, 1982, and republished, as corrected, this issue. Applicant: STEWCO, INC., P.O. Box 728, Waskom, TX 76592. Representative: Fredrick S. Wetzel III, P.O. Box 5606, North Little Rock, AR 72119, 501–376–3700. Transporting *commodities in bulk,* between points in Arkansas and Phillips Counties, AR, on the one hand, and on the other, points in the U.S. (except AK and HI). The purpose of this republication is to correct the territorial description.

MC 145042 (Sub-19), filed June 15, 1982. Applicant: ZEELAND FARM SERVICES, INC., 2468 84th Ave., Zeeland, MI 49464. Representative: James R. Neal, 1200 Bank of Lansing Building, Lansing, MI 48933, 517–482–2400. Transporting (1) *clay, stone and glass products,* (2) *containers, container closures, glassware, packaging products, container components and scrap materials,* between those points in the U.S. in and east of ND, SD, NE, KS, OK and TX.

MC 145773 (Sub-20), filed June 21, 1982. Applicant: KIRK BROS. TRANSPORTATION, INC., 800 Vandemark Rd., Sidney, OH 45365. Representative: A. Charles Tell, Suite 1800, 100 E. Broad St., Columbus, OH 43215, 614–228–1541. Transporting *such commodities* as are dealt in or used by manufacturers and distributors of welding equipment and welding wires, between points in the U.S. (except AK and HI), under continuing contract(s) with Hobart Brothers Company, of Troy, OH.

MC 147203 (Sub-7), filed June 21, 1982. Applicant: HUDSON PRODUCTS, INC., Monroe Ave. North and 4th St., North Hudson, WI 54016. Representative: Grant J. Merritt, 4444 IDS Center, Minneapolis, MN 55402, (612) 339–4546.Transporting *such commodities* as are dealt in or used by manufacturers and distributors of grass-catcher lawn mower bags, between points in MN, on the one hand, and, on the other, points in the U.S. (except AK and HI).

MC 154283 (Sub-2), filed June 21, 1982. Applicant: ELGIN MILK SERVICE, INC., Rte. 1, Elgin, MN 55932. Representative: Stephen F. Grinnel, 1600 TCF Tower, 121 South 8th St., Minneapolis, MN 55402, 612–333–1341. Transporting *food and related products* between points in the U.S., under continuing contract(s) with Associated Milk Producers, Inc., of Rochester, MN.

MC 162082, filed May 18, 1982. Applicant: ADOBE GROUP TOURS, 964 Chorro St., Suite 1, San Luis Obispo, CA 93401. Representative: Michael E. McLarney, 229 Westmont Ave., San Luis Obispo, CA 93401, (805) 544–2089. As a *broker* at San Luis Obispo, CA, in arranging for the transportation, by motor vehicle, of *passengers and their baggage, in the same vehicle with passengers,* in special and charter operations, beginning and ending at points in CA, and extending to points in the U.S.

MC 162112, filed June 15, 1982. Applicant: DOUG GAUT, d.b.a. LITTLE EAGLE EXPRESS, 2132 Neubert Rd., Knoxville, TN 37914. Representative: Kathleen D. Day, 4507 Doris Circle, Knoxville, TN 37918, 615–922–7453. Transporting *food and related products,* between Louisville and Lexington, KY, on the one hand, and, on the other, Rossville, GA, and Strawberry Plains, Knoxville, and Kingsport, TN, under continuing contract(s) with Volunteer Foods Corp., of Rossville, GA, Smokey Mountain Sales, Inc., of Strawberry Plains, TN, Pyramid Brokerage, Inc., of Knoxville, TN, and Giant Foods, Inc., of Kingsport, TN.

MC 162472, filed June 14, 1982. Applicant: ROLLAND G. PHILLIPS, d.b.a. PHILLIPS TRUCKING, 3 Moss Street, Hudson Falls, NY 12839. Representative: W. Norman Charles, P.O. Box 724, Glens Falls, NY 12801, 518–792–0957. Transporting *such commodities* as are dealt in or used by manufacturers of electrical equipment, electrical products, energy systems, and plastic articles, between points in Washington County, NY, on the one hand, and, on the other, points in AL, CT, DE, FL, GA, IL, IN, KY, MA, MD, ME, MI, MS, NH, NJ, NY, NC, OH, PA, RI, SC, TN, VA, VT, WV, WI, and DC.

MC 162523, filed June 21, 1982. Applicant: ROCCO G. ONORATO, d.b.a. NATICK CITGO, 62 E. Central St., Natick, MA 01760. Representative: Francis J. Lynch, 1627 Main St., Brockton, MA 02401, 617–583–7268. Transporting *motor vehicles,* between points in CT, DE, RI, NJ, NY, GA, VA, WV, SC, VT, MI, ME, FL, OH, PA, NH, MD, MA, and DC.

MC 162563, filed June 21, 1982. Applicant: JEAN AND DAN FORD TRAVEL AGENCY, INC., P.O. Box 798, Main St., Taylorville, MS 39168. Representative: Jean K. Ford, (same address as applicant), 601–785–6553. As a *broker,* at Taylorsville, MS, in arranging for the transportation by motor vehicle, of *passengers and their baggage,* between points in MS, on the one hand, and, on the other, points in the U.S.

Volume No. OP3–098

Decided: June 25, 1982.

By the Commission, Review Board No. 2, Members Carleton, Fisher, and Williams.

MC 106074 (Sub-193), filed June 14, 1982. Applicant: B AND P MOTOR LINES, INC., Shiloh Rd. and U.S. Hwy. 221, S., Forest City, NC 28043. Representative: Clyde W. Carver, P.O. Box 720434, Atlanta, GA 30342, (404) 256–4320. Transporting *petroleum and petroleum products,* between Tulsa, OK, Denver, CO, Casper, WY, Hammond, IN, Whiting, IN, Doraville, GA, and Guntersville, AL, on the one hand, and on the other, points in the U.S. (except AK and HI).

MC 11504 (Sub-12), filed June 17, 1982. Applicant: STARR TRANSIT CO., INC., 2531 E. State St., Trenton, NJ 08619. Representative: Alan R. Squires, 818 Widener Bldg., 1339 Chestnut St., Philadelphia, PA 19107. Over regular routes, transporting *passengers and their baggage,* in the same vehicle with passengers, between Philadelphia, PA, and Atlantic City, NJ: from Philadelphia over Interstate Hwy 76 to junction Atlantic City Expressway, and then over the Atlantic City Expressway to Atlantic City, and return over the same route, serving no intermediate points.

MC 124905 (Sub-10), filed June 14, 1982. Applicant: GARY W. GRAY TRUCKING, INC., P.O. Box 48, Delaware, NJ 07833. Representative: Joseph A. Keating, Jr., 121 S. Main St., Taylor, PA 18517, (717) 344–8030. Transporting *cement,* between points in the U.S. (except AK and HI), under continuing contract(s) with Best Block Co., Inc., of Metuchen, NJ, and its affiliates, Best Block of Toms River, of Toms River, NJ, Best Block of Belmar, of Belmar, NJ, Best Block of New Jersey, Best Block of Yardville, of Yardville, NJ, Best Block of Trenton, of Trenton, NJ, and Diversified Concrete Products, Inc., of South Plainfield, NJ.

MC 130475 (Sub-2), filed June 17, 1982. Applicant: ELEANOR B. YORK, d.b.a. YORK TOURS, 345 N. Bartlett St., Medford, OR 97501. Representative: Jerry R. Woods, 1600 One Main Pl., 101 SW Main St., Portland, OR 97204, (503) 224–5525. Transporting *passengers and their baggage,* in charter and special operations, between points in Jackson and Josephine Counties, OR, on the one hand, and, on the other, points in the U.S. (except AK and HI).

MC 135154 (Sub-11), filed June 14, 1982. Applicant: BADGER LINES, INC., P.O. Box 2049, Milwaukee, WI 53201. Representative: William P. Dineen, 710 North Plankinton Ave., Milwaukee, WI 53203, (404) 273–7410. Transporting *paper and related products,* between points in Marion Country, IN, on the one hand, and, on the other, points in IA, IL, KY, MI, MN, MO, OH, PA, TN, WI, and WV.

MC 138184 (Sub-5), filed May 26, 1982. Applicant: WALLACE TRUCKING COMPANY, Rt. 4, Box A–71, Laurinburg, NC 28352. Representative: F. Kent Burns, P.O. Box 2479, Raleigh, NC 27602, (919) 828–2421. Transporting *medical supplies and health care products,* between points in the U.S. (except AK and HI).

MC 150124 (Sub-3), filed June 17, 1982. Applicant: MARBERN TRUCKING, INC., RD #1, Box 75, Albany St., West Winfield, NY 13491. Representative: Murray J.S. Kirshtein, 118 Bleecker St., Utica, NY 13501, (315) 797–1970. Transporting (1) *steel,* (2) *finished metal stamping,* (3) *sand blasting sand,* (4) *castings,* (5) *coatings,* (6) *manufacturing equipment,* (7) *metal fabrications,* (8) *tanks,* (9) *pressure vessels,* (10) *furnace parts,* and (11) *boilers and weldaments,* between points in the U.S. (except AK and HI), under continuing contract(s) with Mohawk Metal Products, Co., Inc., of Frankfort, NY.

MC 150844 (Sub-3), filed June 16, 1982. Applicant: WILLIAM J. KLEIN, P.O. Box 334, Douglasville, PA 19518. Representative: Nicholas E. Chimicles, 110 Montgomery Ave., Bala Cynwyd, PA 19004, (215) 667–170. Transporting *passengers and their baggage,* in the same vehicle with passengers, in special and charter operations, beginning and ending at points in Berks, Chester and Montgomery Counties, PA, and that part of Lancaster County, PA east of PA Hwy 322, and extending to points in the U.S. (except AK and HI).

MC 153714 (Sub-3), filed June 14, 1982. Applicant: WILLIAM A. MURRAY, d.b.a. FREDDY'S TRUCKING, 2200 S.E. 45th #49, Hillsboro, OR 97123. Representative: William A. Murray (same address as applicant), (503) 640–8303. Transporting (1) *alcoholic beverages,* between points in CA and those points in Multnomah and Hood River Counties, OR, Humboldt and Clark Counties, NV, Salt Lake County, UT, Denver County, CO, Laramie County, WY, Lewis and Clark County, MT, Ada County, ID, Pima and Maricopa Counties, AZ, and King and Spokane Counties, WA, (2) *Beer and wine,* between points in Marion and Multnomah Counties, OR, and King County, WA, and (3) *pulp, paper and related products,* between Orange and Los Angeles Counties, CA, and Lane, Marion, and Multnomah Counties, OR, King and Spokane Counties, WA, and Latah and Kootena Counties, ID.

MC 155044 (Sub-2), filed June 15, 1982. Applicant: WILKE FREIGHT LINE, INCORPORATED, 843 West College Ave., Waukesha, WI 53186. Representative: Joseph E. Ludden, P.O. Box 1567, 2702 South Ave., La Crosse, WI 54601, (608) 788–2000. Transporting *general commodities* (except classes A and B explosives, household goods, and commodities in bulk), between points in the U.S. (except AK and HI).

MC 155694 (Sub-1), filed June 14, 1982. Applicant: DYNASTY CORPORATION,

R.D. 1, Box 1097, Nescopeck, PA 18635. Representative: Peter Wolff, 722 Pittston Ave., Scranton, PA 18505, (717) 342–7595. Transporting *furniture and fixtures, machinery, rubber and plastic products,* between points in the U.S., under continuing contract(s) with Berwick Lighting Company, of Berwick, PA.

MC 162495, filed June 14, 1982. Applicant: WANDER LAND TOURS, INC., 9800 Watson Rd., St. Louis, MO 63126. Representative: W. R. England III, P.O. Box 456, Jefferson City, MO 65102, (314) 634–7166. As a *broker,* at St. Louis, MO, in arranging for transportation of *passengers and their baggage,* by motor vehicle, in special and charter operations, beginning at St. Louis, MO, and points in St. Louis, Franklin, Jefferson, and St. Charles Counties, MO, and Clinton, Monroe, and St. Clair Counties, IL, and extending to points in the U.S. (except HI).

MC 162514, filed June 15, 1982. Applicant: WEB TRANSPORT, Div. of Taylor Enterprises, Inc., 700 East Pratt Blvd., Elk Grove Village, IL 60007. Representative: Abraham A. Diamond, 29 South La Salle St., Chicago, IL 60603, (312) 236–0548. Transporting *general commodities* (except classes A and B explosives, household goods, and commodities in bulk), between points in the U.S. (except AK and HI).

MC 162525, filed June 17, 1982. Applicant: 3 C, INC., P.O. Box 18425, Oklahoma City, OK 73154. Representative: Jim Patton, 3925 N.W. 10th St., Box 75613, Oklahoma City, OK 73147, (405) 943–2466. Transporting *oilfield equipment, materials and supplies,* between points in OK, on the one hand, and, on the other, points in TX.

Volume No. OP4–231

Decided: June 24, 1982.

Bt the Commission, Review Board No. 2, Members Carleton, Fisher, and Williams.

MC 149406 (Sub-15), filed June 14, 1982. Applicant: E.W. WYLIE CORPORATION, P.O. Box 1188, Fargo, ND 58107. Representative: Robert D. Gisvold, 1600 TCF Tower, 121 S 8th St., Minneapolis, MN 55402. Transporting *general commodities* (except classes A and B explosives, household goods and commodities in bulk), between points in the U.S. (except AK and HI), under continuing contract(s) with ITOFCA, Inc., of Downers Grove, IL.

MC 150896 (Sub-2), filed June 11, 1982. Applicant: HUMCO, INC, E Furnace Branch Rd., Suite TC–106, Glen Burnie, MD 21061. Representative: Richard P. Taylor, 1250 Connecticute Ave. NW., Washington, D.C. 20036 (202) 862–2126. Transporting *motor vehicles,* between points in DE, FL, IL, MD, NJ, NY, NC, OH, PA, VA, WY and DC.

MC 151566 (Sub-24), filed June 14, 1982. Applicant: PERRY TRANSPORT, INC., 14375, 172nd Ave., Grand Haven, MI 49417. Representative: Richard O. Peel (same address as applicant), (616) 842–3550. Transporting *metal products,* between points in the U.S. (except AK and HI), under continuing contract(s) with Technology Incorporated, or Grand Haven, MI.

MC 159876 (Sub-1), filed June 17, 1982. Applicant: K–K JR. TRUCKING, a division of K–K Jr. Enterprises, Inc., 14266 Catalina St., San Leandro, CA 94577. Representative: Eugene Q. Carmody, 15523 Sedgeman St., San Leandro, CA 94579, (415) 357–6236. Transporting *magazines, scrap or waste paper for recycling,* and *such commodities* as are manufactured, dealt in or used by printing and publishing plants and houses, between points in the U.S. (except AK and HI), under continuing contract(s) with Pacific Press, Inc., Division of Arcata Graphics, of Vernon, CA.

MC 162346, filed June 17, 1982. Applicant: BREAK BULK SERVICE, INC., d.b.a. BBST, 2211 Wood St., Oakland, CA 94607. Representative: Albert Lau (same address as applicant), (415) 763–6175. Transporting *general commodities* (except classes A and B explosives, household goods, and commodities in bulk), between San Francisco, CA and points in Alameda County, CA, on the one hand, and, on the other, points in Butte, Colusa, Fresno, Kings, Lake, Madera, Mendocino, Merced, Napa, Placer, San Benito, Santa Clara, Shasta, Solano, Sonoma, Sutter, Tehama, Tulare, Glenn, Yolo, Yuba, Marin, Monterey, Sacramento, San Mateo, Santa Cruz, Amador, Contra Costa, Kern, San Joaquin, and Stanislaus Counties, CA.

MC 162546, filed June 18, 1982. Applicant: CHIP TRUCKING, INC., Route 130, Cranbury, NJ 08512. Representative: George A. Olsen, P.O. Box 357, Gladstone, NJ 07934, (201) 234–0301. Transporting *general commodities* (except classes A and B explosives, household goods, and commodities in bulk), between points in NJ, on the one hand, and, on the other, points in the U.S. (except AK and HI).

Volume No. OP4–233

Decided: June 23, 1982.

By the Commission, Review Board No. 2, Members Carleton, Fisher, and Williams. (Member Williams not participating.)

MC 98937 (Sub-2), filed May 27, 1982. Applicant: WILBRAHAM TRUCKING CORP., 70 Windsor St., W. Springfield, MA 01090. Representative: James M. Burns, 1383 Main St., Suite 13, Springfield, MA 01103, (413) 871–8205. Transporting *general commodities* (except classes A and B explosives, household goods and commodities in bulk), between points in CT, MA, RI, and VT. Condition: This grant of authority is condition upon cancellation, at applicant's written request of Certificate of Registration No. MC–98937 Sub 1.

MC 156707 (Sub-1), filed June 11, 1982. Applicant: MWK TRANSPORT CO., INC., 5401 W Donges Bay Rd., Mequon, WI 53092. Representative: Michael J. Wyngaard, 150 E Gilman St., Madison, WI 53703, (608) 256–7444. Transporting *textile mill products,* between points in U.S. (except AK and HI), under continuing contract(s) with Junior House, Inc., of Milwaukee, WI.

MC 159037 filed June 18, 1982. Applicant: B & D MACHINERY SERVICES, LTD., P.O. Box 116, Elrose, Saskatchewan Canada S0L 0Z0.Representative: Robert N. Maxwell, P.O. Box 2471, Fargo, ND 58108, (701) 237–4223. Transporting *machinery,* between the ports of entry on the International Boundary line between the U.S. and Canada at points in MT and ND, on the one hand, and, on the other, points in MT, ND, and SD.

Volume No. OP4–235

Decided: June 28, 1982.

By the Commission, Review Board No. 2, Members Carleton, Fisher, and Williams.

FF–606, filed June 18, 1982. Applicant: APOLLO FORWARDERS, INC., 260 21st St., Richmond, CA 94801. Representative: Alan F. Wohlstetter, 1700 K St., N.W., Washington, DC 20006, (202) 833–8884. As a freight forwarder in the transportation of *used household goods, unaccompanied baggage, and used automobiles,* between points in the U.S.

MC 144776 (Sub-18), filed June 21, 1982. Applicant: APACHE TRANSPORT, INC., 833 Warner St., SW., Atlanta, GA 30310. Representative: Virgil H. Smith, 74 Hwy N. Box 245, Tyrone, GA 30290, (404) 969–1980. Transporting *such commodities* as are dealt in or used by the manufacturers and distributors of carbon paper, between Chicago, IL, Los Angeles, CA, and points in De Kalb County, GA, on the one hand, and, on the other, points in the U.S. (except AK and HI).

MC 146496 (Sub-15), filed June 18, 1982. Applicant: JOSEPH MOVING & STORAGE CO., INC., d.b.a. ST. JOSEPH MOTOR LINES, 5724 New Peachtree

Rd., Chamblee, GA 30341. Representative: Thomas H. Davis (same address as applicant), (404) 452–1744.Transporting *tires and tire related products,* between points in the U.S. under continuing contract(s) with Dunlop Tire Company, Div. of Dunlop Tire & Rubber Corporation, of Buffalo, NY.

MC 157406 (Sub-3), filed June 21, 1982. Applicant: AUTAUGA TRANSPORT, INC., 1410 South Memorial Dr., Prattville, AL 36067. Representative: Terry P. Wilson, 428 South Lawrence, Montgomery, AL 36104 (205) 262–2756. Transporting (1) *wood and steel reels,* and (2) *pulp, paper and related products,* between points in the U.S., under continuing contract(s) with Sonoco Products Company, of Hartsville, SC.

MC 159766 (Sub-1), filed June 18, 1982. Applicant: G & G DRAYAGE, INC., 22 Mill Race Dr., St. Peters, MO 63376. Representative: Robert L. Graves (same address as applicant), (314) 441–3357. Transporting *such commodities* as are dealt in and used by manufacturers of printer's ink, between points in the U.S. (except AK and HI), under continuing contract(s) with Crown Zellerbach, Inc., Ink Div. of St. Louis, MO.

MC 162486, filed June 14, 1982. Applicant: R. CRAIG McGLOTHLEN and ANTHONY J. DERDA d.b.a. COZY LIMO TRAVEL, 3102 Western Ave., South Bend, IN 46619. Representative: R. Craig McGlothlen (same address as applicant), (219) 288–2331. Transporting *passengers and their baggage,* between South Bend, IN and Chicago O'Hare International Airport, Chicago, IL.

Volume No. OP4–236

Decided: June 28, 1982.

By the Commission, Review Board No. 2, Members Carleton, Fisher, and Williams.

FF 16 (Sub-2), filed June 14, 1982. Applicant: SPRINGMEIER SHIPPING COMPANY, INC., 1116 Cass Ave., St. Louis, MO 63106. Representative: Russell F. Kroeger (same address as applicant), (314) 241–0860. As a *freight forwarder,* in connection with the transportation of *general commodities* (except classes A and B explosives, household goods and commodities in bulk), between points in the U.S. (except AK and HI).

MC 144476 (Sub-1), filed June 14, 1982. Applicant: METZ BEVERAGE COMPANY, P.O. Box 828, Sheridan, WY 82801. Representative: Timothy R. Stivers, P.O. Box 1576, Boise, ID 83701, (208) 343–3071. Transporting *such commodities* as are dealt in or used by retail grocery and food business houses, between points in CA, CO, OR and WA, on the one hand, and, on the other, points in MT, NE and WY.

MC 147916 (Sub-8), filed June 22, 1982. Applicant: GUMPAC EXPRESS, INC., P.O. Box 2489, Kirkland, WA 98203. Representative: Richard J. Howard, 3201 Bank of California Center, Seattle, WA 98124, (206) 464–4224. Transporting *food and related products,* between points in the U.S., under continuing contract(s) with American Fine Foods, Inc., of Payette, ID.

MC 149546 (Sub-33), filed June 23, 1982. Applicant: D & T TRUCKING CO., INC., P.O. Box 12505, New Brighton, MN 55112. Representative: Samuel Rubenstein, P.O. Box 5, Minneapolis, MN 55440, (612) 542–1121. Transporting *food and related products,* between points in the U.S. (except AK and HI).

MC 155316 (Sub-1), filed June 15, 1982. Applicant: EARL EDWARD KLADSTRUP JR., d.b.a. SEE TAHOE TOURS, P.O. Box 8128, Incline Village, NV 89450. Representative: Randall M. Faccinto, P.O. Box 2819, Truckee, CA 95734, (916) 587–3862. Transporting *passengers and their baggage,* in special or charter operations, in sightseeing and pleasure tours, in vehicles of a maximum capacity of 25 passengers, between points in Storey and Lyon Counties, NV, and Sierra, Alpine and Mono Counties, CA.

MC 156606 (Sub-1), filed June 14, 1982. Applicant: ROBERT L. LAVER AND WALMA J. LAVER, d.b.a. LAVER TRUCKING, Rt. 1, LaHarpe, KS 66751. Representative: Eugene W. Haitt, 207 Casson Bldg., 603 Topeka Blvd., Topeka, KS 66603, 1–(913) 232–7263. Transporting *general commodities* (except classes A and B explosives, household goods and commodities in bulk), between points in TX, OK, KS, NE, AR, MO, LA, SD, CO, and IA.

MC 157816 (Sub-1), filed June 22, 1982. Applicant: DANIEL E. KOCH, INC., Star Route Box 20, Scappoose, OR 97056. Representative: Russell M. Allen, 1200 Jackson Tower, Portland, OR 97205, (503) 224–4840. Transporting *metal products,* between points in OR and CA, on the one hand, and, on the other, points in NV, CA and ID.

MC 161836, filed June 21, 1982. Applicant: RONALD W. PETERS d.b.a. R.W. PETERS, TRUCKING CO., Rt. 2, Box 498, Ridgeway, VA 24148. Representative: Ronald W. Peters (same address as applicant), (703) 957–2732. Transporting *furniture,* between points in Henry and Smyth Counties, VA, on the one hand, and, on the other, points in the U.S. (except AK and HI).

MC 162516, filed June 14, 1982. Applicant: GRACE G. PHINICIE, d.b.a. PHINICIE'S BUS TOURS, 217 Ridge Ave., Waynesboro, PA 17268. Representative: Grace G. Phinicie (same address as applicant), (717) 672–8791. As a *broker,* at Waynesboro, PA, in arranging for the transportation of *passengers and their baggage,* between points in PA, on the one hand, and, on the other, points in the U.S. (except AK and HI).

MC 162556, filed June 18, 1982. Applicant: AMERICAN ORIENT FORWARDING COMPANY, 11209 S La Cienega Blvd., Los Angeles, CA 90045. Representative: John C. Wiesener, Jr., 48 Farnwood Rd., Mt. Laurel, NJ 08054, (609) 234–5541. Transporting *general commodities* (except classes A and B explosives, household goods and commodities in bulk), between points in the U.S. (except AK and HI).

MC 162586, filed June 21, 1982. Applicant: MAR–LYN TRANSPORT CORPORATION, 104 Marilyn Place, Clifton, NJ 07011. Representative: Edward L. Nehez, P.O. Box Y, Roseland, NJ 07068, (201) 992–2200. Transporting *general commodities* (except classes A and B explosives, household goods and commodities in bulk), between points in the U.S. (except AK and HI), under continuing contract(s) with Crest Chemical Corp., of Newark, NJ, Heller & Usdan, Inc., of Moonachie, NJ, Ilford, Inc., of Paramus, NJ, Barra Corp., of W Caldwell, NJ, and Fintex, Inc., of Elmwood Park, NJ.

Volume No. OP4–237

Decided: June 28, 1982.

By the Commission, Review Board No. 2, Members Carleton, Fisher, and Williams.

MC 60157 (Sub-35), filed June 17, 1982. Applicant: C. A. WHITE TRUCKING COMPANY, 5327 N. Central Expressway, Suite 316, Dallas, TX 75205. Representative: Bernard H. English, 6270 Firth Rd., Forth Worth, TX 76116, (817) 7301–8431. Transporting (1) *Mercer commodities,* (2) *earth drilling machinery and equipment, and machinery, equipment, materials, supplies and pipe* incidental to, used in, or in connection with (a) the transportation, installation, removal, operation, repair, service, maintenance, and dismantling of drilling machinery and equipment, (b) the completion of holes or wells drilled, (c) the production, storage, and transmission of commodities resulting from drilling operations at well or hole sites and (d) the injection or removal of commodities into or from holes or wells, betweeen points in the U.S., including AK, but excluding HI.

MC 139927 (Sub-1), filed June 21, 1982. Applicant: HOWES & HOWES TRUCKING, INC., 5301 North M–37, Messick, MI 49668. Representative: William B. Elmer, P.O. Box 801, Traverse City, MI 49684, (616) 941–5313. Transporting *ores and minerals, and fertilizer,* between points in Mi, on the one hand, and, on the other, points on the International Boundary Line between the U.S. and Canada.

MC 148987 (Sub-4), filed June 21, 1982. Applicant: W. C. CARRIERS, INC., 5229 N.W. 5th St., P.O. Box 519, Bethany, OK 73008. Representative: Kenneth L. Peacher, 3925 N. Ann Arbor, Oklahoma City, OK 73122, (405) 495–6915. Transporting *water well pumps, tanks, filters, motors, purifiers,* and *related products,* between points in OK , on the one hand, and, on the other, points in TX, LA, AR, MO, KS, NM, CO, WY, NE, SD, ND, AZ, CA, and UT.

MC 148987 (Sub-5), filed June 21, 1982. Applicant: W. C. CARRIERS, INC., 5229 N.W. 5th St., P.O. Box 519, Bethany, OK 73008. Representative: Kenneth L. Peacher, 3925 N. Ann Arbor, Oklahoma City, OK 73122, (405) 495–6915. Transporting *dry drilling fluid additives,* between points in Benton and Washington Counties, AR, and Kimble County, TX, on the one hand, and, on the other, points in the U.S. ont the west of a line beginning at the mouth of the Mississippi River, and extending along the Mississippi River to its junction with the western boundary of Itasca County, MN, then northward along the western boundaries of Itasca and Koochiching Counties, MN.

MC 154127 (Sub-4), filed June 17, 1982. Applicant: A. LUURTSEMA PRODUCE, INC., 5367 School St., P.O. Box 67, Hudsonville, MI 49426. Representative: Michael D. McCormick, 1301 Merchants Plaza, Indianapolis, IN 46204, (317) 638–1301. Transporting *food and related products,* between points in the U.S., under continuing contract(s) with New Era Canning Company, of New Era, MI, Oceana Canning Company, of Shelby, MI and National Fruit Products, Inc. of Winchester, VA.

MC 154757 (Sub-1), filed June 21, 1982. Applicant: ATLANTIC TRANSPORT CO., 2152 Hanover Ave., Allentown, PA 18103. Representative: James W. Patterson, 1200 Western Savings Bank Bldg., Philadelphia, PA 19107, (215) 735–3090. Transporting *such commodities* as are dealt in by manufacturers and distributors of beverages, (1) between points in DE, MD, NJ, NY, PA, and DC, and (2) between points in (1) above, on the one hand, and, on the other, points in VA, WV, NC, SC, GA, OH, IN, IL, MI, and WI.

MC 155287 (Sub-1), filed June 21, 1982. Applicant: GARY B. FLOSS, d.b.a. FLOSS TRUCKING, 2235 Lincoln St., Lot 27, Cedar Falls, IA 50613. Representative: Stanley C. Olsen, Jr., 5200 Willson Rd., Suite 307, Edina, MN 55424, (612) 927–8855. Transporting *mobile homes and portable buildings,* between points in MN, ND, SD, IA, MO, NE, WI, IL, and IN.

MC 162557, filed June 18, 1982. Applicant: JACK BENOFF, 9710 Glenhope Road, Philadelphia, PA 19115. Representative: Edward Benoff, 1710 Two Girard Plaza, Philadelphia, PA 19102, (215) 665–1555. To operate as a *broker at* points in Bucks and Philadelphia Counties, PA, in arranging for the transportation of *passengers and their baggage,* between points in PA, on the one hand, and, on the other, points in the U.S. (except AK and HI).

MC 162627, filed June 23, 1982. Applicant: ROUNDS TRAVEL & TOURS, INC., 35 Dorrance St., Providence, RI 02903. Representative: Stephen E. Miller (same address as applicant), (401) 272–2600. To operate as a *broker,* at Providence, RI, in interstate or foreign commerce, in arranging for the transportation of *passengers and their baggage,* in special and charter operations, between points in the U.S.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 82–18027 Filed 7–1–82; 8:45 am]

BILLING CODE 7035–01–M

[Docket No. AB–6 (Sub-No. 117]

Railroads; Burlington Northern Railroad Co.; Abandonment Between Rolla and St. John, ND; Findings

Notice is hereby given pursuant to 49 U.S.C. 10903 that the Commission, Review Board Number 3, has issued a certificate authorizing the abandonment of a line of railroad known as the Rolla, ND, to St. John, ND line extending from milepost 47.75 near Rolla, ND, to milepost 54.99 at the end of the line near St. John, ND, a distance of 7.24 miles, in Rolette County, ND, subject to certain conditions. Since no investigation was instituted, the requirement of § 1121.38(b) of the regulations that publication of notice of abandonment decisions in the **Federal Register** be made only after such a decision becomes administratively final was waived.

Upon receipt by the carrier of an actual offer of financial assistance, the carrier shall make available to the offeror the records, accounts, appraisals, working papers, and other documents used in preparing Exhibit I (Section 1121.45 of the Regulations). Such documents shall be made available during regular business hours at a time and place mutually agreeable to the parties.

The offer must be filed with the Commission and served concurrently on the applicant, with copies to Louis E. Gitomer, Room 5417, Interstate Commerce Commission, Washington, DC 20423, no later than 10 days from publication of this Notice. The offer, as filed, shall contain information required pursuant to § 1121.38(b) (2) and (3) of the Regulations. If no such offer is received, the certificate of public convenience and necessity authorizing abandonment shall become effective 30 days from the service date of the certificate.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 82–18023 Filed 7–1–82; 8:45 am]

BILLING CODE 7035–01–M

[Docket No. AB–6 (Sub-No. 118)]

Railroads; Burlington Northern Railroad Co.; Abandonment Between Montana City and Basin, In Jefferson County, MT; Findings

Notice is hereby given pursuant to 49 U.S.C. 10903 that the Commission, Review Board Number 3, has issued a certificate authorizing the Burlington Northern Railroad Comapny to abandon a line of railroad known as the Montana City to Basin, Montana Line extending from railroad milepost 222.76 near Montana City, to railroad milepost 256.95 at the end of the line near Basin, a distance of 34.19 miles, in Jefferson County, MT, subject to certain conditions. Since no investigation was instituted, the requirement of § 1121. 38(b) of the Regulations that publication of notice of abandonment decisions in the **Federal Register** be made only after such a decision becomes administratively final was waived.

Upon receipt by the carrier of an actual offer of financial assistance, the carrier shall make available to the offeror the records, accounts, appraisals, working papers, and other documents used in preparing Exhibit I (Section 1121.45 of the Regulations). Such documents shall be made available during regular business hours at a time and place mutually agreeable to the parties.

The offer must be filed with the Commission and served concurrently on the applicant, with copies to Louis E. Gitomer, Room 5417, Interstate Commerce Commission, Washington, DC 20423, no later than 10 days from

publication of this Notice. The offer, as filed, shall contain information required pursuant § 1121.38(b) (2) and (3) of the Regulations. If no such offer is received, the certificate of public convenience and necessity authorizing abandonment shall become effective 30 days from the service date of the certificate.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 82-18020 Filed 7-1-82; 8:45 am]

BILLING CODE 7035-01-M

[Docket No. AB-36 (Sub-No. 16)]

Railroads; Oregon Short Line Railroad Co.; Abandonment and Discontinuance of Service by Union Pacific Railroad Co. Between Richfield and Ketchum, ID; Findings

Notice is hereby given pursuant to 49 U.S.C. 10903 that the Commission, Review Board Number 3, has issued a certificate authorizing abandonment by Oregon Short Line Railroad Company and discontinuance of service by Union Pacific Railroad Company on a line of railroad known as the Ketchum Branch extending from railroad milepost 15.65 near Richfield, ID, to the end of the line at milepost 69.84 near Ketchum, ID, a distance of 54.19 miles, in Blaine and Lincoln Counties, ID, subject to certain conditions. Since no investigation was instituted, the requirement of § 1121.38(b) of the Regulations that publication of notice of abandonment decisions in the **Federal Register** be made only after such a decision becomes administratively final was waived.

Upon receipt by the carrier of an actual offer of financial assistance, the carrier shall make available to the offeror the records, accounts, appraisals, working papers, and other documents used in preparing Exhibit I (Section 1121.45 of the Regulations). Such documents shall be made available during regular business hours at a time and place mutually agreeable to the parties.

The offer must be filed with the Commission and served concurrently on the applicant, with copies to Louis E. Gitomer, Room 5417, Interstate Commerce Commission, Washington, DC 20423, no later than 10 days from publication of this Notice. The offer, as filed, shall contain information required pursuant to § 1121.38(b) (2) and (3) of the Regulations. If no such offer is received, the certificate of public convenience and necessity authorizing abondonment shall become effective 30 days from the service date of the certificate.

Agatha L. Mergenovitch,

Secretary.

[FR Doc. 82-18021 Filed 7-1-82; 8:45 am]

BILLING CODE 7035-01-M

[No. 38828]

Three Way Corp.; Petition for Exemption From Tariff Filing Requirements

AGENCY: Interstate Commerce Commission.

ACTION: Notice of provisional exemption.

SUMMARY: Three Way Corporation, an applicant for motor contract carrier authority, has requested exemption from the tariff requirements in 49 U.S.C. 10702, 10761, and 10762. The sought relief is provisionally granted.

DATES: Comments are due by July 19, 1982. The sought relief will become effective on August 3, 1982 if no adverse comments are received.

ADDRESS: Send an original and six copies of comments to: Section of Rates, Interstate Commerce Commission, Room 5340, Washington, DC 20423.

FOR FURTHER INFORMATION CONTACT: Douglas Galloway, (202) 275-7277, or Stuart Postow, (202) 275-6439.

SUPPLEMENTARY INFORMATION: Petitioner, Three Way Corporation, is a specialist in the transportation of so-called "third proviso" household goods described in 49 CFR 1056.1(a)(3). It holds nationwide common carrier authority for this traffic, pursuant to which it serves the transportation needs of the aerospace, electronic, medical, scientific, and other high-technology industries. Recently it decided to expand into contract carrier service and has filed its first (temporary authority) application, No. MC-151878 (Sub-No. 6-2TA).

Three Way seeks an exemption from the tariff-filing requirements of 49 U.S.C. 10702, 10761, and 10762 for the contract operations in its pending application. Petitioner is anxious to avoid unnecessary expenses which may handicap its efforts to provide economical and efficient service.

We do not feel that, in the absence of compelling circumstances, it is in the public interest to consider exemptions of such a limited nature as are involved in an application for temporary authority or other instances restricted by time or breadth. On the other hand, there is nothing in the petition indicating that Three Way would be adverse to an exemption for all of its contract operations, and we will consider the petition on this basis. Petitioner may, of course, submit comments indicating why a more limited exemption would be appropriate.

Relying on exemptions granted to another carrier, Three Way has offered to provide a copy of the rate provisions of its contract to interested parties upon request. However, in No. 38749, *UTF Carriers, Inc.—Petition for Exemption from Tariff Filing Requirements under 49 U.S.C. 10761(b)*, decided May 28, 1982 (not printed), the Commission recently granted an exemption without the requirements that the carrier furnish this information. Since the offer to make rates available appears to be based solely on a perception that the petition might be denied without this feature, which has been clarified by the Commission to the contrary, and since the petition is predicated on a desire to avoid all unnecessary costs of doing business in a regulated environment, we will consider the petition as though the offer had not been made.

We therefore provisionally grant the sought exemption. If we receive timely filed adverse comments, we will issue a further decision addressing them and deciding whether this tentative approval ought to be made final.

This decision would not appear to have a significant effect on either the quality of the human environment or conservation of energy resources. However, comments may be submitted on these issues.

(49 U.S.C. 10702(b), 10761(b) and 10762(f))

Decided: June 25, 1982.

By the Commission, Division 2, Commissioners Gresham, Taylor, and Simmons. Commissioner Taylor is assigned to this Division for the purpose of resolving tie votes. Since there was no tie in this matter, Commissioner Taylor did not participate.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 82-18022 Filed 7-1-82; 8:45 am]

BILLING CODE 7035-01-M

DEPARTMENT OF JUSTICE

Attorney General

Proposed Consent Decree in an Action To Require Compliance With Provisions of the Clean Water Act

In accordance with Department Policy, 28 CFR 50.7, 38 FR 19029, notice is hereby given that on May 6, 1982 a Consent Decree resolving two cases styled *United States* v. *Rockingham Poultry Marketing Cooperative*, Civil Action Nos. 78-0089 and 79-0045, was

lodged with the United States District Court for the Western District of Virginia. The proposed decree requires Defendant to install waste treatment equipment, to pay a civil penalty and to comply with its National Pollution Discharge Elimination System permits.

The Department of Justice will receive for thirty (30) days from the date of publication of this notice written comments relating to the proposed decree. Comments should be addressed to the Assistant Attorney General, Land and Natural Resources Division, Department of Justice, Washington, D.C., and refer to *United States* v. *Rockingham Poultry Marketing Cooperative*, (W.D. Va., Civil Action Nos. 78–0089 and 79–0045), DOJ Nos. 90–5–1–1055 an 90–5–1–1–1196.

The proposed decree may be examined at the Office of the Clerk, U.S. Distirict Court, Roanoke, Virginia; Office of the United States Attorney, P.O. Box 1709 Roanoke, Virginia 24008; Region III Office of the Environmental Protection Agency, Office of Regional Counsel, Sixth and Walnut Streets, Philadelphia, Pennsylvania 19106 and the Environmental Enforcement Section, Land and Natural Resources Division, Department of Justice, Ninth and Pennsylvania Avenue, N.W., Room 1515, Washington, D.C. 20530. In requesting a copy, please enclose a check in the amount of $1.40 payable to the Treasurer of the United States ($.10 per page reproduction cost).

Anthony C. Liotta,

Acting, Assistant Attorney General, Land and Natural Resources Division.

[FR Doc. 82–18065 Filed 7–1–82; 8:45 am]

BILLING CODE 4410–01–M

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

Voluntary Protection Programs To Supplement Enforcement and To Provide Safe and Healthful Working Conditions

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Notice of implementation of revised voluntary protection programs.

SUMMARY: OSHA announces the implementation of three Voluntary Protection Programs. The programs, revised from the January 19, 1982, notice in the Federal Register (47 FR 2796), seek out and recognize exemplary safety and health programs as a means of expanding worker protection. Companies, general contractors, and small business organizations which meet specified programmatic safety and health criteria, which go beyond OSHA standards in providing safe and healthful workplaces for their employees, and which want to do more than is required to help the agency accomplish the goals of the Act are the applicants OSHA seeks for these voluntary programs. In return, OSHA will remove participants from general schedule inspection lists and give priority attention to any which request a variance.

The programs are called "Star," "Try," and "Praise." "Star" is aimed at those workplaces having superior safety and health programs that go beyond OSHA standards in providing worker protection, through either employee participation or management initiative efforts. "Star" is designed to demonstrate that good safety and health programs can prevent injury and illness. "Try" is a broader and, in a sense, more flexible program. On one hand, "Try" is designed to evaluate alternative internal safety and/or health systems for the prevention of workplace injuries and illnesses. On the other hand, "Try" allows participation by firms which have good safety records or are anxious to improve them. Finally, "Praise" is a recognition program for employers in low-hazard industries with good safety programs who have been successful in preventing injuries. The unifying purpose of all these programs is injury and illness prevention.

We have simplified the Voluntary Protection Programs. The six experimental programs originally announced in the earlier Federal Register notice have been reduced to three. "Star" now applies to any industries. In addition, while labor management committees were originally required for participation, the new Star Program will be available for either employee participation or management initiative projects. "Try" has also been expanded to allow management initiative projects. "Praise" remains a recognition program for companies which have good safety records.

Applicants now eligible for "Star" and "Try" include companies, general contractors, or groups of small businesses. Applicants which operate a single site, a multiple-employer single site, or multiple sites organized by one company, corporation, or organization may be eligible. While the group approach, allowing several small firms to participate as one applicant, is not feasible for "Praise," many small businesses may individually qualify for participation in the program.

Internal complaint mechanisms will be required for "Star" and "Try" programs to give participants an opportunity to resolve complaints without OSHA involvement. Agency and internal complaint records will be reviewed as part of each program's evaluation. Complaints to OSHA from employees whose employer is participating in a voluntary program will be handled in accordance with OSHA procedures. For evaluation purposes the employee will be queried regarding his/her knowledge and use of the internal system.

Instead of the Resource Liaison contemplated in the earlier Federal Register notice, an OSHA official with technical expertise will be designated as the contact person for each Voluntary Protection Program. Except for construction sites under "Star" and the experimental programs under "Try," the contact person will have no required on-site presence. On-site assistance for the two excepted situations will be arranged before approval.

Pre-approval program reviews will be conducted except where information gathered by an inspection within the last 18 months can be used to verify the information submitted by the applicant. Where reviews are necessary, they will be done by OSHA staff from the national office and field. Information gathered in such reviews will not be made available to enforcement personnel. Each review will be arranged at the applicant's convenience and will take no more than two days. Experience rates are only one factor that OSHA will weigh in considering these programs. These provide an indication, not a conclusive measure, of performance. The other qualifications are spelled out in the program descriptions which follow. Those accepted into "Star" will be evaluated after three years, unless serious problems are identified earlier, and "Try" participants will be evaluated annually.

We have clarified labor-management committee responsibilities for those programs where such committees are used. Assuring abatement is a management prerogative and responsibility, and we have made this clear in the revised programs.

The agency will accept applications from interested parties for any of the programs, and, in accordance with the guidelines set forth above, may conduct on-site reviews of sites which appear to meet all of the program requirements, and will approve a limited number of participants in each category. We will remain cooperative and flexible in considering programs which will achieve our purpose. We will not, however, in any way diminish employer

or employee rights and responsibilities. OSHA will periodically evaluate the Voluntary Protection Programs to determine what changes, if any, the agency should make.

EFFECTIVE DATE: July 6, 1982.

FOR FURTHER INFORMATION CONTACT: Frank Frodyma, Office of Policy Analysis, Integration and Evaluation, Occupational Safety and Health Administration, 200 Constitution Avenue, N.W., Washington, D.C. 20210, (202) 523–8021.

SUPPLEMENTARY INFORMATION:

I. Background

A. Introduction

On January 19, 1982, the Occupational Safety and Health Administration ("OSHA" and the "agency") published in the **Federal Register** a notice requesting information and comment about several possible initiatives to provide incentives for voluntary safety and health protection efforts by employers and employees. The agency invited public comments on the specified programs and requested suggestions for alternative programs. Comments were to be submitted by March 15, 1982.

The agency received numberous comments from businesses, unions, trade associations, State Labor Departments, and others. All submissions were made part of the official record and were considered.

B. Statutory Framework

The Occupational Safety and Health Act of 1970, 29 U.S.C. 651 et seq. (the "Act" and the "OSH Act"), was enacted "to assure so far as possible every working man and woman in the Nation safe and healthful working conditions and to preserve our human resources."

Section 2(b) provides a blueprint of activities which OSHA can use to carry out these purposes. In particular, the following provisions constitute the legislative authority for the Voluntary Protection Programs announced herein:

"* * * (1) by encouraging employers and employees in their efforts to reduce the number of occupational safety and health hazards at their places of employment, and to stimulate employers and employees to institute new and to perfect existing programs for providing safe and healthful working conditions;"

"* * * (4) by building upon advances already made through employer and employee initiative for providing safe and healthful working conditions;"

"* * * (13) by encouraging joint labor-management efforts to reduce injuries and disease arising out of employment."

II. Voluntary Protection Programs

OSHA will accept applications for three Voluntary Protection Programs. The core program is the Star Program. As its name suggests, it is based on the characteristics of the most comprehensive safety and/or health programs used by American industry. Its standards are high, and it is not expected that large numbers of interested applicants will have the qualifications required for participation. It does recognize excellence in achieving significant accident reductions in high hazard industries by permitting applicants whose rates are lower than the average for their specific industry, but not necessarily lower than the national average for all manufacturing, to qualify if the other structural requirements are met.

Those employers whose programs and/or rates do not meet the "Star" requirements may be qualified for the more flexible experimental Try Program. In order to keep the flexibility desired in the program, OSHA has set very minimal and general requirements for "Try." Employers applying for "Try," however, will be expected to demonstrate to OSHA's satisfaction that significant accident or illness prevention will occur under the program.

Finally, the Praise Program provides the opportunity for OSHA to give recognition to employers in low-hazard industries who have better records than average for their industries. The Praise Program is a very different concept than "Star" or "Try," and different results should be expected from it. Protections, precautions and criteria found in "Star" and "Try" are neither necessary nor appropriate for "Praise." Only the lowest hazard firms of low-hazard industries are eligible for this performance recognition program. Because these firms are in low-hazard industries which do not appear on OSHA's targeting lists, they do not now receive routine inspections.

The emplasis in all of these programs is on implemented safety and/or health programs which encompass not just OSHA standards but all aspects of health or safety relevant to the worksite covered by the program. They are voluntary programs in that they are not and will not be mandated. It is completely the decision of individual businesses and, where applicable, their unions, as to whether they wish to apply for participation. OSHA is seeking only those who want to cooperate in good faith with the agency to demonstrate the importance of good internal safety and/or health systems for the prevention of injuries and illnesses. OSHA encourages program participants to set goals for realistic reduction of injuries, illnesses and workplace hazards and for improved safety and/or health planning and programming. An applicant may be a company, a general contractor, or an organization of small businesses. An applicant which operates a single site, a multiple-employer single site, or multiple sites organized by one company, corporation or organization may be eligible.

Certain requirements pertain to all three programs. All require implemented safety programs. In all cases where employees take on safety-related duties for a voluntary program, the employer must assure that those employees will be protected from discriminatory actions resulting from those duties, just as Section 11(c) of the Act protects employees for the exercise of rights under the Act. Without such assurance, employees could not be expected to carry out these assigned safety duties with complete confidence.

It is also necessary to assure that voluntary programs are implemented in an atmosphere of cooperation if they are to succeed. Therefore, if a site covered by an application for any of these programs has a significant proportion of its employees organized by one or more collective bargaining agents, the employer must be able to demonstrate that the collective bargaining agent(s) do(es) not object to participation in such a program. Without such a demonstration, OSHA will not be able to approve program participation.

Once an applicant has been approved for participation in a program, all employees at the specific site covered by the approval, including new hires as they arrive, must be informed of the specifics of the approved program. Employees who understand these programs will be more likely to be aware of safety needs and will be able to help the programs succeed.

In all of these programs at all times, as in all agency initiatives, OSHA shall assure that participation in any of these programs shall not in any way diminish existing employer and employee rights and responsibilities under the Occupational Safety and Health Act of 1970. More specific information about each of the programs follows.

The Praise Program

The Praise Program is directed toward employers in low-hazard industries who have good safety records and active safety programs. It is designed to provide recognition for past achievement in safety and to encourage

continued improvements where possible. It will cover safety only.

Goals and Objectives

1. To recognize employers who have provided effective safety protection.
2. To encourage continued improvement in workplace safety conditions.

Qualifications

1. The applicant must be a member of a low-hazard industry which is defined as an industry which has an average lost workday injury case rate below the national average for the private sector; and,
2. The applicant must have an average lost workday injury case rate and injury incidence rate for the last five years below the national average for the specific (three or four digit SIC) relevant industry.

a. An applicant in business for less than five years but more than two may be considered on the basis of the average rates for the years actually in business.

b. OSHA shall reserve the right to review injury rates annually.

The Star Program

The Star Program is aimed at leaders in injury, illness and accident prevention programs. The Star Program may cover either safety or health, or both. There are two types of Star Programs, employee participation programs requiring the use of labor-management committees and management initiative programs requiring management accountability for safety and/or health and the provision of information feedback to all establishment employees. Due to the unique nature of the construction industry, particularly the seriousness of hazards, changing worksite conditions, its expanding and contracting workforce and high turnover, we will, for the foreseeable future, consider only proposals for employee participation programs in this industry. All participants in the Star Program shall be evaluated every three years.

Goals and Objectives

1. To demonstrate the importance of comprehensive safety and/or health programs in the prevention of workplace injuries and/or illnesses.
2. To provide recognition to safety and health leaders.
3. To form a nucleus of workplaces for increased cooperative approaches to occupational safety and health problems.
4. To maintain excellent employee protection and to improve it where possible through the internal systems of the workplace.

General Qualifications for All Star Programs

1. The applicant must have an average of *both* lost workday injury case rates and injury incidence rates for the most recent three year period at or below the national average for the specific (three or four digit SIC) relevant industry.
2. If the applicant has been inspected by OSHA in the last three years, the inspection and abatement history should indicate good faith efforts to improve safety and health. For example, the company will not be eligible if it has received any upheld citations for willful violations of OSHA standards in the last three years.
3. The applicant must provide agreed-upon evaluation data for OSHA review.
4. The applicant must provide to OSHA written evidence of a safety program which establishes basic objectives in terms of the specific needs and problems of the company; addresses hazards specific to the workplace; includes any necessary personal protective equipment requirements; includes an employee training program in safe work practices; is effectively communicated and enforced; clearly assigns responsibilities for workplace safety and demonstrates high-level commitment and involvement.
5. The applicant must have an internal mechanism for responding to employee safety (and health) complaints in a timely fashion.
6. If health is to be covered by the program, the applicant shall provide a description of the program (which may be part of the safety program) which establishes basic objectives in terms of the specific health needs and problems of the company. It must include, as appropriate, an outline for company implementation and a means for monitoring and evaluating the program. Company procedures should include, as appropriate: industrial hygiene sampling and surveying; personal protective equipment program rules; employee training in personal protective devices, work practices and hazardous material handling; and medical recordkeeping. The health program must include:

(1) The services of appropriately trained personnel for initial and periodic monitoring of the workplace;

(2) A medical program including the availability of physician services; and,

(3) Testing, analyzing and sampling or surveys performed in accordance with nationally recognized procedures.

Additional Qualifications for Star Employee Participation Programs Only

1. The applicant must be able to demonstrate that it has a joint employer-employee committee for safety (and health) with the following characteristics:

a. A minimum of one year's experience providing safety (and health) advice and making periodic site inspections (construction applicants are exempted from this requirement);

b. Has at least equal representation by bona fide worker representatives who work at the site and who are either elected by all employees or selected by a duly authorized representative organization;

c. Meets regularly, keeps minutes of the meetings, and has a quorum consisting of at least half of the members of the committee with representatives of both employees and management; and,

d. Makes workplace inspections (with at least one worker representative) regularly, as needed, and has provided for at least yearly coverage of the whole worksite.

2. The joint committee must be allowed to:

a. Observe or assist in the investigation and documentation of major accidents;

b. Have access to all relevant safety and health information; and,

c. Have training so that the committee can recognize hazards, and have continued training as needed.

3. The applicant must assure that:

a. All hazards noted during site inspections by the joint committee or by management will be abated in a timely manner; and,

b. The following information will be retained and available for OSHA review during the pre-approval stage and for evaluation:

(1) Safety (and health, where applicable) program(s);

(2) Copies of the log of injuries and illnesses and the OSHA 101 or its equivalent;

(3) Agreement between management and the employee representatives concerning the functions of the committee and its organization;

(4) Minutes of each committee meeting;

(5) Committee inspection and accident investigation records; and,

(6) Records of employee safety (and health) complaints received and action taken, taking into account appropriate privacy interests.

Additional Qualifications for Star Management Initiative Programs Only

1. The applicant must be able to demonstrate that, for at least one year, it has had the following characteristics:

a. Reasonable site access to certified safety (and health) professionals as well as medical personnel;

b. A system for holding line managers and supervisors accountable for safety (and health) conditions;

c. Routine site inspections by safety (and health) professionals which provide for at least yearly coverage of the whole worksite and for written reports of findings and abatement; and,

d. Internal safety (and health) audit or evaluation.

2. The applicant must routinely review job hazards for inclusion in training and hazard control programs.

3. The applicant must demonstrate that:

a. All hazards noted during management site inspections will be abated in a timely manner; and,

b. The following information will be retained and available for OSHA review:

(1) Written safety (and health) program(s);

(2) Copies of the log of injuries and illness and the OSHA 101 or its equivalent;

(3) Monitoring and sampling records (if health is covered by the program);

(4) Staff inspection and accident investigation records which also shall be available upon request for review by employees included in the program;

(5) Records of employee safety (and health) complaints received and action taken, taking into account appropriate privacy interest; and

(6) Annual internal evaluations or audits.

The Try Program

The Try Program is an experimental program to determine the effectiveness of alternative internal safety and health systems and to provide an opportunity for participation by employers who want to cooperate closely with OSHA to improve their safety and health performance. Unlike "Star," qualifications for firms wishing to take part in "Try" are fairly general. This will allow the greatest flexibility in experimental program design. OSHA will, however, review each program to assure that it contains the elements necessary for success in meeting stated goals. Because of the experimental nature of "Try" and OSHA's limited resources, OSHA may not be able to accept all applicants satisfying minimum requirements.

Like "Star," "Try" may cover either safety or health or both. There are also both employee-participation and management initiative versions of "Try." Also like "Star," only proposals for employee participation programs will be considered in the construction industry. "Try" programs will be established for a period of time agreed upon in advance of approval and will be evaluated annually. The evaluation design will not be standardized but will instead be molded to fit each program. Demonstrably successful "Try" programs or ideas may be incorporated into "Star."

Goals and Objectives

1. To demonstrate the importance of complete safety (and health) programs in the prevention of workplace injuries (and illnesses).

2. To provide recognition and support to the provision of innovation in safety (and health) programs.

3. To increase safety (and health) protection through the internal systems of the workplace.

4. To develop and evaluate alternative internal systems for the prevention of workplace injuries (and illnesses).

General Qualifications for All Try Programs

1. The applicant should have an average of either the lost workday injury case rate *or* the injury incidence rate for the most recent three-year period which is at or below the national average for the specific industry (three or four digit SIC), show a downward trend over a three-year period, or indicate goals for reducing these rates and the methods by which the goals will be achieved.

2. If the applicant has been inspected by OSHA in the last three years, the inspection and abatement history should indicate good faith efforts to improve safety (and health).

3. The applicant must provide to OSHA written evidence of a program giving official recognition to the voluntary program, and the program itself must establish basic objectives in terms of the specific needs and problems of the company; address hazards specific to the workplace(s); include personal protective equipment requirements and an employee training program in safe work practices; be effectively communicated and enforced; clearly assign responsibilities for workplace safety (and health) and demonstrate high-level commitment and involvement.

4. The applicant must provide agree-upon evaluation data.

5. The applicant must make regular site inspections, conduct accident investigations, and have an internal mechanism for responding to employee safety (and health) complaints in a timely fashion.

6. The applicant should have available sufficient safety (and health) resources for the size of the establishment(s) covered and the types of hazards faced.

Additional Qualifications for Try Employee Participation Programs

1. The program must have some aspect of active (rather than passive) employee participation.

2. Where employee representatives are used, they should be elected by all employees or selected by a duly authorized respresentative organization.

Additional Qualifications for Try Management Initiative Programs

1. The program should include a system for holding managers accountable for safety (and health) conditions.

2. The applicant should be willing to institute an internal system of audit or evaluation, if not already in place.

3. Staff inspection and accident investigation reports shall be available upon request for review by covered employees.

OSHA Responsibilities for "Praise," "Star" and "Try"

OSHA Contact Person

An OSHA technical official will be assigned to each program as a contact person. This person will be available to assist the participants as needed to assure smooth interface with OSHA and to provide expertise as required.

Pre-Approval Program Review

The "Praise" review will be confined to a review of records and a general assessment of safety conditions and facilities. Pre-approval review for "Star" and "Try" will include interviewing relevant parties such as committee representatives in employee participation programs, as well as reviewing records and a general assessment of (health and) safety conditions and facilities. Such information will not be made available to enforcement personnel. Preapproval program reviews will be arranged at the convenience of the applicant, if on-site review is necessary. If the applicant has been inspected within the last 18 months, an on-site review may not be necessary.

Enforcement Activity

Programmed Inspections. Work sites enrolled in a program will be removed

from OSHA's general schedule inspection list.

Workplace Complaints. Complaints will be handled in accordance with standard OSHA procedures. The employee will be queried regarding his knowledge and use of the internal complaint system.

Fatalities and Accidents. All fatalities or accidents shall be handled in accordance with standard OSHA procedures.

Variances

If a participant desires a variance from a standard, the OSHA contact will be available to assist in formulating the application, if requested. OSHA will ensure that the application receives attention in a timely manner. If the request is approved, OSHA will grant an interim order permitting the variance while the formal procedures are implemented.

Evaluation

OSHA will monitor the Praise Program by reviewing annual injury incidence and lost workday injury case rates. OSHA reserves the right to conduct on-site visits, in coordination with the company, to validate the safety program if serious problems arise.

All "Star" programs shall be evaluated every three years with a yearly review of experience rates and complaint activity. All "Try" programs will be evaluated annually for the duration of the program.

The following factors will be used to measure the effectiveness of "Star" and "Try" programs:

1. Comparison of rates to the industry average;
2. Satisfaction of the participants; and,
3. Nature and validity of complaints received by OSHA.

Employee participation programs will also be evaluated on the effectiveness of the joint committees. "Try" programs will have other individually designed evaluation measures.

Termination of Participation in the Programs

Participation can be terminated in either of two ways:

1. The firm or (where applicable) the employee representative(s) or (where applicable) the sponsoring organization may send a written notification of termination to OSHA and to any other party or parties 30 days prior to termination (except where another time period has been agreed upon before approval); or,
2. OSHA may withdraw approval with written notification to the firm and (where applicable) to the employee representative(s) or (where applicable) to the sponsoring organization 30 days prior to termination (except where another time period has been agreed upon before approval).

Program Application

Effective this date, initial applications for any of the three programs should be sent directly to the OSHA Office of Policy Analysis, Integration and Evaluation (see contact address). After an initial period to allow adjustment to the application process for streamlining and other improvements, applications may also be forwarded to the appropriate OSHA Regional Administrator(s). OSHA staff will assist interested parties in the preparation of complete applications. OSHA assumes that these programs will generate widespread interest and expects a significant number of applications. Should the number of applicants exceed OSHA's available resources, OSHA may limit the number initially approved to achieve appropriate geographical and industry distribution and to establish firmly the principles of the different programs.

III. Summary and Analysis of Comments

Clarification

Several misconceptions about the agency's intentions regarding Voluntary Protection Programs were evidenced in the comments. Some commentors interpreted "voluntary" to mean that employers could choose whether or not to comply with OSHA regulations. In fact, what is voluntary is the choice to participate in these special programs, not whether to comply with OSHA regulations.

A few commentors suggested that OSHA planned to require the use of labor-management safety and health committees in all cases. The agency recognizes that, in many areas, particularly in unionized workplaces, labor-management committees have made important contributions to worker protection. On the other hand, OSHA is well aware that there are employers without labor-management committees who have been successful in providing safe workplaces. The Voluntary Protection Programs are designed to recognize the effective efforts in both the use of labor-management committees and management intensive systems and possibly in alternative systems. We understand, however, that a voluntary program can succeed in a unionized establishment only if a non-adversarial climate exists. We will, therefore, expect an applicant with an organized workplace to demonstrate that the relevant union does not object to the firm's proposal. We anticipate that recognition of good systems will encourage innovation in providing safe and healthful workplaces.

A few commentors expressed concern that all of the requirements suggested for participation in the voluntary programs would be mandatory for all companies. Although, for the construction industry, safety programs and self-inspections are already required by OSHA standards, it was never OSHA's intention that any firm would have to adopt any particular method or establish any system not already required or in place. As one commentor stated, "To restructure existing programs which have been effective will not be an acceptable option." We whole-heartedly agree. OSHA designed the Voluntary Protection Programs primarily for those companies with demonstrated records of success and with superior safety and health programs already in place.

One commentor urged that OSHA hold public hearings. While there is no requirement to hold hearings on the voluntary programs, OSHA already has held numerous meetings with representative groups to elicit opinions and has established a record of public comment which provided ample opportunity for proponents and opponents to make their views known. Hearings would, therefore, be redundant, costly and serve no useful purpose.

The January **Federal Register** notice indicated that the Voluntary Protection Programs would be started on an experimental basis with a few pilot projects; however, OSHA feels confident that the programs as now structured will not require this developmental stage. On the other hand, the number of participants will be limited by OSHA's resources for review, assistance, and evaluation. At this point the agency plans to use the voluntary programs to form a strategy of positive impact. The programs are intended to encourage the formation of a nucleus of companies with superior health and/or safety programs for a progressively more cooperative, non-adversarial relationship with OSHA; to provide recognition to companies with good programs and to encourage their expanded use; and to facilitate the provision of safety and health programs to groups of small businesses.

Simplification

Many commentors expressed the view that the programs should be simplified and criteria for participation expressed in performance-oriented terms. In an

effort to keep the programs simple and uncluttered, the six previously announced programs have been condensed to three.

The agency has combined the concepts of STAR, "Build" and PRIME into one program, retained the "Star" title and aimed the program at the best workplaces which can form a nucleus of cooperative activity with OSHA. There will be two types of "Star" workplaces: "Star" employee participation and "Star" management initiative. "Try" will be retained and expanded to include management initiative programs so that OSHA can evaluate alternative internal systems for the prevention of workplace injuries and illnesses and so that firms who have good safety records or are anxious to improve them may participate. "Praise" remains a recognition program for companies in low-hazard industries which have good safety records and active safety programs. The agency has simplified qualifications for the programs so that companies with different safety and health systems, with quantifiable results, may be eligible for participation.

Applicant Eligibility

The question of whether programs should be approved by individual site or for multiple sites prompted a variety of responses. Those favoring approval on an individual site basis pointed out that the conditions, as well as the severity of hazards, vary from one site to another within a corporation and that the normal management structure is organized by site. Those favoring multi-site approval maintained that a corporate-wide program is managed by the same executive, that a good corporate safety and health program could only be effective if implemented corporate-wide, and that a small facility could utilize corporate resources. Other commentors expressed the view that companies should be allowed to choose which form of participation would be most effective for them based on the structure of their safety and health programs. One commentor observed that control of the safety and health program is the central issue, and where control can be demonstrated, participation should be permitted on a corporate-wide basis. To provide flexibility and meet the needs of potential applicants, the agency has decided to allow participation for companies either by site or by multiple sites. Each participating site will, at OSHA's discretion, receive an individual evaluation.

The agency has concluded that a good way to provide for small businesses that cannot qualify on their own for participation in "Star" or "Try" is to allow the participation of organizations representing groups of small businesses. Since this is a new concept, the agency does not expect many small business groups to meet the qualifications for "Star," although OSHA will accept applications fro any which think they do. Such groups, more likely, will be eligible for "Try." If, in reviewing initial applications, the agency finds that. organizations of small businesses do not fit well into either the Star or Try Programs as designed, the agency will make the necessary changes and announce them in the **Federal Register.**

Incentives

The record confirms OSHA's suggestion that exemption from general schedule inspections should serve as an incentive for participation in Voluntary Protection programs.

Several commentors suggested that OSHA provide expedited procedures for granting variances to standards for participants. Recognizing that a variance will be granted only where an employer can demonstrate that the conditions are as safe and healthful as those required by the standards, OSHA will work with participants to ensure that variances, where warranted, are authorized in a timely fashion. As with all variances, employees would have to be notified of the variance application, when submitted, and an interim order, if granted.

Complaints

As indicated in the January **Federal Register** notice, accidents, fatalities and complaints of imminent danger will be handled through standard OSHA procedures.

The question of complaint handling received much attention. Some commentors recommended that all complaints should be referred to the participating organizations. Others recommended that all complaints be handled in accordance with OSHA procedures. We now recognize that the complaint procedure suggested in the former **Federal Register** notice added to the complexity of the programs. Therefore, we have reached what we feel is the appropriate middle ground by, on one hand, requiring that all participants in the "Star" or "Try" voluntary programs have some means whereby employees can notify their employers of hazardous conditions that they believe are present in their workplaces. On the other hand, OSHA will handle employee complaints in accordance with its current system. We think that we ought to recognize, however, the fact that there may always be some well-intentioned individuals who simply may not be aware of the existence of an internal system at their workplaces. Therefore, when an employee whose employer is participating in a voluntary program calls an OSHA office to register a complaint, the individual will be queried regarding his or her knowledge and use of the internal system. This will give us a means, admittedly imprecise, to measure a participant's communications with employees and employees' reactions to the internal system.

Resource Liaison

In discussing the role of the Resource Liaison (RL), a wide variety of commentors, representing unions, trade associations, businesses, and academics, expressed concern that the previously described role of the RL would be a strain on OSHA's limited resources and would detract from OSHA's enforcement efforts. Others pointed out that companies with superior programs do not need more intensive oversight from OSHA than they are currently receiving in order for them to provide safe and healthful workplaces.

These are valid considerations, and accordingly, OSHA has concluded that instead of an RL there will be a contact person designated for each program. This individual will be available to provide assistance on request but will not have a specific on-site monitoring role. There are two exceptions. Where a labor-management committee is newly organized for participation in the Star Program in construction, there will be some oversight required to be agreed upon by the parties. Each Try program also will require more supervision to be negotiated on a case-by-case basis.

Pre-Approval Program Review

The comments confirm the need for pre-approval program review to verify the information submitted by the applicant. OSHA will conduct an on-site program review of each program for which verification information does not exist from a recent (within 18 months) inspection. On-site review, where necessary, will take no more than two days at each site and will be conducted by OSHA staff from the national office and field. The review will include a records check, talks with relevant parties and a general evaluation of safety and health conditions. A review will be conducted only after the agency is satisfied that, on paper, the applicant meets the requirements for participation. The review will be arranged at the convenience of the applicant, and

information gathered will not be made available to enforcement personnel.

Evaluation

The record also substantiates the need for periodic evaluation. Each "Star" program will be evaluated after three years' operation, unless serious problems are identified earlier. "Star" management initiative programs will also be required to conduct at least annual self-evaluations. "Try" programs will continue to be evaluated annually by OSHA, although a successful "Try" program may eventually move into the "Star" category and thereby modify the evaluation requirements.

Most commentors agreed that a specification requiring that a company maintain evaluation data for OSHA review should be included in the voluntary programs. Commentors recommended several kinds of records that OSHA might review including: internal complaint records; accident investigation reports; self-audit or evaluation reports; worksite inspection reports; health monitoring and sampling records, where applicable; labor-management committee records, where applicable; and the injury-illness log. The parties to voluntary programs will have to make a good faith effort to evaluate the needs and accomplishments of each individual program. There is no universal yardstick to measure every aspect of a voluntary program. Thus, the particular data needed for each evaluation will be tailored to a certain extent to the individual safety (and health) program.

Experience Rates

Many commentors expressed concern that OSHA might base program evaluation solely on experience rates such as injury incidence rates, lost workday injury case rates or experience modification factors assigned by insurance companies. Our position is that experience rates must be considered as an indicator, not a conclusive measure, of performance. The Voluntary Protection Programs are designed to verify our belief that a comprehensive prevention program will provide a safe workplace.

A few commentors suggested that falsification of records could be a potential problem. Some commentors suggested having the responsible person sign the record. The OSHA 101 form and the OSHA 200 summary require signatures now. Since OSHA will use experience rates in conjuction with other measures, the agency does not consider that falsification will be a major concern. In addition, as many commentors noted, the criminal penalties for records falsification that OSHA already has in place are a considerable deterrent.

Some commentors questioned the use of workers' compensation data since that data may be affected by various factors unrelated to safety and health. OSHA is aware that, even under the best of circumstances, workers' compensation data will not provide a "match" to the OSHA log; however, we believe that first reports of injury (workers' compensation information) can provide some useful data. Another objection raised to the use of workers' compensation data was that it was an intrusion into an area beyond our jurisdiction. Under current OSHA regulations, employers may use workers, compensation reports instead of the OSHA form 101 to supplement the information on the OSHA 200 log. OSHA will only use workers compensation reports in Voluntary Protection Programs when the employer has chosen to substitute them in this manner.

The use of experience rating modification factors was suggested as the sole measure of performance by one commentor. While OSHA recognizes that experience rating has worked well for the insurance industry, experience modifiers have limitations that preclude the agency's using them as the single criteria for participation. This notice has already addressed the question of basing these programs on experience rates alone. In addition, experience modifiers are not universally available and may be skewed if a firm pays the injured worker's compensation costs rather than submitting a claim. Where the employer makes the experience modifier available and its use is valid, OSHA will accept it as one indicator of a firm's safety performance.

In responding to the question concerning what experience rates OSHA should use in its criteria, commentors strongly favored using both lost workday injury case rates and injury incidence rates averaged over three years and compared to the national average for the specific industry. As one commentor stated, "Qualification based on a combination of lost workday cases and incidence rates will give a better picture of the recent effectiveness of an employer's accident prevention program than qualification based on lost workday cases alone." The agency has adapted that recommendation to each Voluntary Protection Program, giving consideration to the other qualifications for participation in each. The individual program descriptions elaborate upon the requirements.

Committee Responsibilities

A number of comments were received regarding the responsibilities of labor-management committees in those programs where they are used. Most commentors thought that the responsibilities suggested by OSHA were reasonable and proper. Many commentors did, however, express concern that committee members might be held liable for workplace injuries and illnesses. This is not our intent, and it is important to guard against such liability. The committees, any organizations represented on them, and any individuals serving on them are not assuming the employer's statutory or common law responsibilities for providing safe and healthful workplaces, and the committees are in no way undertaking to guarantee a safe and healthful work environment. Instead, the committees are an additional tool to be used with those provided for in the law. Thus, the firm will continue to assure that any hazard in violation of OSHA standards noted by the committee will be abated in a timely fashion.

Many commentors expressed the view that requiring a specific frequency for labor-management committee meetings and inspections was unnecessarily rigid and that the optimum frequency should be determined on an individual basis by the participants. OSHA agrees that this is an area where more achievement-oriented criteria should be applied. Although OSHA prefers monthly meetings and inspections, the agency would consider less frequent arrangements depending on the size of the firm and the hazards in the workplaces if the arrangements are agreed to by all parties. In all cases, OSHA would expect that, at a minimum, the entire worksite would be inspected once each year.

The agency requested comment on training of new hires and of labor-management committee members. The record in regard to training new hires on the existence of the Voluntary Protection Program and the use of the labor-management committee clearly recognizes the need to include these topics in the new hire's initial orientation, and that is what OSHA will expect. Commentors suggested various alternatives for committee training, including OSHA's 10-hour course, use of the OSHA-funded consultation service, private consultants and insurance companies. The agency believes this is another area where achievement-oriented language is appropriate. OSHA's major concern is that committee members are able to

recognize hazards. The applicant must be able to demonstrate this to OSHA's satisfaction.

Construction

Since the structure for establishing and monitoring construction programs is not substantively dissimilar to "Star," the agency concluded that a separate program is not needed. OSHA has addressed this issue in the integration of the construction voluntary protection program into "Star." In integrating the proposed "Build" program into "Star", OSHA has also transferred the elements drawn up by the Construction Advisory Committee to apply to construction sites only. These include construction site eligibility for employee participation programs only, the acceptance of new labor-management committees for "Star" and a stronger role for the OSHA contact person.

The restriction of construction applicants to employee participation programs is a reflection of the seriousness of the hazards in the construction industry and the need for cooperation between employees and management to alleviate those hazards. Since management initiative programs will not be open to construction sites and since employee participation is relatively new in the construction industry, committees will not be required to have one year's experience as they are in other industries with long histories of effective cooperative problem solving. In these cases, the OSHA contact person assigned to assist the site program will have an expanded role as agreed upon before approval.

In addition, based upon the comments received, we have decided, that for a particular site to be eligible for participation in "Star," all subcontractors at the site must be covered by a participatory arrangement with the general contractor. Since the agency is offering participation to organizations of small businesses, OSHA will consider applications from associations of contractors which provide a system of protection to the participating worksites. Even in this case, however, the agency expects that all the subcontractors on each site will be included in the general contractor's program. The size of these group programs, the duration of the general contractor's involvement at a particular worksite, or the stage of construction at any site will not be relevant criteria for choosing group programs, but they are important considerations for a program at a single site.

Consultation

While OSHA-funded consultation services can be useful resources for businesses needing help in establishing good health and safety programs, the consultation services cannot be used to provide routine services or run a firm's safety and health program. The agency expects that companies which apply for participation in the Star Program will already have established superior health and safety programs and probably have no need for OSHA-financed consultation services. Those companies and small businesses which need help in improving their programs would find the Try Program more appropriate for them.

State Plans

The agency, in an effort to obtain the views of those potentially affected, requested comment on how State participation in any of these voluntary programs should be implemented. Most commentors favored encouraging some type of State participation.

OSHA will provide States with information from the voluntary programs and will work with them to develop an equitable method for handling employers under their jurisdiction who wish to participate in any of the Voluntary Protection Programs. Indeed, many States already have programs similar to "Praise". The agency expects that other States may choose to develop voluntary programs similar to "Star" and "Try".

Termination

Two questions were posed by OSHA concerning termination of individual Voluntary Protection Programs. The first addressed what changes in experience rates, if any, should cause termination. Many commentors expressed the view that participants should be allowed a range of acceptable performance and that deviation above the range should be investigated. Since experience rates are only one consideration that OSHA will use, the agency may examine rate increases to determine why they have occurred.

The second question addressed the need for immediate termination. Our conclusion is that the question of continuing approval should depend on whether or not a program is constituted properly to respond to situations as they develop. OSHA has the authority to cancel a program, or to take other appropriate action, as well as the obligation to investigate fatalities or accidents and to issue necessary citations. Even when good faith is shown, however, we realize that some situations will not yield dramatic changes quickly. We recognize, nevertheless, that situations may arise where one of the parties may want to withdraw from the program, and we feel it is equitable, in most cases, to establish a 30-day notice period prior to termination.

IV. Decision

After carefully reviewing all the submissions in the record and having made every effort to be responsive to the concerns raised, the Assistant Secretary has decided to implement the Voluntary Protection Programs as revised herein.

V. Effective Date

July 6, 1982.

VI. Authority

This document was prepared under the direction of Thorne G. Auchter, Assistant Secretary of Labor for Occupational Safety and Health, United States Department of Labor, 200 Constitution Avenue, NW., Washington, D.C. 20210.

Signed at Washington, D.C., this twenty-ninth day of June, 1982.

Thorne G. Auchter,

Assistant Secretary of Labor.

[FR Doc. 82-18014 Filed 7-1-82; 8:45 am]

BILLING CODE 4510-26-M

Office of Pension and Welfare Benefit Programs

[Prohibited Transaction Exemption 82-105; Exemption Application No. D-3186]

Exemption From the Prohibitions for Certain Transactions Involving the Anderson's Employees Profit Sharing Trust Located in Newport, Minnesota

AGENCY: Office of Pension and Welfare Benefit Programs, Labor.

ACTION: Grant of Individual Exemption.

SUMMARY: This exemption will permit the sale of an unimproved parcel of real property (the Property) by the Anderson's Employees Profit-Sharing Trust (the Trust) to Mr. Dale G. Anderson (Mr. Anderson), a disqualified person with respect to the Trust. Because Mr. Anderson is the sole owner of Dale G. Anderson Construction, Inc., the sponsor of the Trust, and is the only participant in the Trust, there is no jurisdiction under Title I of the Employee Retirement Income Security Act of 1974 (the Act) pursuant to 29 CFR 2510.3-3(b). However, there is jurisdiction under Title II of the Act pursuant to section 4975 of the Internal Revenue Code of 1954 (the Code).

FOR FURTHER INFORMATION CONTACT: Mr. David Stander of the Office of Fiduciary Standards, Pension and Welfare Benefit Programs, Room C-4526, U.S. Department of Labor, 200 Constitution Avenue, N.W., Washington, D.C. 20216. (202) 523-8881. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: On May 21, 1982, notice was published in the **Federal Register** (47 FR 22248) of the pendency before the Department of Labor (the Department) of a proposal to grant an exemption from the sanctions resulting from the application of section 4975 of the Code by reason of section 4975(c)(1) (A) through (E) of the Code, for the above-described transaction. The notice set forth a summary of facts and representations contained in the application for exemption and referred interested persons to the application for a complete statement of the facts and representations. The application has been available for public inspection at the Department in Washington, D.C. The notice also invited interested persons to submit comments on the requested exemption to the Department. In addition the notice stated that any interested person might submit a written request that a public hearing be held relating to this exemption. No public comments and no requests for a hearing were received by the Department.

The notice of pendency was issued and the exemption is being granted solely by the Department because, effective December 31, 1978, section 102 of Reorganization Plan No. 4 of 1978 (43 FR 47713, October 17, 1978) transferred the authority of the Secretary of the Treasury to issue exemptions of the type proposed to the Secretary of Labor.

General Information

The attention of interested persons is directed to the following:

(1) The fact that a transaction is the subject of an exemption granted under section 4975(c)(2) of the Code does not relieve a fiduciary or disqualified person with respect to a plan to which the exemption is applicable from certain other provisions of the Code. These provisions include any prohibited transaction provisions to which the exemption does not apply; nor does the fact the transaction is the subject of an exemption affect the requirement of section 401(a) of the Code that a plan must operate for the exclusive benefit of the employees of the employer maintaining the plan and their beneficiaries.

(2) This exemption does not extend to transactions prohibited under section 4975(c)(1)(F) of the Code.

(3) This exemption is supplemental to, and not in derogation of, any other provisions of the Code, including statutory or administrative exemptions and transitional rules. Furthermore, the fact that a transaction is subject to an administrative or statutory exemption or transitional rule is not dispositive of whether the transaction is, in fact, a prohibited transaction.

Exemption

In accordance with section 4975(c)(2) of the Code and the procedures set forth in Rev. Proc. 75-26, 1975-1 C.B. 722, and based upon the entire record, the Department makes the following determinations:

(a) The exemption is administratively feasible;

(b) It is in the interests of the Trust and of its participant and beneficiaries; and

(c) It is protective of the rights of the participant and beneficiaries of the Trust.

Accordingly, the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) (A) through (E) of the Code, shall not apply to the cash sale of the Property by the Trust to Mr. Anderson for $195,000, provided that this amount is not less than the fair market value of the Property on the date of sale.

The availability of this exemption is subject to the express condition that the material facts and representations contained in the application are true and complete, and that the application accurately describes all material terms of the transaction to be consummated pursuant to this exemption.

Signed at Washington, D.C., this 24th day of June, 1982.

Alan D. Lebowitz,

Assistant Administrator for Fiduciary Standards, Pension and Welfare Benefit Programs, Labor-Management Services Administration, U.S. Department of Labor.

[FR Doc. 82-18090 Filed 7-1-82; 8:45 am]

BILLING CODE 4510-29-M

[Prohibited Transaction Exemption 82-106; Exemption Application Nos. D-3210 and D-3211]

Exemption From the Prohibitions for Certain Transactions Involving the Bell System Trust Located in New York, New York

AGENCY: Office of Pension and Welfare Benefit Programs, Labor.

ACTION: Grant of Individual Exemption.

SUMMARY: This exemption permits: (1) The lease (the Lease) of a portion of an office building (the Building) by the Bell System Trust (the Trust) to Citicorp Acceptance Corporation (CAC), a wholly-owned subsidiary of Citicorp which is a party in interest with respect to the Trust; and (2) the future renewal or extension of the Lease.

FOR FURTHER INFORMATION CONTACT: Mr. Robert Sandler of the Office of Fiduciary Standards, Pension and Welfare Benefit Programs, Room C-4526, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, D.C. 20216. (202) 523-8195. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: On May 7, 1982, notice was published in the **Federal Register** (47 FR 19815) of the pendency before the Department of Labor (the Department) of a proposal to grant an exemption from the restrictions of section 406(a) of the Employee Retirement Income Security Act of 1974 (the Act) and from the sanctions resulting from the application of section 4975 of the Internal Revenue Code of 1954 (the Code) by reason of section 4975(c)(1) (A) through (D) of the Code, for the above-described transactions. The notice set forth a summary of facts and representations contained in the application for exemption and referred interested persons to the application for a complete statement of the facts and representations. The application has been available for public inspection at the Department in Washington, D.C. The notice also invited interested persons to submit comments on the requested exemption to the Department. The applicant has represented that a copy of the notice was distributed in accordance with the requirements set forth in the proposed exemption. No public comments were received by the Department. The notice of pendency was issued and the exemption is being granted solely by the Department because, effective December 31, 1978, section 102 of Reorganization Plan No. 4 of 1978 (43 FR 47713, October 17, 1978) transferred the authority of the Secretary of the Treasury to issue exemptions of the type proposed to the Secretary of Labor.

General Information

The attention of interested persons is directed to the following:

(1) The fact that a transaction is the subject of an exemption granted under section 408(a) of the Act and section 4975(c)(2) of the Code does not relieve a fiduciary or other party in interest or disqualified person with respect to a plan to which the exemption is applicable from certain other provisions of the Act and the Code. These

provisions include any prohibited transaction provisions to which the exemption does not apply and the general fiduciary responsibility provisions of section 404 of the Act, which among other things require a fiduciary to discharge his or her duties respecting the plan solely in the interest of the participants and beneficiaries of the plan and in a prudent fashion in accordance with section 404(a)(1)(B) of the Act; nor does the fact the transaction is the subject of an exemption affect the requirement of section 401(a) of the Code that a plan must operate for the exclusive benefit of the employees of the employer maintaining the plan and their beneficiaries.

(2) This exemption does not extend to transactions prohibited under section 406(b) of the Act and section 4975(c)(1)(E) and (F) of the Code.

(3) This exemption is supplemental to, and not in derogation of, any other provisions of the Act and the Code, including statutory or administrative exemptions and transitional rules. Furthermore, the fact that a transaction is subject to an administrative or statutory exemption or transitional rule is not dispositive of whether the transaction is, in fact, a prohibited transaction.

Exemption

In accordance with section 408(a) of the Act and section 4975(c)(2) of the Code and the procedures set forth in ERISA Procedure 75-1 (40 FR 18471, April 28, 1975), and based upon the entire record, the Department makes the following determinations:

(a) The exemption is administratively feasible;

(b) It is in the interests of the Trust and of its participants and beneficiaries; and

(c) It is protective of the rights of the participants and beneficiaries of the Trust.

Accordingly, the restrictions of section 406(a) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) (A) through (D) of the Code, shall not apply to: (1) The Lease by the Trust to CAC; and (2) the renewal or extension of the Lease, provided that the terms and conditions of the Lease and any extension or renewal thereof are and will remain at least as favorable to the Trust as those it could obtain from an unrelated party.

The availability of this exemption is subject to the express condition that the material facts and representations contained in the application are true and complete, and that the application accurately describes all material terms of the transactions to be consummated pursuant to this exemption.

Signed at Washington, D.C., this 28th day of June 1982.

Alan D. Lebowitz,

Assistant Administrator for Fiduciary Standards, Pension and Welfare Benefit Programs, Labor-Management Services Administration, U.S. Department of Labor.

[FR Doc. 82-18091 Filed 7-1-82; 8:45 am]

BILLING CODE 4510-29-M

NATIONAL FOUNDATION FOR THE ARTS AND THE HUMANITIES

National Council on the Humanities Advisory Committee; Meeting

June 28, 1982.

Pursuant to the provisions of the Federal Advisory Committee Act (Pub. L. 92-463, as amended) notice is hereby given that a meeting of the National Council on the Humanities will be held in Washington, D.C. on July 29-30, 1982.

The purpose of the meeting is to advise the Chairman of the National Endowment for the Humanities with respect to policies, programs, and procedures for carrying out his functions, and to review applications for financial support and gifts offered to the Endowment and to make recommendations thereon to the Chairman.

The meeting will be held in the Shoreham Building, 806 15th Street, N.W., Washington, D.C. A portion of the morning and afternoon sessions on July 29 and the afternoon session on July 30, 1982 will not be open to the public pursuant to subsections (c)(4), (6) and (9)(B) of section 552b of Title 5, United States Code because the Council will consider information that may disclose: Trade secrets and commercial or financial information obtained from a person and privileged or confidential; information of a personal nature the disclosure of which will constitute a clearly unwarranted invasion of personal privacy; and information the disclosure of which would significantly frustrate implementation of proposed agency action. I have made this determination under the authority granted me by the Chairman's Delegation of Authority dated January 15, 1978.

The agenda for the sessions on July 29, 1982 follows:

(Open to the public)

8:00-9:00—Coffee for Council Members in Chairman's Office

9:00-10:30—Committee Meetings—Policy Discussion

Education and State Programs, Room 1025

Fellowship Programs, Room 314

General Programs, Room 807

Research and Office of Planning, Room 1134

10:30 to Adjourn—Consideration of specific applications, (closed to the public for the reasons stated above).

The morning session on July 30, 1982 will convene at 8:30 a.m. in the 1st Floor Conference Room and will be open to the public. The agenda for the morning session will be as follows: (Coffee for Staff and Council Attending Meeting will be served from 8:30 a.m.—9:00 a.m.).

Minutes of the Previous Meeting

Reports

A. Introductory Remarks
B. Introduction of New Staff
C. Chairman's Grants
D. Application Report
E. Gifts and Matching Report
F. FY 1982 Program Funding
G. FY 1983 Appropriations Request
H. FY 1984 Budget Planning
I. Ratification of Actions of 64th Meeting
J. Conflicts of Interest Resolution
K. President's Initiative on Historically Black Colleges and Universities
L. Recommendation of Applications by Council Members
M. Committee Reports on Policy and General Matters
   a. Education Programs
   b. State Programs
   c. General Programs
   d. Research Programs
   e. Planning and Assessment Studies
   f. Fellowship Programs

The remainder of the proposed meeting will be given to the consideration of specific applications (closed to the public for the reasons stated above).

Further information about this meeting can be obtained from Mr. Stephen J. McCleary, Advisory Committee Management Officer, Washington, D.C. 20506, or call area code 202-724-0367.

Stephen J. McCleary,

Advisory Committee Management Officer.

[FR Doc. 82-18042 Filed 7-1-82; 8:45 am]

BILLING CODE 7536-01-M

NATIONAL SCIENCE FOUNDATION

Subcommittee for Oversight and Evaluation of the Ocean Sciences Research Section; Meeting

In accordance with the Federal Advisory Committee Act, Pub. L. 92-463, as amended, the National Science

Foundation announces the following meeting.

Name: Subcommittee for Oversight and Evaluation of the Ocean Sciences Research Section of the Advisory Committee for Ocean Sciences

Date and time: July 15 and 16 and 21 and 22, 1982; 9 a.m. to 5 p.m. each day

Place: Room 609 and 628, National Science Foundation, 1800 G Street, NW., Washington, D.C. 20550

Type of meeting: Closed

Contact person: Dr. Grant Gross, Director, Division of Ocean Sciences, Room 609, National Science Foundation, Washington, D.C. 20550—Telephone: 202–357–9639

Purpose of subcommittee: To provide expert assistance in carrying out external oversight which is concerned with the examination of decisions made, procedures and policies in effect and focuses on operations and activities, priorities, program balance, and selection of awards.

Agenda: Review and comparison of proposals (and supporting documentation) including review of peer review materials and other privileged materials.

Reason for closing: The subcommittee will be reviewing grants and declination jackets which contain the names of applicant institutions and principal investigators and privileged information contained in declined proposals. This session will also include a review of the peer review documentation pertaining to applicants. These matters are within exemptions (4) and (6) of 5 U.S.C. 552b(c), Government in the Sunshine Act.

Authority to close meeting: This determination was made by the Committee Management Officer pursuant to provisions of Section 10(d) of Pub. L. 92–463. The Committee Management Officer was delegated the authority to make such determination by the Director, NSF, on July 6, 1979.

Reason for late notice: This meeting notice was inadvertently misplaced by administrative staff.

M. Rebecca Winkler,

Committee Management Coordinator.

June 29, 1982.

[FR Doc. 82–18000 Filed 7–1–82; 8:45 am]

BILLING CODE 7555–01–M

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–317]

Baltimore Gas & Electric Co.; Issuance of Amendment To Facility Operating License

The U.S. Nuclear Regulatory Commission (the Commission) has issued Amendment No. 71 to Facility Operating License No. DPR–53, issued to Baltimore Gas and Electric Company, which revised Technical Specifications for operation of the Calvert Cliffs Nuclear Power Plant, Unit No. 1 located in Calvert County, Maryland. The amendment is effective as of the date of issuance.

The amendment authorizes operation of Calvert Cliffs Unit No. 1 during Cycle 6 at a rated thermal power of 2700 MWt.

The application for the amendment complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Chapter I, which are set forth in the license amendment. Notice of Proposed Issuance of Amendment to Facility Operating License in connection with this action was published in the **Federal Register** on May 4, 1982 (47 FR 19256). No request for a hearing or petition for leave to intervene was filed following notice of the proposed action.

The Commission has determined that the issuance of the amendment will not result in any significant environmental impact and that pursuant to 10 CFR 51.5(d)(4) an environmental impact statement, or negative declaration and environmental impact appraisal need not be prepared in connection with issuance of the amendment.

For futher details with respect to this action, see (1) the application for amendment dated February 17, 1982 as supplemented April 29, 1982, (2) Amendment No. 71 to License No. DPR–53, and (3) the Commission's related Safety Evaluation. All of these items are available for public inspection at the Commission's Public Document Room, 1717 H Street, N.W., Washington, D.C. and the Calvert County Library, Prince Frederick, Maryland. A copy of items (2) and (3) may be obtained upon request addressed to the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Director, Division of Licensing.

Dated at Bethesda, Maryland, this 24th day of June, 1982.

For the Nuclear Regulatory Commission.

Robert A. Clark,

Chief, Operating Reactors Branch No. 3, Division of Licensing.

[FR Doc. 82–18117 Filed 7–1–82; 8:45 am]

BILLING CODE 7590–01–M

[Docket Nos. 50–400 OL, 50–401 OL]

Carolina Power & Light Co. and North Carolina Municipal Power Agency No. 3 (Shearon Harris Nuclear Power Plant, Units 1 and 2); Order (Establishing Time and Place of Prehearing Conference)

June 28, 1982.

The Board's Order of June 4, 1982 changed the date for the special prehearing conference previously scheduled for June 14–15, 1982, to July 13–14, 1982. The conference will be held at North Carolina Utilities Commission, Main Hearing Room, Room 217, The Dobbs Government Building, 430 N. Salisbury Street, P.O. Box 991, Raleigh, North Carolina 28602, beginning at 9:00 a.m. The conference may continue on the 15th, if necessary.

Dated at Bethesda, Maryland, this 28th day of June, 1982.

For the Atomic Safety and Licensing Board.

James L. Kelley,

Chairman, Administrative Judge.

[FR Doc. 82–18118 Filed 7–1–82; 8:45 am]

BILLING CODE 7590–01–M

[Docket No. 50–537]

U.S. Department of Energy; Tennessee Valley Authority and Project Management Corp.; Availability of Site Suitability Report for Clinch River Breeeder Reactor Plant

Correction

In FR Doc. 82–17399, published on page 27998, on Monday, June 28, 1982, the heading should read as printed above.

BILLING CODE 1505–01–M

OFFICE OF PERSONNEL MANAGEMENT

Federal Employees Pay Council; Meeting

In accordance with the Federal Advisory Committee Act, Pub. L. 92–463, the President's Pay Agent announces the following meeting:

Name: Federal Employees Pay Council.

Date and time: July 20, 1982, 2:00 p.m.

Place: U.S. Office of Personnell Management, 1900 E Street NW., Washington, D.C., Room 5A06A.

Type of meeting: Open.

Contact person: Samuel Zattiero, staff contact person, U.S. Office of Personnel Management, 1900 E Street NW., Washington, D.C., Telephone (202) 632–4533.

Purpose of meeting: To discuss procedures to govern Agent/Council discussions.

For the President's Pay Agent.

Donald J. Devine,

Director, Office of Personnel Management.

[FR Doc. 82–18047 Filed 7–1–82; 8:45 am]

BILLING CODE 6325–01–M

Proposed Extension of Forms Submitted to OMB for Review

AGENCY: Office of Personnel Management.

ACTION: Notice of proposed extension of forms.

SUMMARY: In accordance with the Paperwork Reduction Act of 1980, this notice announces a proposed extension of forms which collect information from the public. Supplemental Qualifications Statements are completed by applicants for Federal positions throughout the Government. The Office of Personnel Management uses the information to examine the qualifications of applicants. For copies of this proposal, call John P. Weld, Agency Clearance Officer, on (202) 632–7720.

DATES: Comments on this proposal should be received within 10 working days from (date of publication).

ADDRESSES: Send or deliver comments to:

John P. Weld, Agency Clearance Officer, U.S. Office of Personnel Management, 1900 E Street, NW., Room 6H28, Washington, D.C. 20415, and

Mr. Frank Reeder, Information Desk Officer, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, D.C. 20503.

FOR FURTHER INFORMATION CONTACT:

John P. Weld, 632–7720.

Office of Personnel Management.

Donald J. Devine,

Director.

[FR Doc. 82–18055 Filed 7–1–82; 8:45 am]

BILLING CODE 6325–01–M

PACIFIC NORTHWEST ELECTRIC POWER AND CONSERVATION PLANNING COUNCIL

AGENCY: Pacific Northwest Electric Power and Conservation Planning Council (Northwest Power Planning Council).

SUBJECT: Draft annual report.

ACTION: Notice.

SUMMARY: The Council hereby announces the availability of its Draft Annual Report pursuant to section 4(h)(12)(A) of the Northwest Power Act (P.L. 96–501, 94 Stat. 2697, 16 U.S.C. 839) and invites comments.

DATES: Copies of the Draft Annual Report will be available on July 1, 1982. Comments must be submitted on or before August 13, 1982.

ADDRESS: Copies may be requested by calling Ms. Beata Teberg toll free within the Western United States at 1–800–547–0134 or within Oregon and outside the Western United States at (503) 222–5161. Comments should be submitted in writing to Ms.Torian Donohoe, 700 S.W. Taylor Street, Suite 200, Portland, Oregon 97205.

Dated: June 24, 1982.

Edward Sheets,

Executive Director.

[FR Doc. 82–18146 Filed 7–1–82; 8:45 am]

BILLING CODE 0000–00–M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 22552; 70–6680]

Consolidated Natural Gas Co. and CNG Energy Co.; Proposed Acquisition of Common Stock by Holding Company in New Subsidiary

June 28, 1982.

In the matter of Consolidated Natural Gas Company; 100 Broadway, New York, New York 10005 and CNG Energy Company, Four Gateway Center, Pittsburgh, Pennsylvania 15222 (70–6680).

Consolidated Natural Gas Company ("Consolidated"), a registered holding company, and CNG Energy Company ("CNG Energy'), have filed an application-declaration and amendments thereto pursuant to Sections 6, 7, 9(a), 10 and 11 of the Public Utility Holding Company Act of 1935 ("Act") and Rule 50(a)(3) promulgated thereunder.

CNG Energy, a new Delaware corporation organized by Consolidated, has an initial authorized capital stock of $12,500,000 divided into 125,000 shares, each having a par value of $100. No shares have been issued. Consolidated has requested authorization to acquire from time to time through May 31, 1983 and CNG Energy requests authorization to issue up to an aggregate of 21,000 shares of the common stock of CNG Energy for a cash consideration of $100 per share, up to an aggregate of $2,100,000. CNG Energy would apply $1,800,000 of the proceeds for feasibility studies, payment of bills incurred to date of approximately $200,000 and such other costs as may be incurred to May 31, 1983 with respect to energy projects. The balance of approximately $300,000 would be applied to CNG Energy's Natural Gas Vehicle Division ("NGV") which would engage in the distribution, installation, servicing and financing of duel fuel conversion equipment for short-haul automotive fleets and fueling stations. Approximately $25,000 of that balance would be applied to operation requirements of NGV and approximately $275,000 would be applied to NGV customer financing through May 31, 1983 for the proposed NGV activities. It is stated that the authorization requested in this proceeding does not constitute approval of participation in energy projects other than the proposed activities of CNG Energy through its NGV Division.

The NGV Division of CNG Energy proposes to acquire the necessary dual fuel conversion epuipment, including engine adjustment apparatus and compression and storage equipment for resale to customer fleets. The equipment would be financed by lease or notes. NGV Division would install fleet vehicles and a refueling station on the fleet owner's premises and make any necessary connections to a system distribution company's gas line. The NGV Division in some instances would co-own and operate shared fueling stations to achieve economies; for example, a small town's school buses and municipal fleet may want to use a common fueling station. The NGV Division may also enter into service contracts for the maintenance of refueling station compression equipment.

NGV Division estimates it could distribute, install and service conversion equipment for 30–35 vehicles per month. The prospective customers of NGV Division are municipalities, school districts and private companies having fleets of automobiles, trucks and buses which travel in the range of 100 to 250 miles before returning. Some 450,000 fleet vehicles are in the Consolidated System's retail distribution area although not all can be considered candidates for conversion. The application states that conversion to natural gas as a vehicle fuel is economic. Propane, however, is stated to be the major competitor. Natural gas currently costs about 55 cents per gallon in terms of gasoline equivalence whereas gasoline costs $1.10 to $1.20 per gallon. The cost differential would permit a return on and return of capital expended by customers for conversion to natural gas. There is generally a 2–3 year simple payback period. Installed equipment cost is approximately $1,500 for an automobile and $2,200 for a truck. Refueling station equipment averages $1,000 to $1,500 per vehicle. Most of the conversion equipment is expected to outlive the vehicle and is transferable to other vehicles with minimal reinstallation costs.

Initially, the NGV Division would not have any full time employees. It would rely on employees from the system service company to provide accounting, financial, clerical support and one or more system subsidiaries to provide credit, management, operating and technical support. Services normally

provided to customers by a distribution subsidary would also be provided to natural gas vehicle customers by the local distribution subsidiary. Services not normally provided such as maintenance service on refueling stations, would be charged, at cost, and paid by NGV which would, in turn, be reimbursed by the customer. The NGV Division may initially arrange for independent contractors to install conversion kits, maintain the equipment and construct the refueling stations because of lack of qualified personnel in the distribution companies to handle this business. Work performed by independent contractors would be paid by the NGV Division but reimbursed by the customer. Charges to customers would reflect an element of profit.

The application-declaration and any amendments thereto are available for public inspection through the Commission's Office of Public Reference. Interested persons wishing to comment or request a hearing should submit their views in writing by July 22, 1982, to the Secretary, Securities and Exchange Commission, Washington, D.C. 20549, and serve a copy on the applicant-declarant at the address specified above. Proof of service (by affidavit or, in the case of an attorney at law, by certificate) should be filed with the request. Any request for a hearing shall identify specifically the issues of fact or law that are disputed. A person who so requests will be notified of any hearing, if ordered, and will receive a copy of any notice or order issued in this matter. After said date, the application-delcaration, as amended or as it may be further amended, may be permitted to become effective.

For the Comission, by the Division of Corporate Regulation, pursuant to delegated authority.

George A. Fitzsimmons,

Secretary.

[FR Doc. 82-18078 Filed 7-1-82; 8:45 am]

BILLING CODE 8010-01-M

[Release No. 12509; 812-5194]

Real Estate Associates Limited V, et al.; Filing of Application

June 28, 1982.

In the matter of Real Estate Associates Limited V, National Partnership Investments Corp., and National Partnership Investments Associates II, 1880 Century Park East, Los Angeles, CA 90067 (812-5194).

Notice is hereby given that Real Estate Associates Limited V ("Partnership"), a California limited partnership, and its general partners, National Partnership Investments Corp. ("NAPICO"), and National Partnership Investments Associates II ("NPIA II") (NAPICO AND NPIA II are hereinafter collectively referred to as "General Partners" and, with the Partnership, as "Applicants"), filed an application on May 27, 1982, and an amendment thereto on June 22, 1982, for an order of the Commission, pursuant to Section 6(c) of the Investment Company Act of 1940 ("Act"), exempting the Partnership from all provisions of the Act. All interested persons are referred to the application of file with the Commission for a statement of the representations contained therein, which are summarized below.

Applicants state that the partnership was formed under the California Limited Partnership Act for the primary purpose of providing a vehicle for private investment in government-assisted rental housing for low and moderate income families in accordance with the express determination by Congress in Section 901 of Title IX of the Housing and Urban Development Act of 1968 ("Title IX"). It is asserted that the Partnership will operate as a "two-tier" partnership, *i.e.*, the Partnership will invest primarily in other limited partnerships which, in turn, will be engaged in the development, building, ownership, or leasing of to-be-constructed, rehabilitated, or existing housing projects for low and moderate income persons. The application states that NPIA II is a California limited partnership, and that the general partner of NPIA II is Charles H. Boxenbaum, who is Chairman of the Board of NAPICO, and the limited partners of NPIA II are Nicholas G. Ciriello, who is the President of NAPICO, and Leonard A. Crosby, III, who is an executive officer of NAPICO. It is asserted that the Partnership is organized as a limited partnership because a limited partnership is the only form of organization which provides an investor with both (1) the ability to claim on this individual tax return the deductions, losses, credits and other tax items the Partnership can pass through and (2) liability limited to his capital investment.

The application states that the Partnership will publicly offer units, consisting of two limited partnership interests and a warrant ("Warrant") to purchase two additional limited partnership interests, exercisable approximately twelve months after the initiation of the offering of Units. It is asserted that in the event that any Warrant is not exercised, the related limited partnership interest may be sold by the Partnership to other qualified offerees. Applicants represent that the Partnership will file a registration statement on Form S-11 covering 1,500 units to be offered at a maximum price of $5,000 per unit including selling commissions, and an additional 3,000 limited partnership interests to be purchased upon exercise of the Warrants or otherwise sold to qualified investors. It is asserted that in order to provide for the orderly closing of the offering, in the event subscriptions for in excess of 1,500 units are received, the Partnership is registering 150 additional units over and above the 1,500 maximum number of units and an additional 300 limited partnership interests for sale upon the exercise of the Warrants.

Applicants represent that offers to sell and sales to the public of the units and the limited partnership interests sold upon the non-exercise of the Warrants are proposed to be effected, on a best-efforts basis, through E. F. Hutton & Company Inc., and other selected members of the National Association of Securities Dealers, Inc., none of which owns or holds any interest in either of the General Partners or will have or has any other material relationship with their respective directors, officers or partners. The application states that the total capital of the Partnership, assuming all units are sold and all Warrants are exercised, will be $15,017,050 before deductions for sales commissions and expenses of the offering. This amount includes subscription notes for $12,500 and $4,550 from the General Partners and initial limited partners, respectively. Applicants represent that if only the minimum number of units are sold and no Warrants are exercised, the total capital of the Partnership after deductions for sales commissions and expenses of the offering will be approximately $1,073,050; of this amount, $12,500 will be contributed by the General Partners, $4,550 by the initial limited partner, and approximately $1,056,000 will be received from public investors, net of selling commissions, on the sale of Units alone.

It is asserted that the General Partners will be entitled, regardless of the number of Units and of limited partnership interests sold, to receive 1% of the Partnership's profits, losses and distributions.

Applicants represent that the amount of distributions of net cash flow from the Partnership that the General Partners are entitled to receive, by reason of their 1% interest, is reduced, however, by the amount of the annual management fees paid to them, and that therefore, it is

anticipated that as a practical matter the General Partners will not receive any distributions from cash flow.

The application states that the Partnership will invest not less than 75% of the total to be invested in properties in local limited partnerships which own or lease housing projects benefitting from federal, state or local government assistance. It is asserted that the Partnership may invest up to 25% of such proceeds in conventional residential projects or in local limited partnerships owning residential projects which do not participate in any government-assistance programs. Applicants represent that the Partnership has not yet identified any specific local limited partnerships or projects in which it proposes to invest. The application states that the General Partners will assess each project before the Partnership invests. The Partnership's prospectus states that there is no assurance that any interests in local limited partnerships will be available in suitable locations or upon satisfactory terms. It is asserted in the prospectus that, in the event such investments are not immediately available on satisfactory terms, the Partnership may temporarily invest all or part of the proceeds of the offering in short-term, highly liquid investments, such as United States Treasury Bills, and other short-term government contracts, commercial paper (investment grade), bank certificates of deposit and tax-exempt bonds and notes or registered investment companies holding such securities.

Applicants state that the Partnership will be controlled by the General Partners pursuant to the Partnership Agreement, and that the limited partners, consistent with their limited liability status, will not be entitled to participate in the control of the Partnership's business. It is asserted, however, that a majority in interest of the limited partners will have the right to amend the Partnership Agreement, dissolve the Partnership, remove one or more of the General Partners and elect successor general partners, and continue the Partnership upon the death, insanity, retirement, or bankruptcy of a General Partner. Applicants represent that, also under the Partnership Agreement, each limited partner or his representative is entitled to review the records of the Partnership at reasonable times. The application states that, as provided in the Partnership Agreement, each limited partner will receive an annual report within 120 days after the end of each fiscal year containing a balance sheet, statement of income, partners' equity, and changes in financial position for such fiscal year, all of which shall be prepared in accordance with generally accepted accounting principles and accompanied by a report and opinion of an independent accountant. The annual report shall also include a report of the Partnership's activities during the year and a cash flow statement setting forth distributions to limited partners and specifying the sources of cash for those distributions. It is asserted that the General Partners will also distribute interim reports of operations to the Limited Partners. Applicants further state that the Partnership will file with the Commission, pursuant to Section 15(d) of the Securities Exchange Act of 1934, all required annual reports, quarterly reports, and current reports on Forms 10–K, 10–Q, and 8–K, as well as any other reports required by that act. Further, NAPICO, a registered investment adviser, will file with the Commission all reports required under the Investment Advisers Act of 1940.

The application states that the General Partners and the officers and directors of the corporate General Partner may not be liable to the Partnership for certain acts and omissions to act since provision has been made in the Partnership Agreement for indemnification of the General Partners. It is asserted, however, that indemnification is conditioned upon the General Partners and the officers and directors of the corporate General Partner sued being successful in whole or in part in such litigation, or that the subject proceeding is settled with approval of the court; in any event, the court must find that such person's conduct fairly and equitably merits indemnity in the amount claimed. The Partnership's prospectus states that, insofar as indemnification for liabilities arising under the Securities Act of 1933, as amended, may be provided to officers, directors, and controlling persons, the General Partners have been advised that, in the opinion of the Commission, such indemnification is contrary to public policy and is, therefore, unenforceable.

Applicants state that, as set forth in the Partnership Agreement and described in the prospectus, the General Partners will receive certain fees for the services that render to the Partnership. It is stated in the Prospectus that none of such fees was determined as a result of arm's length negotiations. Applicants represent that all of such fees are in substantial conformity with the standards imposed by the Statement of Policy Regarding Real Estate Programs adopted by the North American Securities Administrators Association, Inc., effective March 30, 1982, and the Rules of the California Corporate Commissioner as to Real Estate Programs, and to the best of the General Partners' knowledge all such fees are in compliance with the current Statement and Rules promulgated by those authorities.

Section 6(c) of the Act provides, in pertinent part, that the Commission, by order upon application, may conditionally or unconditionally exempt any person, security or transaction from the provisions of the Act and the rules promulgated thereunder if and to the extent that such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act.

Without conceding that the Partnership is an investment company as that term is defined in the Act, Applicants request that the Partnership be exempted from the provisions of the Act. In support of this request, Applicants state that the requested exemption is both necessary and proper in the public interest and consistent with the protection of investors and the purposes and policies underlying the Act.

Applicants state that, by investing in limited partnership interests of local limited partnerships which develop housing for low and moderate income persons, the Partnership is implementing the national policy enunciated by Congress in Title IX. It is asserted that investment in subsidized low and moderate income housing is not economically suitable for private investors without the tax and organizational advantages of the limited partnership form The application states that the limited partnership form of organization is, however, incompatible with the operational framework of the Act. Applicants represent that to discourage the two-tier limited partnership arrangements by application of the Act would result in elimination of the best available means of attracting private equity capital into government-assisted housing, and would frustrate national policy.

The application states that the Partnership's structure, policies, and protective provisions are consistent with the principal investor protection sections of the Act. In addition, it is asserted that the Units and additional limited partnership interests will be sold only to relatively sophisticated investors who have special qualifications. Applicants represent that, in order to

become a limited partner, an investor must represent, *inter alia*, that he (i) has (A) a net worth (exclusive of home, furnishings and automobiles) of at least $30,000 and (B) an annual gross income of at least $30,000, or (ii) has a net worth (exclusive of home, furnishings, and automobiles) of at least $200,000 or is purchasing in a fiduciary capacity for a person or entity which has such net worth and annual income as set forth in clause (i) or such net worth as set forth in clause (ii), and that he is aware of the risks involved in investing in the Partnership. Further, he must represent that some part of his income for 1983 will be subject to federal income tax at the rate of 38% or more and that he anticipates that some part of his income for the next four years will, but for his investment in the Units or other tax shelters, be taxable at the federal tax rate of 38% or more. Finally, Applicants state that, in addition to the basic fact that the contemplated arrangement is not susceptible to abuses of the sort the Act was designed to remedy, the controls imposed on the Partnership by various state and federal agency regulations and under the Partnership's governing instruments provide protection to investors comparable to that provided by the Act.

Notice is further given that any interested person may, not later than July 23, 1982, at 5:30 p.m., submit to the Commission in writing a request for a hearing on the application accompanied by a statement as to the nature of his interest, the reasons for such request, and the issues, if any, of fact or law proposed to be controverted, or he may request that he be notified if the Commission shall order a hearing thereon. Any such communication should be addressed: Secretary, Securities and Exchange Commission, Washington, D.C. 20549. A copy of such request shall be served personally or by mail upon Applicants at the address stated above. Proof of such service (by affidavit or, in the case of an attorney-at-law, by certificate) shall be filed contemporaneously with the request. As provided by Rule 0–5 of the Rules and Regulations promulgated under the Act, an order disposing of the application herein will be issued as of course following said date unless the Commission thereafter orders a hearing upon request or upon the Commission's own motion. Persons who request a hearing, or advice as to whether a hearing is ordered, will receive any notices and orders issued in this matter, including the date of the hearing (if ordered) and any postponements thereof.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

George A. Fitzsimmons,

Secretary.

[FR Doc. 82–18077 Filed 7–1–82; 8:45 am]

BILLING CODE 8010–01–M

[Release No. 12506; 812–5064]

T. Rowe Price Growth Stock Fund, Inc., et al.; Filing of Application

June 25, 1982.

In the matter of T. Rowe Price Growth Stock Fund, Inc., T. Rowe Price Tax-Free Income Fund, Inc., T. Rowe Price Associates, Inc., 100 East Pratt Street, Baltimore, Maryland 21202, (812–5064).

Notice is hereby given that T. Rowe Price Growth Stock Fund, Inc. ("Growth Stock"), T. Rowe Price Tax-Free Income Fund, Inc. ("Tax-Free") (collectively referred to as the "Funds"), and T. Rowe Price Associates, Inc. ("Price Associates") (collectively referred to with the Funds as the "Applicants") filed an application on December 28, 1981, and an amendment thereto on April 26, 1982, requesting an order of the Commission, pursuant to Section 6(c) of the Investment Company Act of 1940 ("Act"), declaring that Richard W. Case, a director of the Funds, shall not be deemed an interested person of Price Associates or of the Funds as defined in Section 2(a)(19) of the Act. All interested persons are referred to the application on file with the Commission for a statement of the representations contained therein, which are summarized below.

The Funds are Maryland corporations registered under the Act as open-end, management investment companies. Price Associates, a Maryland corporation registered as an investment adviser under the Investment Advisers Act of 1940, serves as investment adviser to the Funds.

Mr. Case is a member of the Maryland bar who is, and since 1955 has been, a member of the law firm of Smith, Sommerville & Case ("SS & C") of Baltimore, Maryland. Mr. Case is, and since 1961 has been, a member of the board of directors of Growth Stock and he is, and since 1979 has been, a member of the board of directors of Tax-Free.

Applicants state that SS & C has rendered legal services to and received legal fees from Price Associates in recent years (including 1981 but excluding 1980), but that the firm has never provided legal services to or received legal fees from either of the Funds or from any of the other investment companies advised by Price Associates. Therefore, Mr. Case has been classified as an "interested director" of each of the Funds in accordance with the provisions of Section 2(a)(19)(A)(iii) of the Act, which provides, in substance, that any person who is an interested person of the investment adviser to an investment company is an interested person of that investment company, and Section 2(a)(19)(B)(iv) of the Act, which provides, in substance, that any partner or employee of any law firm which acted as legal counsel to an investment adviser to an investment company within the last two fiscal years of such investment company is an interested person of such investment adviser.

Applicants state that Mr. Case has advised the board of directors of each of the Funds that, notwithstanding the receipt of fee income in 1981, SS & C effectively ceased to serve Price Associates as legal counsel prior to 1980, and that the 1981 fee income arose from services relating to a Maryland state income tax refund claim for the years 1972 and 1973 that SS & C undertook to prosecute on behalf of Price Associates, on a contingent fee basis. Applicants further state that Mr. Case has advised the boards of directors of the Funds that he was not involved in or in any way responsible for the matter. It was handled by another partner of SS & C, David Bielawski; SS & C's primary reason for undertaking the matter was to give Mr. Bielawski experience in tax litigation involving a legal question of importance to Maryland corporations generally.

Applicants represent that the legal fees received by SS & C for legal services to Price Associates during the period 1972 to 1981 were not material when compared to the total revenues of SS & C during that period. Applicants further represent that during that period SS & C did not act as general counsel to Price Associates, did not bear overall responsibility for the corporate legal affairs of Price Associates, and its work generally did not involve responsibility for such affairs. In addition, the legal services rendered by SS & C in the years subsequent to 1976 did not involve the relationship of Price Associates to either of the Funds or to any other investment company served by Price Associates as investment adviser. Finally, Applicants represent that Price Associates will not utilize the legal services of SS & C as counsel in the future.

Section 6(c) of the Act provides, in pertinent part, that the Commission, by order, upon application, may conditionally or unconditionally exempt any person or transaction from any

provision of the Act, if and to the extent that such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act.

Applicants state that the directors of the Funds consider Mr. Case to be a man of experience and high standing at the bar, with a long and distinguished tenure as a director of the Funds. Applicants further state that, while nominally an interested director because of the relationship of his firm to Price Associates, Mr. Case has always been, and has been regarded by his colleagues on the boards of the Funds as, a man of outstanding intelligence, integrity and independence of mind, who has always made the well-being of the stockholders of the Funds his primary concern.

Applicants state that, for these reasons, the disinterested directors on the boards of directors of the Funds, as well as the representatives of Price Associates on those boards, have concluded that the interests of the Funds, and their stockbrokers, would be enhanced by a change in the status of Mr. Case that would enable him to participate in the deliberations of the directors (including but not limited to the annual deliberations with respect to the continuation of the investment advisory agreement and the fidelity bond) in the capacity of a disinterested director.

Accordingly, Applicants submit that the requested exemption is appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act.

Notice is further given that any interested person may, not later than July 19, 1982, at 5:30 p.m., submit to the Commission in writing a request for a hearing on the application accompanied by a statement as to the nature of his/her interest, the reason for such a request, and the issues, if any, of fact or law proposed to be controverted, or he/she may request that he/she be notified if the Commission shall order a hearing thereon. Any such communication should be addressed: Secretary, Securities and Exchange Commission, Washington, D.C. 20549. A copy of such request shall be served personally or by mail upon the Applicants at the address stated above. Proof of such service (by affidavit or, in the case of an attorney-at-law, by certificate) shall be filed contemporaneously with the request. As provided by Rule 0–5 of the Rules and Regulations promulgated under the Act, an order disposing of the application will be issued as of course following said date unless the Commission thereafter orders a hearing upon request or upon the Commission's own motion. Persons who request a hearing, or advice as to whether a hearing is ordered, will receive any notices and orders issued in this matter, including the date of the hearing (if ordered) and any postponements thereof.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Shirley E. Hollis,

Assistant Secretary.

[FR Doc. 82–18079 Filed 7–1–82; 8:45 am]

BILLING CODE 8010–01–M

[Release No. 22548, 70–6428]

Systems Fuels, Inc., et al.; Changes in Financing Arrangements Related To Purchase of Fuel by Nonutility Subsidiary for Use by Operating Companies

June 25, 1982.

In the matter of System Fuels, Inc., Noro Plaza, 666 Poydras, New Orleans, Louisiana 70130, Arkansas Power & Light Company, 142 Delaronde Street, New Orleans, Louisiana 70174, Mississippi Power & Light Company, Electric Building, Jackson, Mississippi 39205, and New Orleans Public Service Inc., 317 Baronne Street, New Orleans, Louisiana 70112 (70–6428).

Arkansas Power & Light Company, Louisiana Power & Light Company, Mississippi Power & Light Company, and New Orleans Public Service Inc. (collectively, the "Operating Companies"), all public utility subsidiary companies of Middle South Utilities, Inc. ("Middle South"), a registered holding company, together with System Fuels, Inc. ("SFI"), a jointly owned nonutility subsidiary company of the Operating Companies, have filed with this Commission a post-effective amendment to the declaration previously filed in this proceeding pursuant to Sections 6(a), 7, 12(b) and 12(f) of the Public Utility Holding Company Act of 1935 ("Act") and Rules 45 and 50(a)(5) thereunder.

Pursuant to the Commission's orders, dated May 21, 1980 and May 19, 1981 (HCAR Nos. 21584 and 22056), SFI, in order to finance fuel oil inventory, has, together with the Operating Companies, entered into a loan agreement, dated as of May 28, 1980, as amended ("Loan Agreement"), with Clipper Oil Corporation ("Clipper"). Under the Loan Agreement, Clipper makes loans to SFI in amounts not in excess of $100,000,000 at any one time outstanding out of the proceeds of commercial paper notes issued and sold by Clipper or the proceeds of revolving credit borrowings obtained by Clipper under a Credit Agreement, dated as of May 28, 1980, as amended ("Credit Agreement"), between Clipper and Bank of America National Trust and Savings Association. (HCAR No. 21584, May 21, 1980), (HCAR No. 22056, May 19, 1981.)

Pursuant to the provisions of the Loan Agreement, SFI has notified Clipper of its desire to extend the term of the Loan Agreement for an additional twelve month period, to July 31, 1983, and Clipper has agreed to such extension. The effectiveness of such extension is subject to the receipt of Commission approval. A corresponding extension of the term of the Credit Agreement would also be made. Authorization by the Commission is hereby requested to extend the term of the Loan Agreement and for SFI to continue to make borrowings thereunder during such extended term. No further changes in the transactions previously authorized have been or are expected to be effected thereby.

SFI is currently conducting negotiations to further amend the Loan Agreement to provide for, among other things, a three year renewal period. Such further amendment to the Loan Agreement will be the subject of a separate filing with the Commission. In the event that the Loan Agreement is not so amended, authorization is hereby requested for additional twelve-month extensions of the Loan Agreement without further Commission authorization. The Loan Agreement may be terminated if, at any time, SFE gives Clipper five days prior written notice thereof and pays various amounts owed in connection with the Loan Agreement, including payment of all loans (as that term is defined in the Loan Agreement) and other amounts owed to Clipper thereunder.

The amended declaration and any amendments thereto are available for public inspection through the Commission's Office of Public Reference. Interested persons wishing to comment or request a hearing should submit their views in writing by July 16, 1982, to the Secretary, Securities and Exchange Commission, Washington, D.C. 20549, and serve a copy on the declarants at addresses specified above. Proof of service (by affidavit or, in the case of an attorney at law, by certificate) should be filed with the request. Any request for a hearing shall identify specifically the issues of fact or law that are disputed. A person who so requests will be notified of any hearing,

if ordered, and will receive a copy of any notice or order issued in this matter. After said date, the declaration, as filed or as it may be amended, may be permitted to become effective.

For the Commission, by the Division of Corporate Regulation, pursuant to delegated authority.

Shirley E. Hollis,

Assistant Secretary.

[FR Doc. 82-18082 Filed 7-1-82; 8:45 am]

BILLING CODE 8010-01-M

[Release No. 12508; 812-5182]

Tax-Exempt Money Market Fund, Inc.; Filing of Application

June 25, 1982.

In the matter of Tax-Exempt Money Market Fund, Inc., 120 South LaSalle Street, Chicago, Illinois 60603, (812-5182).

Notice is hereby given that Tax-Exempt Money Market Fund, Inc. ("Applicant"), registered under the Investment Company Act of 1940 ("Act") as an open-end, diversified, management investment company, filed an application on April 29, 1982, requesting an order of the Commission pursuant to Section 6(c) of the Act exempting Applicant to the extent necessary from (1) the provisions of Section 2(a)(41) of the Act and Rules 2a-4 and 22c-1 thereunder to permit Applicant (a) to compute its net asset value per share using the amortized cost method of valuation, (b) to consider the maturity of variable rate demand notes and loan participations in its portfolio as the longer of the notice period required before the Applicant would be entitled to prepayment on the not or the period remaining until the note's next interest rate adjustment; and (c) to value in the manner described herein, rights acquired from issuers, dealers, or banks to sell portfolio securities to such persons; and (2) the provisions of Section 12(d)(3) of the Act to permit Applicant to acquire rights to sell its portfolio securities to brokers or dealers. All interested persons are referred to the application on file with the Commission for a statement of the representation therein, which are summarized below.

Applicant states that is a "money market" fund organized under the laws of Maryland to provide, through investment in a professionally-managed portfolio of high quality municipal securities, current income which is exempt from Federal income taxes to the extent consistent with stability of capital. Applicant further states that municipal securities in which it may invest ("municipal Securities") consist of obligations issued by or on behalf of state, territories, or possessions of the United States and the District of Columbia and their political subdivisions, agencies, or instrumentalities, the income from which is exempt from federal income tax.

Applicant represents that, in pursuing its investment objectives, it will only invest in "high quality" Municipal Securities, which at the time of purchase: (a) are rated within the two highest ratings for municipal obligations (Aaa or Aa) assigned by Moody's Investor's Service, Inc. ("Moody's") or (AAA or AA) assigned by Standard & Poor's Corporation ("S&P"); (b) are guaranteed or insured by the U.S. Government as to payment of principal and interest, such as tax-exempt project notes; (c) are fully collaterized by an escrow of U.S. Government securities or other securities acceptable to the Fund's adviser; (d) have a Moody's short-term municipal securities rating of MIG-2 or higher or a municipal commercial paper rating of A-2 or higher; (e) are unrated, if longer term municipal securities of that issuer are rated within the two highest rating categories by Moody's or S&P; or (f) are determined to be at least equal in quality to one more of the above ratings in the discretion of Applicant's investment adviser. Applicant further state that from time to time on a temporary basis, Applicant's portfolio may be invested in taxable short-term investments subject to quality limitations similar to those applicable for rated municipal Securities. Applicant represents that it seeks to maintain a $1.00 constant net asset value per share by keeping its dollar-weighted average portfolio maturity below 120 days, excluding from dividends unrealized gains and losses and gains and losses realized on the disposition of portfolio securities prior to maturity, and computing net asset value per share according to the amortized cost method of valuation.

As here pertinent, Section 2(a)(41) of the Act defines value to mean: (1) with respect to securities for which market quotations are readily available, the market value of such securities, and (2) with respect to others securities and assets, fair value as determined in good faith by the board of directors. Rule 22c-1 adopted under the Act provides, in part, that no registered investment company or principal underwriter therefor issuing and redeemable security shall sell, redeem or repurchase any such security which is next computed after receipt of a tender of such security for redemption or of an order to purchase or sell such security.

Rule 2a-4 adopted under the Act provides, as here relevant, that the "current net asset value" of a redeemable security issued by a registered investment company used in computing its price for the purposes of distribution, redemption and repurchase shall be an amount which reflects calculations made substantially in accordance with the provisions of that rule, with estimates used where necessary or appropriate. Rule 2a-4 further states that portfolio securities with respect to which market quotations are readily available shall be valued at current market value and other securities and assets shall be valued at fair value as determined in good faith by the board of directors of the investment company. Prior to the filing of the application, the Commission expressed its view that, among other things, (1) Rule 2a-4 under the Act requires that portfolio instruments of "money market" funds be valued with reference to market factors, and (2) it would be inconsistent generally, with the provisions of Rule 2a-4 for a "money market" fund to value its portfolio instruments on an amortized cost basis (Investment Company Act Release No. 9786, May 31, 1977). In view of the foregoing, Applicant requests exemptions from Section 2(a)(41) of the ACT and Rules 2a-4 and 22c-1 thereunder to the extent necessary to permit Applicant to value its portfolio by means of the amortized cost method of valuation.

In support of the relief requested, Applicant represents that amortized cost value represents the fair value of its portfolio securities. Applicant further states that its board of directors believes that the use of the amortized cost valuation method will benefit Applicant and its shareholders. It is stated that Applicant's investors would have, if the requested exemptions are granted, all the conveniences and advantages of a stable price of $1.00 per share under conditions designed to provide adequate safeguards concerning portfolio quality and in accordance with procedures designed to assure equitable treatment of investors and shareholders. In addition, Applicant has consented to the imposition of the following conditions in an order granting the exemptive relief it requests:

1. In supervising Applicant's operations and delegating special responsibilities involving portfolio management to Applicant's investment adviser, Applicant's Board of Directors undertakes—as a particular responsibility within its overall duty of care owed to Applicant's shareholders—

to establish procedures reasonably designed, taking into account current market conditions and Applicant's investment objective, to stabilize Applicant's net asset value per share, as computed for the purposes of distribution, redemption, redemption and repurchase, at $1.00 per share.

2. Included within the procedures to be adopted by the Board of Directors shall be the following:

(a) Review by the Board of Directors as it deems appropriate and at such intervals as are reasonable in light of current market conditions, to determine the extent of deviation, if any, of Applicant's net asset value per share as determined by using available market quotations from the $1.00 amortized cost price per share, and maintenance of records of such review.[1]

(b) In the event such deviation from Applicant's $1.00 amortized cost price per share exceeds ½ of 1 percent, a requirement that the Board of Directors will promptly consider what action, if any, should be initiated.

(c) Where the Board of Directors believes that the extent of any deviation from Applicant's $1.00 amortized cost price per share may result in material dilution or other unfair results to investors or existing shareholders, it shall take such action as it deems appropriate to eliminate or to reduce to the extent reasonably practicable such dilution or unfair results, which action may include: redeeming shares in kind; selling portfolio instruments prior to maturity to realize capital gains or losses, or to shorten Applicant's average portfolio maturity; withholding dividends; or utilizing a net asset value per share as determined by using available market quotations.

3. Applicant will maintain a dollar-weighted average portfolio maturity appropriate to its objective of maintaining a stable net asset value per share; provided, however, that Applicant will not (a) purchase any instrument with a remaining maturity of greater than one year, or (b) maintain a dollar-weighted average portfolio maturity which exceeds 120 days.[2]

4. Applicant will record, maintain and preserve permanently in an easily accessible place a written copy of the procedures (and any modifications thereto) described in condition 1 above, and Applicant will record, maintain and preserve for a period of not less than six years (the first two years in an easily accessible place) a written record of the Board of Directors' considerations and actions taken in connection with the discharge of its responsibilities, as set forth above, to be included in the minutes of the Board of Directors' meetings. The documents preserved, pursuant to this condition, shall be subject to inspection by the Commission in accordance with Section 31(b) of the Act as though such documents were records required to be maintained pursuant to rules adopted under Section 31(a) of the Act.

5. Applicant will limit its portfolio investments, including repurchase agreements, to those United States dollar-denominated instruments which the Board of Directors determines present minimal credit risks, and which are of high quality as determined by any major rating service, or in the case of any instrument that is not rated, of comparable quality as determined by Applicant's Board of Directors.

6. Applicant will include in each quarterly report, as an attachment to Form N–1Q, a statement as to whether any action pursuant to condition 2(c) above was taken during the preceding fiscal quarter, and, if any action was taken, will describe the nature and circumstances of such action.

Applicant states that the proliferation of tax-exempt mutual funds has significantly increased the demand for short-term tax-exempt instruments and, as a result, available yields on such instuments have tended to decline. At the same time, Applicant states, certain issuers of tax-exempt instruments have sought to lengthen their maturities for reasons including the costs associated with repeated short-term issues. It is stated that these factors have lead to the offering of an increasing number of variable rate instruments.

Applicant states that it expects to invest a substantial portion of its assets in "variable rate" notes and "variable rate" loan participations. It is stated that these instruments have rates of interest which are renegotiated at least every 60 days, such that the value of the instrument should be equivalent to par value on each interest rate adjustment date. Applicant further states that the interest rate on variable rate notes is ordinarly determined by reference to or is a percentage of a bank's prime rate, the ninety-day U.S. Treasury Bill rate, the rate of return on commerical paper or bank certificates of deposit, or some similar objective standard at the time of renegotiation. It is also stated that variable rate loan participations are similar to variable rate notes except that they are made available through a commerical bank which arranges the tax-exempt loan.

Applicant further states that, in order to induce long-term borrowing relationships, issuers have begun offering higher yields on variable rate notes and loan participations containing a "demand" feature allowing either party to terminate the obligation with relatively short notice. Applicant states that it believes that the acquisition of such variable rate demand instruments would provide shareholders with a higher tax-exempt return without subjecting them to increased investment risk.

Applicant represents that, in accordance with the foregoing factors, it proposes to acquire, normally in negotiated transactions with the issuers, tax-exempt variable rate demand notes having the following features: (1) each instrument would have an interest rate determined by a prescribed formula and adjusted at periodic intervals not to exceed 60 days; (2) Applicant could at any time demand prepayment of the unpaid principal balance plus accrued interest thereon and would be entitled to repayment within a prescribed notice period not to exceed seven calendar days; (3) issuers could, at their discretion, prepay the outstanding principal plus accrued interest thereon upon notice to Applicant within a period comparable to the notice periods required for Applicant to demand prepayment; (4) absent an earlier exercise by Applicant or an issuer of their respective prepayment privileges, the principal and interest under each note would be payable on a date exceeding one year from the date of purchase by Applicant; (5) each note purchased by Applicant would be determined under procedures prescribed by Applicant's Board of Directors to present minimal credit risks and would be rated by a major rating service within its two highest rating categories or, if not rated, would be determined by Applicant's investment adviser to be comparable to tax-exempt securities within such rating of i.e., "high quality". Applicant states that the issuer's obligation to pay principal on its obligations would be supported by an irrevocable, unconditional bank letter or

[1] To fulfill this condition, Applicant intends to use actual quotations or estimates of market value reflecting current market conditions chosen by its Board of Directors in the exercise of its discretion to be appropriate indicators of value, which may include among others, (i) quotations or estimates of market value for individual portfolio instruments, or (ii) values obtained from yield data relating to classes of money market instruments published by reputable sources.

[2] In fulfilling this condition, if the disposition of a portfolio instrument results in a dollar-weighted average portfolio maturity in excess of 120 days, Applicant states that it will invest its available cash in such a manner as to reduce the dollar-weighted average portfolio maturity to 120 days or less as soon as reasonably practicable.

credit where necessary to ensure that the instruments were of "high quality" (i.e., where the Board of Directors could not determine that a note is of "high quality" without a letter of credit). Applicant states that, if a letter of credit is a feature of an instrument when it is purchased by Applicant, the instrument will continue to be supported by such letter of credit unless the quality of the instrument raises to within the two highest ratings, or the equivalent, without the letter of credit.

Applicant represents that its investment adviser intends to evaluate not less frequently than monthly the credit of the issuers of variable rate instruments and the backing banks in accordance with other procedures used to evaluate the quality of portfolio securities. Applicant further represents that it will dispose of any instrument (by exercising the demand privilege, where beneficial on notes having such right) where, due to an adverse change in the issuer's credit, Applicant's investment adviser or any rating service concludes that the note is no longer or "high quality" or is otherwise unsuitable for continued investment by Applicant.

Applicant states that it will normally have an unconditional right to sell the notes at any time. Applicant represents that any variable rate instrument that is not freely assignable would be required to be backed by an irrevocable, unconditional letter of credit from banks which would, in the opinion of Applicant's investment adviser, present minimal risk of default and would be major United States commercial banks having outstanding certificates of deposit suitable for inclusion in portfolios of high quality short-term money market instruments.

Applicant states that it proposes to acquire variable rate notes, variable rate loan participations and variable rate demand notes and loan participations as described above and to consider the maturity of such obligations for purposes of computing its dollar-weighted average portfolio maturity, as the longer of the notice period required before Applicant is entitled to prepayment under the instrument or the period remaining until the instrument's next interest rate adjustment.

Applicant further states that where the period remaining until the next interest rate adjustment is different from the notice period required for payment (i.e., for those securities with a demand feature), it would utilize the longer of the two periods for purposes of computing weighted average maturity. Applicant asserts that this approach would be the most conservative under the circumstances.

Applicant states, in addition, that in the case of variable rate notes or variable rate loan participations which do not have a demand feature, Applicant will only invest in instruments having a remaining maturity on the face of the instrument of one year or less. It is asserted that this practice, in addition to Applicant's requirement that the instruments be renegotiable at least every sixty days, should result in such notes having a value equal to par on each interest rate adjustment date.

Applicant submits that there are two general reasons for restricting the maturities of Applicant's portfolio securities. First, it is stated, lengthening the period to maturity of a fixed rate debt security valued according to the amortized cost method generally increases the risk that unrealized gains or losses will cause the security's amortized cost value to deviate materially from its current market value. Applicant states that this risk (because it primarily results from fluctuations in prevailing interest rates) is the "market risk". The second reason for limiting maturity, Applicant states, is that the"credit risk" represented by an instrument is generally perceived to increase as the instrument's maturity is lengthened. Applicant asserts that neither its proposed purchase of variable rate notes, variable rate loan participations and variable rate demand notes and loan participations nor its proposed method of computing its dollar-weighted average portfolio maturity would conflict with the intent of the order sought herein. Applicant states that because a note's interest rate adjustment provision reflects the prevailing rate from time to time on comparable tax-exempt securities, unrealized gains and losses with respect to any instrument would be eliminated as of each interest rate adjustment date. Absent unusual circumstances, Applicant asserts that the rate adjustment provision will permit the instruments to be sold at par on each interest rate adjustment date. Applicant further states that if the interest rate, as adjusted, does not sufficiently eliminate material unrealized appreciation or depreciation on the adjustment day (due to unforeseen circumstances other than a decline in the rating of the instruments to below high quality), Applicant undertakes to demand prepayment of the instrument in full. Applicant also states that it would sell the instruments or exercise its demand privilege (whichever is more beneficial) if, due to an advers change in the issuer's credit, the instruments are no longer high quality. Applicant asserts that the maturity of a note for purposes of determining its market risk is appropriately measured by the notice period required before Applicant is entitled to prepayment in full and that for purposes of measuring either of these risks, the maturity of an instrument would never exceed one year.

In connection with its proposed use of the amortized cost valuation method, subject to the conditions specified hereinabove, Applicant requests an exemption pursuant to Section 6(c) of the Act, to the extent necessary, to acquire variable rate demand notes and loan participations as described above and to consider the maturing of such instruments, for purposes of computing its dollar-weighted average portfolio maturity, as the longer of the notice period required before Applicant would be entitled to prepayment thereon, or the period remaining until the instrument's next interest rate adjustment. Applicant states that such exemption is appropriate in the public interest, and consistent with the protection of investors. Applicant asserts the ability to acquire variable rate demand notes and loan participations under the conditions described above is appropriate because it would not increase the credit or market risk to which Applicant and its shareholders will be exposed and is in the public interest because it would permit Applicant to purchase portfolio securities with possibly higher yields than would be available for fixed-rate securities of comparable quality.

Applicant further states that, in addition to a constant net asset value per share, its shareholders require the ability to receive same-day redemption proceeds in federal funds. It is stated further that "expedited" wire redemption orders received before 11:00 a.m., Chicago time, will be effected at the net asset value determined at 11:00 a.m. and shareholders will receive same-day redemption proceeds in federal funds. Applicant states that the federal funds "wire" closes for transmission purposes at 3:00 p.m. Eastern time, and that therefore Applicant has little time to obtain, either from maturing portfolio securities or settlements arranged that day on sales of securities, the cash needed to meet net redemptions. It is further stated that because periods of net redemptions cannot be predicted and the maturity dates of Municipal Securities held in Applicant's portfolio normally are non-negotiable, Applicant maintains that it cannot rely on scheduled maturities to meet net redemptions. In addition, Applicant asserts that regular settlement on sales of portfolio securities may take

five business days; thus, it is stated, unless prior arrangements assuring immediate liquidity have been made, the negotiation of same-day settlements on sales of portfolio securities within the brief time available is frequently impossible or may require Applicant to receive a less favorable execution price on a sale even though the securities sold have a short remaining maturity.

Applicant states that it proposes to improve its portfolio liquidity by assuring same-day settlements on portfolio sales, and thus facilitate the same-day payments of redemption proceeds in federal funds, through the acquisition of "Standby Commitments", sometimes characterized as "puts". A Standby Commitment, Applicant states, is a right of a fund, when it purchases a Municipal Security for its portfolio from an issuer, dealer, or bank, to sell the same principal amount of such securities back to the seller, at the fund's option, at a specified price. Applicant states further that its investment policies permit the acquisition of Standby Commitments solely to facilitate portfolio liquidity, and that the acquisition or exercisability of a Standby Commitment will not affect the valuation or maturity of its underlying portfolio.

Applicant states that the Standby Commitments will have the following features: (1) they will be in writing and will be physically held by Applicant's custodian; (2) they may be exercisable by Applicant at any time prior to the underlying security's maturity; (3) Applicant's rights to exercise them will be unconditional and unqualified; (4) they will be entered into only with dealers, or banks who, in the investment adviser's opinion, present a minimal risk of default; (5) although they will not be transferable, Municipal Securities pruchased subject to such commitments could be sold to a third party at any time, even though the commitment was outstanding; and (6) their exercise price will be (i) Applicant's acquisition cost of the Municipal Securities which are subject to the commitment (excluding any acrued interest paid on their acquisition) less any amortized market premium or plus any amortized market or original issue discount during the period Applicant owned the securities, plus (ii) all interest accrued on the securities since the last interest payment date during the period the securities were owned by Applicant. Applicant further states that since it will value its Municipal Securities on an amortized cost basis, the amount payable under a Standby Commitment will be substantially the same as the value assigned by Applicant to the underlying securities. Moreover, Applicant submits that there is little risk of an event occurring which would make the amortized cost valuation of its portfolio securities inappropriate; however, Applicant represents that in the unlikely event that the market or fair value of securities in its portfolio were not substantially equivalent to their amortized cost value, the securities would be valued on the basis of available market information and held to maturity. Applicant represents that it expects to refrain from exercising the Standby Commitments in such a situation to avoid imposing a loss on an issuer, dealer, or bank and jeopardizing Applicant's business relationship with that entity.

Applicant states that it expects that Standby Commitments generally will be available without the payment of any direct or indirect consideration. However, if necessary or advisable, Applicant states that it will pay for Standby Commitments, either separately in cash or by paying a higher price for portfolio securities which are acquired subject to the commitment.

Applicant asserts that it is difficult to evaluate the likelihood of use of the potential benefit of a Standby Commitment. Therefore, Applicant states that its Board of Directors will determine that Standby Commitments have a "fair value" of zero, regardless of whether any direct or indirect consideration is paid. Where Applicant has paid for a Standby Commitment, Applicant states that its cost will be reflected as unrealized depreciation for the period during which the commitment is held. In addition, for purposes of complying with the other conditions of its amortized cost order that the dollar-weighted average maturity of its portfolio shall not exceed 120 days, Applicant states that the maturity of a portfolio security shall not be considered shortened or otherwise affected by any Standby Commitment to which such security is subject.

Applicant states that it has been advised by its counsel that the Internal Revenue Service ("IRS") has issued a favorable private ruling to the effect that a registered investment company will be the owner of municipal securities acquired subject to a put option and that interest on the securities will be tax-exempt to the company. Applicant states, however, that it does not intend to seek a favorable ruling from the IRS with respect to its Standby Commitments. Applicant further states that there is no assurance that Standby Commitments will be available to it nor does Applicant assume that such commitments would continue to be available under all market conditions.

Section 12(d) of the Act, in relevant part, prohibits any registered investment company from purchasing or otherwise acquiring any security issued by or any other interest in the business of any person who is a broker, a dealer, is engaged in the underwriting, or is an investment adviser. Therefore, Applicant requests an order pursuant to Section 6(c) of the Act exempting it from the provisions of Section 12(d)(3) of the Act to the extent necessary to permit its acquisition of Standby Commitments from brokers or dealers. Applicant also requests, pursuant to Section 6(c) of the Act, an exemption from the provisions of Section 2(a)(41) of the Act and Rules 2a–4 and 22c–1 thereunder, pemitting it to value Standby Commitments in the manner described hereinabove.

Applicant asserts that this relief is appropriate in the public interest, and consistent with the protection of investors. Applicant asserts that the proposed acquisition of Standby Commitments will not affect its net asset value per share for purposes of sales and redemptions and will not pose new investment risks, but rather will improve its liquidity and ability to pay redemption proceeds the same day in federal funds. Applicant states that its reliance upon the credit of issuers, dealers, or banks from which it purchases commitments will be secured to the extent of the value of the underlying municipal securities which are subject to these commitments. Therefore, Applicant asserts that a Standby Commitment presents less risk than a bank certificate of deposit and will be qualitatively no greater a risk than the risk of loss faced by any investment company which is holding securities pending settlement after having agreed to sell the securities to a broker or dealer in the ordinary course of business. Moreover, Applicant states that its investment adviser intends to evaluate periodically the credit of institutions issuing Standby Commitments. For that reason and in light of determining Applicant's net asset value, Applicant states that the acquisition of such commitments will not meaningfully expose its assets to the entrepreneurial risks of the investment banking business, nor require it to evaluate the credit of brokers or dealers in determining its net asset value.

Notice is hereby given that any interested person may, not later than July 20, 1982, at 5:30 p.m., submit to the Commission in writing a request for a hearing on the application accompanied

by a statement as to the nature of his/her interest, the reasons for such request, and the issues, if any, of fact or law proposed to be controverted, or he/she may request that he/she be notified if the Commission shall order a hearing thereon. Any such communication should be addressed: Secretary, Securities and Exchange Commission, Washington, D.C. 20549. A copy of such request shall be served personally or by mail upon Applicant at the address stated above. Proof of such service (by affidavit or, in the case of an attorney-at-law, by certificate) shall be filed contemporaneously with the request. As provided by Rule 0–5 of the Rules and Regulations promulgated under the Act, an order disposing of the application herein will be issued as of course following said date unless the Commission thereafter orders a hearing upon request or upon the Commission's own motion. Persons who request a hearing, or advice as to whether a hearing is ordered, will receive any notices and orders issued in this matter, including the date of the hearing (if ordered) and any postponements thereof.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Shirley E. Hollis,

Assistant Secretary.

[FR Doc. 82–18083 Filed 7–1–82; 8:45 am]

BILLING CODE 8010–01–M

Boston Stock Exchange, Inc.; Application for Unlisted Trading Privileges and of Opportunity for Hearing

June 28, 1982.

The above named national securities exchange has filed an application with the Securities and Exchange Commission pursuant to Section 12(f)(1)(B) of the Securities Exchange Act of 1934 and Rule 12f–1 thereunder, for unlisted trading privileges in the common stock of:

Delmed Inc., Common Stock, $.10 Par Value (File No. 7–6255)

This security is listed and registered on one or more other national securities exchanges and is reported on the consolidated transaction reporting system.

Interested persons are invited to submit on or before July 20, 1982 written data, views and arguments concerning the above-referenced application. Persons desiring to make written comments should file three copies thereof with the Secretary of the Securities and Exchange Commission, Washington, D.C. 20549. Following this opportunity for hearing, the Commission will approve the application if its finds, based upon all the information available to it, that the extension of unlisted trading privileges pursuant to such application is consistent with the maintenance of fair and orderly markets and the protection of investors.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

George A. Fitzsimmons,

Secretary.

[FR Doc. 82–18081 Filed 7–1–82; 8:45 am]

BILLING CODE 8010–01–M

Pacific Stock Exchange, Inc.; Applications for Unlisted Trading Privileges and of Opportunity for Hearing

June 28, 1982.

The above named national securities exchange has filed applications with the Securities and Exchange Commission pursuant to Section 12(f)(1)(B) of the Securities Exchange Act of 1934 and Rule 12f–1 thereunder, for unlisted trading privileges in the following stocks:

Southmark Corporation, Common Stock, $1 Par Value (File No. 7–6253)

Genuine Parts Company, Common Stock, $1 Par Value (File No. 7–6254)

These securities are listed and registered on one or more other national securities exchanges and are reported in the consolidated transaction reporting system.

Interested persons are invited to submit on or before July 20, 1982 written data, views and arguments concerning the above-referenced applications. Persons desiring to make written comments should file three copies thereof with the Secretary of the Securities and Exchange Commission, Washington, D.C. 20549. Following this opportunity for hearing, the Commission will approve the applications if it finds, based upon all the information available to it, that the extensions of unlisted trading privileges pursuant to such applications are consistent with the maintenance of fair and orderly markets and the protection of investors.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

George A. Fitzsimmons,

Secretary.

[FR Doc. 82–18080 Filed 7–1–82; 8:45 am]

BILLING CODE 8010–01–M

[Release No. 18845; File No. SR–CBOE–82–8]

Filing and Immediate Effectiveness of Proposed Rule Change by the Chicago Board Options Exchange, Inc.

June 28, 1982.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act"), 15 U.S.C. 78s(b)(1), notice is hereby given that on June 9, 1982, the Chicago Board Options Exchange, Incorporated ("CBOE") filed with the Securities and Exchange Commission the proposed rule change as described herein. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

The proposed rule change provides a clarification of the Exchange's interpretation of Rule 4.11 on position limits. The proposed rule change indicates that the Exchange, in aggregating options positions, will consider not only a person's ownership interest in different accounts, but also the person's actual ability to exercise control over the position. Under the proposed rule change, CBOE will determine, on a case-by-case basis, whether a person is able to control an options position. The CBOE has indicated that the proposed rule change will not have an impact on competition.

The foregoing change has become effective, pursuant to Section 19(b)(3)(A) of the Act and subparagraph (e) of Rule 19b–4 under the Act. At any time within 60 days of the filing of such proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest for the protection of investors, or otherwise in furtherance of the purposes of the Act.

Interested persons are invited to submit written data, views and arguments concerning the submission by July 23, 1982. Persons desiring to make written comments should file six copies thereof with the Secretary of the Commission, Securities and Exchange Commission, 500 North Capitol Street, Washington, DC 20549. Reference should be made to File No. SR–CBOE–82–8.

Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change which are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those which may be withheld from the public in accordance with the provisions of 5

U.S.C. 552, will be available for inspection and copying at the Commission's Public Reference Room, 1100 L Street, N.W., Washington, D.C. Copies of the filing and of any subsequent amendments also will be available for inspection and copying at the principal office of the above-mentioned self-regulatory organization.

For the Commission, by the Division of Market Regulation pursuant to delegated authority.

George A. Fitzsimmons,

Secretary.

[FR Doc. 82-18084 Filed 7-1-82; 8:45 am]

BILLING CODE 8010-01-M

[Release No. 18844; SR-OCC-82-6]

Options Clearing Corporation ("OCC"); Order Approving Proposed Rule Change

June 25, 1982.

On February 24, 1982, OCC filed with the Commission pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934, 15 U.S.C. 78s(b)(1), (the "Act") and Rule 19b-4 thereunder, a proposed rule change that allows OCC to implement its pilot Escrow Receipt Depository ("ERD") program on a full-scale basis. ERD automates the processing of escrow deposits and allows related premium settlements between clearing members and ERD participating banks to be effected through OCC's facilities.

Notice of the proposed rule change together with the terms of substance of the proposed rule change was given by publication of a Commission Release (Securities Exchange Act Release No. 18689, April 16, 1982) and by publication in the **Federal Register** (47 FR 18080, April 27, 1982). No letters of comment were received by the Commission.

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to registered clearing agencies, and in particular, the requirements of Section 17A of the Act.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act, that the proposed rule change be, and it hereby is, approved.

For the Commission, by the Division of Market Regulation pursuant to delegated authority.

Shirley E. Hollis,

Assistant Secretary.

[FR Doc. 82-18085 Filed 7-1-82; 8:45 am]

BILLING CODE 8010-01-M

SMALL BUSINESS ADMINISTRATION

[License No. 06/06-0258]

Texas Commerce Investment Co.; Issuance of a License To Operate as a Small Business Investment Company

On March 26, 1982, a notice was published in the **Federal Register** (47 FR 13071), stating that Texas Commerce Investment Company, located at 712 Main Street, Houston, Texas 77002, has filed an application with the Small Business Administration pursuant to 13 CFR 107.102 (1982), for a license to operate as a small business investment company under the provisions of Section 301(c) of the Small Business Investment Act of 1958, as amended.

The period for comment expired on April 12, 1982, and no significant comments were received.

Notice is herey given that considering the application and other pertinent information, SBA has issued License No. 06/06-0258 to Texas Commerce Investment Company.

(Catalog of Federal Domestic Assistance Program No. 59.011, Small Business Investment Companies)

Dated: June 25, 1982.

Robert G. Lineberry,

Acting Deputy Associate Administrator for Investment.

[FR Doc. 82-18089 Filed 7-1-82; 8:45 am]

BILLING CODE 8025-01-M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Privacy Act of 1974; Proposed Revision of a System of Records

AGENCY: Internal Revenue Service, Treasury.

ACTION: Proposed Revision of a System of Records.

SUMMARY: Pursuant to the requirements of the Privacy Act of 1974 (5 U.S.C. 552a), the Department of the Treasury, Internal Revenue Service, gives notice of proposed revisions to Treasury/IRS System of Records entitled, TDA (Taxpayer Delinquent Accounts)—Treasury/IRS 26.019. Treasury/IRS 26.019 is being modified to include child support obligation accounts which are collected by the Internal Revenue Service.

DATES: Public comments must be received on or before August 2, 1982. If no comments are received, to which the Department publishes a revision to incorporate comments, this system will become effective on August 31, 1982.

ADDRESS: Assistant Commissioner (Collection), Internal Revenue Service, 1111 Constitution Avenue NW., Washington, D.C. 20224.

FOR FURTHER INFORMATION CONTACT: Mr. Robert Goldsmith, Chief, Office of Planning and Management, Assistant Commissioner (Collection), Internal Revenue Service, 1111 Constitution Avenue NW., Washington, D.C. 20224, (202) 566-4250.

Dated: June 22, 1982.

George Astengo,

Acting Assistant Secretary (Administration).

Notice of Revised System of Records

Treasury/IRS 26.019

The following system is revised:

TREASURY/IRS 26.019

SYSTEM NAME:

TDA (Taxpayer Delinquent Accounts) including subsystems: (a) Adjustment and Payment Tracer Files, (b) Collateral Files, (c) Seized Property Records, (d) Tax Collection Waiver (Form 900) Files, and (e) Accounts on Child Support Obligations, OP:C—Treasury/IRS.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Taxpayers on whom Federal tax assessments have been made and persons who owe child support obligations.

CATEGORIES OF RECORDS IN THE SYSTEM:

Taxpayer name, address, taxpayer identification number, information about basis of assessment, including class of tax, period, dollar amounts, chronological investigative history, cancelled checks, amended returns, claims, collateral submitted to stay collection, copies of notices of Federal tax liens, revenue officer reports, waivers to extend statutory period for collection, etc., and similar information about persons who owe child support obligations. This system includes installment agreement files; Delinquent Account Inventory Profiles (DAIPs); Currently Not Collectible Registers; Currently Not Collectible Registers (over $25,000); advance dated remittance check files; currently not collectible accounts files; a file of taxpayer names entered in the Treasury Enforcement Communications System; and, a code identifying taxpayers that threatened or assaulted IRS employees.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301 and 26 U.S.C. 6305, 7801 and 7802.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Routine disclosure may be made to the extent provided by law or regulation (included 26 U.S.C. 6103 and 26 CFR 404.6103 where applicable). For additional routine uses, see Appendix AA.

RETRIEVABILITY:

By name of taxpayer or person who owes child support obligations.

SAFEGUARDS:

Access controls will be not less than that provided for by IRM 1(16)12, Manager's Security Handbook.

RETENTION AND DISPOSAL:

As specified in IRM 1(15)59.24, Records Control Schedule 204 for Collection, Taxpayer Service and Problem Resolution Program—District Offices, and IRM 1(15)59.26, Records Control Schedule 206 for Service Centers.

[FR Doc. 82-18094 Filed 7-1-82; 8:45 am]

BILLING CODE 4830-01-M

Public Information Collection Requirements Submitted to OMB for Review

During the period June 18 through June 24, 1982, the Department of Treasury submitted the following public information collection requirements to OMB, for review and clearance under the Paperwork Reduction Act of 1980, P.L. 96-511. Copies of these submissions may be obtained from the Treasury Department Clearance Officer, by calling (202) 634-2179. Comments regarding these information collections should be addressed to the Treasury Reports Management Officer, Information Resources Management Division, Room 309, 1625 I St. NW., Washington, D.C. 20220; *and* to the OMB reviewer listed at the end of each entry.

Date Submitted: June 23, 1982.

Submitting Bureau: Bureau of Government Financial Operations.

OMB Number: 1510-0019.

Form Number: TFS 1133.

Type of Submission: Revision.

Title: Claim Against the United States for the Proceeds of a Government Check.

Purpose: This form is used to record information pertaining to adjudicating the payee's request for payment for a lost, mutilated or stolen U.S. Government check.

OMB Reviewer: Suzanne Evinger, (202) 395-6880, Office of Management and Budget, Room 3208, New Executive Office Building, Washington, D.C. 20503.

Date Submitted: June 24, 1982.

Submitting Bureau: U.S. Customs Service.

OMB Number: 1515-0014.

Form Number: CF 4455.

Type of Submission: Extension.

Title: Certificate of Registration.

Purpose: The executed form certifies that the returned articles meeting Customs requirements are the same as those previously exported for the purpose of alterating, repair, use abroad, replacement, processing or other, and are therefore entitled to duty free entry.

OMB Reviewer: Suzanne Evinger, (202) 395-6880, Office of Management and Budget, Room 3208, New Executive Office Building, Washington, D.C. 20503.

Date Submitted: June 24, 1982.

Submitting Bureau: Internal Revenue Service.

OMB Number: 1545-0232.

Form Number: 6497.

Type of Submission: Extension.

Title: Information Return of Energy Grants or Subsidized Energy Financing.

Purpose: The form is to be filed by any governmental agency (Federal, State, or local) or its agent that makes grants or subsidized financing for energy conservation projects. The information is required to be reported under IRC section 6050D. The information is used to be sure that energy credits are not taken for government-financed projects.

OMB Reviewer: Michael Abrahams, (202) 395-6880, Office of Management and Budget, Room 3208, New Executive Office Building, Washington, D.C. 20503.

Date Submitted: June 21, 1982.

Submitting Bureau: Internal Revenue Service.

OMB Number: 1545-0387.

Form Number: 4419.

Type of Submission: Revision.

Title: Application for Magnetic Media Reporting of Information Returns.

Purpose: 26 U.S.C. 6041 and 6042 require that all persons engaged in a trade or business and making payments of taxable income are required to file reports of this income with IRS. Payers who wish to file these returns on magnetic media instead of paper documents must complete Form 4419 to receive authorization for filing on tape.

OMB Reviewer: Michael Abrahams, (202) 395-6880, Office of Management and Budget, Room 3208, New Executive Office Building, Washington, D.C. 20503.

Date Submitted: June 24, 1982.

Submitting Bureau: Internal Revenue Service.

OMB Number: 1545-0212.

Form Number: 5558.

Type of Submission: Revision.

Title: Application for Extension of Time to File Certain Employee Plan Returns.

Purpose: Used by employers to request extensions of time to file employee plan annual information returns and the employee plan excise tax return (Form 5330). The data supplied in this form is used to determine if such extension of time is warranted.

OMB Reviewer: Michael Abrahams, (202) 395-6880, Office of Management and Budget, Room 3208, New Executive Office Building, Washington, D.C. 20503.

Joy Tucker,

Departmental Reports Management Officer.

June 28, 1982.

[FR Doc. 82-18054 Filed 7-1-82; 8:45 am]

BILLING CODE 4810-25-M

Sunshine Act Meetings

Federal Register
Vol. 47, No. 128
Friday, July 2, 1982

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

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1

FEDERAL DEPOSIT INSURANCE CORPORATION

Agency Meeting

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b), notice is hereby given that the Federal Deposit Insurance Corporation's Board of Directors will meet in open session at 2:00 p.m. on Tuesday, July 6, 1982, to consider the following matters:

Summary Agenda: No substantive discussion of the following items is anticipated. These matters will be resolved with a single vote unless a member of the Board of Directors requests that an item be moved to the discussion agenda.

Disposition of minutes of previous meetings.

Recommendations regarding the liquidation of a bank's assets acquired by the Corporation in its capacity as receiver, liquidator, or liquidating agent of those assets:

Case No. 45,284-L—Franklin National Bank, New York, New York
Case No. 45,286-L—American City Bank & Trust Company, National Association, Milwaukee, Wisconsin
Case No. 45,287-SR—Farmers Bank of Petersburg, Petersburg, Kentucky
Case No. 45,290-SR—The Peoples Bank of the Virgin Islands, Charlotte Amalie, Virgin Islands
Case No. 45,292—The Greenwich Savings Bank, New York, New York

Recommendation with respect to payment for legal services rendered and expenses incurred in connection with receivership and liquidation activities:

Gibbs, Roper, Loots & Williams, Milwaukee, Wisconsin, in connection with the liquidation of American City Bank & Trust Company, National Association, Milwaukee, Wisconsin.

Memorandum and resolution re: Delegation of authority to administer petty cash funds.

Report of committees and officers:

Minutes of the actions approved by the standing committees of the Corporation pursuant to authority delegated by the Board of Directors.
Reports of the Division of Bank Supervision with respect to applications or requests approved by the Director or Associate Director of the Division and the various Regional Directors pursuant to authority delegated by the Board of Directors.
Report of the Director, Division of Liquidation:
Memorandum re: Morrice State Bank, Morrice, Michigan, Termination of Field Liquidation Office
Report of the General Counsel:
Memorandum re: Report of Actions Approved Under Delegated Authority: Settlements of Claims and Attorneys' Fees Approved for Payment
Reports of the Director, Office of Corporate Audits:
Memorandum re: Office of Corporate Audits' Quarterly Certification of Division of Liquidation Approvals Under Delegated Authority
Audit Report re: Project Review of the Accounts Receivable Subsystem—Interim Audit Report #2, dated June 1, 1982.

Discussion Agenda:

No matters scheduled.

The meeting will be held in the Board Room on the sixth floor of the FDIC Building located at 500 17th Street, N.W., Washington, D.C.

Requests for information concerning the meeting may be directed to Mr. Hoyle L. Robinson, Executive Secretary of the Corporation, at (202) 389-4425.

Dated: June 29, 1982.

Federal Deposit Insurance Corporation.

Hoyle L. Robinson,

Executive Secretary.

[S-971-82 Filed 6-30-82; 11:11 am]

BILLING CODE 6714-01-M

2

FEDERAL DEPOSIT INSURANCE CORPORATION

Agency Meeting

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b), notice is hereby given that at 2:30 p.m. on Tuesday, July 6, 1982, the Federal Deposit Insurance Corporation's Board of Directors will meet in closed session, by vote of the Board of Directors pursuant to sections 552b (c)(2), (c)(6), (c)(8), and (c)(9)(A)(ii), of Title 5, United States Code, to consider the following matters:

Summary Agenda: No substantive discussion of the following items is anticipated. These matters will be resolved with a single vote unless a member of the Board of Directors requests that an item be moved to the discussion agenda.

Recommendations with respect to the initiation, termination, or conduct of administrative enforcement proceedings (cease-and-desist proceedings, termination-of-insurance proceedings, suspension or removal proceedings, or assessment of civil money penalties) against certain insured banks or officers, directors, employees, agents, or other persons participating in the conduct of the affairs thereof:

Names of persons and names and locations of banks authorized to be exempt from disclosure pursuant to the provisions of subsections (c)(6), (c)(8), and (c)(9)(A)(ii) of the "Government in the Sunshine Act" (5 U.S.C. 552b (c)(6), (c)(8), and (c)(9)(A)(ii)).

Note.—Some matters falling within this category may be placed on the discussion agenda without further public notice if it becomes likely that substantive discussion of those matters will occur at the meeting.

Discussion Agenda:

Recommendations regarding the liqudiation of a bank's assets acquired by the Corporation in its capacity as receiver, liquidator, or liquidating agent of those assets:

Case No. 45,272-NR—United States National Bank, San Diego, California
Memorandum and Resolution re: The Hamilton National Bank of Chattanooga, Chattanooga, Tennessee.

Memorandum re: Corporation policy regarding leave-without-pay for the purpose of obtaining an advanced degree or taking a sabbatical to teach or study in a job-related area.

Personnel actions regarding appointments, promotions, administrative pay increases, reassignments, retirements, separations, removals, etc.:

Names of employees authorized to be exempt from disclosure pursuant to the provisions of subsections (c)(2) and (c)(6) of the "Government in the Sunshine Act" (5 U.S.C. 552b (c)(2) and (c)(6)).

The meeting will be held in the Board Room on the sixth floor of the FDIC Building located at 550 17th Street, N.W., Washington, D.C.

Requests for information concerning the meeting may be directed to Mr. Hoyle L. Robinson, Executive Secretary of the Corporation, at (202) 389–4025.

Dated: June 29, 1982.

Federal Deposit Insurance Corporation.

Hoyle L. Robinson,

Executive Secretary.

[S-972-82 Filed 6-30-82; 11:11 am]

BILLING CODE 6714-01-M

3

FEDERAL DEPOSIT INSURANCE CORPORATION

Change in Subject Matter of Agency Meeting

Pursuant to the provisions of subsection (e)(2) of the "Government in the Sunshine Act" (5 U.S.C. 552b(e)(2)), notice is hereby given that at its open meeting held at 2:00 p.m. on Monday, June 28, 1982, the Corporation's Board of Directors determined, on motion of Chairman William M. Isaac, seconded by Director Irvine H. Sprague (Appointive), concurred in by Director C. T. Conover (Comptroller of the Currency), that Corporation business required the addition to the agenda for consideration at the meeting, on less than seven days' notice to the public, of the following matter:

Memorandum and Resolution re: Proposed amendments to Parts 303, 304, and 347 of the Corporations's rules and regulations, entitled "Applications, Requests, Submittals, and Notices of Acquisition of Control," "Forms, Instructions, and Reports," and "Foreign Activities of Insured State Nonmember Banks," respectively, which would expedite the processing of applications for consent to establish foreign and domestic branches (including remote service facilities) and to relocate offices.

By the same majority vote, the Board further determined that no earlier notice of these changes in the subject matter of the meeting was practicable.

Dated: June 30, 1982.

Federal Deposit Insurance Corporation.

Hoyle L. Robinson,

Executive Secretary.

[S-75-82 Filed 6-30-82; 3:40 pm]

BILLING CODE 6714-01-M

4

FEDERAL DEPOSIT INSURANCE CORPORATION

Changes in Subject Matter of Agency Meeting

Pursuant to the provisions of subsection (e)(2) of the "Government in the Sunshine Act" (5 U.S.C. 552b(e)(2)), notice is hereby given that at its closed meeting held at 2:30 p.m. on Monday, June 28, 1982, the Corporation's Board of Directors determined, on motion of Chairman William M. Isaac, seconded by Director Irvine H. Sprague (Appointive), concurred in by Director C. T. Conover (Comptroller of the Currency), that Corporation business required the addition to the agenda for consideration at the meeting, on less than seven days' notice to the public, of the following matters:

Discussion of an FDIC assistance agreement with an insured bank.

Discussion of a proposal regarding a branch of an insured bank.

The Board further determined, by the same majority vote, that no earlier notice of the changes in the subject matter of the meeting was practicable; that the public interest did not require consideration of the matters in a meeting open to public observation; and that the matters could be considered in a closed meeting by authority of subsections (c)(6), (c)(8), (c)(9)(A)(ii), and (c)(9)(B) of the "Government in the Sunshine Act" (5 U.S.C. 552b (c)(6), (c)(8), (c)(9)(A)(ii) and (c)(9)(B)).

Dated: June 30, 1982.

Federal Deposit Insurance Corporation.

Hoyle L. Robinson,

Executive Secretary.

[S-976-82 Filed 6-30-82; 3:07 pm]

BILLING CODE 6714-01-M

5

FEDERAL DEPOSIT INSURANCE CORPORATION

Cancellation of Agency Meeting

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b), notice is hereby given that the special open meeting of the Corporation's Board of Directors scheduled for 2:00 p.m. on Wednesday, June 30, 1982, at which the Board was to take up the following matter, has been cancelled:

Petition of the Investment Company Institute seeking a public hearing and certain other relief in connection with the creation and operation by The Boston Five Cents Savings Bank, Boston, Massachusetts, of two wholly-owned subsidiaries to advise and distribute shares in a mutual fund.

No earlier notice of the cancellation of the meeting was practicable.

Dated: June 30, 1982.

Federal Deposit Insurance Corporation.

Hoyle L. Robinson,

Executive Secretary.

[S-977-82 Filed 6-30-82; 3:08 pm]

BILLING CODE 6714-01-M

6

FEDERAL RESERVE SYSTEM

TIME AND DATE: Approximately 11 a.m., Wednesday, July 7, 1982, following a recess at the conclusion of the open meeting.

PLACE: 20th Street and Constitution Avenue, NW., Washington, D.C. 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.
2. Federal Reserve Bank and Branch director appointments.
3. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board (202) 452–3204.

Dated: June 29, 1982.

James McAfee,

Associate Secretary of the Board.

[S-969-82 Filed 6-30-82; 8:50 am]

BILLING CODE 6210-01-M

7

FEDERAL RESERVE SYSTEM

TIME AND DATE: 10 a.m., Wednesday, July 7, 1982.

PLACE: Board Building, C Street entrance between 20th and 21st Streets, NW., Washington, D.C. 20551.

STATUS: Open.

MATTERS TO BE CONSIDERED:

1. Proposals with respect to contemporaneous reserve requirements. (Proposed earlier for public comment: Docket No. R–0371)
2. Any items carried forward from a previously announced meeting.

Note.—This meeting will be recorded for the benefit of those unable to attend. Cassettes will be available for listening in the Board's Freedom of Information Office, and copies may be ordered for $5 per cassette by calling (202) 452–3684 or by writing to: Freedom of Information Office, Board of Governors of the Federal Reserve System, Washington, D.C. 20551.

CONTACT PERSON FOR MORE INFORMATION:

Mr. Joseph R. Coyne, Assistant to the Board (202) 452–3204.

Dated: June 29, 1982.

James McAfee,

Associate Secretary of the Board.

[S-968-82 Filed 6-30-82; 8:49 am]

BILLING CODE 6210-01-M

8

FEDERAL TRADE COMMISSION

TIME AND DATE: 2 p.m., Tuesday, July 6, 1982.

PLACE: Room 432, Federal Trade Commission Building, 6th Street and Pennsylvania Avenue, NW., Washington, D.C. 20580.

STATUS: Open.

MATTER TO BE CONSIDERED: Policy Review Session on Civil Penalties.

CONTACT PERSON FOR MORE INFORMATION:

Susan B. Ticknor, Office of Public Information: (202) 523-1892; Recorded Message: (202) 523-3806.

[S-970-82 Filed 6-30-82; 10:34 am]

BILLING CODE 6750-01-M

9

SECURITIES AND EXCHANGE COMMISSION

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: To be published.

STATUS: Closed meeting.

PLACE: Room 825, 500 North Capitol Street, Washington, D.C.

DATE PREVIOUSLY ANNOUNCED: Tuesday, June 22, 1982.

CHANGES IN THE MEETING: Additional meeting. The following item will be considered at a closed meeting scheduled for Tuesday, June 29, 1982, at 5:30 p.m.:

Settlement of injunctive actions.

Chairman Shad and Commissioners Evans, Thomas and Longstreth determined by vote that Commission business required consideration of this matter and that no earlier notice thereof was possible.

At times changes in Commission priorities require alterations in the scheduling of meeting items. For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact: Bob Zutz at (202) 272-2091.

June 29, 1982.

[S-973-82 Filed 6-30-82; 11:41 am]

BILLING CODE 8010-01-M

10

TENNESSEE VALLEY AUTHORITY

TIME AND DATE: 10:15 a.m. (e.d.t.), Wednesday, July 7, 1982.

PLACE: TVA, West Tower Auditorium, 400 West Summit Hill Drive, Knoxville, Tennessee.

STATUS: Open.

Action Items

A—Project Authorizations

1. Project Authorization No. 3241.4—Amendment to project authorization for wet-process phosphoric acid pilot-plant processes.

B—Purchase Awards

1. Request for delegation of procurement authority for negotiation of discounted enrichment services.
2. Amendment to contract 80K34-827436 with The Babcock & Wilcox Company, Barberton, Ohio, for boiler balanced-draft conversion at Paradise Steam Plant units 1 and 2.
3. Proposed contracts with the Louisville & Nashville Railroad for unit-train transportation of coal.

C—Power Items

*1. Proposed uranium loan to Urangesellschaft U.S.A., Inc.
*2. Cogeneration agreement with Weyerhaeuser Company, Columbus, Mississippi.
3. Lease and amendatory agreement with Cumberland Electric Membership Corporation covering arrangements for lease of TVA's Ashland City, Green Brier, Lone Oak, Orlinda, and Shady Grove 69-kV substations to permit higher voltage service.
4. Deed covering conveyance of TVA's Hamilton 46-kV Substation property to Kerr-McGee Chemical Corporation at Hamilton, Mississippi.
5. Adoption of supplemental resolution authorizing 1982 Series C power bonds.
6. Resolution authorizing the Chairman and other executive officers to take further action relating to issuance and sale of 1982 Series C power bonds.

D—Personnel Items

1. Renewal of consulting contract with John M. Kellberg, Knoxville, Tennessee, for advice and assistance in connection with design and construction of hydro and thermal power plants, requested by the Office of Engineering Design and Construction.
2. Renewal of consulting contract with Roland A. Kampmeier, Chattanooga, Tennessee, for advice and assistance in connection with TVA's power programs and energy-related programs, requested by the Office of Power.
3. Amendment to personal services contract with Wyle Laboratories, Huntsville, Alabama, for engineering and related services, requested by the Office of Engineering Design and Construction.
4. Personal services contract with Allied Nuclear, Inc., Freemont, California, for services of health physics technicians, requested by the Office of Power.
5. Personal services contract with Sasser's Consulting Services, Inc., Tavares, Florida, for services of health physics technicians, requested by the Office of Power.

F—Unclassified

1. Revised budget plan for fiscal year 1982—midyear review.

CONTACT PERSON FOR MORE INFORMATION: Craven H. Crowell, Jr., Director of Information, or a member of his staff can respond to requests for information about this meeting. Call (615) 632-3257, Knoxville, Tennessee. Information is also available at TVA's Washington Office (202) 245-0101.

Dated: June 30, 1982.

[S-974-82 Filed 6-30-82; 2:09 pm]

BILLING CODE 8120-01-M

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*Items approved by individual Board members. This would give formal ratification of the Board's action.

federal register

Friday
July 2, 1982

Part II

Department of Health and Human Services

Food and Drug Administration

Orthopedic Devices; General Provisions and Classification of 77 Devices

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 888

[Docket No. 78N-2830]

Orthopedic Devices; General Provisions and Classification of 77 Devices

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing general rules applicable to the classification of orthopedic devices in commercial distribution. The Medical Device Amendments of 1976 require the agency to classify all medical devices intended for human use into three categories: class I, general controls; class II, performance standards; and class III, premarket approval. In the preamble, FDA describes the development of the proposed regulation classifying 77 orthopedic devices. The preamble also describes the activities of the Orthopedic Device Section of the Surgical and Rehabilitation Devices Panel (formerly the Orthopedic Device Classification Panel), an FDA advisory committee that makes recommendations to FDA concerning the classification of orthopedic devices.

DATES: Comments by October 1, 1982. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register**.

ADDRESS: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James G. Dillon, Bureau of Medical Devices (HFK-410), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:

Device Classification System

The Medical Device Amendments of 1976 (the amendments) (Pub. L. 94-295), establish a comprehensive system for the regulation of medical devices intended for human use. One provision of the amendments, section 513 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360c) establishes three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories are as follows: class I, general controls; class II, performance standards; and class III, premarket approval.

Most devices are not classified under section 513 of the act until after FDA has (1) received a recommendation from a device panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. These steps must precede the classification of any device that was in commercial distribution before May 28, 1976 (the date of enactment of the amendments) and that was not previously regarded by FDA as a new drug under section 505 of the act (21 U.S.C. 355). A device that is first offered for commercial distribution after May 28, 1976, and that is substantially equivalent to a device classified under this scheme, is classified in the same class as the device to which it is substantially equivalent.

A device that FDA previously regarded as a new drug, or a newly offered device that is not substantially equivalent to a device that was in commercial distribution before the amendments, is classified by statute into class III. These two types of devices are classified into class III without any FDA rulemaking proceedings. The agency determines whether new devices are substantially equivalent to previously offered devices by means of the premarket notification procedure in section 510(k) of the act (21 U.S.C. 360(k)) and Part 807 of the regulations (21 CFR Part 807).

Related Regulations

In the **Federal Register** of July 28, 1978 (43 FR 32988), the agency issued final regulations describing the procedures for classifying devices intended for human use. These regulations, which were proposed in the **Federal Register** of September 13, 1977 (42 FR 46028), supplement the agency's regulations in Part 14 (21 CFR Part 14) governing the use of advisory committees. The agency also issued interim device classification procedures in a notice published in the **Federal Register** of May 19, 1975 (40 FR 21848).

Activities of Panel

Anticipating enactment of the amendments, FDA established several advisory committees to make preliminary recommendations on device classification. The Orthopedic Device Classification Panel (the Panel) was originally chartered on April 25, 1972, as the Panel on Review of Orthopedic Devices. FDA placed a report of the Panel's tentative classification recommendations on file with the Dockets Management Branch (HFA-305), Food and Drug Administration, and announced the availability of the report to the public by notice published in the **Federal Register** of June 25, 1976 (41 FR 26245). On August 9, 1976, the Panel and other preamendments device classification panels were rechartered to reflect their new responsibilities under the amendments. The agency directed each panel to reconsider its preamendments classification recommendations in light of the new requirements. In 1976 and 1977, the Panel reviewed all devices that FDA had referred to it to make certain that its recommendations were in accord with the amendments. Throughout the Panel's deliberations, interested persons were given an opportunity to present their views, data, and other information concerning the classification of orthopedic devices. The Panel also invited experts to testify and sought information from the published literature on many devices.

In October 1977, the Panel submitted to FDA a preliminary report of its recommendations. The report included a roster of current and former Panel members and consultants and listed all meeting dates. The agency placed a copy of the report in the Dockets Management Branch (HFA-305), Food and Drug Administration, and announced its availability to the public by notice published in the **Federal Register** of November 29, 1977 (42 FR 60792). Also available in the Dockets Management Branch are summary minutes from all Panel meetings, verbatim transcripts of meetings held after May 28, 1976 (the date of enactment of the amendments), and all references cited in this proposal.

On April 28, 1978, the agency terminated all of the device classification panels and then reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). The Orthopedic Device Classification Panel was terminated, and its functions are now conducted by the Orthopedic Device Section of the Surgical and Rehabilitation Devices Panel.

Most of the Panel classification recommendations published in this preamble are those made in 1977 by the earlier Orthopedic Device Classification Panel. But recommendations on the following nine orthopedic devices are

those made on November 19, 1980, by the Orthopedic Device Section of the Surgical and Rehabilitation Devices Panel (Ref. 1):

Section	Device	Docket No.	Class
888.3300	Hip joint metal constrained prosthesis.	78N-3070...	III.
888.3310	Hip joint metal/polymer constrained prosthesis.	78N-3071...	III.
888.3370	Hip joint (hemi-hip) acetabular metal prosthesis.	78N-3076...	III.
888.3400	Hip joint femoral (hemi-hip) resurfacing prosthesis.	78N-3080...	II.
888.3510	Knee joint femorotibial metal/polymer constrained prosthesis.	78N-3084...	II.
888.3680	Shoulder joint glenoid (hemi-shoulder) prosthesis.	78N-3058...	III.
888.5940	Cast components	78N-3123...	I.
888.5960	AC-powered cast removal instruments.	78N-3124...	II.
888.5980	Manual cast application/removal instruments.	78N-3125...	I.

Relationship Between the Device Names in the Device Registration and Listing Codes and the Device Names in Classification Regulations

Some manufacturers have become accustomed to identifying a device by its registration and listing name and code used for purposes of device listing under section 510 of the act (21 U.S.C. 360). However, FDA is still making changes in the names and identifications of generic types of devices in the classification regulations for all devices for which final regulations have not been published. Because FDA has not used the present device registration and listing names in the proposed and final classification regulations, FDA has prepared an index of names of generic types of medical devices used in classification regulations to aid a manufacturer in matching its device with the proper classification regulation. The index shows the device registration and listing product code for each device reviewed by a classification panel and the corresponding name of the generic type of device and classification panel in which device classification will be published in the **Federal Register.** The agency announced the availability of this index in the **Federal Register** of March 6, 1979 (44 FR 12269). If necessary, this index will be updated and the availability of the revised index will be reannounced in the **Federal Register.** FDA believes that, because this index is available, it is unnecessary to include or cross-reference the present device registration and listing name and product code in the classification regulations. In the future, following publication of most of the device classification regulations, the agency will revise and reissue the device registration and listing product code, so the device names to be used for registration and listing correspond to the device names in the final device classification regulations.

List of Orthopedic Devices

In 1972, FDA surveyed device manufacturers to identify the devices for which classification regulations would be needed. Following this survey, FDA developed a list of orthopedic devices. The Panel supplemented the list using its members' knowledge of orthopedic devices in use. Devices that were solely for experimental or investigational use, that were not generally available, or that had been regarded as new drugs were not included. Additional orthopedic devices, which were not included in this list and which were commercially available before May 28, 1976, will be added to the list as necessary.

FDA is proposing to establish a new Part 888 in Title 21 of the Code of Federal Regulations. Part 888 will consist of sections identifying each orthopedic device with a brief narrative description and stating the classification of that device. The list of orthopedic devices appears elsewhere in this preamble.

Orthopedic Device Classifications

FDA is proposing to classify 77 orthopedic devices. The agency is proposing to classify 15 orthopedic devices into class I (general controls), 38 orthopedic into class II (performance standards), and 24 orthopedic devices into class III (premarket approval). The agency also is publishing the recommendations of the Panel regarding these devices, as required by section 513 (c)(2) and (d)(1) of the act (21 U.S.C. 360c (c)(2) and (d)(1)).

Panel Recommendations

The Panel recommendation concerning an orthopedic device includes the information described below.

1. *Identification.* Both the Panel recommendation and the proposed FDA classification include a brief narrative identification of the generic type of the device. The identification statement is necessarily broad because it applies to a category or type of device rather than to a specific device. As explained in proposed § 888.1, any manufacturer of a newly offered device who files a premarket notification submission under section 510(k) of the act (21 U.S.C. 360(k)) and Part 807 (21 CFR Part 807) of the regulations cannot show merely that the device is accurately described by the section title and identification provisions of a classification regulation. Although a newly offered device may be described accurately by the title and identification in a classification regulation, it is nevertheless in class III under section 513(f) of the act if it is not substantially equivalent to a preamendments device (or to a postamendments device that has already been reclassified from class III into class I or class II). It is not practical for FDA to publish an identification of each type of device that is so detailed as to anticipate every product feature that may be relevant in determining whether a new device is substantially equivalent to previous devices classified by the regulation. The agency believes that this problem was recognized in, and addressed by, the premarket notification procedures in section 510(k) of the act. Accordingly, any manufacturer who submits a premarket notification submission should state why the manufacturer believes the device is substantially equivalent to other devices in commercial distribution, as required by § 807.87 (21 CFR 807.87), and whether the device is described in a classification regulation.

Some products have both medical and nonmedical uses. FDA will regulate a multipurpose product as a medical device if it is intended for a medical purpose, i.e., for "use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease," or "to affect the structure or any function of the body." (Section 201(h) of the act (21 U.S.C. 321(h)).) FDA will determine the intended use of a product based upon the expressions of the person legally responsible for its labeling and by the circumstances surrounding its distribution. The most important factors the agency will consider in determining the intended use of a particular product are the labeling, advertising, and other representations accompanying the product. Products that have medical uses only are clearly intended for medical purposes and, therefore, will be regulated as medical devices whether or not medical claims are made for them.

Composition of materials used in orthopedic prosthetic devices: The Panel believed that the generic chemical formula of materials should be omitted from the proposed name of the device, although material specifications may be placed in the device's identification. Use of the general term "metal" in the proposed name of the device means that a component of the device is made of one or more kinds of metal or metal alloys. Use of the general term "polymer" in the proposed name of the

device means that a component is made of one or more kinds of synthetic compounds, usually of high molecular weight, consisting of up to millions of repeated, linked units, each a relatively low molecular weight molecule.

Resurfacing technique: Because of resurfacing techniques, certain joint prostheses require far less bone resection than other devices intended to repair or replace the same joint. The amount of bone resection may or may not affect the safety and effectiveness of the implantation of the prosthesis. When a resurfacing technique is used, the proposed name of the prosthesis includes this information.

Degree of constraint: Certain joint prostheses provide more constraint of joint movement than others. FDA believes that the degree of constraint is an important factor affecting the safety and effectiveness of orthopedic prostheses. Consequently, FDA considered the degree of constraint imposed by the prosthesis when determining whether to propose classification of the device into class II or class III. Because of the lack of consistent descriptive terminology in the literature, FDA is proposing the following standard terms for categorizing the degree of constraint, based on concepts developed by Chao and Mullen (Ref. 2).

(a) A *constrained* joint prosthesis is used for joint replacement and prevents dislocation of the prosthesis in more than one anatomic plane and consists of either a single, flexible, across-the-joint component or more than one component linked together or affined.

(b) a *semi-constrained* joint prosthesis is used for partial or total replacement and limits translation and rotation of the prosthesis in one or more planes via the geometry of its articulating surfaces. It has no across-the-joint linkage.

(c) A *non-constrained* joint prosthesis is used for partial or total joint replacement and restricts minimally prosthesis movement in one or more planes. Its components have no across-the-joint linkage.

Standardized names of orthopedic prosthetic devices intended for joint replacement. Based on recommendations made by Panel members and on current terminology used in the medical literature, FDA is proposing that certain information be included in the names of the generic types of orthopedic prosthetic devices intended for joint replacement. FDA proposes that the generic names of devices intended for joint replacement identify:

(1) The joint or tissue being replaced and, if appropriate, the articulating bone surfaces;

(2) The general type of materials used in the device, if appropriate;

(3) The degree of constraint being imposed by the device, if appropriate;

(4) When a resurfacing technique is used;

(5) When the device is not implanted into the bone with a polymethylmethacrylate-type luting agent (bone cement), if appropriate; and

(6) That the device is a prosthesis.

2. *Recommended classification.* Each Panel's recommendation describes whether the device is recommended for classification into class I, class II, or class III.

For each device recommended for classification into class I, the Panel considered whether the device should be exempt from any requirements under certain sections of the act; section 510 (21 U.S.C. 360, registration), section 519 (21 U.S.C. 360i, records and reports), and section 520(f) (21 U.S.C. 360j(f), the good manufacturing practice (GMP) requirements). The Panel recommended that the manufacturers of several devices be exempted from section 510, section 519, and section 520(f) of the act. The agency's policy concerning these exemption recommendations is discussed below in the section of this proposal concerning "Exemptions for Class I Devices."

A Panel recommendation that a device be classified into class II includes the Panel's recommended priority ("high," "medium," or "low") for establishing a performance standard for the device. Similarly, each Panel recommendation that a device be classified into class III includes the Panel's recommended priority ("high," "medium," or "low") for application of premarket approval requirements to that device. As explained below in the section of this notice concerning "Priorities for Class II and Class III Devices," however, the agency is not proposing the establishment of FDA priorities at this time.

3. *Summary of reasons for recommendation.* The summary of reasons for the Panel's recommendation explains why the Panel believes that a particular device meets the statutory criteria for classification into class I, II, or III.

Except in those instances in which FDA's classification proposal differs from the Panel's recommendation, FDA is adopting the Panel's summary of reasons as the agency's statement of the reasons for issuing the regulations, as required by section 517(f) of the act (21 U.S.C. 360g(f).

4. *Summary of data on which the recommendation is based.* In many cases, the Panel based its recommendations on the Panel members' personal knowledge of, and clinical experience with, the devices under review. The Panel particularly relied upon clinical experience and judgement when considering a simple device that had been used extensively and was accepted widely before the amendments were enacted. The legislative history of the amendments provides that the term "data" has a special meaning in section 513(c)(2)(A) of the act, which requires that a Panel recommendation summarize the data upon which a recommendation is based. As used in that section, "data" refer not only to the results of scientific experiments, but also to less formal evidence, other scientific information, or judgements of experts (House Committee on Interstate and Foreign Commerce, Medical Device Amendments of 1976, H.R. Rept. No. 94-853, 94th Congress, 2d Session 40 (1976)). FDA has determined that clinical experience and judgment constitute valid scientific evidence for classifying certain devices.

In many cases, FDA sought more data and information concerning the classification of a device than were cited by the Panel. References to these data and information are found in the section for each orthopedic device under the heading "Panel Recommendations and FDA's Proposed Classifications."

The agency is adopting as its statement of the basis for issuing the regulation under section 517(f) of the act, the Panel's summary of the data on which a recommendation to classify a device is based, together with any additional data and information cited in FDA's proposed classifications.

5. *Risks to health.* In identifying the risks to health presented by orthopedic devices, the Panel recognized that few devices are completely free of risk. The Panel listed the risks it considered most significant, especially those that are unique to the individual device. In some cases, FDA has identified risks to health presented by a device in addition to those listed by the Panel. These additional risks are set out for each device in the preamble under the heading "Panel Recommendations and FDA's Classifications."

In addition to those hazards explicitly mentioned, the Panel and FDA recognize that there are general hazards associated with orthepedic prosthetic devices, such as risk of infection, risk of thromboemboli generation, risk of corrosion of metal implants, risk of

reoperation, and other possible complications due to use of bone cement and metal alloys. Specifically, Rae (Ref. 3) has shown that ingested particles of orthopedic alloys induce cellular damage. His work demonstrates that the alternations in phagocytic activity could be a factor in the development of late infections complicating joint replacement. This inhibition is one of several virulence enhancement mechanisms postulated by Elek and Conen (Ref. 4) to explain the 10,000-fold enhancement of infection in humans by the presence of a foreign body. A recent study by Johnson and Fromm (Ref. 5) corroborates the importance of a foreign body in decreasing a host's resistance to infection. Merritt and coworkers (Ref. 6) believe that the frequently occurring fibrous encapsulation of a prosthesis results in an avascular zone in which pathogens (disease-producing organisms) can grow; and both groups confirm experimentally that the presence of an implant inhibits the host's ability to combat infection.

Swanson, et al. (Ref. 7) performed laboratory testing of an orthopedic implant that is composed of cobalt-chromium-molybdenum, a widely used alloy. Swanson showed that wear debris was evident for the device examined. When the wear debris produced was injected into rats, tumorogenesis was observed among a significant proportion of the rats. The tests by Swanson showed that the wear debris from this device had a cancer-causing effect in rats. The clinical significance of this finding is unknown. Recent preliminary investigations by Memoli, et al. (Ref. 8) indicate a trend suggesting that animals with metal implants, especially those containing nickle, may be at a greater risk for the increased development of malignancy, especially sarcomas and lymphoreticular neoplasms.

Berger and Salzman (Ref. 9) provide a review of the nature and mechanisms of the complications subsequent to thromboemboli generation. They note that the surface of an implanted prosthesis can initiate or enhance the formation of thromboemboli. Walldius (Ref. 10) summarizes a portion of the literature enumerating deaths attributable to lipoemboli released from medullary cavities during prosthesis implantation. Walldius also notes hypotension, cardiac arrest, and other cardiovascular disturbances that result from the local and systemic toxicity of the polymethylmethacrylate (bone cement) monomer.

Also, polymethylmethacrylate bone cement, which generates heat during polymerization, is considered by some authors (Refs. 10, 11, and 12) to cause thermal damage, bone death, and subsequent bone resorption, which could be important factors in device loosening (Refs. 12 and 13). However, others (Refs. 14 and 15) believe that the heat of cement polymerization during implantation procedures is not great enough to cause permanent damage. These researchers believe that use of the cement and the revascularization of bone leads to the formation of a fibrous membrane which is a factor in loosening. When a joint is replaced with a prosthesis, the patient may have, over time, an increased risk of mutagenesis (Ref. 16), carcinogenesis (Refs. 17 through 26), and teratogenesis (Refs. 27, 28, and 29). The clinical significance of these increased risks is unknown.

Because the classification recommendations and FDA regulations may not identify all risks to health presented by orthopedic devices, future regulations establishing performance standards under section 514 of the act (21 U.S.C. 360d) or requiring premarket approval under section 515(b) of the act (21 U.S.C. 360e(b)) may identify additional risks to health to be addressed by FDA requirements.

Proposed Classification

Each section for an orthopedic device under the heading "Panel Recommendations and FDA's Proposed Classifications," states whether or not FDA agrees with the Panel's recommendation and describes the agency's proposed classification of the device.

FDA is proposing to classify into class III 11 orthopedic prosthetic devices that the earlier Orthopedic Device Classification Panel had, in 1976 and 1977, recommended be classified into class II. As explained in greater detail below in the preambles to these proposals, the agency has determined that performance standards will not adequately assure the safe use of these devices, because their designs, or the materials used in the devices, have not had sufficient clinical use to establish fully the persons for whom the devices are intended and the proper conditions of use.

After receiving the Panel recommendations, FDA in 1980 reviewed all data on orthopedic devices and prepared summaries based on this review. At FDA's request (Ref. 30), these summaries were reviewed for scientific completeness and accuracy, but not for regulatory recommendations, by individual orthopedic surgeons specializing in the use of the devices being classified, through the assistance of the American Academy of Orthopedic Surgeons.

Based on this review and reassessment of the device classifications recommended by the earlier Panel, FDA has made the present proposed classifications. On November 19, 1980, these proposed classifications as well as the reasons for the changes, were presented to the Orthopedic Device Section. At that time the current panel made general recommendations regarding certain generic types of devices (Ref. 30). FDA is proposing to classify into class II several orthopedic devices for which various complications have been reported. The majority of the complications involved were determined not to be device-related, such as failures due to the design of or materials used in the devices. Instead, these complications were determined to be primarily attributable to various nondevice related factors for which premarket approval would not necessarily provide additional assurance of safety and effectiveness. For example, orthopedic devices usually are implanted in aged patients with progressive diseases, particularly osteoarthritis and rheumatoid arthritis. Also, the skill of the orthopedic surgeon performing the implant procedure is an important variable in clinical outcomes. FDA believes that requiring additinal studies on these devices to be undertaken in support of a PMA would not result in new information that would help reduce the risks to health presented by use of these devices. Moreover, FDA believes that sufficient data already exist to establish the persons for whom these devices are intended and the proper conditions of their use. In proposing that these devices be classified into class II, FDA relied heavily on the scientific and clinical judgment of the members of the advisory panel, who are knowledgeable about the history and development of these devices.

FDA cautions that the final classification of a device may differ from the proposal. Factors that may cause such a change include comments, FDA's reconsideration of existing data and information, and FDA's consideration of new data and information.

Priorities for Class II and Class III Devices

When the Panel recommends classification of a device into class II or class III, section 513(c)(2)(A) of the act requires that the Panel recommendation include, to the extent practicable, a recommendation for the assignment of a

priority for establishment of performance standards for the device or premarket approval requirements. In developing its advice concerning the priorities ("high," "medium," or "low") to be accorded devices recommended for classification into class II or class III, the Panel compared each device with other orthopedic devices, based on information available to the Panel members concerning the relative importance of use of the device and the relative risks presented by the device.

The Panel recommended assignment of a "high priority" only to those class II or class III devices which the Panel believed should receive the agency's immediate attention.

FDA is not proposing at this time to establish priorities for development of performance standards for all class II devices. Section 513(d)(3) of the act authorizes, but does not require, establishment of these priorities. In the **Federal Register** of February 1, 1980 (45 FR 7489 and 45 FR 7493), FDA published notices identifying the class II devices the agency determined to warrant a high priority for the development of performance standards. At a later date, the agency will establish priorities for the development of standards for the remaining class II devices. All priorities established by the agency are based on the panel's recommendations, available resources, and other relevant factors. The agency's priorities will be reflected in the agency's annual budget request and other publicly available documents and may be published in the **Federal Register.**

FDA intends to proceed as quickly as the agency's and the Panel's resources permit to require premarket approval of devices classified into class III. Two factors affect the length of time before FDA requires submission of premarket approval applications for any particular device that is classified by an FDA regulation into class III: the number of devices reviewed by a panel and the priority of a particular device in relation to other class III devices considered by a panel. For example, where FDA classifies into class III only a few devices within a Panel's specialty area, FDA may, at the same time, publish regulations under section 515(b) of the act requiring premarket approval for any of the class III devices considered by the Panel, regardless of whether of a high or a low priority. Where practical, FDA will publish these section 515(b) regulations during the grace period (30 months) following classification. During this 30-month period a device classified into class III by FDA regulation may lawfully remain on the market without a premarket approval application. The grace period is authorized by section 501(f) of the act (21 U.S.C. 351(f)).

Exemptions for Class I Devices

Section 513 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c) provides that FDA may exempt a device recommended for classification into class I from a requirement under the following sections of the act: section 510 (21 U.S.C. 360), registration; section 519 (21 U.S.C. 360i), records and reports, and section 520(f) (21 U.S.C. 360j(f)), good manufacturing practice.

Under section 510 of the act, a person "engaged in the manufacture, preparation, propagation, compounding or processing of * * * a device or devices" must register with FDA (section 510(b) through (i)), file a list of devices (section 510(j)), and notify FDA at least 90 days before beginning commercial distribution of a device (section 510(k)). (See 21 CFR Part 807.) Section 510(g)(4) authorizes the agency to exempt a device from section 510 if it finds that compliance with that section is not necessary for the protection of the public health. In § 807.65 (21 CFR 807.65), FDA has exempted certain classes of persons from section 510 of the act. Several device panels have recommended that manufacturers of certain class I devices also be exempted from all or some of the requirements of section 510. The agency has determined that protection of the public health requires that manufacturers of medical devices, other than those already exempt under § 807.65, register and list their products with FDA to ensure that the agency can identify these manufacturers and their products and conduct necessary inspections.

The agency has determined, however, that it is not necessary for the protection of the public health that FDA receive premarket notification submissions for certain devices. Thus, the agency has proposed to exempt manufacturers of certain devices from Subpart E of Part 807 of the regulations, which implements section 510(k) of the act. The agency does not, at this time, anticipate that premarket approval will be required for these devices. The agency believes that the semiannual updating of device listing under section 510(j)(2) of the act will provide FDA with adequate notice of new products within these generic types of devices.

Section 519 of the act authorizes FDA to issue regulations requiring device manufacturers, importers, and distributors to establish and maintain such records, make such reports, and provide such information as the agency may reasonably require to assure that devices are not adulterated or misbranded and to otherwise assure their safety and effectiveness. The records and reports requirements in several of FDA's present device regulations are authorized, wholly or in part, by section 519. The most extensive of these requirements are found in the device good manufacturing practice (GMP) regulation under Part 820 (21 CFR Part 820), published in the **Federal Register** of July 21, 1978 (43 FR 31508). In the future, FDA will publish other regulations under section 519 of the act, including final regulations requiring reports to FDA of experiences with medical devices. (A proposed regulation to require such reports was published in the **Federal Register** of November 18, 1980 (45 FR 76183).) Until final records and reports regulations are issued, FDA believes that it cannot properly issue exemptions from them. Whenever the agency proposes device regulations that include records and reports requirements, interested persons may submit comments requesting that certain classes of manufacturers or other persons be exempted from the requirements, and FDA will issue exemptions that are appropriate.

The only type of exemption from records and reports requirements that FDA is proposing now, in device classification regulations, is an exemption of certain manufacturers from most requirements of the device GMP regulation. As explained below, the exemption will not extend to two device GMP records requirements.

The device GMP regulation was published in final form in the **Federal Register** of July 21, 1978 (43 FR 31508). At the time of the earlier Orthopedic Device Classification Panel's recommendations, the GMP regulation had not yet been promulgated, and the agency had not yet developed criteria for exempting manufacturers of a class I device from GMP requirements. The agency has now decided that, if any one of the following criteria is met, FDA will consider exempting from the GMP regulation manufacturers of a class I device that is not labeled or otherwise represented as sterile. The agency will not, however, exempt manufacturers of a device from general requirements concerning records or complaint files. The criteria are:

1. FDA has determined, based on adequate information about current practices in the manufacture of the device and about user experience with the device, that application of the GMP regulation is unlikely to improve the safety and effectiveness of the device.

2. FDA has determined that all possible defects relating to the safety and effectiveness of the device are readily detectable before use, either through visual examination by the user or by routine testing, e.g., testing a clinical laboratory reagent with positive and negative controls.

3. FDA has determined that any defect in the device that is not readily detectable will not result in a device failure that could have an adverse effect on the patient or other user.

FDA has determined that no device that is labeled or otherwise represented as sterile will be exempted from the device GMP regulation. A sterile device must be subject to the entire GMP regulation to ensure that manufacturers adequately reduce during the manufacturing process the bioburden (number of microorganisms) on the device and in its components. This reduction is accomplished through adherence to a comprehensive quality assurance program, such as that required by the GMP regulation, with adequate environmental controls, trained personnel, appropriate maintenance and calibration of sterilization equipment, recordkeeping concerning lot sterility, strict packaging and labeling controls, and other quality assurance measures.

The agency also has determined that no exemption from the device GMP regulation will extend to § 820.180, with respect to general requirements concerning records, or § 820.198, with respect to maintenance of complaint files. The agency believes that granting exemptions from these sections would not be in the public interest and that compliance with these sections is not unduly burdensome for device manufacturers. To ensure that device manufacturers have adequate systems for complaint investigation and followup, all manufacturers are required to comply with the complaint file requirements. All device manufacturers also are required to comply with the general requirements concerning records to ensure that FDA has access to complaint files, is able to investigate device-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective actions are adequate, and can determine whether the exemption from other sections of the GMP regulation is still appropriate.

In general, FDA has not initiated proposals to exempt manufacturers of devices from requirements under section 510 or 520(f) of the act, but has acted on the basis of exemption recommendations of the device classification panels. However, occasionally FDA has proposed to exempt manufacturers of certain devices classified into class I or class II from the requirements of certain sections of the GMP regulation, according to the prescribed exemption criteria. Manufacturers and other interested persons may submit comments on the appropriateness of the proposed exemptions of manufacturers of devices, whether the exemptions are proposed in response to recommendations of the panels or on the agency's initiative. Comments requesting additional exemptions should be supported by information showing that the exemption of manufacturers of a device from the premarket notification requirement or the GMP regulation is consistent with the criteria discussed above.

Guidelines for Preparing Petitions Requesting Exemption or Variance from the Device GMP Regulation for Devices Classified into Class I or Class II

FDA has prepared guidelines on the procedures that should be followed by persons who wish to submit petitions for exemption or variance from the device GMP regulation. These petitions may be submitted in accordance with provisions of section 520(f)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)(2)). The agency announced the availability of the guidelines in a notice published in the **Federal Register** of January 18, 1980 (45 FR 3671).

List of Orthopedic Devices

The following is a list of orthopedic devices that FDA is proposing to classify, the section and subpart of Part 888 in Title 21 of the Code of Federal Regulations under which the regulation classifying the device will be codified, the docket number of the proposed classification regulation, and the proposed classification of each device.

Section	Device	Docket No.	Class
	Subpart B—Orthopedic Diagnostic Devices		
888.1100	Arthroscope	78N-3041	II.
888.1240	AC-powered dynamometer	78N-3300	II.
888.1250	Nonpowered dynamometer	78N-3042	I.
888.1500	AC-powered goniometer	78N-3043	II.
888.1520	Nonpowered goniometer	78N-3044	I.
	Subpart D—Orthopedic Prosthetic Devices		
888.3000	Bone cap	78N-3046	II.
888.3010	Bone fixation cerclage	78N-3051	II.
888.3020	Intramedullary fixation rod	78N-3056	II.
888.3025	Passive tendon prosthesis	78N-3098	II.
888.3030	Single/multiple component metallic bone fixation appliances and accessories.	78N-3049	II.
888.3040	Smooth or threaded metallic bone fixation fastener.	78N-3053	II.
888.3050	Spinal interlaminal fixation orthosis.	78N-3047	II.
888.3060	Spinal intervertebral body fixation orthosis.	78N-3048	II.
888.3100	Ankle joint metal/composite semi-constrained prosthesis.	78N-3059	III.
888.3110	Ankle joint metal/polymer semi-constrained prosthesis.	78N-3060	II.
888.3120	Ankle joint metal/polymer non-constrained prosthesis.	78N-3061	III.
888.3150	Elbow joint constrained prosthesis.	78N-3062	III.
888.3160	Elbow joint semi-constrained prosthesis.	78N-3063	II.
888.3170	Elbow joint radial (hemi-elbow) prosthesis.	78N-3064	II.
888.3180	Elbow joint humeral (hemi-elbow) uncemented prosthesis.	78N-3065	III.
888.3200	Finger joint metal/metal constrained uncemented prosthesis.	78N-3066	III.
888.3210	Finger joint metal/metal constrained prosthesis.	78N-3301	III.
888.3220	Finger joint metal/polymer constrained prosthesis.	78N-3067	III.
888.3230	Finger joint polymer constrained prosthesis.	78N-3068	II.
888.3300	Hip joint metal constrained prosthesis.	78N-3070	III.
888.3310	Hip joint metal/polymer constrained prosthesis.	78N-3071	III.
888.3320	Hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis.	78N-3072	III.
888.3330	Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis.	78N-3073	III.
888.3340	Hip joint metal/composite semi-constrained prosthesis.	78N-3074	III.
888.3350	Hip joint metal/polymer semi-constrained prosthesis.	78N-3075	II.
888.3360	Hip joint femoral (hemi-hip) metallic prosthesis.	78N-3077	II.
888.3370	Hip joint (hemi-hip) acetabular metal prosthesis.	78N-3076	III.
888.3380	Hip joint femoral (hemi-hip) trunnion-bearing metal/polyacetal prosthesis.	78N-3078	III.
888.3390	Hip joint femoral (hemi-hip) metal/polymer prosthesis.	78N-3079	II.
888.3400	Hip joint femoral (hemi-hip) resurfacing prosthesis.	78N-3080	II.
888.3410	Hip joint metal/polymer semi-constrained resurfacing prosthesis.	78N-3081	III.
888.3480	Knee joint femorotibial metallic constrained prosthesis.	78N-3082	II.
888.3490	Knee joint femorotibial metal/composite non-constrained prosthesis.	78N-3083	III.
888.3500	Knee joint femorotibial metal/composite semi-constrained prosthesis.	78N-3302	III.
888.3510	Knee joint femorotibial metal/polymer constrained prosthesis.	78N-3084	II.
888.3520	Knee joint femorotibial metal/polymer non-constrained prosthesis.	78N-3085	II.
888.3530	Knee joint femorotibial metal/polymer semi-constrained prosthesis.	78N-3086	II.
888.3540	Knee joint patellofemoral polymer/metal semi-constrained prosthesis.	78N-3087	III.
888.3550	Knee joint patellofemorotibial polymer/metal/metal constrained prosthesis.	78N-3088	II.

Section	Device	Docket No.	Class
888.3560	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained prosthesis.	78N-3090	II.
888.3570	Knee joint femoral (hemiknee) metallic uncemented prosthesis.	78N-3091	III.
888.3580	Knee joint patellar (hemiknee) metallic resurfacing uncemented prosthesis.	78N-3092	II.
888.3590	Knee joint tibial (hemiknee) metallic resurfacing uncemented prosthesis.	78N-3093	II.
888.3640	Shoulder joint constrained prosthesis.	78N-3094	III.
888.3650	Shoulder joint non-constrained prosthesis.	78N-3095	III.
888.3660	Shoulder joint semi-constrained prosthesis.	78N-3096	III.
888.3680	Shoulder joint glenoid (hemi-shoulder) prosthesis.	78N-3058	III.
888.3690	Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis.	78N-3097	II.
888.3720	Toe joint constrained uncemented prosthesis.	78N-3099	II.
888.3730	Toe joint phalangeal (hemi-toe) prosthesis.	78N-3100	II.
888.3750	Wrist joint carpal lunate prosthesis.	78N-3101	II.
888.3760	Wrist joint carpal scaphoid prosthesis.	78N-3102	II.
888.3770	Wrist joint carpal trapezium prosthesis.	78N-3304	II.
888.3780	Wrist joint polymer constrained uncemented prosthesis.	78N-3103	II.
888.3790	Wrist joint metal constrained prosthesis.	78N-3305	III.
888.3800	Wrist joint semi-constrained prosthesis.	78N-3104	II.
888.3810	Wrist joint ulnar (hemiwrist) prosthesis.	78N-3105	II.
	Subpart E—Orthopedic Surgery Devices		
888.4150	Calipers for clinical use	78N-3106	I.
888.4200	Cement dispenser	78N-3107	I.
888.4210	Cement mixer for clinical use.	78N-3108	I.
888.4220	Cement monomer vapor evacuator.	78N-3109	I.
888.4230	Cement ventilation tube	78N-3110	I.
888.4300	Depth gauge for clinical use.	78N-3111	I.
888.4540	Orthopedic manual surgical instrument.	78N-3114	I.
888.4580	Sonic surgical instrument and accessories/attachments.	78N-3116	II.
888.4600	Protractor for clinical use	78N-3117	I.
888.4800	Template for clinical use	78N-3118	I.
888.5850	Nonpowered orthopedic traction apparatus and accessories.	76N-3120	I.
888.5890	Noninvasive traction components.	78N-3122	I.
888.5940	Cast components	78N-3123	I.
888.5960	AC-powered cast removal instruments.	78N-3124	II.
888.5980	Manual cast application/removal instruments.	78N-3125	I.

Devices Considered by Two or More Panels

Many devices were reviewed by two or more device panels. The Orthopedic Device Section of the Surgical and Rehabilitation Devices panel and the other sections or panels listed below made classification recommendations concerning the following devices:

Device	Other sections or panel(s)
Clamp	General and Plastic Surgery Device Section of the Surgical and Rehabilitation Devices Panel.
Hemostat	Do.
Elevator	Do.
Forceps	Do.
Guide	Do.
Knife	Do.
Mallet	Do.
Rasp	Do.
Retractor	Do.
Spatula	Do.
Staple	Do.
Surgical table with orthopedic accessories.	Do.
AC-powered surgical table with orthopedic accessories.	Do.
Air pressure tourniquet	Do.
Hip prosthesis acetabular mesh	Do.
Hip prosthesis cement restrictor	Do.
Curette	Do.
Bone hook	Do.
Cutting instrument	Do.
Osteotome	Do.
Surgical pliers	Do.
Powered orthopedic surgical instrument motors and accessories/attachments.	Do.
Pneumatically powered orthopedic surgical instrument motors and accessories/attachments.	Do.
Diaphram stimulator	Neurological Device Section of the Respiratory and Nervous System Devices Panel.
Internal peroneal extremity stimulator.	Do.

The agency is not at this time publishing the recommendations of the Orthopedic Device Section of the Surgical and Rehabilitation Devices Panel to classify the devices listed above. The agency has published these recommendations and proposed classification regulations along with the recommendations of other Panels that reviewed the devices. These other Panel's recommendations have already been published in the **Federal Register.** The following table shows the current structure of the advisory committees involved with classification of medical devices and a list of all proposed and final classification regulations published to date:

Panel/Section Name and Publication Date in **Federal Register**

Circulatory Systems Devices Panel—March 9, 1979 44 FR 13284–13434 (proposals); February 5, 1980, 45 FR 7904–7971 (final regulations).

Clinical Chemistry and Hematology Devices Panel:
- Clinical Chemistry Device Section—February 2, 1982, 47 FR 4802–4929 (proposals).
- Clinical Toxicology Device Section—February 2, 1982, 47 FR 4802–4929 (proposals).
- Hematology and Pathology Device Section—September 11, 1979, 44 FR 52950–53063 (proposals); September 12, 1980, 45 FR 60576–60651 (final regulations).

General Medical Devices Panel:
- General Hospital and Personal Use Device Section—August 24, 1979, 44 FR 49844–49954 (proposals); October 21, 1980, 45 FR 69678–69737 (final regulations).
- Gastroenterology-Urology Device Section—January 23, 1981, 46 FR 7562–7641 (proposals).

Immunology and Microbiology Devices Panel:
- Obstetrics-Gynecology Device Section—April 3, 1979, 44 FR 19894–19971 (proposals); February 26, 1980, 45 FR 12682–12720 (final regulation).
- Microbiology Device Section—April 22, 1980, 45 FR 27204–27359 (proposals).

Obstetrics-Gynecology and Radiologic Devices Panel:
- Obstetrics-Gynecology Device Section—April 3, 1979, 44 FR 19894–19971 (proposals): February 26, 1980, 45 FR 12682–12720 (final regulations).
- Radiology Device Section—January 29, 1982, 47 FR 4406–4451 (proposals).

Ophthalmic; Ear, Nose, Throat; and Dental Devices Panel:
- Ophthalmic Device Section—January 26, 1982, 47 FR 3694–3749 (proposals).
- Ear, Nose, and Throat Device Section—January 22, 1982, 47 FR 3280–3325 (proposals).
- Dental Device Section—December 30, 1980, 45 FR 85962–86168 (proposals).

Respiratory and Nervous System Devices Panel:
- Anesthesiology Device Section—November 2, 1979, 44 FR 63292–63426 (proposals).
- Neurological Device Section—November 28, 1978, 43 FR 54640–55732 (proposals); September 4, 1979, 44 FR 51726–51778 (final regulations).

Surgical and Rehabilitation Devices Panel:
- Physical Medicine Device Section—August 28, 1979, 44 FR 50458–50537 (proposals).
- Orthopedic Device Section—(*Insert date of publication in the* **Federal Register**) (proposals).
- General and Plastic Surgery Device Section—January 19, 1982, 47 FR 2810–2853 (proposals).

Panel Recommendations and FDA's Proposed Classifications

§ 888.1100; Docket No. 78N–3041; Arthroscope.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of arthroscopes:

1. Identification: An arthroscope is a type of electrically powered endoscope that is intended to make visible the interior of a joint. The arthroscope may be combined with accessories to permit surgency in selected anatomic locations.

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel

recommends that arthroscopes be classified into class II because the electrical properties of the device must be controlled by a performance standard to prevent electrical shock to the patient or operator. The Panel believes that general controls alone will not provide sufficient control over these characteristics. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that sufficient information exists to establish a standard. The Panel also recommends that the device's labeling include instructions for the proper care of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Electrical shock: Excessive current leakage from this device may cause electrical shock to the patient or operator. (b) Infection: The introduction of microbes associated with a nonsterile device may cause infection. (c) Tissue Trauma: Defective components or faulty construction of the device could result in breakage of the arthroscope while inside the joint, resulting in tissue trauma.

EDA agrees with the Panel recommendation and is proposing that arthroscopes be classified into class II. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to minimize the risks to health presented by use of the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

§ 888.1240; Docket No. 78N–3300; AC-powered dynamometer.

The Orthopedic Device Classification Panel and the Anesthesiology Device Classification Panel, FDA advisory committees, made the following recommendations regarding the classification of AC-powered dynamometers:

1. Identification: An AC-powered dynamometer is an electrically powered device intended for medical purposes to assess neuromuscular function or degree of neuromuscular blockage by measuring, with a force transducer (a device that translates force into electrical impulses), the grip-strength of a patient's hand.

2. Recommended classification: Class II. The Panels recommend that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: Both Panels recommend that AC-powered dynamometers be classified into class II because the electrical properties of the device must be controlled by a performance standard to prevent electrical shock to the patient or operator. The Anesthesiology Device Classification Panel also believes that the accuracy and reproducibility of the device must be controlled by a performance standard to prevent the generation of erroneous grip-strength data that may lead to inaccurate estimates of neuromuscular blockage. The Panels believe that general controls alone will not provide sufficient control over these characteristics. The Panels believe that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that sufficient information exists to establish a standard.

4. Summary of data on which the recommendation is based: Both Panels based their recommendations on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Electrical shock: Excessive current leakage from this device may cause electrical shock to the patient or operator. (b) Misdiagnosis and inappropriate therapy: Failure of the device to provide accurate data may lead to error in the estimates of neuromuscular function or blockage in the patient. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the recommendations of the Orthopedic Device Classification Panel and the Anesthesiology Device Classification Panel and is proposing that AC-powered dynamometers be classified into class II. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to minimize the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device, and sufficient information exists to establish a performance standard. The agency has reviewed both Panels' recommendations for AC-powered dynamometers and has concluded that the classification of this device should be published in the part of the Code of Federal Regulations for orthopedic devices.

§ 888.1250; Docket No. 78N–3042; Nonpowered dynamometer.

The Orthopedic Device Classification Panel, the Neurology Device Classification Panel, and the Physical Medicine Device Classification Panel, FDA advisory committees, made the following recommendations regarding the classification of nonpowered dynamometers:

1. Identification: A nonpowered dynamometer is a mechanical device intended for medical purposes to measure the pinch and grip muscle strength of a patient's hand.

2. Recommended classification: All three Panels recommend that nonpowered dynamometers be classified into Class I. The Orthopedic Device Classification Panel recommends that this device be exempt from the premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)) and the good manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 360j(f)). The Neurology Device Classification Panel and the Physical Medicine Device Classification Panel recommend that there be no exemptions.

3. Summary of reasons for recommendation: The three Panels recommend that nonpowered dynamometers be classified into class I because general controls are sufficient to provide reasonable assurance of the saftey and effectiveness of the device. The Orthopedic Panel recommends that the manufacturer be exempt from premarket notification procedures and the GMP regulation because it believes that adherence to the regulation would not improve the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panels based their recommendations on the Panel members' knowledge of, and clinical experience with, nonpowered dynamometers.

5. Risks to health: None identified.

FDA agrees with the recommendations of the three Panels and is proposing that nonpowered dynamometers be classified into class I. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

In response to the Orthopedic Device Classification Panel's recommendation that manufacturers of nonpowered dynamometers be exempt from section 510(k) of the act (21 U.S.C. 360(k)), FDA is proposing that these manufacturers be subject to registration and device listing under section 510 (a) through (j) of the act, but exempt from premarket notification under section 510(k) of the act and Subpart E of Part 807 of the regulations. Under section 510(g)(4) of the act, the agency may exempt a

manufacturer from section 510 only if it finds that compliance with the section is not necessary for the protection of the public health. In the case of registration and listing by manufacturers of nonpowered dynamometers, the agency cannot make the required finding. To protect the public health, the agency needs to be able to identify the firms manufacturing this device and to conduct necessary inspections. The agency has determined, however, that it is not necessary for the protection of the public health that FDA receive premarket notification submissions concerning nonpowered dynamometers. The agency does not anticipate at this time that premarket approval will be required for this device. The agency believes that the semiannual updating of device listing under section 510(j)(2) of the act will provide FDA with adequate notice concerning new products within this generic type of device.

In response to the Orthopedic Device Classification Panel's recommendation that manufacturers of nonpowered dynamometers be exempt from the device GMP regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that these manufacturers be exempt from all requirements of the GMP regulation with the exception of § 820.180, regarding general requirements concerning records, and § 820.198, regarding maintenance of complaint files. Based on available information about current practices used in the manufacture of the device and user experience with the device, the agency has determined that application of the GMP regulation, other than §§ 820.180 and 820.198, is unlikely to improve the safety and effectiveness of the device. The agency believes, however, that manufacturers of nonpowered dynamometers should be required to comply with the complaint file requirements of § 820.198 to ensure that these manufacturers have adequate systems for complaint investigation and followup. The agency also believes that manufacturers of nonpowered dynamometers should be required to comply with the general requirements concerning records in § 820.180 to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulation is still appropriate. See the discussion under the heading "Exemptions for Class I Devices" for further explanation of the agency's policies concerning exemptions.

The agency has reviewed the three Panel's recommendations for nonpowered dynamometers and has concluded that the classification of this device should be published in the part of the Code of Federal Regulations for orthopedic devices.

§ 888.1500; Docket No. 78N–3043; AC-powered goniometer.

The Physical Medicine Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of AC-powered goniometers:

1. Identification: An AC-powered goniometer is an AC-powered measuring and recording device intended to evaluate joint function by measuring ranges of motion, acceleration, or forces exerted by a joint.

2. Recommended classificatioin: Class II. The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that AC-powered goniometers be classified into class II because the electrical properties of the device must be controlled by a performance standard to prevent electrical shock to the patient or operator. The Panel believes that general conrols alone will not provide sufficient control over these characteristics. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that sufficient information exists to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: Electrical shock: Excessive current leakage from this device may cause electrical shock to the patient or operator.

FDA agrees with the Panel recommendation and is proposing that AC-powered goniometers be classified into class II. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to minimize the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device. FDA has reviewed the recommendation of the Physical Medicine Device Classification Panel for AC-powered goniometers and has concluded that the classification of this device should be published in the part of the Code of Federal Regulations for orthopedic devices.

§ 888.1520; Docket No. 78N–3044; Nonpowered goniometer.

The Orthopedic Device Classification Panel and the Physical Medicine Device Classification Panel, FDA advisory committees, made the following recommendations regarding the classification of nonpowered goniometers:

1. Identification: A nonpowered goniometer is a mechanical device intended for medical purposes to measure the range of motion of joints.

2. Recommended classification: Both Panels recommend that nonpowered goniometers be classified into class I. The Orthopedic Device Classification Panel recommends that this device be exempt from premarket notification procedures under section 510(k) of the act and the GMP regulation under section 520(f) of the act. The Physical Medicine Device Classification Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panels recommend that nonpowered goniometers be classified into class I because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Orthopedic Device Classification Panel believes that manufacturers of the device should not be required to comply with premarket notification procedures or with the GMP regulation in manufacturing the device because it believes that adherence to these regulations would not improve the safety and effectiveness of the device. The Orthopedic Device Classification Panel believes that this simple device presents no risks to health and all possible defects are readily detectable before use.

4. Summary of data on which the recommendation is based: Both Panels based their recommendations on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

FDA agrees with the recommendations of the Orthopedic Device Classification Panel and the Physical Medicine Device Classification Panel and is proposing that nonpowered goniometers be classified into class I. The agency believes that general controls are sufficient to provide

reasonable assurance of the safety and effectiveness of the device.

In response to the Panel's recommendation that manufacturers of nonpowered goniometers be exempt from section 510(k) and 520(f) of the act, FDA is proposing that manufacturers of this device be exempt from premarket notification under section 510(k) of the act and Subpart E of Part 807 of the regulations. FDA is proposing that a manufacturer of these devices be exempt from all requirements in the GMP regulation with the exception of § 820.180, regarding general requirements concerning records, and § 820.198, regarding maintenance of complaint files. See § 886.1250 *Nonpowered dynamometer* in an earlier section of the preamble and the discussion under the heading "Exemptions for Class I Devices" for further explanation of the agency's policies concerning exemptions.

The agency has reviewed the Panels' recommendations for nonpowered goniometers and has concluded that the classification of this device should be published in the part of the Code of Federal Regulations for orthopedic devices.

§ 888.3000; Docket No. 78N–3046; Bone cap.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of bone caps:

1. Identification: A bone cap is a mushroom-shaped implanted device made of either silicone elastomer or ultra-high molecular weight polyethylene. It is intended to cover the severed end of a long bone, such as the humerus or tibia, to control bone overgrowth in juvenile amputees.

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that bone caps be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent loss or reduction of limb function, adverse tissue reaction, or infection. The Panel believes that general controls alone will not provide sufficient control over these characteristics. Although bone caps are implanted devices, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of these devices.

4. Summary of data on which the recommendation is based: The Panel based its recommendations on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Loss or reduction of function: Improper design or inadequate mechanical properties of the device, such as its lack of strength or resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the Panel recommendation and is proposing that bone caps be classified into class II. FDA has reviewed the data on which the Panel recommendation is based and has sought additional information on the safety and effectiveness of these devices. Silicone bone caps have been used since 1963 to control the bone overgrowth phenomenon in juvenile amputees. They have been found to successfully control bone overgrowth and provide a pain-free amputation stump (Ref. 31). Implantation of the device in animals has shown that the bone end heals and contours to the inside surface of the device (Ref. 32).

Although bone caps are implanted devices, FDA has determined that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of these devices. In addition, FDA has identified and assessed the major risks to health associated with use of these devices. FDA believes that the major risks, i.e., loosening, infection, and adverse tissue reaction, are related to biological responses of the human body to the presence of the device and the device design, and not to physical failure(s) of the device. Clinical experience with these devices has established the persons for whose use the devices are intended and the proper conditions of use. FDA has determined that the probable benefit to health from proper use of these devices outweighs any likelihood of injury or illness resulting from their use. FDA further believes that informative labeling and compliance with general controls may greatly reduce the risks to health associated with the use of these devices. The agency believes that a performance standard is necessary because general controls alone are insufficient to minimize the risks to health presented by these devices.

§ 888.3010; Docket No. 78N–3051; Bone fixation cerclage.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of bone fixation cerclages:

1. Identification: A bone fixation cerclage is an implanted device that is made of alloys, such as cobalt-chromium-molybdenum, and that consists of a metallic ribbon of flat sheet or a wire. When implanted, the device is wrapped around the shaft of a long bone, anchored to the bone with wire or screws, and used in the fixation of fractures.

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that bone fixation cerclages be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent loss or reduction of limb function, nonunion or malunion of bone, adverse tissue reaction, or infection. The Panel believes that general controls alone will not provide sufficient control over these characteristics.

Although bone fixation cerclages are implanted devices, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that the labeling for the device include information on the dimensions and mechanical properties of the device, and identify the materials used in the device by both their common names and engineering classifications.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, bone fixation cerclages and on a review of the recent

medical literature, which indicates that there are few device-related complications. Buhler (Ref. 33) reported one case of infection and two cases of delayed unions out of a total of 198 cases. There were no reported implant failures.

Fenyo (Ref. 34) reviewed cases of fractures treated with bone fixation cerclages over a 12-year period and reported that there were no reported device failures. Two authors (Refs. 35 through 37) reported that nonunion or malunion, a risk associated with the use of this device, may be due to improper application of the cerclage wire.

5. Risks to health: (a) Adverse tissues reaction: Inadequate biologial or mechanical properties of the device, such as its lack of biocompatibility, may result in an adverse tissue reaction due to dissolution or corrosion of the implant and the release of materials from the device to the surrounding tissues and systemic circulation. (b) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection. (c) Nonunion or malunion: Delayed or malunion of the bone fracture may occur due to inappropriate tension on the device, inadequate mechanical strength, or other mechanical imperfections, leading to device failure and loss of fracture fixation.

FDA agrees with the Panel recommendation and is proposing that bone fixation cerclages be classified into class II. Although bone fixation cerclages are implanted devices, FDA has determined that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of these devices. In addition, FDA has identified and assessed the major risks to health associated with the use of these devices. FDA believes that the major risks, i.e., infection and adverse tissue reaction, are related to biological responses of the human body to the presence of the device and the device design, and not to physical failure(s) of the device. Clinical experience with these devices has established the persons for whose use the devices are intended and the proper conditions of use. FDA has determined that the probable benefit to health from proper use of these devices outweighs any likelihood of injury or illness resulting from their use. FDA further believes that informative labeling and compliance with general controls may greatly reduce the risks to health associated with the use of these devices. The agency believes that a performance standard is necessary because general controls alone are insufficient to minimize the risks to health presented by these devices.

§ 888.3020; Docket No. 78N–3056; Intremedullary fixation rod.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of intramedullary fixation rods;

1. Identification: An intramedullary fixation rod is an implanted device that consists of a rod made of alloys, such as cobalt-chromium-molybedenum and stainless steel. It is inserted into the medullary (bone marrow) canal of long bones for the fixation of fractures.

2. Recommended classification: Class II. The Panel recommends that establishment of a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that intramedullary fixation rods be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent loss or reduction of limb function, adverse tissue reaction, or infection. The Panel believes that general controls alone will not provide sufficient control over these characteristics.

Although intramedullary fixation rods are implanted devices, the Panel believes that premarket approval is not necessary because there is sufficient information to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of these devices. The Panel also recommends that the labeling of the device provide information on the dimensions and mechanical properties of the device, and identify the materials used in the device by both their common names and engineering classifications.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device, and on a review of the medical literature. Bohles (Ref. 38) reported that, of 283 patients with closed fractures treated with an intramedullary rod, 8 (2.8 percent) developed infections. In addition, of 25 patients with open fractures (4 percent) treated by implanting the device, 1 developed an infection. Despite these infections, union of the fracture was accomplished in all cases. Schneider (Ref. 39) concluded that, after 18 years of experience with more than 260 cases of open reduction and internal fixation of the femur with four-flanged self cutting intramedullary fixation rods, it is his opinion that the operation is safe and effective. Clawson, et al. (Ref. 40), reported that intramedullary reaming and implantation of an intramedullary fixation rod is a safe method for treating most femoral shaft fractures and for obtaining early functional recovery. He stated that, regardless of the severity of injury, 20 percent of the patients he treated by intramedullary reaming and implantation of an intramedullary fixation rod were fully weight-bearing in 1 week, and 73 percent were fully weight-bearing within 2 months. Cristensen (Ref. 41) concluded that the Kuentscher method provides remarkably rapid consolidation and restoration of function even in difficult cases of nonunion of shaft fracture, particularly of the femur. Allen, et al. (Ref. 42), reported that excellent fixation was achieved and very early weight-bearing was possible in 40 patients with traumatic and pathological fractures and osteotomies of the femur. In all fresh fractures and uninfected nonunions, union occurred promptly, and, in most instances, bone grafting was not required.

5. Risks to health: (a) Loss or reduction of limb function: Improper design or inadequate mechanical properties of the device, such as its lack of strength or rigidity, may result in nonunion or malunion of the bone due to flexing, fracture, or deformation of the device and subsequent loss of limb function. Migration of the fractured device may cause damage to adjacent hard and soft tissues. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or corrosion of the device and the release of materials to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the Panel recommendation and is proposing that intramedullary fixation rods be classified into class II. Although intramedualllary fixation rods are implanted devices, FDA has determined that premarket approval is not necessary because suffcient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of these devices. In addition, FDA has identified and

assessed the major risks to health associated with the use of these devices. FDA believes that the major risks, i.e., loosening, infection, and adverse tissue reaction, are related to biological responses of the human body to the presence of the device and the device design, and not to physical failure(s) of the device. Clinical experience with these devices has established the persons for whose use the devices are intended and the proper conditions of use. FDA has determined that the probable benefit to health from proper use of these devices outweighs any likelihood of injury or illness resulting from their use. FDA further believes that informative labeling and compliance with general controls will greatly reduce the risks to health associated with the use of these devices. The agency believes that a performance standard is necessary because general controls alone are insufficient to minimize the risks to health presented by these devices.

§ 888.3025; Docket No. 78N–3098; Passive tendon prosthesis.

The Orthopedic Device Classification Panel and the General and Plastic Surgery Device Classification Panel, FDA advisory committees, made the following recommendations regarding the classification of passive tendon prostheses:

1. Identification: A passive tendon prosthesis is an implanted device made of silicone elastomer or a polyester reinforced medical grade silicone elastomer intended for use in the surgical reconstruction of a flexor tendon of the hand. The device is implanted for a period of 2 to 6 months to aid growth of a new tendon sheath. The device is not intended as a permanent implant nor to function as a replacement for the ligament or tendon nor to function as a scaffold for soft tissue ingrowth.

2. Recommended classification: Class II. Both Panels recommend that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: Both Panels recommend that passive tendon prostheses be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent loss or reduction of hand function, adverse tissue reaction, or infection. The Panels believe that general controls alone will not provide sufficient control over these characteristics.

Although passive tendon prostheses are implanted devices, the Panels believe that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of these devices.

4. Summary of data on which the recommendation is based: Both Panels based their recommendations on the Panel members' personal knowledge of, and clinical experience with, the device and on a review of the pertinent medical literature. The device is used when the tendon injury is so severe that good results would not be expected with conventional tendon grafting (Refs. 43 through 45). Weinstein, et al. (Ref. 45), reported on 28 cases of device implantation and noted that while there were frequent complications after both stages of the two-stage surgical procedure used in tendon reconstructions, the device was valuable in the treatment of severely damaged fingers. Hunter, et al. (Ref. 46), reported on 74 cases of implantation of the device. Hunter noted that the satisfactory results obtained using the device were distinctly better than results previously obtained without the use of the device. Animal studies (Ref. 47) and histological examination of tissue removed from patients receiving the device (Ref. 43) indicated that the device was well tolerated by the body.

5. Risks to health: (a) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection. (b) Adverse tissue reaction: Inadequate biological properties of the device, such as its lack of biocompatibility, may result in an adverse tissue reaction due to dissolution and the release of materials from the device to the surrounding tissues and systemic circulation.

FDA agrees with the recommendations of both Panels and is proposing that passive tendon prostheses be classified into class II. Although passive tendon prostheses are implanted devices, FDA has determined that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of these devices. In addition, FDA has identified and assessed the major risks to health associated with the use of these devices. FDA believes that the major risks, i.e., infection and adverse tissue reaction, are related to biological responses of the human body to the presence of the device and the device design, and not to physical failure(s) of the device. Clinical experience with these devices has established the persons for whose use the devices are intended and the proper conditions of use. FDA has determined that the probable benefit to health from proper use of these devices outweighs any likelihood of injury or illness resulting from their use. FDA further believes that informative labeling and compliance with general controls may greatly reduce the risks to health associated with use of these devices. The agency believes that a performance standard is necessary because general controls alone are insufficient to minimize the risks to health presented by these devices.

The agency has reviewed the recommendations of both Panels for passive tendon prostheses and has concluded that classification of this device should be published in the part of the Code of Federal Regulations for orthopedic devices.

§ 888.3030; Docket No. 78N–3049; Single/multiple component metallic bone fixation appliances and accessories.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of single/multiple component metallic bone fixation appliances and accessories:

1. Identification: Single/multiple component metallic bone fixation appliances and accessories are implanted devices, consisting of one or more metallic components and their metallic fasteners. The devices contain a plate, a nail/plate combination, or a blade/plate combination that is made of alloys, such as cobalt-chromium-molybdenum, stainless steel, or titanium, that is intended to be held in position with fasteners, such as screws and nails, or bolts, nuts, and washers. These devices are intended to be used for fixation of fractures of the proximal or distal end of long bones, such as intracapsular, intertrochanteric, intercervical, supracondylar, or condylar fractures of the femur; for fusion of a joint; or for surgical procedures that involve cutting a bone. The device is intended to be implanted or attached through the skin so that a pulling force (traction) may be applied to the skeletal system.

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that the device be classified into class II because the

design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent nonunion of fractures, bone necrosis, infection, or adverse tissue reaction. The Panel believes that general controls alone will not provide sufficient control over these characteristics.

Although single/multiple component metallic bone fixation appliances and accessories are implanted devices, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of these devices. The Panel recommends that the labeling for the device include information on the device dimensions and mechanical properties and identify the materials used in the device by both their common names and engineering classifications.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and its review of the medical literature. Elliott (Ref. 48) reported his clinical experience using a femoral condyle blade/plate on 17 patients. All fractures healed without infections, and there were no instances of nonunion of the fractures and no bending or breakage of the device. Chiron, et al. (Ref. 49), reported on 72 fractures of the distal third of the femur treated by condylar plates. He reported that all fractures healed, and that excellent or good results were obtained with 72 percent of the fractures. Banks (Ref. 50) concludes that the incidence of nonunion in displaced intracapsular femoral neck fractures may be decreased by accurate reduction, adequately placed internal fixation, and carefully supervised postoperative care.

Brown, et al. (Ref. 51), reported that in 17 supracondylar and 5 intercondylar fracture cases, all but 2 of the patients regained 65 degrees of flexion within 10 to 12 weeks. Shelton, et al. (Ref. 52), reported that among 14 supracondylar fractures, excellent restoration was obtained in almost every instance. There were 2 instances of slight plat malalignment resulting in 5 degrees varus and 5 degrees valgus angulation. Each patient achieved rapid clinical union and satisfactory knee movement. The average patient had at least 90 degrees flexion by the third month, and after 1 year had achieved an average of 125 degrees flexion. Two patients had a very slight radiographic malunion. Shelton, et al., concluded that the two malunions were clinically insignificant and were due to improper positioning of the plate.

Burwell (Ref. 53) conducted a survey of 181 fractures of the tibial shaft that were treated by implantation of rigid fixation plates. After 1 year followup, there were three delayed unions (about 2 percent) and eight nonunions (about 4.4 percent). Infection developed in 12 patients (about 6.6 percent). No mechanical failures of the implant were reported, and no patient had residual stiffness of the knee after implantation. Berkin and Marshall (Ref. 54) reported an overall postoperative infection rate of 4.8 percent in 135 tibial fixations and 1.7 percent infection rate in 57 femoral fixations. All the infections eventually healed and the fractures achieved solid union 4 to 24 months after operation.

Scales and Perry (Ref. 55) analyzed 393 bone plates out of 4,769 implanted plates that had been removed from patients. Several clinical reasons for removal were given: one hundred and seventy-eight plates were removed routinely, 126 because of pain, and 14 because of defects in the plates. At no time was corrosion stated by the surgeon to be the reason for removal of the implant.

Ruedi, et al. (Ref. 56), reported that, among over 400 tibia fractures, good to very good results were obtained in 90 percent of the open fractures and in 97 percent of the closed fractures.

Reported complications relating to use of bone fixation screws include: (a) screw loosening (Refs. 53 and 56 through 60) often resulting in loss of fracture fixation and, in one instance, limb paralysis due to traumatization of an artery (Ref. 60); (b) formation of a bursa (a cyst caused by friction or other mechanical cause) over the head of the screw (Ref. 59); and (c) screw fracture (Ref. 53). Several authors (Refs. 53, 61, and 62) noted that if screws cannot be properly tightened, micromotion between the screw and the bone may occur and may lead to bone resorption and loosening of the device. Scales and Perry (Ref. 55) reported that the fracture rates of screws were 0.85 percent for stainless steel screws, 6.0 percent for cobalt-chromium-molybdenum screws, and 7.7 percent for titanium screws.

A review of the recent medical literature on implanted bolts, nuts, and washers revealed that complications associated with these articles include fracture of devices (Refs. 55 and 63), corrosion of the metal at contacting surfaces (Refs. 55 and 64), and bone weakening due to the presence of holes drilled for bolts (Ref. 65).

5. Risks to health: (a) Nonunion of fractures: Improper design or performance of the device may result in nonunion of a fracture. (b) Bone necrosis (destruction): The presence of the device may sever the blood supply to a significant segment of bone. Since bone tissue, especially cortical bone, requires the integrity of its canalicular mechanism for nutrition, any permanent interruption of the vasculature leads to irreversible necrosis (Ref. 66). (c) Infection: The presence of the prothesis within the body may lead to an increased risk of infection. Improper configuration of the device or the finish on the device's surfaces can also lead to infection. (d) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility, may result in an adverse tissue reaction due to dissolution or corrosion of the implant and the release of materials to the surrounding tissues and systemic circulation. (e) Loss or reduction in limb function: Inadequate mechanical properties, such as its lack of strength, rigidity, or improper design of the device, may result in nonunion or malunion due to flexing, fracture, or deformation of the device and subsequent loss or reduction of limb function. Migration of the fractured device may cause damage to adjacent hard and soft tissues.

FDA agrees with the Panel recommendation for single/multiple component metallic bone fixation appliances and accessories and is proposing that these devices be classified into class II. FDA has sought additional data and documentation on the use of these devices. Black (Ref. 67) reported that this treatment of hip fractures is generally a successful procedure, with a small number of clinical failures, a small number of device failures, and a still smaller number of device failures that result in clinical failure. Black summarized several clinical studies that reported an average failure rate of 6 percent.

Holt (Ref. 68) reported that, after 16 years of use, the Holt nail offers distinct advantages in the management of trochanteric fractures in both young and old patients. The incidence of complications is low, and mechanical failures of the implant have been virtually eliminated.

Fielding (Ref. 69) reported that, from 1955 to 1971, the telescoping Pugh nail was used in 256 displaced intracapsular fractures with known end results. Ninety percent united and avascular necroses were seen in 18.5 percent of the united fractures. Since many of the patients

with avascular necrosis had no pain, they were considered satisfactory results.

Ecker, et al. (Ref. 70), reported the results of sixty-two intertrochanteric hip fractures treated with a compression screw. Three nonunions and one malunion gave the technique a failure rate of only 6.4 percent. Seinsheimer (Ref. 71) reported no failures of bone fixation in a total of 47 cases. Banks (Ref. 50) reported that, with adequate reduction, impaction and accurate internal fixation, intracapsular fracture of the femoral neck can be expected to heal in at least 90 percent of the patients. Friedmann (Ref. 72) reported that the Massie nail has been used in 25 cases, with satisfactory results in 23 cases.

Harrington, et al. (Ref. 73), reported that a sliding compression screw-plate combination was used in 72 patients who were followed for more than 12 months after surgery. Sixty-seven fractures progressed to rapid union with good valgus reduction maintained. The average time to fracture union was 3.5 months. Jacobs, et al. (Ref. 74), reported that, of 101 patients treated with a sliding screw-plate developed by Pohl, 2 cases failed because of loss of fixation, 3 cases because of symptomatic penetration, and 1 case because of malunion, with a total failure rate of 6 percent. Hansen, et al. (Ref. 75), reported that, in 42 out of 48 cases (88 percent), fractures were united successfully after a single operative procedure. Six patients (12.5 percent) experienced nonunion and required further surgery. Baker (Ref. 76) reported that overall end results were rated excellent in 67.7 percent and poor in 32.3 percent of the fractures. Massie (Ref. 77) reported that nonunion has not been observed where the patient was completely immobilized.

Cohen, et al. (Ref. 78), reported that corrosion of cobalt-chromium implants is rare, despite widespread use of alloys with slightly different composition and forming techniques between plates and screws. The authors concluded that corrosion may be present to some degree but may not cause clinical problems. Rose, et al. (Ref. 79), reported that analysis of a broken vitallium nail/plate device used to fix an intertrochanteric fracture of the hip revealed that the nail was composed of cast vitallium and the plate of wrought vitallium. The condition of the fracture surface led the authors to believe that brittle failure had occurred and that the fracture crack had initiated from the region of nail/plate contact. These authors suggested that wrought and cast vitallium should not be used in combination.

Zickel (Ref. 80) reported that the Zickel devices obtain an adequate anchor in both proximal and distal fragments of the femur. He stated that the devices provide strong immobilization, permit early ambulation, and control angulation and rotation of fragments. Mickelson, et al. (Ref. 81), reported that of 21 patients who were treated with a Zickel nail for neoplastic pathological fracture or impending pathological fracture, 19 patients were restored to bed-chair status by the third postoperative day and 20 were able to walk. Failure of fixation did not occur in any patient, and there were no infections. Cuthbert, et al. (Ref. 82), reported excellent results with use of the Kuntscher Y Nail in the treatment of intertrochanteric and subtrochanteric fractures of the femur.

Although single/multiple component metallic bone fixation appliances and accessories are implanted devices, FDA has determined that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of these devices. In addition, FDA has identified and assessed the major risks to health associated with the use of these devices. FDA believes that the major risks, i.e., loosening, infection, and adverse tissue reaction, are related to biological responses of the human body to the presence of the device and device design, and not to physical failure(s) of the device. Clinical experience with these devices has established the persons for whose use the devices are intended and the proper conditions of use. FDA has determined that the probable benefit to health from proper use of these devices outweighs any likelihood of injury or illness resulting from their use. FDA believes that informative labeling and compliance with general controls may greatly reduce the risks to health associated with the use of these devices. The agency believes that a performance standard is necessary because general controls alone are insufficient to minimize the risks to health presented by these devices.

§ 888.3040; Docket No. 78N–3053; Smooth or threaded bone fixation fastener.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of smooth or threaded metallic bone fixation fasteners:

1. Identification: A smooth or threaded metallic bone fixation fastener is an implanted device that consists of a stiff wire segment or rod made of alloys, such as cobalt-chromium-molybdenum and stainless steel, and that may be smooth on the outside, fully or partially threaded, straight or U-shaped; and may be either blunt pointed, sharp pointed or have a formed, slotted head on the end. It is intended to be used for fixation of bone fractures, bone reconstructions, as a guide pin for insertion of other implants, or to be implanted through the skin so that a pulling force (traction) may be applied to the skeletal system.

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that smooth or threaded metallic bone fixation fasteners be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent loss or reduction of limb function, adverse tissue reaction, or infection. The Panel believes that general controls alone will not provide sufficient control over these characteristics.

Although smooth or threaded bone fixation fasteners are implanted devices, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that the labeling for the device include information on the dimensions and the mechanical properties of the device, and identify the materials used in the device by both their common names and engineering classifications.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a review of the recent medical literature.

The medical literature regarding smooth metallic bone fixation fasteners reveals that there a few implant-related complications or implant failures associated with the device. A review by Fenyo (Ref. 83), covering a 12-year period and 41 cases, revealed no fractures of implants. Jones and Esah (Ref. 84) reported on six cases of radial fracture fixation in which there were no implant-related complications. Green

(Ref. 85) reported on 75 cases of intraarticular fractures treated with pin fixation, in which the results were evaluated as "good to excellent" in 86 percent of the cases. The most common complication Green reported was failure to maintain the restoration of radial length and inclination achieved by the initial reduction. He noted that up to 5 millimeters of radial length was lost due to bending of the device.

Another report (Ref. 86) noted that when the device was used in 30 patients to fuse shoulder joints, 20 patients (66 percent) attained a primary fusion, and 5 patients (17 percent) required a third operation to achieve a solid fusion. Once fusion was attained, 86 percent of the patients had excellent or good results. The chief cause of failure of arthrodesis was immoblization for too short a period of time.

Device-related complications were reported by Flynn, Matthews, and Benoit (Ref. 87) in a review of a series of 52 supracondylar fractures of the humerus in children. Both smooth and threaded pins were used. During long-term followup, the authors concluded that satisfactory results were achieved in 98 percent of the cases. They reported the following complications: vascular complications (18 percent), vascular and neuropathy complications (8 percent), muscular complications (1 percent), loss of fracture reduction (3 percent), and pin extrusion (1 percent). There were no instances of device fracture. Other reports in the medical literature involving bone fixation screws list the following device-related complications: (a) screw loosening (Refs. 57, 88, and 90 through 93) often resulting in loss of fracture fixation and, in one instance, limb paralysis due to traumatization of an artery (Ref. 93); (b) formation of a bursa (a cyst caused by friction or other mechanical cause) over the head of the screw (Ref. 92); and (c) device fracture (Ref. 94). Several authors (Refs. 62, 88, and 95) noted that if screws cannot be properly tightened, micromotion between the screw and the bone may occur and may lead to bone resorption and loosening of the device. Scales and Perry (Ref. 94) reported that the fracture rates of screws is 0.85 percent for stainless steel screws, 6.0 percent for cobalt-chromium-molybdenum screws, and 7.7 percent for titanium screws.

5. Risks to health: (a) Loss or reduction of limb function: Improper design or inadequate mechanical properties of the device, such as its lack of strength or rigidity, may result in nonunion or malunion due to flexing, fracture, or deformation of the device and subsequent loss of limb function. When the device is used as a guide pin for other implants, device failure due to inadequate mechanical properties could lengthen the time of surgery and result in an increased risk of operative complications. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility, may result in an adverse tissue reaction due to dissolution or corrosion of the implant and the release of materials to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk infection. (d) Nonunion or malunion of a fracture: Improper design or faulty performance of the device could result in a loss of traction and nonunion or malunion of a fracture.

FDA agrees with the Panel recommendation and is proposing that smooth or threaded metallic bone fixation fasteners be classified into class II. Although smooth or threaded metallic bone fixation fasteners are implanted devices, FDA has determined that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of these devices.

In addition, FDA has identified and assessed the major risks to health associated with use of these devices. FDA believes that the major risks, i.e., breakage, plastic deformation, and excessive elastic deformation, are bulk-material mechanical property failures of the device and the risks are attributed primarily to the device design and/or material and secondarily to host-tissue effects upon the device/material. Clinical experience with these devices has established the persons for whose use the devices are intended and the proper conditions of use. FDA has determined that the probable benefit to health from proper use of these devices outweighs any likelihood of injury or illness resulting from their use. FDA believes that informative labeling and compliance with general controls may greatly reduce the risks to health associated with the use of these devices. The agency believes that a performance standard is necessary because general controls alone are insufficient to minimize the risk to health presented by these devices.

§ 888.3050; Docket No. 78N-3047; Spinal interlaminal fixation orthosis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of spinal interlaminal fixation orthoses:

1. Identification: A spinal interlaminal fixation orthosis is an implanted device made of an alloy, such as stainless steel, that consists of various hooks and a posteriorly placed compression or distraction rod. The device is implanted, usually across three adjacent vertebrae, to straighten and immobilize the spine to allow bone grafts to unite and fuse the vertebrae together. The device is used primarily in the treatment of scoliosis (a lateral curvature of the spine), but it also has been used in the treatment of fracture or dislocation of the spine, grades 3 and 4 of spondylolisthesis (a dislocation of the spinal column), and lower back syndrome.

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that spinal interlaminal fixation orthoses be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent adverse tissue reaction, infection, or paralysis. The Panel believes that general controls alone will not provide sufficient control over these characteristics.

Although a spinal interlaminal fixation orthosis is an implanted device, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that the labeling for the device provide information on the strength of the device and identify the materials used in the device by both their common names and engineering classifications.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a review of the medical literature.

5. Risks to health: (a) Adverse tissue reaction: Inadequate properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or corrosion of the implant and a release of materials from the device to the surrounding tissues and the systemic circulation. (b) Infection: The presence of the orthosis within the body may lead to an increased risk of infection. (c) Paralysis:

Paralysis may occur with loosening, migration, or breakage of the device.

FDA agrees with the Panel recommendation and is proposing that spinal interlaminal fixation orthoses, such as the Harrington device, be classified into class II. FDA has sought additional data on the use of the devices. The most common spinal interlaminal fixation orthosis is the Harrington device. As shown by the quantity of published literature, the Harrington device is widely used in the correction of scoliosis (lateral curvature of the spine). Reports in the literature differ as to whether untreated scoliosis causes significant problems, such as pain, disability, cardiopulmonary decompensation, and death. Nachemson (Ref. 97) reported that scoliotic patients had a mortality rate double that of the general population and that those patients with a severe thoracic curve had a mortality rate four times that of the general population. Nachemson also indicated that patients generally exhibited increasing respiratory troubles with increasing age and an increasing spinal curve. In contrast, Collis and Ponsetti (Ref. 98) found a death rate in untreated scoliotics similar to that of the normal population.

In studies reviewed by the Panel, the success of the Harrington device in maintaining a surgical reduction in spinal curvature was suggested. In 1962, Harrington (Ref. 99) reported on a study of use of the device in three clinical groups. Group I showed 58 percent reduction in spinal curvature, Group II showed 59 percent, and Group III, 84 percent. In 1973, Harrington and Dickson (Ref. 100) reported the results of an 11-year investigation of 578 cases. This study was divided into 8 consecutive study groups. With each of the 8 groups, the study took "a step in the evolution of the design of the device and a corresponding change either in spinal fusion procedure or the postoperative management." The investigators reported an average spinal curvature reduction of about 63 percent. Dickson and Harrington (Ref. 101), reported an average spinal curve reduction of 65.3 percent. O'Brien and Yau's (Ref. 102) clinical studies showed an 88 percent reduction of spinal curvature.

When Harrington reported the initial results of implantation of the device in 129 patients, complications were high (Ref. 99). Twenty-seven instrument fractures were reported. Bone erosion occurred in 28 percent of the cases. Nonunion (failed fusion) was reported in 10 cases. Fifty-eight percent of the device fractures occurred in the first 19 of the 129 cases. Failures of the device were minimized through changes in the design of the device, surgical technique, and postoperative care.

In the 11-year investigation of 578 cases reported by Harrington and Dickson (Ref. 100), the major complications included: nonunion (3 percent), broken rod with overlap (10 percent), hematoma (1 percent), wound infection (1 percent), hepatitis (one case), and death (one case). The overall major complication rate started with a 29 percent occurrence in group 1, and gradually diminished, with no major complications reported in group 8.

Dawson, et al. (Ref. 103), used the Harrington device in a study of 82 adult scoliotic patients. With an average followup of 3.5 years, Dawson reported the following complication rates: nonunion—27 percent, infection—21 percent (subsequently lowered to 2 to 3 percent when prophylactic antibiotics were used) with no chronic infection, and death—6 percent; however, all patients who died had severe pulmonary disease.

Kostuik, et al. (Ref. 104), used the Harrington device in 107 patients and reported the following late complication rates: nonunion (10 percent), chronic infection (0 percent), painful instrumentation (4 percent), loose rods (1 percent), donor site numbness (1 percent), neuroma (1 percent), and loss of lumbar lordosis (1 percent).

Dickson and Harrington (Ref. 101) reported on use of the device in 384 patients. Genitourinary infection (5 percent) was the most prevalent early complication, and device fracture (6 percent) was the most prevalent late complication.

Bonnet and Brown (Ref. 105) reported one rod fracture in 150 cases. Nonunion was the most prevalent complication in Bonnet's study. This complication occurred initially in 38 percent of the cases, but was reduced to 27 percent in the latest clinical group.

Goldstein reported no device fractures in 107 patients (Ref. 106). Dolan and MacEwen (Ref. 107), in a review of 173 cases involving the Harrington device, reported nonunion in 15 patients and only 3 device fractures.

Spinal interlaminal fixation orthoses are implantable devices purported or represented for a use which is of substantial importance in preventing impairment of human health. FDA believes that clinical experience with the designs of these devices and the materials used in them have established the persons for whose use the devices are intended and the proper conditions of use. The agency believes that the probable benefit to health from use of these devices outweighs any likelihood of illness or injury resulting from their use. FDA believes that informative labeling will help minimize the risks to health associated with the use of these devices.

Although spinal interlaminal fixation orthoses are implanted devices, FDA believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of these devices. The agency believes that a performance standard is necessary because general controls alone are insufficient to minimize the risks to health presented by these devices.

§ 888.3060; Docket No. 78N-3048; Spinal intervertebral body fixation orthosis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of spinal intervertebral body fixation orthoses:

1. Identification: A spinal intervertebral body fixation orthosis is an implanted device made of titanium. It consists of various vertebral plates that are punched into each of a series of vertebral bodies. An eye-type screw is inserted in a hole in the center of each of the plates. A braided cable is threaded through each eye-type screw. The cable is tightened with a tension device and it is fastened or crimped at each eye-type screw. The device is intended to apply force to a series of vertebrae to correct "sway back", scoliosis (lateral curvature of the spine), or other conditions.

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendations: The Panel recommends that spinal intervertebral body fixation orthoses be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent adverse tissue reaction, infection, or paralysis. The Panel believes that general controls alone will not provide sufficient control over these characteristics.

Although these are implanted devices, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that the labeling

for the device include information on the dimensions and kinematics of the device and its strength and wear characteristics.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and the systemic circulation. (b) Infection: The presence of the orthosis within the body may lead to an increased risk of infection. (c) Paralysis: Paralysis may occur with loosening, migration, or breakage of the device.

FDA agrees with the Panel recommendation and is proposing that spinal intervertebral body orthoses, such as the Dwyer device, be classified into class II. The agency has obtained additional data and information describing the use of spinal intervertebral body fixation orthoses (Refs. 108 through 119). The device is intended primarily for use in the treatment of scoliosis, but it is also intended for fixation of the spine so that bone grafts can unite properly. Because the device is implanted on the front of the spine, implantation requires a more extensive surgical exposure than required for the implantation of spinal interlaminal fixation orthoses (§ 888.3050).

The safety and effectiveness of implantation of spinal intervertebral body fixation orthoses in the treatment of scoliosis is still being assessed (Ref. 114). Recent studies (Refs. 114, 116, and 117) report use of the device for a variety of treatments, i.e., idiopathic thoracolumbar and lumbar spinal curves, spinal curves associated with deficient posterior elements, spinal curves with marked forward curve of the lumbar spine (lordosis), and spinal curves associated with muscle paralysis. Because the device may be placed on the front of the spine, it is implanted to treat "sway back." Paralytic scoliosis is a lateral curvature of the spine caused by muscle paralysis on one side of the spinal column. Paralytic spinal curves usually involve a series of vertebra, and bone grafts inserted to correct such curves have a higher incidence of nonunion (Ref. 114). Although spinal intervertebral body fixation orthoses are indicated for use alone in the treatment of paralytic spinal curves, the preferred method of treatment is the combined use of both spinal intervertebral body fixation orthoses and spinal interlaminal fixation orthoses (§ 888.3050), a posteriorly placed compression or distraction rod (Refs. 113, 114, 116, 117, and 118). Use of spinal intervertebral body fixation orthoses is contraindicated for use in treatment of both high thoracic curves and "hunchback" (Refs. 114, 116, and 117).

FDA's search of the medical literature revealed only three studies showing long-term use of spinal intervertebral body fixation orthoses (Refs. 110, 111, and 114). Dwyer (Ref. 110) reported use of the device in 51 patients. The major complication reported involved the patients' respiratory system and two instances of nonunion of bone grafts. Most of the respiratory complications are attributed to the extensive surgery required to implant the device, and not to problems with the device itself. Dwyer, et al. (Ref. 111), reported use of the device in 77 patients with an overall complication rate of 43 percent. The complications reported included progressive "hunchback" in 18 patients, loss of correction in 22 patients, nonunion of bone grafts in 15 patients, device failure in 5 patients, deep paravertebral infection in 3 patients, and retroperitoneal fibrosis (fibrosis between the lining of the intestinal cavity and the spine) in one patient. Hall (Ref. 113) reported use of the device in 77 patients and the major complication involved nonunion of bone grafts. Twelve percent of the patients had a major nonunion resulting in reoperation. Fourteen percent had a minor nonunion with implant failure, but without serious impairment of function of the patient.

Two recent case reports in the literature (Refs. 112 and 115) provide information on complications associated with use of spinal intervertebral body fixation orthoses. Eisenstein and O'Brien (Ref. 112) reported chylothorax (an accumulation of chyle, a milky fluid, in the pleural cavity). Silber and McMaster (Ref. 115) reported a case of retroperitoneal fibrosis with hydronephrosis (a collection of urine in the distended pelvis of the kidney caused by obstructed outflow—pressure of the urine in time causes atrophy of the kidney structure, and the whole organ is converted to a large cyst). Both of the above complications may be caused by the demanding surgery involved with implanting the device, and not from the device itself. Additionally, Schafer, et al. (Ref. 119), reported that improper crimping of the head of the eye-screw inserted into the intervertebral body could shred the cable, eventually resulting in cable failure. The authors noted that 5 out of 6 heads of eye-screws and 2 out of 4 heads of eye-screws were found to be cracked following improper crimping.

Thus, spinal intervertebral body fixation orthoses are implanted devices that are purported or represented to be for use in relieving disabling pain and restoring or minimizing further loss of functional use of the spine. FDA believes these uses are of substantial importance in preventing impairment of human health. FDA further believes that clinical experience with these devices or the materials used in these devices has established the persons for whose use the devices are intended and the proper conditions of use. The agency believes that the probable benefit to health from use of the devices outweighs any likelihood of illness or injury resulting from their use. FDA further believes that informative labeling will help minimize the risks to health associated with the use of these devices.

Although spinal intervertebral body fixation orthoses are implanted devices, FDA believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of these devices. The agency believes that a performance standard is necessary because general controls alone are insufficient to minimize the risks to health presented by these devices.

§ 888.3100; Docket No. 78N-3059; Ankle joint metal/composite semi-constrained prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of ankle joint metal/composite semi-constrained prostheses:

1. Identification: An ankle joint metal/composite semi-constrained prosthesis is an implanted device intended to replace an ankle joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that consist of a talar resurfacing component made of alloys, such as cobalt-chromium-molybdenum, and a tibial resurfacing component fabricated from a carbon fiber reinforced ultra-high molecular weight polyethylene composite, and is limited to those devices intended for implantation with a polymethylmethacrylate luting agent (bone cement).

2. Recommended classification: Class III. The Panel recommends that premarket approval of this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that ankle joint metal/composite semi-constrained prostheses be classified into class III because the device is implanted and is intended to be used in relieving disabling pain and in restoring or minimizing futher loss of functional use of a joint or limb. The Panel believes these users are of substantial importance in preventing impairment of human health.

The Panel believes that general controls alone will not provide sufficient control over these characteristics. The Panel also believes that it is not possible to establish an adequate performance standard for the device. There is a lack of safety and effectiveness data to demonstrate the satisfactory performance of the device. The Panel has found that insufficient information exists to support the conclusion that general controls or performance standards will be adequate to provide reasonable assurance of the safety and effectiveness of the device. Therefore, the device must be subject to premarket approval to assure its safety and effectiveness.

The Panel also recommends that the labeling for the device include information on the dimensions and kinematics of the device and its strength and wear characteristics.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' clinical experience with similar devices and a series of presentations to the Panel (Refs. 120 and 121). Dr. Robert Johnson (Rensselaer Polytechnic Institute) compared the physical properties of the carbon fiber reinforced ultra-high molecular weight polyethylene composite material with the physical properties of conventional polyethlene material. He found that the reinforced material was superior to the conventional polyethylene material regarding compressive deformation, flexural stress, compressive creep, modulus of elasticity, and fatigue. Dr. Johnson also noted that the technology of composite materials such as carbon-fiber-reinforced polyethylene is in its infancy with regard to engineering in general.

Dr. Jack Lemons (University of Alabama) presented the results of toxicity tests on the carbon fiber reinforced material. The results of in vitro tests showed the material, and extracts from the material, to be noncytotoxic to monolayers of cells and nonhemolytic to rabbit blood. The results of in vivo tests indicated that the material was nonirritating, nontoxic, and did not produce adverse effects after up on 15 months of implantation. The results of subacute toxicity tests indicated that intracutaneous extracts of the material were nonirritating when injected into rabbits; that systemic injections produced no adverse effects in mice; and that when the material was implanted along the backs of rabbits, it was nontoxic when it was evaluated at 6 and 12 weeks. The results of the chronic toxicity tests indicated that polyethylene material reinforced with carbon fibers was noncytotoxic, nontoxic, nonirritating, and produced no adverse effects when it was injected into the knee spaces of four rabbits and evaluated 15 months later. Dr. Lemons determined that these tests show that the carbon fiber reinforced material is biocompatible.

Dr. Joel Schilling (Portland, OR) presented a report on the histological examination of pieces of tissue removed from a patient who had received an ultra-high molecular weight polyethylene prosthesis in one ankle and a carbon fiber reinforced ultra-high molecular weight polyethylene composite prosthesis in the other. Dr. Schilling found that there was minimal tissue reaction to either type of material and that there seemed to be very little reaction to the carbon fragments.

Dr. Robert Volz (University of Arizona) presented a comparison of the effect of temperature on the conventional ultra-high molecular weight polyethylene and on the carbon fiber reinforced material. Dr. Volz concluded that the carbon fiber reinforced material offered considerable improvement in its resistance to deformation at body temperatures (i.e., 37° C) and at 96° C, the temperature reached during polymerization of methylmethacrylate cement.

At the July Panel meeting (Ref. 121), Robert Fuson, M.D. (Zimmer-USA), summarized the clinical experience with prostheses made from the carbon fiber reinforced material. A total of 86 acetabular components for total hip prostheses, 18 tibial components for total knees, and 23 tibial components for total ankles have been implanted. Of these, 65 hip, 18 knee, and 22 ankle components have been implanted for more than 6 months. Only 61 hip components, 11 knee components, and 12 ankle components have been implanted for over 1 year. Only five implantations (ankle) had been clinically followed for 2 years. No adverse reactions related to these prostheses were reported.

5. Risks to health: (a) Loss or reduction of joint function: Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to a dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the Panel recommendation and is proposing that ankle joint metal/composite semi-constrained prostheses be classified into class III. FDA finds that these implanted devices are intended to be used in relieving disabling pain and in restoring or minimizing further loss of functional use of a joint or limb. FDA believes these uses are of substantial importance in preventing impairment of human health. FDA believes that insufficient clinical experience exists to fully establish the persons for whose use the devices are intended and the proper conditions of use. The agency believes that the probable benefit to health from use of the devices does not compare favorably with the likelihood of illness or injury resulting from their use.

Because of the lack of adequate data to demonstrate the safety and effectiveness of these implanted devices, FDA believes that use of the ankle joint metal/composite semi-constrained prosthesis presents an unreasonable risk of illness or injury. Because these devices are intended to be implanted in the human body, the Federal Food, Drug, and Cosmetic Act requires that they be classified into class III unless FDA determines that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of these devices. On the basis of available information, FDA cannot make this determination. Moreover, FDA believes that insufficient information exists to support the conclusion that general controls or performance standards will provide reasonable assurance of the safety and effectiveness of these devices. Therefore, FDA is proposing that these devices be classified into class III.

§ 888.3110; Docket No. 78N–3060; Ankle joint metal/polymer semi-constrained prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of ankle joint metal/polymer semi-constrained prostheses:

1. Identification: An ankle joint metal/polymer semi-constrained prosthesis is an implanted device intended to replace an ankle joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces and has no linkage across-the-joint. This generic type of device includes prostheses that have a talar resurfacing component made of alloys, such as cobalt-chromium-molybdenum, and a tibial resurfacing component made of ultra-high molecular weight polyethylene, and is limited to those devices intended for implantation with a polymethylmethacrylate luting agent (bone cement).

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that ankle joint metal/polymer semiconstrained prostheses be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent loss or reduction of joint function, adverse tissue reaction, or infection. The Panel believes that general controls alone will not provide sufficient control over these characteristics.

Although ankle joint metal/polymer semi-constrained prostheses are implanted devices, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that the labeling for the device include information on the dimensions and kinematics of the device and its strength and wear characteristics.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on three oral presentations to the Panel, and the Panel members' knowledge of the medical literature. On July 15, 1977, oral presentations to the Panel were made by Drs. Harry Groth, Theodore Waugh, and Arthur Steffee (Ref. 122). Dr. Groth discussed the clinical results obtained following implantation of 31 Oregon design ankle prostheses. Seventeen of these devices had been implanted for 1 year or more. The maximum time of implantation was reported as 2 years. The clinical results were reported as "fair" in 4 patients, and as "good" or "excellent" in the remaining 27.

Dr. Waugh presented the clinical results obtained using the University of California at Irvine (UCI) design ankle prosthesis. This prosthesis had been implanted in 63 patients, 35 to 40 of whom had had the devices implanted for more than 2 years.

Dr. Steffee discussed the clinical results obtained following implantation of 37 Bech-Steffee design ankle prostheses. The minimum time of implantation of these devices was reported as 2 months, and the maximum time was 46 months.

Drs. Groth, Waugh, and Steffee reported the following total complications associated with use of the three prosthesis designs they studied: five cases of device loosening, two cases of joint infection, one case of joint instability, two cases of malpositioning of the prosthesis, eight cases of wound healing problems, and two cases of pulmonary embolism.

In another oral presentation before the Panel on November 19, 1980 (Ref. 123), Dr. Paul Thompson discussed the results he obtained using the TPR® ankle prosthesis. He said that the device had been implanted in 43 patients over a 6-year period and that excellent or good results were obtained in 75 percent of these patients, and poor results were obtained in 25 percent. Complete freedom from pain was achieved in 32 percent. Sixty-five percent of the patients complained of mild discomfort and 7 percent had constant pain. Reoperations were done on eight patients (19 percent) for loosened prostheses; two patients of the eight had two reoperations, the remaining six had one reoperation.

5. Risks to health: (a) Loss or reduction of joint function: Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: the presence of the prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the Panel recommendation and is proposing that ankle joint metal/polymer semi-constrained prostheses be classified into class II. FDA has sought additional data and information on the safety and effectiveness of these devices. Several publications (Refs. 124 and 125) were available describing the biomechanics of the ankle joint prosthesis and the rationale behind a number of ankle prosthesis designs. Other publications (Refs. 126 through 129) presented clinical results obtained using the devices.

Stauffer (Ref. 126) reported that the early results obtained with the Mayo design prosthesis were favorable. He stated that, of 20 patients in whom the Mayo design ankle prosthesis was implanted, six complications occurred: 3 cases of fracture of the medial malleolus; 1 case of impingement of the lateral malleolus or the talus; 1 case of loosening of the tibial component, following a patient's fall, and 1 case of rotation of the subtalor joint by the anchoring fins of the talar component. In a subsequent publication (Ref. 127), Stauffer reported the clinical results obtained from 72 patients involving 76 implantations. In 63 of these patients, the devices had been implanted for more than 6 months. Of these 63 patients, good results were obtained in 52, fair results in 6, and poor results in 5. A number of complications were reported: one case of deep infection requiring removal of the components; five cases of delayed wound healing; one case of thrombophlebitis; five cases of fracture of the medial malleolus; and three cases of device loosening. Reoperations were required in five patients due to impingement of the lateral malleolus or the talus.

Evanski and Waugh (Ref. 128) reported on ankle prostheses that had been implanted in 29 patients. Twenty-five patients received the UCI design ankle prosthesis and four received the Smith design ankle prosthesis. The authors stated that sufficient data were available to evaluate the results in 28 patients. The average period of followup for these patients was 9 months. Significant improvement was noted in function, pain relief, and range of motion. Complications included: three cases of wound healing problems and two cases of malalignment of the components, one requiring reoperation. There were two failures: one patient required a joint fusion and the other an

amputation following postoperative occlusion of the posterior tibial artery.

Scholz (Ref. 129) reported on the implantation of 31 devices of his design in 30 patients who were candidates for ankle arthrodesis. The devices were implanted over a 2-year period. It was reported that, in general, pain was eliminated or reduced, function was improved, and motion of the joint was generally sufficient to allow normal heal-toe gait without a limp. It was also reported that there were no major complications associated with the device. However, reoperation was necessary in one patient to reposition a tibial component that had been incorrectly aligned and had loosened. Scholz stated that no devices had been removed to arthrodese the joint, but that arthrodesis was possible if the components had to be removed at a future date.

Although ankle joint metal/polymer semi-constrained prostheses are implanted devices, FDA has determined that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of these devices. In addition, FDA has identified and assessed the major risks to health associated with the use of these devices. FDA believes that the major risks, i.e., loosening, infection, and adverse tissue reaction, are related to biological responses of the human body to the presence of the device, the device design, and the underlying joint pathology, and not to physical failure(s) of the device. Thrombophlebitis and infection are risks of any serious operation and are not necessarily caused by poor performance of the device. Clinical experience with these devices has established the persons for whose use the devices are intended and the proper conditions of use. FDA has determined that the probable benefit to health from proper use of these devices outweighs any likelihood of injury or illness resulting from their use. FDA further believes that informative labeling and compliance with general controls may greatly reduce the risks to health associated with the use of these devices. The agency believes that a performance standard is necessary because general controls alone are insufficient to minimize the risks to health presented by these devices.

§ 888.3120; Docket No. 78N–3061; Ankle joint metal/polymer non-constrained prosthesis.

The Orthopedic Device Classification Panel, an FDA Advisory committee, made the following recommendation regarding the classification of ankle joint metal/polymer non-constrained prostheses:

1. Identification: An ankle joint metal/polymer non-constrained prosthesis is an implanted device intended to replace an ankle joint. The device limits minimally (less than normal anatomic constraints) translation in one or more planes. It has no linkage across-the-joint. This generic type of device includes prostheses that have a tibial component made of alloys, such as cobalt-chromium-molybdenum, and a talar component made of ultra-high molecular weight polyethylene, and is limited to those devices intended for implantation with a polymethylmethacrylate luting agent (bone cement).

2. Recommended classification: Class III. The Panel recommends that premarket approval of this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that ankle joint metal/polymer non-constrained prostheses be classified into class III because these implanted devices are intended to be used in relieving disabling pain and in restoring or minimizing further loss of functional use of a joint or limb. The panel believes these uses are of substantial importance in preventing impairment of human health.

The Panel believes that general controls alone will not provide sufficient control over these characteristics. The Panel also believes that it is not possible to establish an adequate performance standard for the device. There is a lack of safety and effectiveness data to demonstrate the satisfactory performance of the device. The Panel has found that insufficient information exists to support the conclusion that general controls of performance standards will be adequate to provide reasonable assurance of the safety and effectiveness of the device. Therefore, the device must be subject to premarket approval to assure its safety and effectiveness.

The Panel also recommends that the labeling for the device include information on the dimensions and kinematics of the device and its strength and wear characteristics.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of the device and on the available medical literature. According to Freeman (Ref. 130), "It is still too early to say whether this operation (total ankle joint replacement) offers any advantages over arthrodesis * * *. It would appear a comfortable mobile ankle can be produced but how reliably this can be done and how long the results will last is impossible to say."

5. Risks to health: (a) Loss or reduction of joint function: Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrouding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the Panel recommendation and is proposing that ankle joint metal/polymer non-constrained prostheses be classified into class III. The agency has reviewed the Panel recommendation and has sought additional information describing the safety and effectiveness of these devices. The only available clinical study on the device has been done by S. E. Newton (Ref. 131). Since 1973, 50 patients have had this prosthesis implanted. There have been 20 (40 percent) reported failures. FDA believes these data are insufficient to establish the safety and effectiveness of ankle joint metal/polymer non-constrained prostheses.

FDA finds that ankle joint metal/polymer non-constrained prostheses are implanted devices that are intended to be used in relieving disabling pain and in restoring or minimizing further loss of functional use of a joint or limb. FDA believes these uses are of substantial importance in preventing impairment of human health. FDA believes that insufficient clinical experience exists to fully establish the persons for whose use the devices are intended and the proper conditions of use. The agency believes that the probable benefit to health from use of the devices does not compare favorably with the likelihood of illness or injury resulting from their use.

Because of the lack of adequate data to demonstrate the safety and effectiveness of these implanted devices, FDA believes that use of the ankle joint metal/polymer non-constrained prosthesis presents an

unreasonable risk of illness or injury. Because these devices are intended to be implanted in the human body, the Federal Food, Drug, and Cosmetic Act requires that they be classified into class III unless FDA determines that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of these devices. On the basis of available information, FDA cannot make that determination. Moreover, FDA believes that insufficient information exists to support the conclusion that general controls or performance standards will provide reasonable assurance of the safety and effectiveness of these devices. Therefore, FDA is proposing that these devices be classified into class III.

§ 888.3150; Docket No. 78N–3062; Elbow joint constrained prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of elbow joint contrained prostheses:

1. Identification: An elbow joint constrained prosthesis is an implanted device made exclusively of alloys, such as cobalt-chromium-molybdenum, or made from these alloys and ultra-high molecular weight polyethylene, that is intended to replace an elbow joint. The device prevents dislocation in more than one anatomic plane and consists of two components which are linked together (or affined). The generic type of device is limited to those prostheses intended for implantation with a polymethylmethacrylate luting agent (bone cement).

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that elbow joint constrained prostheses be classified into class II because the design, material composition, and mechanical properties of the device, such its flexibility, rigidity, strength, and surface finish, should be controlled to prevent loss or reduction of joint function, adverse tissue reaction, or infection. The Panel believes that general controls alone will not provide sufficient control over these characteristics.

Although these are implanted devices, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Panel also recommends that the labeling for the device include information on the dimensions and kinematics of the device and its strength and wear characteristics.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on an oral presentation to the Panel and their knowledge of the medical literature. On April 14, 1977, the Panel heard an oral presentation by Dr. Rowland Pritchard (Ref. 132). Dr. Pritchard summarized his experience with the Pritchard-Walker prosthesis which has a metallic ulnar component and a polyethylene humeral component. Dr. Pritchard reported that he had implanted 25 of the devices and that 18 (72 percent) of the patients were free from pain. Dr. Pritchard indicated that the devices had been implanted for as little as 2 years in some patients and as long as 3 years in others. Dr. Pritchard stated that the polyethylene humeral component of two of the devices (8 percent) had fractured and that there were two other complications, one case of infection and one case of radial nerve palsy (paralysis).

5. Risks to health: (a) Loss or reduction of joint function: Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity.

(b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility or resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA disagrees with the Panel recommendation and is proposing that contrained elbow joint prostheses be classified into class III. FDA has sought additional information on the safety and effectiveness of the device. The agency has reviewed the current medical literature pertinent to elbow joint constrained prostheses. The literature reviewed pertains to both the earlier designs of constrained elbow prostheses, the "rigid-hinge" devices such as the St. George and Coonrad designs, and the more recent "loose-hinge" devices, such as the Schlein, Ewald, Pritchad-Walker, and Mayo designs.

Although good results with the rigidly hinged devices were found initially, several investigators (Refs. 132 through 134) reported that serious complications were associated with long-term implantation of these devices. Souter (Ref. 134) described three serious long-term complications associated with the use of these devices: (1) loosening of the devices resulting in joint instability, (2) bone erosion and resorption resulting in fracture of the bone surrounding the devices, and (3) the difficulty in salvaging the joint if the device is removed.

A high incidence of complications, particularly loosening, was reported by many investigators using a variety of constrained elbow designs. Dee (Ref. 133) evaluated 40 patients 2 to 5 years after they had received an elbow joint metallic rigid-hinged prosthesis. Eleven (27.5 percent) of the prostheses had loosened; the majority of these loosening 2 or more years after surgery. Only two cases of loosening had been evident 1 year after implantation, and only six after 3 years. Souter (Ref. 134) reported that 12 out of 25 prostheses (48 percent) had loosened after an average time of implantation of 5 years and 3 months. Eleven (44 percent) of the patients had unstable joints. Devas (Ref. 135) used a rigid-hinged device with metallic humeral and ulnar components and a polyethylene bushing in nine patients. He reported that four out of nine (44 percent) of the devices had loosened or were suspected of being loose and concluded that the long-term results did not warrant continuing the procedure.

Gshwend, Sheier, and Bahler (Ref. 136) and Ewald (Ref. 137) reported on their clinical results with the G.S.B metallic rigid-hinged device. Gshwend, et al. (Ref. 136), reported that one-third of the 40 prostheses implanted in their study were subject to loosening 1 to 5 years after implantation. Ewald (Ref. 137) reported that in his study, 2 out of 13 (15 percent) of the devices had loosened 10 to 21 months after implantation. Other reported hazards and complications include fracture of the polyethylene components of devices due to inadequate mechanical strength of the material (Ref. 138), metal sensitivity in patients with metallic prostheses due to the accumulation of metallic wear debris (Ref. 133), and the potential for extensive bone infection related to the long intramedullary stems of the devices (Ref. 134). The high incidence of complications with these devices has been attributed to the inability of a "rigid" hinge to accommodate the torque forces that

occur during axial rotation of the forearm (Refs. 134, 138, and 139). FDA recognizes that the "loose" hinge elbow prosthesis (e.g., Pritchard-Walker) is designed to allow some side-to-side motion and thus reduce the rate of loosening found with the "rigid" hinged devices. Dr. Pritchard reported to the Panel that there were no cases of devices loosening in 25 patients, 2 to 3 years after implantation of the devices.

Schlein (Ref. 140) reported that over 400 loose-hinged elbow prostheses were implanted over a 3-year period. Schlein reported the following complications in the series of 400 implantations: 11 cases of device loosening (2.75 percent); 4 cases of infection (1 percent); 2 cases of device fractures (0.5 percent); and 6 cases of bone fractures (1.5 percent). FDA notes that: (1) The high incidence of device loosening associated with the constrained elbow prostheses (i.e., Dee, Shiers, McKee, modified McKee, Coonrad, and G.S.B. designs) has been attributed to inadequate device design (Refs. 133 through 135, 139, and 141 through 143); (2) the biomechanics of the elbow joint are reportedly not well understood (Refs. 144 and 145); and (3) biomedical analysis is reportedly needed to establish design criteria for development of optimum design for the prosthesis (Ref. 141).

FDA finds that elbow joint constrained prostheses are implanted devices that are intended to be used in relieving disabling pain and in restoring or minimizing further loss of functional use of a joint or limb. FDA believes these uses are of substantial importance in preventing impairment of human health. FDA believes that insufficient clinical experience exists to fully establish the persons for whose use the devices are intended and the proper conditions of use. The agency believes that the probable benefit to health from use of the devices does not compare favorably with the likelihood of illness or injury resulting from their use.

Because of the lack of adequate data to demonstrate the safety and effectiveness of these implanted devices, FDA believes that uncontrolled use of the elbow joint constrained prosthesis presents an unreasonable risk of illness or injury.

Because these devices are intended to be implanted in the human body, the Federal Food, Drug, and Cosmetic Act requires that they be classified into class III unless FDA determines that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of these devices. On the basis of available information, FDA cannot make this determination. Moreover, FDA believes that insufficient information exists to support the conclusion that general controls or performance standards will provide reasonable assurance of the safety and effectiveness of these devices. Therefore, FDA is proposing that these devices be classified into class III.

§ 888.3160; Docket No. 78N–3063; Elbow joint semi-constrained prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of elbow joint semi-constrained prostheses:

1. Identification: An elbow joint semi-constrained prosthesis is an implanted device intended to replace an elbow joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that consist of a humeral resurfacing component made of alloys, such as cobalt-chromium-molybdenum, and a radial resurfacing component made of ultra-high molecular weight polyethylene. This generic type of device is limited to those devices intended for implantation with a polymethylmethacrylate luting agent (bone cement).

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that elbow joint semi-constrained prostheses be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent loss or reduction of joint function, adverse tissue reaction, or infection. The Panel believes that general controls alone will not provide sufficent control over these characteristics.

Although elbow joint semi-constrained prostheses are implanted devices, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that the labeling for the device include information on the dimensions and kinematics of the device and its strength and wear characteristics.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Loss or reduction of joint function: Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction in joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility or resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the Panel recommendation and is proposing that elbow joint semi-constrained prostheses be classified into class II. FDA has sought additional data and information on the safety and effectiveness of the device. Cavendish and Elloy (Ref. 144) discuss 10 Liverpool prostheses that had been implanted from 18 months to 3 years. One failed due to infection and one due to bone fracture. The other eight cases resulted in an adequate range of motion and the patients were pain free. Ewald, et al. (Ref. 147), reported on 50 implantations of the Ewald prosthesis. The maximum followup was reported as 2 years and 9 months, the minimum as 6 months, and the median as 18 months. Pain relief and functional improvement were reported to have been uniformly excellent. Complications included: two cases (4 percent) of dislocation of the device; two cases (4 percent) of infection; two cases (4 percent) of ulnar nerve palsy, one of which was permanent; and one (2 percent) unstable elbow attributed to the failure of a previous operative procedure. The authors concluded that the angle of the device stem caused inherent elbow instability and dislocation in some patients. These complications prompted the authors to design four additional stem angles. The biomechanics of the elbow joint are still being characterized (Refs. 144, 145, and 150), and continuing studies are needed to optimize the design of the device (Refs. 150 through 153).

Although elbow joint semi-constrained prostheses are implanted devices, FDA has determined that premarket approval is not necessary because sufficient information exists to establish a performance standard that

will provide reasonable assurance of the safety and effectiveness of these devices. In addition, FDA has identified and assessed the major risks to health accompanying the use of these devices. FDA believes that the major risks, i.e., loosening, infection, and adverse tissue reaction, are related to biological responses of the human body to the presence of the device, the device design, and the underlying joint pathology, and not to physical failure(s) of the device. Clinical experience with these devices has established the persons for whose use the devices are intended and the proper conditions of use. FDA has determined that the probable benefit to health from proper use of these devices outweighs any likelihood of injury or illness resulting from their use. FDA further believes that informative labeling and compliance with general controls may greatly reduce the risks to health associated with the use of these devices. The agency believes that a performance standard is necessary because general controls alone are insufficient to minimize the risks to health presented by these devices.

§ 888.3170; Docket No. 78N–3064; Elbow joint radial (hemi-elbow) prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of elbow joint radial (hemi-elbow) prostheses:

1. Identification: An elbow joint radial (hemi-elbow) prosthesis is an implanted device made of medical grade silicone elastomer intended to replace the proximal end of the radius. The device is intended for implantation without a polymethylmethacrylate luting agent (bone cement).

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that elbow joint radial (hemi-elbow) uncemented prostheses be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent loss or reduction of joint function, adverse tissue reaction, or infection. The Panel believes that general controls alone will not provide sufficient control over these characteristics.

Although elbow joint radial (hemi-elbow) prostheses are implanted devices, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that the labeling for the device include information on the dimensions and kinematics of the device and its strength and wear characteristics.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Loss or reduction of joint function: Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device components, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissue and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the Panel recommendation and is proposing that elbow joint radial (hemi-elbow) prostheses be classified into class II. FDA has sought additional data and information on the safety and effectiveness of these devices. Swanson (Ref. 154) reported on the implantation of the devices in 44 patients, including 9 patients who were operated on bilaterally. Of these 53 implanted devices, 28 were followed for 6 months to 2 years, and 25 were followed for 2 to 5 years. Results were evaluated with regard to pain relief, stability, and mobility of the elbow joint. Pain was reported to have been relieved in all 53 elbows, and stability was reported to be good. There was also a reported increase in range of motion of the joint, especially in pronation and supination. Roentgenograms made 6 months to 5 years after surgery were used to evaluate the condition of the bone surrounding the implant. Examination of the roentgenograms demonstrated good acceptance of the implant. In one case, the bone around the stem of the implant was found to have resorbed, and the implant was noted to have loosened. However, there were no adverse clinical effects associated with this anomaly. The advantages of the use of the prosthesis over simple resection of the radial head (without use of an implant) were summarized by the researcher to be: (1) better pain relief; (2) increased range of motion; (3) preservation of joint alignment and prevention of migration of the radial shaft; and (4) prevention of bone overgrowth and spiking at the resected end of the radius.

Although elbow joint radial (hemi-elbow) protheses are implanted devices, FDA has determined that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of these devices. In addition, FDA has identified and assessed the major risks to health associated with the use of these devices. FDA believes that the major risks, i.e., loosening, infection, and adverse tissue reaction, are related to biological responses of the human body to the presence of the device, the device design, and the underlying joint pathology, and not to physical failure(s) of the device. Clinical experience with these devices has established the persons for whose use the devices are intended and the proper conditions of use. FDA has determined that the probable benefit to health from proper use of these devices outweighs any likelihood of injury or illness resulting from their use. FDA further believes that informative labeling and compliance with general controls may greatly reduce the risks to health associated with the use of these devices. The agency believes that a performance standard is necessary because general controls alone are insufficient to minimize the risks to health presented by these devices.

§ 888.3180; Docket No. 78N–3065; Elbow joint humeral (hemi-elbow) uncemented prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of elbow joint humeral (hemi-elbow) uncemented prostheses:

1. Identification: An elbow joint humeral (hemi-elbow) uncemented prosthesis is an implanted device made of alloys, such as cobalt-chromium-molybdenum, that is intended to replace the distal end of the humerus formed by the trochlea humeri and the capitulum humeri. The device is intended for implantation without a polymethylmethacrylate luting agent (bone cement).

2. Recommended classification: Class II. The Panel recommends that

establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that elbow joint humeral (hemi-elbow) uncemented prostheses be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent loss or reduction of limb function, adverse tissue reaction, or infection. The Panel believes that general controls alone will not provide sufficient control over these characteristics.

Although these are implanted devices, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Panel also recommends that the labeling for the device include information on the dimensions and kinematics of the device and its strength and wear characteristics.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Loss or reduction of joint function: Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in the loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA disagrees with the Panel recommendation and is proposing that elbow joint humeral (hemi-elbow) uncemented prostheses be classified into class III. FDA has sought additional data and information on the safety and effectiveness of these devices. The agency has reviewed the available medical literature pertaining to elbow joint humeral (hemi-elbow) uncemented prostheses. A recent publication (Ref. 155) reported that the devices have been implanted in over 100 patients worldwide. However, the only available clinical data are the results of 2 surgeons who implanted 18 devices over a 10-year period (Ref. 155). An earlier publication (Ref. 156) discusses the clinical results in what appears to be the first 10 of these 18 implantations. The devices had been implanted in nine patients (one patient had prostheses implanted bilaterally). These patients were evaluated 1 to 7 years later and only four patients (44 percent) had stable, pain-free elbows with a functional range of motion. New bone growth restricted or totally blocked elbow joint motion in three patients. The device was removed in two other patients; because of joint pain and swelling in one; and because the device had dislocated and was eroding through the skin in the other.

FDA finds that elbow joint humeral (hemi-elbow) uncemented prostheses are implanted devices that are intended to be used in relieving disabling pain and in restoring or minimizing further loss of functional use of a joint or limb. FDA believes these uses are of substantial importance in preventing impairment of human health. FDA believes that insufficient clinical experience exists to establish the persons for whose use the devices are intended and the proper conditions of use. The agency believes that the probable benefit to health from use of these devices does not compare favorably with the likelihood of illness or injury resulting from their use.

Because of the lack of adequate data to demonstrate the safety and effectiveness of these implanted devices, FDA believes that use of the elbow joint humeral (hemi-elbow) uncemented prosthesis presents an unreasonable risk of illnes or injury. Because these devices are intended to be implanted in the human body, the Federal Food, Drug, and Cosmetic Act requires that they be classified into class III unless FDA determines that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of these devices. On the basis of available information, FDA cannot make this determination. Moreover, FDA believes that insufficient information exists to support the conclusion that general controls or performance standards will provide reasonable assurance of the safety and effectiveness of these devices. Therefore, FDA is proposing that these devices be classified into class III.

§ 888.3200; Docket No. 78N–3066; Finger joint metal/metal constrained uncemented prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of finger joint metal/metal constrained uncemented prostheses:

1. Identification: A finger joint metal/metal constrained uncemented prosthesis is an implanted device intended to replace a metacarpophalangeal or proximal interphalangeal (finger) joint. The device prevents dislocation in more than one anatomic plane and consists of two components which are linked together. This generic type of device includes prostheses made by alloys, such as cobalt-chromium-molybdenum, or prostheses made from alloys and ultra-high molecular weight polyethylene. This generic type of device is limited to prostheses intended to be implanted without a polymethylmethacrylate luting agent (bone cement).

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that finger joint metal/metal constrained uncemented prostheses be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent loss or reduction of limb function, adverse tissue reaction, or infection. The Panel believes that general controls alone will not provide sufficient control over these characteristics.

Although finger joint metal/metal constrained uncemented prostheses are implanted devices, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectivness of the device. The Panel also recommends that the labeling for the device include information on the dimensions and kinematics of the device and its strength and wear characteristics.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with the device.

5. Risks to health: (a) Loss or reduction of joint function: Improper

design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or lossening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA disagrees with the Panel recommendation and is proposing that finger joint metal/metal constrainted uncemented prostheses he classified into class III. FDA has reviewed the available medical literature pertaining to these prostheses. The only finger joint metal/metal constrained uncemented proshtesis discussed in the literature is a two-pronged stainless steel hinged prosthesis which was developed by Flatt for use in the metacarpophalangeal (MCP) and the proximal interphalangeal (PIP) joints of the fingers.

Flatt presented clincial results with the Flatt finger prosthesis in a series of publications over a 12-year period (Refs. 157 through 162). Thirty-one prostheses had been implanted for 6 months or more (6 months to 34 months); 23 in the PIP joint and 8 in the MCP joint (Ref. 157). In the earliest of these reports (Ref. 157), Flatt noted that despite early encouraging clinical results, the long-term outlook for the device did not look favorable. In particular, Flatt noted that the bone absorption which occurs around the neck of the prosthesis may possibly lead to obstruction of flexion. Flatt also noted that possible complications from use of the device might be: (1) Bone erosion in patients in whom the intramedullary prongs have been forced together in the medullary canal, and (2) metal fatigue and fracture of the intramedullary prongs.

Subsequent publications by Flatt (Refs. 161 and 162) show that the predicted complications did, in fact, occur. Flatt and Ellison (Ref. 161) reported on the implantation of 242 prostheses (167 in the MCP joint and 75 in the PIP joint) with an average followup of 6.2 years (range 1 to 12 years). Twenty-six (10.7 percent) of the prostheses (15 MCP and 11 PIP) had to be removed for the following reasons: periarticular fibrosis (bone resorption) and settling, 14; failure (i.e., fracture) of both intramedullary prongs, 2; failure of the screw holding the hinge together, 2; breakdown of the skin over the prosthesis, 5; and infection, 3. The author reported that of the prostheses that required removal, more than half were removed because of settling within the recipient bones. Bone absorption around the intramedullary prongs, scarring, or heterotrophic bone formation around the hinge caused sufficient mechanical difficulties to necessitate removal of the prosthesis. Flatt and Ellison noted that the gradually progressing periarticular fibrosis (bone resorption) resulted in a decreased range of joint motion and was related to very active use of the hand.

Girzados and Clayton (Ref. 163) reported on the implantation of 23 Flatt finger prostheses in 11 patients with an average followup of 44 months (range 24 to 73 months). Of the 23 prostheses implanted, 11 were in the MCP joints of the fingers, 8 were in the PIP joints of the fingers, and 4 were in the MCP joints of the thumb. Bone absorption around the neck and stems of the prosthesis occurred in 16 of the 23 (69 percent) joints. Six prostheses (26 percent) were rated as poor results: three had no motion postoperatively; one was grossly unstable; and two were implanted in a patient with active rheumatoid disease who, over a period of 64 months, had intermittent swelling and pain over the joints that had been replaced with the prostheses. The authors reported that "good" or "fair" results were obtained in 13 (56 percent) of the joints. However, the number of patients having pain-free stable joints with a useful range of motion (defined as "good") as opposed to those with limited motion, minimal pain, and instability (defined as "fair") could not be determined.

Problems associated with the Flatt finger prosthesis have been recognized by many authors (Refs. 164 through 170). Several authors (Refs. 164 and 165) reported that these prostheses have not been generally accepted because of the accompanying bone resorption. McFarland (Ref. 166) reported that the Flatt prosthesis has been only moderately successful, that complications are frequent and include bone overgrowth with loss of motion, migration of the prosthesis due to bone erosion, and metal failures (i.e., device fractures). Smith and Broudy (Ref. 170) and Goldner and Urbaniak (Ref. 168) noted that the bone resorption and subsequent migration of the devices is caused by the use of a rigid material in osteoporotic bone. Smith and Broudy (Ref. 170) also noted that the intramedullary prongs frequently migrate through the cortex and occasionally the hinge will break or the overlying skin will ulcerate, causing tendon rupture and infection.

FDA finds that finger joint metal/metal constrained uncemented prostheses are implanted devices that are intended to be used in relieving disabling pain and in restoring or minimizing further loss of functional use of a joint or limb. FDA believes these uses are of substantial importance in preventing impairment of human health. FDA believes that insufficient clinical experience exists to fully establish the persons for whose use the devices are intended and the proper conditions of use. The agency believes that the probable benefit to health from use of these devices does not compare favorably with the likelihood of injury of illness resulting from their use.

Because of the lack of adequate data to demonstrate the safety and effectiveness of these implanted devices, FDA believes that use of the finger joint metal/metal constrained uncemented prosthesis presents an unreasonable risk of illness or injury. Because these devices are intended to be implanted in the human body, the Federal Food, Drug, and Cosmetic Act requires that they be classified into class III unless FDA determines that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of these devices. On the basis of available information, FDA cannot make that determination. Moreover, FDA believes that insufficient information exists to support the conclusion that general controls or performance standards will provide reasonable assurance of the safety and effectiveness of these devices. Therefore, FDA is proposing that these devices be classified into class III.

§ 888.3210; Docket No. 78N-3301; Finger joint metal/metal constrained prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of finger joint metal/metal constrained prostheses:

1. Identification: A finger joint metal/metal constrained prosthesis is an implanted device intended to replace a metacarpophalangeal (finger) joint. This device prevents dislocation in more than one anatomic plane and has components which are linked together. This generic type of device includes prostheses that are made of alloys, such as cobalt-chromium-molybdenum, and is limited

to those devices intended for implantation with a polymethylmethacrylate luting agent (bone cement).

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that finger joint metal/metal constrained prostheses be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent loss or reduction of limb function, adverse tissue reaction, or infection. The Panel believes that general controls alone will not provide sufficient control over these characteristics.

Although these are implanted devices, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that the labeling for the device include information on the dimensions and kinematics of the device and its strength and wear characteristics.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel member's personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Loss or reduction of joint function: Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA disagrees with the Panel recommendation and is proposing that finger joint metal/metal constrained prostheses be classified into class III. FDA has sought additional information on the safety and effectiveness of these devices and has reviewed the available medical literature pertaining to these devices. Two types of these prostheses were discussed in the literature: (1) The Link prosthesis, a metallic hinge intended to replace the metacarpophalangeal joint of a finger or thumb, and (2) the Biomedical Laboratories of the University of Cincinnati (BLUC) prosthesis, a hinged metallic prosthesis intended to replace the metacarpophalangeal joint of the thumb.

Devas and Shah (Refs. 171 and 172) reported on the implementation of 51 Link prostheses in 25 patients with an average postoperative followup of 4 years (range 2 to 6 years). In 15 (30 percent) of these implantations, the patient had persistent pain in the joint and what was described as a useless finger. The authors believed that the proportion of patients with pain was far too large to make the treatment method freely available. They noted that the main cause of failure was due to loosening of the prostheses with disruption (erosion) of the bone. They also noted that in most of the joints with good and fair results the prosthesis had become loose but that the patients were free from symptoms at the time of evaluation. It was believed that prosthesis loosening may have been caused by fixation of the components by injecting the cement into the metacarpal and phalangeal bone shafts, and it was noted that a modified prosthesis with a different technique of insertion was being considered (Ref. 172). Several papers (Refs. 173 and 174) described the design and testing of the BLUC thumb prostheses. Clinical results, however, were not presented. FDA believes that the data available on the devices, the clinical results of the use of the devices in 25 patients with a reported failure rate of 30 percent, and the recommendation by the authors that the procedure not be made freely available, do not establish the long-term safety and effectiveness of finger joint metal/metal constrained prostheses.

FDA finds that finger joint metal/metal constrained prostheses are implanted devices that are intended to be used in relieving disabling pain and in restoring or minimizing further loss of functional use of a finger joint. FDA believes these uses are of substantial importance in preventing impairment of human health. FDA also believes that insufficient clinical experience exists to establish the persons for whose use the devices are intended and the proper conditions of use. The agency believes that the probable benefit to health from use of the devices does not compare favorably with the likelihood of injury or illness resulting from their use.

Because of the lack of adequate data to demonstrate the safety and effectiveness of these implanted devices, FDA believes that the use of finger joint metal/metal constrained prostheses presents an unreasonable risk of illness or injury.

Because these devices are intended to be implanted in the human body, the Federal Food, Drug, and Cosmetic Act requires that they be classified into class III unless FDA determines that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of these devices. On the basis of available information, FDA cannot make this determination. Moreover, FDA believes that insufficient information exists to support the conclusion that general controls or performance standards will provide reasonable assurance of the safety and effectiveness of these devices. Therefore, FDA is proposing that these devices be classified into class III.

§ 888.3220; Docket No. 78N–3067; Finger joint metal/polymer constrained prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of finger joint metal/polymer constrained prostheses:

1. Identification: A finger joint metal/polymer constrained prosthesis is an implanted device intended to replace a metacarpophalangeal or proximal interphalangeal (finger) joint. The device prevents dislocation in more than one anatomic plane, and consists of two components which are linked together. This generic type of device includes prostheses that are made of alloys, such as cobalt-chromium-molybdenum, and ultra-high molecular weight polyethylene, and is limited to those devices that are intended for implantation with a polymethylmethacrylate luting agent (bone cement).

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that finger joint metal/polymer constrained protheses be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent loss or reduction of joint function, adverse tissue reaction, or

infection. The Panel believes that general controls alone will not provide sufficient control over these characteristics.

Although these are implanted devices, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Panel also recommends that the labeling for the device include information on the dimensions and kinematics of the device and its strength and wear characteristics.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Loss or reduction of joint function: Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA disagrees with the Panel recommendation and is proposing that finger joint metal/polymer constrained prostheses be classified into class III. FDA has sought additional information on the safety and effectiveness of these devices and has reviewed six references which discuss the device. Two (Refs. 175 and 176) discuss the design criteria for these devices; two (Refs. 177 and 178) review the evolution of the design of these devices; and four (Refs. 175, 176, 179, and 180) describe new prosthesis designs. The prosthesis designs discussed in the literature include: the St. George, Steffee, Schultz, Nicolle, Schetrumpf, Vari-Axle, and load stabilizing prostheses, all of which were designed for the metacarpophalengeal (MCP) joint. Smith and Broudy (Ref. 177) reported that a device similar in design to the Steffee prosthesis had been developed for the proximal interphalangeal (PIP) joint.

Clinical results were available for only two prosthesis designs, the Vari-Axle and the Nicolle designs (Refs. 175 and 179). Long-term clinical results, however, are not available for any of the designs. Walker, et al., reported on 21 patients with Vari-Axle prostheses (Ref. 175). The average postoperative time was 15 months (range 6 months to 3 years). While pain relief was noted to be good, the range of motion dropped from 33 degrees preoperatively to 22 degrees, a reportedly disappointing result. These authors noted that short-term and long-term mechanical tests were performed on the device because of the potential distortions which occur in polyethylene intramedullary stems. Based on the results of these tests, the authors concluded that the polyethylene stems of the Vari-Axle prosthesis might fail over the long term. Nicolle (Ref. 179) evaluated 20 patients with Nicolle prostheses. The average postoperative time was 12 months. The range of joint motion was not reported. The author reported that the degree of ulnar drift (joint deformity) was improved by surgery and improved further with postoperative rehabilitation, but that from 12 months on a progressive ulnar drift was observed, the reason for which was not clear. Nicolle noted that a longer followup and additional patients are required before the reported results can be regarded as statistically significant.

Smith and Broudy reported that the various designs of finger joint metal/polymer constrained prostheses are undergoing clinical and laboratory trials (Ref. 177). Walker (Ref. 178) noted that the advantages of the metal/polymer designs need to be shown. Problems associated with other designs of this prosthesis were identified by several authors (Refs. 175, 177, and 178). Walker, et al. (Ref. 175), reported that the postoperative range of motion with the St. George design was often limited due to the ingress of fibrous tissue into the joint. Smith and Broudy (Ref. 177) reported that while satisfactory results had been obtained in 80 percent of the patients with the Steffee prosthesis, the active range of motion was limited to only 50 percent of normal and deformity recurred in some patients, prompting a revision of the prosthesis design. Walker (Ref. 178) commented on the design of the Schultz prosthesis, stating that it allows too must rotation and there is an inadequate bearing between the metal and plastic components.

FDA finds that finger joint metal/polymer constrained prostheses are implanted devices that are intended to be used in relieving disabling pain and in restoring or minimizing further loss of functional use of a finger joint. FDA believes these uses are of substantial importance in preventing impairment of human health. FDA believes that insufficient clinical experience exists to fully establish the persons for whose use these devices are intended and the proper conditions of use. The agency believes that the probable benefit to health from use of these devices does not compare favorably with the likelihood of injury or illness resulting from their use.

Because of the lack of adequate data to demonstrate the safety and effectiveness of these implanted devices, FDA believes that use of the finger joint metal/polymer constrained prosthesis presents an unreasonable risk of illness or injury. Because these devices are intended to be implanted in the human body, the Federal Food, Drug, and Cosmetic Act requires that they be classified into class III unless FDA determines that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of these devices. On the basis of available information, FDA cannot make this determination. FDA believes that insufficient information exists to support the conclusion that general controls will provide reasonable assurance of the safety and effectiveness of these devices. Therefore, FDA is proposing that these devices be classified into class III.

§ 888.3230; Docket No. 78N-3068; Finger joint polymer constrained prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of finger joint polymer constrained prostheses:

1. Identification: A finger joint polymer constrained prosthesis is an implemented device intended to replace a metacarpophalangeal or proximal interphalangeal (finger) joint. This generic type of device includes prosthesis that consist of a single flexible across-the-joint component made from either a silicone elastomer or a combination of polypropylene and polyester material. The flexible across-the-joint component may be covered with a silicone rubber sleeve. These prostheses are intended to be implanted with a polymethyl-methacrylate luting agent (bone cement).

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that finger joint polymer constrained prostheses be classified into class II because the design, material composition, and mechanical properties

of the device, such as its flexibility, rigitity, strength, and surface finish, should be controlled to prevent loss or reduction of joint function, adverse tissue reaction, or infection. The Panel believes that general controls alone will not provide sufficient control over these characteristics.

Although a finger joint polymer constrained prosthesis is an implanted device, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that the labeling for the device include information on the dimensions and kinematics of the device and its strength and wear characteristics.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Loss or reduction of joint function: Improper design of inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the Panel recommendation and is proposing that finger joint polymer constrained prostheses be classified into class II. FDA has sought additional data and information on these prostheses. Clinical results on three designs of finger joint polymer constrained prostheses were presented in the literature: the Calnan-Nicolle prosthesis, intended for use in the metacarpophalangeal (MCP) and proximal interphalangeal (PIP) joints of the fingers; the Niebauer prosthesis also intended for use in the MCP and PIP joints of the fingers; and the Swanson prosthesis intended for use in the MCP and PIP joints of the fingers and for the MCP joint of the thumb.

1. *Calnan-Nicolle Prosthesis.* This device has two components, an across-the-joint component having intramedullary stems and a flexible hinge made of polypropylene, and a silicone rubber sleeve which encapsulates the flexible hinge portion of the device (Ref. 181). Griffiths and Nicolle (Ref. 182) reported on the clinical results 8 to 37 months (average of 20 months) after implantation of the Calnan-Nicolle device in 112 MCP joints in 31 patients. Complete relief from pain was obtained in four (13 percent) patients. There was much improvement over preoperative pain status in 13 (42 percent), moderate pain relief in 10 (32 percent), and little pain relief in 4 (13 percent) patients. These authors reported that a deterioration in the performance of the prosthesis occurred in up to half of the patients between 1 and 2 years after insertion of the prosthesis; and that part of the deterioration in function was due directly to mechanical failure of the prosthesis. The range of joint motion had deteriorated over time in 33 of the 40 (82.5 percent) hands on which surgery was performed. Joint deformity was "corrected and held" in 10 of 31 hands (32 percent), was corrected initially but recurred in 14 of 31 (45 percent) hands and worsened in 7 of 31 (23 percent) hands. The silicone capsule (sleeve) had fractured in 31 of the 112 prostheses (28 percent). The polypropylene stems had fractured in five joints (5 percent). Nicolle (Ref. 179) noted that time and experience had shown that the polypropylene hinge of the Calnan-Nicolle prosthesis does not appear to be strong enough to fully withstand the compression and torsional stresses that may occur in the use of the hand.

2. *Niebauer Prosthesis.* This device consists of a single, flexible, across-the-joint component. The intramedullary stems and the flexible hinge portion of the device are made of silicone to allow tissue penetration and fixation of the stems. Beckenbaugh, et al. (Ref. 184), reported clinical results 12 to 65 months (average 32 months) after implantation in the MCP joints of 68 Niebauer prostheses and found a fracture rate of the device of 38.2 percent (26 devices), recurrence of clinical deformity in 44.1 percent (30 devices) and recurrence of pain in 2 percent. Goldner, et al. (Ref. 185), reported a fracture rate of 29.7 percent in 37 prostheses implanted for 6.5 years and a 17.5 percent fracture rate in 143 prostheses implanted 4 to 6 years. These authors believe that the silicone-polyester material used in the device may absorb lipids and become brittle, and that eventual fracture of the prosthesis is a possibility, but that fracture does not preclude a good functional result. Goldner, et al. (Ref. 186), evaluated 103 patients over a 4-year period. Pain was relieved or greatly diminished postoperatively in all but 8 of the 103 patients. The average active range of motion in these patients was 51 degrees. The range of motion was noted to increase up to about 1 year postoperatively; and then thought to decrease slightly, possibly due to enlarged bony outgrowths from the surface of the bone and impingement of peripheral bone on the hinge of the device. In two (2 percent) of patients, the device had fractured, which was accompanied by deformity and a moderate amount of pain.

Hagert (Ref. 187) conducted x-ray examinations on 41 joints with Niebauer implants. This author reprted that of the 41 prostheses studied, 26 (63.4 percent) were found to be damaged (i.e., cracked within the implant mid-section, fragmented at the midsection, or fractured at the hinge), 1 to 36 months postoperatively. This author believed that the Niebauer implant might be too weak to withstand forces in the MCP joints, and that a possible contributing factor was the use of materials (polyester fiber and silicone rubber) with differing elasticity. This author noted that the Niebauer implant was reported to have withstood 100 million flexions during mechanical tests bending it around a fixed axis, but not exposing it simultaneously to shearing type forces which are present in the MCP joint. These shearing forces were reportedly most probably responsible for the deformation of the implant and the subsequent damage observed. Niebauer, et al. (Ref. 188), reported that destruction of the bone around the hinge of the device had occurred in a few cases and that this atrophy may be the result of pressure from the prosthesis. In an evaluation by x-ray of the 41 Niebauer prostheses, Hagert (Ref. 187) observed bone resorption in 23 of the 41 joints (56 percent). The cortex of the one was penetrated in 13 (32 percent) of these joints. It was reported that the observed erosion of the bone is most likely caused by motion of the intramedullary stems within the medullary cavity, and is exaggerated by the rough polyester surface of the device.

3. *Swanson Prosthesis.* This device is made entirely of silicone rubber and is designed to act as an internal mold, maintaining joint alignment, becoming encapsulated and stabilized by fibrous tissue, and gliding or moving within the medullary cavity rather than being fixed to the bone (Ref. 189). A number of reports (Refs. 184, and 189 through 195) were found describing the use of the Swanson prostheses in the MCP joints

of the fingers, but few reports (Refs. 196 through 199) were available describing the use of this device in the MCP joint of the thumb, or the PIP joints of the fingers. In 1976, it was reported that a new "high performance" silicone elastomer material had been developed for use in the Swanson prosthesis. With the exception of one report (Ref. 198), the available clinical data was obtained using prostheses made from the "conventional" silicone elastomer. Fracture of implants made of the "conventional" silicone elastomer appears to be the most frequently reported failure. Beckenbaugh, et al. (Ref. 184), reported that of 186 Swanson prostheses implanted in the MCP joint for an average of 32 months (range 12 months to 65 months) 26.3 percent (49) had fractured. Hagert, et al. (Ref. 191), reported that of 104 Swanson implants evaluated, 25 percent (26) had failed, either by cracking or fragmenting and fracturing within the followup period of 1.5 to 5 years. Mannerfelt, et al. (Ref. 192), reported a fracture rate of 2.8 percent in 144 joints evaluated 1.5 to 3.5 years (average 2.5 years) after implantation. Ferlic, et al. (Ref. 193), reported a 9 months (average 3.2 years) after implantation. Swanson (Ref. 189) reported the lowest rate of fracture, 0.88 percent, in a field clinic series involving over 3,000 implants with a followup of from 6 to 30 months.

The effects of fracture of the device on the clinical results were evaluated by several authors. Aptekar, et al. (Ref. 194), described the occurrence of detritic synovitis (inflammation of the synovial tissue) due to shards of silicone rubber found in relation to a broken prosthesis. Beckenbaugh, et al (Ref. 184), noted that recurrence of deformity was associated with implant fracture, i.e., ulnar drift, in 14 percent; weakness or instability in 21 percent; hyperextension in 11 percent; and some clinical deformities in 43 percent; but that while the recurrence of deformity implied that soft tissue balance was not present after the implant fractured, it was not clear whether the imbalance caused the fracture or developed because of it.

Hagert (Ref. 195) believed that the increased displacement (i.e., ulnar deviation) noted in some joints with fractured implants may indicate insufficiency of the fibrous capsule surrounding the implant to restrain the forces occurring at the MCP joint. This pressure, combined with movement of the implant within the medullary canal was reportedly found to cause a moderately progressive bone resorption throughout the followup period in all of the 36 joints examined. Resorption was observed around the midsection of the prosthesis where the implant was in close contact with bone and around the intramedullary stems of the device. Erosion of bone around the midsection of the device led to various degrees of migration of the device in 28 out of 36 (78 percent) of the joints examined. The author found that decreased joint flexion was observed due either to the distal migration of the implant or a growing volar bony spur in 13 out of the 39 (33 percent) joints examined. He concluded that the design of the device may be insufficient to fully restrain the volarly and proximally directed forces in the MCP joint and the serious decrease of flexion. Hagert, et al. (Ref. 191), reported that while it is generally accepted that silicone rubber absorbs lipids and other substances, the effects on material changes and degradation is not adequately known. Weightman, et al. (Ref. 196), noted that lipid absorption could contribute to mechanical failure of the prostheses, as chemical deterioration is known to be a prime initiator of fatigue failures of polymers. Other clinical results have been reported in the literature (Refs. 189, 192, 196, and 198) on the use of this prosthesis in large numbers of patients. These results were very similar to those summarized previously.

Although finger joint polymer constrained prostheses are implanted devices, FDA has determined that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of these devices. In addition, FDA had identified and assessed the major risks to health associated with the use of these devices. FDA believes that the major risks, i.e., fracture, loosening, and adverse tissue reaction, are related to biological responses of the human body to the presence of the device, the device design, and the underlying joint pathology. Clinical experience with these devices has established the persons for whose use the devices are intented and the proper conditions of use. FDA has determined that the probable benefit to health from proper use of these devices outweights any likelihood of injury of illness resulting from their use. FDA further believes that informative labeling and compliance with general controls may greatly reduce the risks to health associated with the use of these devices. The agency believes that a performance standard is necessary because general controls alone are insufficient to minimize the risks to health presented by these devices.

§ 888.3300; Docket No. 78N–3070; Hip joint metal constrained prosthesis.

The Orthopedic Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of hip joint metal constrained prostheses:

1. Identification: A hip joint metal constrained prosthesis is an implanted device intended to replace a hip joint. The device prevents dislocation in more than one anatomic plane and has components that are linked together. This generic type of device includes prostheses that have a femoral component made of alloys, such as cobalt-chromium-molybdenum, and a acetabular component made of an alloy with an ultra-high molecular weight polyethylene insert, and is limited to those devices intended for implantation with a polymethyl-methacrylate luting agent (bone cement).

2. Recommended classification: Class III. The Panel recommends that premarket approval of this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that hip joint metal constrained prostheses be classified into class III because the device is implanted and is intended to be used in relieving disabling pain and in restoring or minimizing further loss of functional use of a joint or limb. The Panel believes these uses are of substantial importance in preventing impairment of human health.

The Panel believes that general controls alone will not provide sufficient control over these characteristics. The Panel also believes that it is not possible to establish an adequate performance standard for the device. There is a lack of safety and effectiveness data to demonstrate the satisfactory performance of the device. The Panel has found that insufficient information exists to support the conclusion that general controls of performance standards will be adequate to provide reasonable assurance of the safety and effectiveness of the device. Therefore, the device must be subject to premarket approval to assure its safety and effectiveness.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: The Panel identified the following risks to health: (a) Loss or reduction of joint function: Improper

design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device, or loosening of the device in the surgical cavity. (d) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in and adverse tissue reaction due to a dissolution or wearing away from the surfaces of the device and the release of material from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the Panel recommendation and is proposing that hip joint metal constrained prostheses be classified into class III. The agency has obtained additional data and information describing the use of hip joint metal constrained prostheses. Sivash (Ref. 200) reported on implantation in 164 patients; followup time was 1 to 9 years. Breakage of the prosthesis was reported in 13 (8 percent) of the patients.

FDA finds that these implanted devices are intended to be used in relieving disabling pain and in restoring or minimizing further loss of functional use of a joint or limb. FDA believes these uses are of substantial importance in preventing impairment of human health. FDA also believes that insufficient clinical experience exists to fully establish the persons for whose use the devices are intended and the proper conditions of use. The agency believes that the probable benefit to health from use of these devices does not compare favorably with the likelihood of injury or illness resulting from their use.

Because of the lack of adequate data to demonstrate the safety and effectiveness of these implanted devices, FDA believes that use of the hip joint metal constrained prosthesis presents an unreasonable risk of illness or injury. Because these devices are intended to be implanted in the human body, the Federal Food, Drug, and Cosmetic Act requires that they can be classified into class III unless FDA determines that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of these devices. On the basis of available information, FDA cannot make this determination. Moreover, FDA believes that insufficient information exists to support the conclusion that general controls or performance standards will provide reasonable assurance of the safety and effectiveness of these devices. Therefore, FDA is proposing that these devices be classified into class III.

§ 888.3310; Docket No. 78N–3071; Hip joint metal/polymer constrained prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of hip joint metal/polymer constrained prostheses:

1. Identification: A hip joint metal/polymer constrained prosthesis is an implanted device intended to replace a hip joint. The device prevents dislocation in more than one anatomic plane and has components that are linked together. This generic type of device includes prostheses that have a femoral component made of alloys, such as cobalt-chromium-molybdenum, and an acetabular component made of ultra-high molecular weight polyethylene. This generic type of device is limited to those devices intended for implantation with a polymethylmethacrylate luting agent (bone cement).

2. Recommended classification: Class III. The Panel recommends that premarket approval of this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that hip joint metal/polymer constrained prostheses be classified into class III because these devices are implanted and are intended to be used in relieving disabling pain and in restoring or minimizing further loss of functional use of a joint or limb. The Panel believes these uses are of substantial importance in preventing impairment of human health.

The Panel believes that general controls alone will not provide sufficient control over these characteristics. The Panel also believes that it is not possible to establish an adequate performance standard for the device. There is a lack of safety and effectiveness data to demonstrate the satisfactory performance of the device. The Panel has found that insufficient information exists to support the conclusion that general controls or performance standards will be adequate to provide reasonable assurance of the safety and effectiveness of the device. Therefore, the device must be subject to premarket approval to assure its safety and effectiveness.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Loss or reduction of joint function: Improper design of inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the Panel recommendation and is proposing that hip joint metal/polymer constrained prostheses be classified into class III. FDA finds that these implanted devices are intended to be used in relieving disabling pain and in restoring or minimizing further loss of functional use of a joint or limb. FDA believes these uses are of substantial importance in preventing impairment of human health. FDA believes that insufficient clinical experience exists to fully establish the persons for whose use the devices are intended and the proper conditions of use. The agency believes that the probable benefit to health from use of the devices does not compare favorably with the likelihood of injury or illness resulting from their use.

Because of the lack of adequate data to demonstrate the safety and effectiveness of these implanted devices, FDA believes that use of hip joint metal/polymer constrained prostheses presents an unreasonable risk of illiness or injury. Because these devices are intended to be implanted in the human body, the Federal Food, Drug, and Cosmetic Act requires that they be classified into class III unless FDA determines that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of these devices. On the basis of available information, FDA cannot make that determination. Moreover, the agency believes that insufficient information exists to support the conclusion that general controls or performance standards will provide reasonable assurance of the safety and effectiveness of these devices. Therefore, FDA is proposing that these devices be classified into class III.

§ 888.3320; Docket No. 78N–3072; Hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of a hip joint metal/metal semi-constrained, with a cemented acetabular component, prostheses.

1. Identification: A hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis is an implanted two-part device intended to replace a hip joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that consist of a femoral and an acetabular component, both made of alloys such as cobalt-chromium-molybdenum. This generic type of device is limited to those devices intended for implantation with a polymethylmethacrylate luting agent (bone cement).

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that hip joint metal/metal semi-constrained, with a cemented acetabular component, prostheses be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, regidity, strength, and surface finish, should be controlled to prevent loss or reduction of joint function, adverse tissue reaction, or infection. The Panel believes that general controls alone will not provide sufficient control over these characteristics.

Although these are implanted devices, the Panel believes that premarket approval is not necessary becuase sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Panel also recommends that the labeling for the device include information on the dimensions and kinematics of the device and its strength and wear characteristics.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and their knowledge of the medical literature. Wilson, et al. (Ref. 201), reported on 100 McKee-Farrar total hip replacements performed in 86 patients. Substantial improvements were observed in walking function and mobility of hips for periods of 2 to 4 years following implantation. Wilson also noted that patients have been so satisfied with the devices, that continued use and further development of this type of operation is warranted. Prosthesis loosening in 20 percent of patients was the main complication.

Bentley, et al. (Ref. 202), performed hip replacements using 101 McKee-Farrar prostheses and 128 Charnley prostheses, both of which have the two components of the device fixed in place with bone cement. Total pain relief was obtained in 83 percent of the patients with the McKee-Farrar hip replacement compared with 96 percent of the patients with the Charnley hip replacement. Range of hip movement of more than 100 degrees was obtained by 88 percent of the patients with the McKee-Farrar hip replacement and 89 percent of the patients with the Charnley prosthesis. However, the Charnley prosthesis allowed an average of over 40 degrees more total range. During followup of patients from 1 to 4 years, complications included three deep wound infections and three cases of loosening of the femoral component of the McKee-Farrar compared with none with the Charnley. Bentley determined that the Charnley prosthesis gave superior results to the McKee-Farrar.

Using radiology, Mendes (Ref. 203) evaluated 100 hips replaced with cemented McKee-Farrar prostheses. A 12 percent failure rate was reported after 2 to 4 years of followup. Also reported was a 4 percent incidence of various radiologic signs which were associated with a high incidence of failure, such as new periosteal bone formation at the level of the prosthetic stem; progressive resorption of the neck stump; line of bone density surrounding the cemented implant; extensive heterotopic ossification; infection; and incidence of sterile (i.e., not associated with an infection) loosening.

5. Risks to health: (a) Loss or reduction of joint function: Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in the loss or reduction of joint function due to excessive wear, fracture, deformation of the device components, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility, may result in an adverse tissue reaction due to dissolution or wearing away of the articulating surfaces of the device and the release of materials from the device to the surrounding tissues and the systemic circulation. (c) Infection: The presense of the prosthesis within the body may lead to an increased risk of infection.

FDA disagrees with the Panel recommendation and is proposing that hip joint metal/metal semi-constrained, with a cemented acetabular component, prostheses be classified into class III. The agency believes that a performance standard is necesary for these devices because general controls alone are sufficient to minimize the risks to health presented by these devices.

FDA finds that hip joint metal/metal semi-constrained, with a cemented acetabular component, prostheses are implanted devices that are intended to be used in relieving disabling pain and in restoring or minimizing further loss of functional use of a joint or limb. FDA believes these uses are of substantial importance in preventing impairment of human health. FDA believes that insufficient clinical experience exists to fully establish the persons for whose use the devices are intended and the proper conditions of use. The agency believes that the probable benefit to health from use of the devices does not compare favorably with the likelihood of injury or illness resulting from their use.

Because of the lack of adequate data to demonstrate the safety and effectiveness of these implanted devices, FDA believes that use of the hip joint metal/metal semi-constrained, with a cemented acetabular component, prostheses presents an unreasonable risk of illness or injury. Because these devices are intended to be implanted in the human body, the Federal Food, Drug, and Cosmetic Act requires that they be classified into class III unless FDA determines that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of these devices. On the basis of available information, FDA cannot make this determination. Moreover, FDA believes that insufficient information exists to support the conclusion that general controls or performance standards will provide reasonable assurance of the safety and effectiveness of these devices. Therefore, FDA is proposing that these devices be classified into class III.

§ 888.3330; Docket No. 78N–3073; Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee,

made the following recommendation regarding the classification of hip joint metal/metal semi-constrained, with an uncemented acetabular component, prostheses:

1. Identification: A hip joint metal/metal semi-constrained, with an uncemented acetabular component, proshtesis is an implanted two-part device intended to replace a hip joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that consist of a femoral and an acetabular component, both made of alloys, such as cobalt-chromium-molybdenum. The femoral component is intended to be fixed with bone cement. The acetabular component is intended to be used without a polymethylmethacrylate luting agent (bone cement).

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that hip joint metal/metal semi-constrained, with an uncemented acetabular component, prostheses be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent loss or reduction of joint function, adverse tissue reaction, or infection. The Panel believes that general controls alone will not provide sufficient control over these characteristics.

Although these are implanted devices, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectivness of the device. The Panel also recommends that the labeling for the device include information on the dimensions and kinematics of the device and its strength and wear characteristics.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and their review of the medical literature.

5. Risks to health: (a) Loss or reduction of joint function: Improper design of inadequate mechanical properties of the device, such as its lack of strenth and resistance to wear, may result in the loss or reduction of joint function due to excessive wear, fracture, deformation of the device's components, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility or resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away of the surfaces of the device and the release of materials from the device to the surrounding tissues and the systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA disagrees with the Panel recommendation and is proposing that hip joint metal/metal semi-constrained, with an uncemented acetabular component, prostheses be classified into class III. FDA has obtained additional information regarding these devices. Ring (Ref. 204) has implemented about 1,000 of the devices using an uncemented acetabular component during an 8-year period with 942 devices available for followup. The early implants (169) had a followup time ranging from 5 to 8 years. In this group, 45 percent had excellent results, 29 percent had good results, 10 percent fair results, and 16 percent poor results. The second group (535) had a followup time of 1 to 5 years with excellent results being obtained in 69 percent of the cases, 21 percent good, 6 percent fair, and 4 percent poor. The remaining 238 cases were the most recent with followup time of less than 1 year. In the 942 cases reviewed, there were 35 revisions performed due to loosening. In the initial series, the revision rate was 14 percent, whereas the revision rate for the second series was only 2 percent. The third series had not had any revisions. Lindholm (Ref. 205) used the Ring prostheses with an uncemented acetabular component and reported 20 percent of the patients had little or no improvement after the device was implanted.

The agency has reviewed the pertinent engineering and clinical literature and has determined that insufficient information exists to establish a performance standard for hip joint metal/metal semi-constrained, with an uncemented acetabular component, prostheses. FDA has found a lack of correlation(s) between pertinent preclinical mechanical tests (i.e., wear rates, fracture resistance, etc.) of this device and clinical findings. The agency notes that there is little information on the devices with an uncemented acetabular component available from investigators other than reports from the inventor/developer of the original design of this device (Ring). FDA believes that the initial clinical experiences of investigator Ring have not been shown to be representative of the anticipated general clinical experience with these devices, and that the available data and information are not sufficient to assure the safety and effectiveness of the device with an uncemented acetabular component.

FDA finds that hip joint metal/metal semi-constrained, with an uncemented acetabular component, prostheses are implanted devices that are intended to be used in relieving disabling pain and in restoring or minimizing further loss of functional use of a joint or limb. FDA believes these uses are of a substantial importance in preventing impairment of human health.

FDA believes that insufficient clinical experience exists to fully establish the persons for whose use the devices are intended and the proper conditions of use. The agency believes that the probable benefit to health from use of these devices does not compare favorably with the likelihood of injury or illness resulting from their use.

Because of the lack of adequate data to demonstrate the safety and effectiveness of these implanted devices, FDA believes that use of the hip joint metal/metal semi-constrained, with an uncemented acetabular component, prostheses presents an unreasonable risk of illness or injury. Because these devices are intended to be implanted in the human body, the Federal Food, Drug, and Cosmetic Act requires that they be classified into class III unless FDA determines that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of these devices. On the basis of available information, FDA cannot make this determination. Moreover, FDA believes that insufficient information exists to support the conclusion that general controls or performance standards will provide reasonable assurance of the safety and effectiveness of these devices. Therefore, FDA is proposing that these devices be classified into class III.

§ 888.3340; Docket No. 78N–3074; Hip joint metal/composite semi-constrained prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of hip joint metal/composite semi-constrained prostheses:

1. Identification: A hip joint metal/composite semi-constrained prosthesis is an implanted two-part device

intended to replace a hip joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that consist of a femoral component made of alloys such as cobalt-chromium-molybdenum, and an acetabular component made of carbon fiber reinforced ultra-high molecular weight polyethylene. Both components are intended to be implanted with a polymethylmethacrylate luting agent (bone cement).

2. Recommended classification: The Panel recommends that hip joint metal/composite semi-constrained prostheses be classified into class III. The Panel recommends that premarket approval of this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that hip joint metal/composite semi-constrained prostheses be classified into class III because these devices are implanted and are intended to be used in relieving disabling pain and in restoring or minimizing further loss of functional use of a joint or limb. The Panel believes these uses are of substantial importance in preventing impairment of human health.

The Panel believes that general controls alone will not provide sufficient control over these characteristics. The Panel also believes that it is not possible to establish an adequate performance standard for the device. There is a lack of safety and effectiveness data to demonstrate the satisfactory performance of the device. The Panel has found that insufficient information exists to support the conclusion that general controls or performance standards will be adequate to provide reasonable assurance of the safety and effectiveness of the device. Therefore, the device must be subject to premarket approval to assure its safety and effectiveness.

The Panel also recommends that the labeling for the device include information on the dimensions and kinematics of the device and its strength and wear characteristics.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel member's clinical experience with similar devices and a series of presentations to the Panel (Refs. 206 and 207). Dr. Robert Johnson (Rensselaer Polytechnical Institute) compared the physical properties of the carbon fiber reinforced ultra-high molecular weight polyethylene composite material with the physical properties of conventional polyethylene material. He found that the reinforced material was superior to the conventional polyethylene material regarding compressive deformation, flexural stress, compressive creep, modulus of elasticity, and fatigue. Dr. Johnson also noted that the technology of composite materials such as carbon fiber reinforced polyethylene is in its infancy with regard to engineering in general.

Dr. Jack Lemons (University of Alabama) presented the results of toxicity tests on the carbon fiber reinforced material. The results of in vitro tests showed the material, and extracts from the material, to be noncytotoxic to monolayers of cells and nonhemolytic to rabbit blood. The results of in vivo tests indicated that the material was nonirritating, nontoxic, and did not produce adverse effects after up to 15 months of implantation. The results of subacute toxicity tests indicated that intracutaneous extracts of the material were nonirritating when injected into rabbits; the systemic injections produced no adverse effects in mice; and that when the material was implanted along the backs of rabbits, it was nontoxic when it was evaluated at 6 and 12 weeks. The result of the chronic toxicity tests indicated that polyethylene material reinforced with carbon fibers was noncytotoxic, nontoxic, nonirritating, and produced no adverse effects when it was injected into the knee spaces of four rabbits and evaluated 15 months later. Dr. Lemons determined that these tests show that the carbon fiber reinforced material is biocompatible.

Dr. Joel Schilling (Portland, OR) presented a report on the histological examination of pieces of tissue removed from the patient who had received an ultra-high molecular weight polyethylene prosthesis in one ankle and a carbon fiber reinforced ultra-high molecular weight polyethylene composite prosthesis in the other. Dr. Schilling found that there was minimal tissue reaction to either type of material and that there seemed to be very little reaction to the carbon fragments.

Dr. Robert Volz (University of Arizona) presented a comparison of the effect of temperature on the conventional ultra-high molecular weight polyethylene and on the carbon fiber reinforced material. Dr. Volz concluded that the carbon fiber reinforced material offered considerable improvement in its resistance to deformation at body temperatures (i.e., 37° C) and at 96° C, the temperature reached during polymerization of methylmethacrylate cement.

At the July Panel meeting (Ref. 207), Robert Fuson, M.D. (Zimmer-USA), summarized the clinical experience with prostheses made from the carbon fiber reinforced material. A total of 86 acetabular components for total hip prostheses, 18 tibial components for total knees, and 23 tibial components for total ankles have been implanted. Of these, 65 hip, 18 knee, and 22 ankle components have been implanted for more than 6 months. Only 61 hip components, 11 knee components, and 12 ankle components have been implanted for over 1 year. Only five implantations (ankle) had been clinically followed for 2 years. No adverse reactions related to these prostheses were reported.

5. Risks to health: (a) Loss or reduction of joint function: Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss of joint function due to excessive wear, fracture, deformation of the device's components, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility or resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away of the articulating surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the Panel recommendation and is proposing that hip joint metal/composite semi-constrained prostheses be classified into class III. FDA finds that these implanted devices are intended to be used in relieving disabling pain and in restoring or minimizing further loss of functional use of a joint or limb. FDA believes these uses are of substantial importance in preventing impairment of human health. FDA believes insufficient clinical experience exists to fully establish the persons for whose use the devices are intended and the proper conditions of use. The agency believes that the probable benefit to health from use of the devices does not compare favorably with the likelihood of illness or injury resulting from their use.

Because of the lack of adequate data to demonstrate the safety and effectiveness of these implanted devices, FDA believes that use of hip joint metal/composite semi-constrained prostheses presents an unreasonable risk of illness or injury. Because these devices are intended to be implanted in the human body, the Federal Food, Drug,

and Cosmetic Act requires that they be classified into class III unless FDA determines that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of these devices. On the basis of available information, FDA cannot make this determination. Moreover, the agency believes that insufficient information exists to support the conclusion that general controls or performance standards will provide reasonable assurance of the safety and effectiveness of these devices. Therefore, FDA is proposing that these devices be classified into class III.

§ 888.3350; Docket No. 78N–3075; Hip joint metal/polymer semi-constrained prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of hip joint metal/polymer semi-constrained prostheses:

1. Identification: A hip joint metal/polymer semi-constrained prosthesis is an implanted device intended to replace a hip joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that have a femoral component made of alloys, such as cobalt-chromium-molybdenum, and an acetabular resurfacing component made of ultra-high molecular weight polyethylene, and is limited to those devices intended for implantation with a polymethylmethacrylate luting agent (bone cement).

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that hip joint metal/polymer semi-constrained prostheses be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent loss or reduction of joint function, adverse tissue reaction, or infection. The Panel believes that general controls alone will not provide sufficient control over these characteristics.

Although hip joint metal/polymer semi-constrained prostheses are implanted devices, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of these devices. The Panel recommends that the labeling for the device include information on the dimensions and kinematics of the device and its strength and wear characteristics.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Loss or reduction of joint function: Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the Panel recommendation and is proposing that hip joint metal/polymer semi-constrained prostheses be classified into class II. FDA has obtained additional data and information on the use of hip joint metal/polymer semi-contsrained prostheses. The following device-related risks to health were either identified by the Panel or reported in the literature: (a) Device loosening, (b) calcar resorption, (c) femoral component fracture, (d) excessive acetabular component wear, and (e) adverse tissue reaction to the wear debris produced by the device.

(a) *Device loosening:* Device loosening has been reported as a complication that results in pain and inability to walk (Ref. 208). FDA notes that the etiology of this complication is not known. Several postulated causes are: (1) sepsis; (2) cancellous bone fatigue; (3) prosthetic failure due to the device design; (4) bone resorption; (5) concentration of stresses due to the varying modulus of elasticity of bone, cement, and prosthesis; (6) granulomatous reaction to wear particles; and (7) bone necrosis and tissue reactions caused by thermal effects of bone cement. Reports in the literature indicate that aseptic loosening of cemented acetabular and femoral components occurs in a significant number of cases (Refs. 209 and 210), and that the rate of loosening may increase over time (Refs. 211 and 212). In a 1977 review of the experience with total hip prostheses, Wilson, et al. (Ref. 213), concluded that further research was needed in preventing the breakdown of the bone/bone cement interface.

A number of writers have discussed the association between device loosening and the presence of a radiolucent line observed as a demarcation between the bone cement that is holding the prosthetic component in place and the underlying supporting bone. Several authors believe that radiolucent lines observed at the bone/bone cement interface do not always signify looseness or implant failure (Refs. 214 through 217). Some writers, however, such as Desemet, et al. (Ref. 215), believe that while radiolucent lines at the edge of the bone cement in the femur are not necessarily associated with clincial evidence of loosening (e.g., severe pain on walking), they do indicate a lack of firm bonding which may predispose the patient to loosening at a later date. Other authors (Refs. 218 and 219) suggest that the progressive development of a radiological separation of the convex curve (lateral border) of the prosthesis from the cement is the first sign of femoral component loosening.

A number of authors (Refs. 220, 221, and 222) identified resorption of bone in the region of the calcar at the proximal end of the femur as contributing factor in device loosening. Simon, et al. (Ref. 223), reported that fatigue of the cancellous bone in the acetabulum is a possible explanation for device lossening. Still other investigators (Refs. 224 and 225) believe that eventual loosening of the prosthesis is due to a foreign body reaction to particles of polyethylene material that leads to replacement by soft tissue of bone at the bone/bone cement interface.

(b) *Calcar resorption:* Resorption of bone in the region of the calcar has been reported (Refs. 222, 226, and 227) as a probable contributing cause of cement failure, prosthesis loosening, or fracture of the femoral component of hip prostheses. The etiology of this complication is not known, but several possible causes have been discussed in the medical literature. Oh and Harris (Ref. 222), for example, reported that calcar resorption may be due to disuse atrophy of the bone in this region, causing increased cement failure, prosthesis loosening, and stem fracture. These authors also noted that the design of the prosthesis affects the transfer of forces to the bone in the calcar region and could contribute to the resorption of the calcar femorale observed after total

hip replacement. Marmor (Ref. 218) described 10 cases of femoral component loosening occurring in patients who were overweight. This author suggested that collapse of the cancellous bone in the region of the calcar and femoral component loosening may be a result of the stress of excessive body weight on the femoral component. Harris, et al. (Ref. 228), described four cases of extensive bone resorption in the region of the calcar occurring 33 months to approximately 5 years postoperatively. These authors noted that while the cause of bone resorption in these cases is not known, they believe that the lysis was secondary to loosening and fragmentation of the bone cement. Charnley and Cupic (Ref. 230) reported that, in some cases of calcar resorption, there may be evidence of harmful tissue reaction to particles of polyethylene worn away from the hip socket. In a subsequent publication, Bocco, Langan, and Charnley (Ref. 220) reported that while the role that wear particles of polyethylene play in destructive changes in the calcar are unknown, there is no doubt that these particles are frequently found during histological examinations of the calcar region.

(c) *Femoral component fracture:* Fracture (fatigue failure) of the femoral component of a hip prosthesis is believed to be a product of repetitive cyclic load (such as occurs during walking), usually initiated at a point of high tensile stress (such as the lateral surface of the stem). Cracks form in the material and grow slowly across the stem until the reamining metal cannot support the body weight and fractures completely (Ref. 227). A number of device-related factors which may predispose an implant to fracture were identified in the literature, including: (1) the use of materials with inadequate mechanical properties (Refs. 227, 231, 232, and 233); (2) inadequate quality controls in manufacture and metallurgical defects in the device (Refs. 227, 233, 234, 235, 236, and 269); (3) device design (Refs. 227 and 236); and (4) mechanical loosening of the femoral component following loss of cement support in the calcar region (Refs. 222, 226, 227, 238, and 270). A number of authors (Refs. 231, 234, 237, and 238) have reported the incidence of femoral stem fracture in their patients to range from 0.23 percent to 11 percent in the first 5 years. Some authors (Refs. 236 and 239) believe that the incidence of fracture increases with longer postoperative followup.

The role of calcar resorption in femoral stem failure was discussed by several authors. Andriacchi, et al. (Ref. 226), found that the loss of proximal stem support at the region of the calcar femorale will result in fatigue failure of the device component. Markolf and Amstutz (Ref. 236) report that a minimal degree of loosening may result in a marked increase in tensile stress imposed on the device. Charnley (Ref. 237) believed that erosion of the bone in the region of the medial femoral neck (i.e., the calcar femorale) leading to defective cement support of the device in this area was possibly the predominant factor leading to fracture of the prosthesis. Marmor (Ref. 218) described the following sequence of events in the patients whose prostheses eventually fractured: bony resorption in the region of the medial femoral neck, followed by fracture of the bone cement, medial displacement of the femoral implant components and, ultimately, bending or breakage of the device.

(d) *Acetabular component wear:* An increased wear rate of the acetabular component of the device is believed to be due to the presence of trapped particles, such as polyethylene wear debris, bone, or bone cement (Refs. 225, 240, 241, and 242). Several aspects of prosthesis design (i.e., the size of the head of the femoral prosthesis) and quality control of the components (i.e., properties of the polyethylene material, and the surface finish of the metallic component) were noted to affect the rate of polyethylene wear (Refs. 241 and 243). Clarke, et al. (Ref. 244), and other authors (Refs. 240, 245, and 246) have examined acetabular components that had been removed from patients. They believe that the in vivo wear rate could be as low as 0.01 millimeter per year but it can increase to as high as 0.5 millimeters per year if bone cement particles are present and induce wear of these components. Dowling, et al. (Ref. 240), believe that laboratory tests alone are not sufficient to predict the long-term wear and deformation of the polyethylene component in the human body. They have found that the device wear rates are higher in the body than laboratory tests predict and believe that this increase is due to the presence of joint fluid and the temperature of the hip joint and may lead to stress corrosion and creep of the polyethylene material.

(e) *Adverse response to wear debris:* A number of authors discussed the possible long-term effects of wear debris. Winter (Ref. 247) noted that the material characteristics responsible for biological reactivity of foreign bodies are size, shape, chemical composition, surface properties, and the number of particles present. While the physical properties of the implant inserted by the surgeon can be specified (i.e., standards on material composition), inevitable wear and corrosion produce undefined soluble and insoluble materials whose potential effects are largely unknown. Bullough (Ref. 248) commented that the physical size of the particles may be very important. This author states that medical experience with particulate wear debris from joint implants is relatively limited compared to experience with other implants such as bone nails and bone plates. Other investigators (Refs. 210 and 224) believe that a foreign body reaction to particles of polyethylene material will lead to replacement by soft tissue of bone at the bone-cement interface and eventually to loosening of the prosthesis.

Summary of clinical results: Clinical results of less than 5 years were available for the following designs of the hip joint metal/polymer semi-constrained prosthesis (Refs. 249 through 268); Charnley-Muller, Aufranc-Turner, Harris, Minneapolis, Leinbach, St. George, Bechtol, Brunswick, and the Trapezoidal-28. Clinical results from use of the devices for 5 or more years were available for only two of these designs, the St. George and the Charnley (Refs. 229, 230, 261, 272, 273, and 274).

Buchholz and Noack (Ref. 261) reported results following implantation of the St. George design prosthesis. They reported followup for over 5 years for 271 cases, followup between 2 to 5 years for 1,731 cases, and less than 2 years followup for 1,203 cases. The average age of the patients at the time of surgery was 61 years (range 17 to 95 years). These authors found that pain was reduced and gait distance and mobility of patients had improved more than 100 percent when compared to the preoperative conditions. The following complications and complication rates were found: aseptic loosening—1.09 percent; fracture of the prosthesis—0.06 percent; transitory nerve damage—1.52 percent; permanent nerve damage—0.41 percent; dislocation of the device components—1.15 percent; periarticular calcification and ossification—7.64 percent; deep infection—2.3 percent; and pulmonary embolism—0.4 percent. There were 248 deaths (7.4 percent). The cause of 13 (0.4 percent) of these deaths was identified and reported to be due to pulmonary embolism.

Results of use of the Charnley prosthesis for over 5 years were reported by Nicholson (Ref. 229) and by Charnley and his coworkers (Refs. 230, 272, 273, and 274). Nicholson reported on the implantation of 900 Charnley prostheses with followup ranging from 1

to 6 years. Results of use for 5 or more years were reported on 30 of these 900 device implantations. The author calculated the incidence of mechanical problems occurring in prostheses which had been implanted for 3 to 4 years. Thirteen (8.5 percent) of the devices (seven femoral components and six acetabular components) had loosened, and the femoral component of one device had fractured. The author also reviewed the radiological results in 250 consecutive cases. The clinical followup times of these cases were not given. Resorption of 5 to 8 millimeters of bone at the proximal end of the femur (calcar femorale) was observed in 57 hips (22.8 percent). The femoral component was observed to have settled in nine (3.6 percent) of the cases.

Charnley and Cupic (Ref. 230) reported on the implantation of 106 Charnley prostheses with a clinical followup of 9 to 10 years. The average age of the patients in this series was reported to be 65 at the time of the operation. Pain, function, and mobility were evaluated in these patients. Eighty-eight hips (83 percent) were rated free of pain and eight others (7.5 percent) were reated as having slight or transient pain. Function was evaluated in 53 hips, and was rated as normal in 45 hips (85 percent), taking into account the advanced-age of a number of patients. Mobility was assessed in 75 hips. Fourteen hips (18.6 percent) were rated normal and 45 (60 percent) as having a total range of motion of between 161 and 120 degrees. The total failure rate was reported as 9.6 percent, three failures (3.0 percent) due to mechanical lossening of the device components, and eight failures (6.6 percent) due to infection.

Griffith, Seidenstein, el al. (Ref. 274), reviewed the long-term results of the Charnley prosthesis used in 461 patients, 86 of whom had hip prostheses implanted in both hips for a total of 547 hip replacement operations. Pain, function, and mobility were evaluated in these patients and of the 547 operated hips, 472 (86 percent) were free of pain; 61 (11 percent) had slight or intermittent pain; 11 (2 percent) had pain; and 3 (0.5 percent) had severe pain. Function and mobility were evaluated in all cases and the operation was reported to be 80 to 85 percent successful. The following complications and complication rates were reported: Three cases of fracture of the femoral component; seven cases of femoral component loosening; five cases of acetabular component loosening; eight cases of device dislocation; and a 2.2 percent incidence of infection. In addition, the authors evaluated the incidence of pathological changes at the cement-bone interface and reported: cavitation of the bone of the calcar in 25 hips (4.5 percent); cavitation of the acetabulum in 1 case; the presence of endosteal cysts in the femur in 2 patients; and subsidence of the femoral component in 49 hips (8.9 percent). There was some degree of cement demarcation of the femqral component in 44 cases (7.9 percent) and of the acetabular component in 294 cases (53.7 percent). The agency reviewed additional publications, but they lacked sufficient information on either the number of patients in whom the devices had been implanted for 5 or more years or the results obtained in these patients (Refs. 258, 259, 260, and 271).

Although hip joint metal/polymer semi-constrained prostheses are implanted devices, FDA has determined that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of these devices. In addition, FDA has identified and assessed the major risks to health that have been associated with use of these devices. FDA believes that the major risks, i.e., loosening, infection, and adverse tissue reaction, are related to biological responses of the human body to the presence of the device, the device design, and the underlying joint pathology, and not to physical failure(s) of the device. Clinical experience with these devices has established the persons for whose use the devices are intended and the proper conditions of use, except the uncertainty of predicting in which patients bone cement problems will arise. FDA has determined that the probable benefit to health from proper use of these devices outweights any likelihood of injury or illness resulting from the use. FDA further believes that informative labeling and compliance with general controls may greatly reduce the risks to health associated with use of these devices. The agency believes that a performance standard is necessary because general controls alone are insufficient to minimize the risks to health presented by these devices.

§ 888.3360; Docket No. 78N-3077; Hip joint femoral (hemi-hip) metallic prosthesis.

The Orthopedic Device Classification Panel, an advisory committee, made the following recommendation regarding the classification of hip joint femoral (hemi-hip) metallic prostheses:

1. Identification: A hip joint femoral (hemi-hip) metallic prosthesis is an implanted device intended to replace a portion of the hip joint. This generic type of device includes prostheses that have a femoral component made of alloys, such as cobalt-chromium-molybdenum. This generic type of device includes designs which are intended to be fixed to the bone with a polmethylmethacrylate luting agent (bone cement), as well as designs which have large window-like holes in the stem of the device and which are intended to be used without bone cement. However, in these latter designs, fixation of the device is not achieved by means of bone ingrowth.

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be high priority.

3. Summary of reasons for recommendation: The Panel recommends that hip joint femoral (hemi-hip) metallic prostheses be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent loss of reduction of joint function, adverse tissue reaction, or infection. The Panel believes that general controls alone will not provide sufficient control over these characteristics.

Although a hip joint femoral (hemi-hip) metallic prosthesis is an implanted device, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that the labeling for the device include information on the dimensions and kinematics of the device and its strength and wear characteristics.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Loss or reduction of joint function: Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from

the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of a prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the Panel recommendation and is proposing that hip joint femoral (hemi-hip) metallic prostheses be classified into class II. FDA believes that the hip joint femoral (hemi-hip) metallic prosthesis presents essentially the same risks to health as that of the femoral component alone, of the hip joint metal/polymer simi-constrained prosthesis used for total hip replacement (see § 888.3350; Docket No. 78N–3075). Therefore, the discussion and references cited in § 888.3350 are incorporated by reference to support the proposed classification of hip joint femoral (hemi-hip) metallic prostheses into class II.

Although hip joint femoral (hemi-hip) metallic prostheses are implanted devices, FDA has determined that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of these devices. In addition, FDA has identified and assessed the major risks to health associated with the use of these devices. FDA believes that the major risks, i.e., loosening, infection, and adverse tissue reaction, are related to biological responses to the human body to the presence of the device, the device design, and the underlying joint pathology, and not to physical failure(s) of the device. Clinical experience with these devices has established the persons for whose use the devices are intended and the proper conditions of use. FDA has determined that the probable benefit to health from proper use of these devices outweighs any likelihood of injury or illness resulting from their use. FDA further believes that informative labeling and compliance with general controls may greatly reduce the risks to health associated with the use of these devices. The agency believes that a performance standard is necessary because general controls alone are insufficient to minimize the risks to health presented by these devices.

§ 888.3370; Docket No. 78N–3076; Hip joint (hemi-hip) acetabular metal prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendations regarding the classification of hip joint (hemi-hip) acetabular metal prostheses:

1. Identification: A hip hoint (hemi-hip) acetabular metal prosthesis is an implanted device intended to replace a portion of the hip joint. This generic type of device includes prostheses that have an acetabular component made of alloys, such as cobalt-chromium-molybdenum. This generic type of device is limited to those devices intended for implantation with a polymethylmethacrylate luting agent (bone cement).

2. Recommended classification: Class III. The Panel recommends that premarket approval of this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that hip joint (hemi-hip) acetabular metal prostheses be classified into class III because these devices are implanted and are intended to be used in relieving disabling pain and in restoring or minimizing further loss of functional use of a joint or limb. The Panel believes these uses are of substantial importance in preventing impairment of human health.

The Panel believes that general controls alone will not provide sufficient control over these characteristics. The Panel believes that it is not possible to establish an adequate performance standard for the device. There is a lack of safety and effectiveness data to demonstrate the satisfactory performance of the device. The Panel has found that insufficient information exists to support the conclusion that general controls or performance standards will be adequate to provide reasonable assurance of the safety and effectiveness of the device. Therefore, the device must be subject to premarket approval to assure its safety and effectiveness.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Loss or reduction of joint function: Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the Panel recommendation and is proposing that hip joint (hemi-hip) acetabular metal prostheses be classified into class III. The agency finds that these implanted devices are intended to be used in relieving disabling pain and in restoring or minimizing further loss of functional use of a joint or limb. FDA believes these uses are of substantial importance in preventing impairment of human health. FDA believes that insufficient clinical experience exists to fully establish the persons for whose use the devices are intended and the proper conditions of use. The agency believes that the probable benefit to health from use of these devices does not compare favorably with the likelihood of injury or illness resulting from their use.

Because of the lack of adequate data to demonstrate the safety and effectiveness of these implanted devices, FDA believes that use of the hip joint (hemi-hip) acetabular metal prosthesis presents an unreasonable risk of illness or injury. Because these devices are intended to be implanted in the human body, the Federal Food, Drug, and Cosmetic Act requires that they be classified into class III unless FDA determines that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of these devices. On the basis of available information, FDA cannot make that determination. Moreover, FDA believes that insufficient information exists to support the conclusion that general controls or performance standards will provide reasonable assurance of the safety and effectiveness of these devices. Therefore, FDA is proposing that these devices be classified into class III.

§ 888.3380; Docket No. 78N–3078; Hip joint femoral (hemi-hip) trunnion-bearing metal/polyacetal prosthesis.

The Orthopedic Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of hip joint femoral (hemi-hip) trunnion-bearing metal/polyacetal prostheses:

1. Identification: A hip joint femoral (hemi-hip) trunnion-bearing metal/polyacetal prosthesis is an implanted two-part device intended to replace the head and neck of the femur. This generic type of device includes prostheses that consist of a metallic stem made of alloys, such as cobalt-chromium-molybdenum, with an integrated

cylindrical trunnion bearing at the upper end of the stem that fits into a recess in the head of the device. The head of the device is made of polyacetal (polyoxymethylene) and it is covered by a metallic alloy, such as cobalt-chromium-molybdenum. The trunnion bearing allows the head of the device to rotate on its stem. The prosthesis stem is intended for implantation with a polymethylmethacrylate luting agent (bone cement).

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendations: The Panel recommends that hip joint femoral (hemi-hip) trunnion-bearing metal/polyacetal prostheses be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent loss or reduction of joint function, adverse tissue reaction, or infection. The Panel believes that general controls alone will not provide sufficient control over these characteristics.

Although hip joint femoral (hemi-hip) trunnion-bearing metal/polyacetal prostheses are implanted devices, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Panel also recommends that the labeling for the device include information on the dimensions and kinematics of the device and its strength and wear characteristics.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel member's personal knowledge of, and clinical experience with, the device and on a presentation to the Panel. Dr. Ian Goldie (University of Goteborg) (Ref. 285) presented the results of several Norwegian studies with these prostheses. Dr. Goldie referred to Christiansen's series of 241 hips in which excellent results were obtained in 57 percent of the cases and good results in 33 percent. In this series, there were five infections, seven cases of loosening of the acetabular cup, two dislocations shortly after operation, two cases of femoral perforation, and three cases of heterotopic ossification. Dr. Goldie then presented the results of his own series of 61 patients. In the 19 patients with 2 years followup, and in the 28 patients with 6 months followup, there were no complications. However, in the remaining 14 patients with a followup of 1 year, there were the following complications: 2 dislocations between the head and the cup, 2 cases of heterotopic ossification, and 2 patients with inexplicable pain.

5. Risks to health: (a) Loss or reduction of joint function: Improper design or inadequate mechnical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction in joint function due to excessive wear, fracture, deformation of the device components, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility or resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away of the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of a prosthesis within the body may lead to an increased risk of infection.

FDA disagrees with the Panel recommendation and is proposing that hip joint femoral (hemi-hip) trunnion-bearing metal/polyacetal prostheses be classified into class III. FDA has sought additional data and information on the safety and effectiveness of these devices. A review of the medical literature revealed a disagreement regarding the resistance to wear of polyacetal materials. McKellop, et al. (Ref. 286), report that laboratory wear rates for polyacetal range from 70 percent lower than polyethylene to 540 percent higher. Dumbleton (Ref. 287) reports wear in the trunnion sleeve of the device and that polyacetal exhibits a low resistance to wear. Because of the potential problems involving its resistance to wear, the long-term effectiveness of this device is questionable. The initial investigator and his associates have been the primary users of this device. Long-term followup data available only from the initial investigator. Clinical cases documenting effectiveness and safety of the device involving usage of less than 3 years.

FDA finds that hip joint femoral (hemi-hip) trunnion-bearing metal/polyacetal prostheses are implanted devices that are intended to be used in relieving disabling pain and in restoring or minimizing further loss of functional use of a joint or limb. FDA believes these uses are of substantial importance in preventing impairment of human health. FDA believes that insufficient clinical experience exists to fully establish the persons for whose use the devices are intended and the proper conditions of use. The agency believes that the probable benefit to health from use of these devices does not compare favorably with the likelihood of illness or injury resulting from their use.

Because of the lack of adequate data to demonstrate the safety and effectiveness of these implanted devices, FDA believes that uncontrolled use of hip joint femoral (hemi-hip) trunnion-bearing metal/polyacetal prostheses presents an unreasonable risk of illness or injury. Because these devices are intended to be implanted in the human body, the Federal Food, Drug, and Cosmetic Act requires that they be classified in class III, unless FDA determines that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of these devices. On the basis of available information, FDA cannot make this determination. Moreover, FDA believes that insufficient information exists to support a conclusion that general controls or performance standards will provide reasonable assurance of the safety and effectiveness of these devices. Therefore, FDA is proposing that these devices be classified into class III.

§ 888.3390; Docket No. 78N-3079; Hip joint femoral (hemi-hip) metal/polymer prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of hip joint femoral (hemi-hip) metal/polymer prostheses:

1. Identification: A hip joint femoral (hemi-hip) metal/polymer prosthesis is an implanted device intended to replace the head and neck of the femur. This generic type of device includes prostheses that have a femoral component made of alloys, such as cobalt-chromium-molybdenum, and a snap-fit acetabular component made of an alloy, such as cobalt-chromium-molybdenum, and ultra-high molecular weight polyethylene. This generic type of device may be fixed to the bone with a polymethyl-methacrylate luting agent (bone cement) or implanted by impaction.

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that hip joint femoral (hemi-hip) metal/polymer prostheses be classified into class II because the design, meterial compostion, and mechanical properties of the device,

such as its flexibility, rigidity, strength, and surface finish should be controlled to prevent loss or reduction of joint function, adverse tissue reaction, or infection. The Panel believes that performance standard will control the risks associated with the device. The Panel recommends that the labeling for the device include information on the dimensions and kinematics of the device and its strength and wear characteristics.

4. Summary of data on which the recommendations is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device, their knowledge of the medical literature, and presentations of clinical data made before the Panel.

Drs. Richard Strauss and Andrew Schildhous (Bronx-Lebanon Hospital Center) made a presentation before the Panel on the clinical performance of the Bateman hip prosthesis (Ref. 288). Dr. Strauss outlined his 5-year experience with the Bateman prosthesis in 84 patients. The primary diagnosis in these patients was intracapsular fracture of the proximal femur. Dr. Strauss stated that the of question of whether the femur stem of the implant should be cemented or noncemented was decided at the time of surgery. The complications reported during the clinical study were for dislocations and two superficial infections. Dr. Strauss pointed out that, to date, there has been no clinical evidence of acetabular wear in any of the cases.

Dr. William Weat (San Leandro, CA) presented to the Panel his experience with the Bateman prosthesis on a series of 55 hips in 53 patients. Complications in the clinical study included two dislocations. In addition, five patients died of unrelated causes, three were converted to total replacement, and two could not be traced. The followup period averaged 19½ months for 43 patients, representing 45 hips. Pain was absent in 36 patients, mild in 6, and significant enough to limit function in 1. Gait was normal in 27 patients, limited by some unrelated problem in 12, and limited by some problem related to the hip prosthesis in 6. The range of motion was considered functional in 39 patients and limited in 6. Overall, the results were considered excellent in 69 percent of the patients, good in 22 percent, and poor in 4 cases (9 percent). Dr. West concluded that the Bateman design of the hip joint femoral (hemi-hip) metal/polymer prosthesis is a satisfactory method of treatment for a number of disorders of the femoral head and neck and that these results will stand the test of, at least, and intermediate period of time. Dr. West commented that fluoroscopic examination of the hip during walking indicated that the prosthesis is capable of functioning as designed for at least 30 months postoperatively.

5. Risks to health: (a) Loss or reduction of joint function: Improper design of inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and the systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the Panel recommendation and is proposing that hip joint femoral (hemi-hip) metal/polymer prostheses be classified into class II. The agency has obtained additional data and information describing the use of the hip joint femoral (hemi-hip) metal/polymer prostheses. The most common problems associated with use of the device that have been reported in the literature are device dislocation and related complications. Anderson (Ref. 289) reported on two cases of dislocation and component separation of the Bateman hip prosthesis, which he believed were due to inadequate immobilization of the patient after surgery. Barmada (Ref. 290) has also reported two cases of dislocations, which he attributes to impingement of the outer cup within the acetabulum while the hip was forced into flexion, adduction and internal rotation. Drinker and Murray (Ref. 291) compared 101 Bateman hemiarthroplasties with 160 cemented Thompson hemiarthroplastics with respect to complications and short-term results. Ten patients with the Bateman implant and 10 with a Thompson device were examined an average of 3.0 and 3.4 years postoperatively. The differences in the mean Harris-hip rating score were significant and probably resulted from the mean differences in their mean ages (74.4 and 81.1 years). There were nine dislocations for seven patients with the Bateman prostheses. Five of the nine could not be rectified by closed reduction. In the Thompson series, 12 dislocations occurred in 7 patients. All were successfully treated via closed reduction. Drinker and Murray believe that motion at the low-friction inner bearing of the Bateman prosthesis, which was expected to provide added stability and lower rates of dislocation compared to conventional single-bearing designs, either does not occur in vivo as predicted or that other more important factors are operative in determining the potential for dislocation. These authors performed motion studies in thirteen patients at 2.0 and 3.4 years postoperatively, and found that far less inner bearing motion existed than is allowed by the implant itself. In half of the patients, there was a reduction in inner bearing motion over time, and in almost all patients studied at any given time there was a marked reduction in inner bearing motion with weight-bearing compared with the supine unloaded position. The reduction in inner bearing motion on weight bearing was believed to be caused by an increase in inner bearing friction when the concentric artificial bearing surfaces of the device are compressed, lose lubricant, and become relatively less mobile, while the less concentric outer bearing surfaces (i.e., the acetabular cartilage and the cobalt-chromium surface of the device) may retain lubricant and remain relatively more mobile.

Langan (Ref. 292) reported on 90 Giliberty bipolar prostheses that he implanted. Sixty-five prostheses were available for followup. The average followup time was 19 months. Eighty-six percent of the operated hips had very good or excellent motion. Roentgenograms were taken immediately after the operations. The cups of the prostheses were seen to be in neutral orientations with the patients own pelvis (i.e., approximately 45 degrees to the transverse axis of the pelvis). By 1 year followup, however, only 12 percent were noted to be in the neutral position; the remainder had gone into a vertical position. Also, four dislocations occurred, which Langan attributed to poor surgical technique or judgment. Langan reported that the short-term clinical results were excellent, but longer term clinical data are needed.

Although hip joint femoral (hemi-hip) metal/polymer prostheses are implanted devices, FDA has determined that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of these devices. In addition, FDA has identified and assessed the major risks to health

accompanying the use of these devices. FDA believes that the major risks, i.e., loosening, infection, dislocation, and adverse tissue reaction, are related to biological responses of the human body to the presence of the device, the device design, and the underlying joint pathology, and not to physical failure(s) of the device. Clinical experience with these devices has established the persons for whose use the devices are intended and the proper conditions of use. FDA has determined that the probable benefit to health from proper use of these devices outweighs any likelihood of injury or illness resulting from their use. FDA further believes that informative labeling and compliance with general controls may greatly reduce the risks to health accompanying the use of these devices. The agency believes that a performance standard is necessary because general controls alone are insufficient to minimize the risks to health presented by these devices.

§ 888.3400; Docket No. 78N–3080; Hip joint femoral (hemi-hip) resurfacing prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of hip joint femoral (hemi-hip) resurfacing prostheses:

1. Identification: A hip joint femoral (hemi-hip) resurfacing prosthesis is an implanted device intended to replace a portion of the hip joint. This generic type of device includes prostheses that have a femoral resurfacing component made of alloys, such as cobalt-chromium-molybdenum.

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that hip joint femoral (hemi-hip) resurfacing prostheses be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent loss or reduction of joint function, adverse tissue reaction, or infection. The Panel believes that general controls alone will not provide sufficient control over these characteristics.

Although hip joint femoral (hemi-hip) resurfacing prostheses are implanted devices, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device. In addition, the Panel reviewed literature pertaining to the device. Aufranc and Sweet (Ref. 293) reported on the clinical results obtained from use in 171 patients. Results were classified as excellent, good, or satisfactory in 164 hips (82 percent) and unsatisfactory in 37 (22 percent). Johnson and Larson (Ref. 294) reported the results of followup of 251 patients with a minimum followup of 3 years. Overall improvement occurred in 90 percent of the patients; pain relief occurred in 67 percent and pain was reduced in 90 percent.

5. Risks to health: (a) Loss or reduction of joint function: Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the Panel recommendation and is proposing that hip joint femoral (hemi-hip) resurfacing prostheses be classified into class II. Although hip joint femoral (hemi-hip) resurfacing prostheses are implanted devices, FDA has determined that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of these devices. In addition, FDA has identified and assessed the major risks to health associated with the use of these devices. FDA believes that the major risks, i.e., loosening, infection, and adverse tissue reaction, are related to biological responses of the human body to the presence of the device, the device design, and the underlying joint pathology, and not to physical failure(s) of the device. Clinical experience with these devices has established the persons for whose use the devices are intended and the proper conditions of use. FDA has determined that the probable benefit to health from proper use of these devices outweighs any likelihood of injury or illness resulting from their use. FDA further believes that informative labeling and compliance with general controls may greatly reduce the risks to health associated with use of these devices. The agency believes that a performance standard is necessary because general controls alone are insufficient to minimize the risks to health presented by these devices.

§ 888.3410; Docket No. 78N–3081; Hip joint metal/polymer semi-constrained resurfacing prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of hip joint metal/polymer semi-constrained resurfacing prostheses:

1. Identification: A hip joint metal/polymer semi-constrained resurfacing prosthesis is an implanted two-part device intended to replace the articulating surfaces of the hip while preserving the femoral head and neck. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that consist of a femoral cap component made of alloy, such as cobalt-chromium-molybdenum, that is placed over a surgically prepared femoral head, and an acetabular resurfacing polymer component. Both components are intended for implantation with a polymethylmethacrylate luting agent (bone cement).

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that the device be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent loss or reduction of joint function, adverse tissue reaction, or infection. The Panel believes that general controls alone will not provide sufficient control over these characteristics.

Although hip joint metal/polymer semi-constrained resurfacing prostheses are implanted devices, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a

performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Panel also recommends that the labeling for the device include information on the dimensions and kinematics of the device and its strength and wear characteristics.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and their knowledge of the medical literature.

5. Risks to health: (a) Loss or reduction of joint function: Improper design or inadequate mechanical properties of the devices, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excesive wear, fracture, deformation of the device components, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away of the articulating surfaces of the device and the release of materials from the device to the surrounding tissues and the systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA disagrees with the Panel recommendation and is proposing that hip joint metal/polymer semi-constrained resurfacing prostheses be classified into class III. The agency has obtained additional data and information on the use of hip joint metal/polymer semi-constrained resurfacing prostheses. Total surface replacement hip arthroplasty developed as a result of experience gained with conventional hip replacement and Smith Petersen's cup arthroplasty. In 1951, Charnley (Ref. 295) carried out the first double cup replacement of the hip utilizing polytetrafluoroethylene. These prostheses were fixed to the bone without bone cement. It is now known that polytetrafluoroethylene is an unsatisfactory material when it articulates against itself. The resultant debris leads to a low grade inflamatory response in which granulation tissue invades the boneprosthesis interface and loosens the prosthesis. Failure, therefore, was not inherent in the concept but resulted from the absense of satisfactory materials and bonding techniques. In 1960, Townley used polyurethane to anchor a metal cup to the femoral head and to resurface the acetabulum. The material and the results were so unsatisfactory that the procedure was abandoned (Ref. 295). The third attempt to modify conventional cup arthroplasty was carried out by Muller in 1968 (Ref. 295). Muller employed components fabricated from cobalt-chrome alloy. The symptomatic results were unsatisfactory and the prostheses were not stable on the femur. As a result, he abondoned the procedure. In 1970, Gerard used cups composed of cobalt-chrome alloy that were not cemented. The results were not fully satisfactory and Gerard therefore introduced a prosthesis in which the acetabular component was made of high density polyethlene and the fermoral component of metal. The high density polyethylene acetabular component moved against both the metal femoral component and the bone, generating polyethlene wear debris. Bone resorption resulted and, hence, Gerard abandoned this prosthesis. Gerard then introduced his third and present prosthesis in which the acetabular component had a metal outer surface moving against the bone of the acetabulum and an inner surface fashioned of polyethylene which moved against the metal femoral component.

During 1970–1977, Gerard (Ref. 296) implanted various designs of his device in 337 hips. He reported that the results in 289 hips which had been followed for over 6 months were excellent in 114, good in 124, fair in 41, and poor in 10. The failures, with the exception of cases of infection or periarticular calcification, were attributed to the early material combinations and to the surgical technique.

In 1971, Trentani at the Rizzoli Institute in Bologna (Ref. 297) and Furuya (Ref. 298) in Tokyo independently carried out a cemented double cup arthroplasty. Trentani reported excellent results in 76 percent of his cases over a 2 to 6 year followup. He reported a total of 9 failures (12 percent) out of 70 patients. Four of the cases were breakage at the base of the neck of the femur following violent trauma. In the other five cases, the femoral component loosend. Furuya (Ref. 298) performed the operation on 13 hips with followup ranging from 3 to 6 years. In seven of these cases, revision was required within a period of 1 through 5 years. The reasons for the failure were fracture of the femoral neck secondary to osteonecrosis in one hip and loosening of the acetabular socket in six hips.

Freeman (Ref. 299) began work on double cup arthroplasty in 1970. From 1972 through 1974, 32 hips were replaced. Fourteen of these devices failed. These failures were attributable to loosening. The first 16 prostheses consisted of a polyethylene femoral component and a metal acetabular component. In five of these hips, one or both components loosened. Freeman believed that the high incidence of loosening in this group of hips was due to the fact that convex polyethylene wears rapidly and thus generates large quantities of intra-articular polyethylene debris. Freeman postulated that eight femoral neck fractures could be attributed to varus placement of the prosthesis and the making of a notch in the superior cortex. The prosthesis was then redesigned so that the femoral component was metal. From November 1974 to December 1977, 116 hips were implanted with the new design. Range of motion was improved in 90 percent of cases. Complications were minimal. One femoral neck fracture was reported along with one incidence of loosening.

Capello (Ref. 300) reported on use of the device in 66 cases. These cases were followed over an average of 22 months. According to the Iowa Hip Rating Scale that Capello employed, an average score of 91.4 out of 100 was reported. The average range of motion was 105 degrees. He reported eight femoral neck fractures and loosening of eight acetabular components.

Wagner (Ref. 301) performed 322 metal resurfacing operations. His results were generally favorable, with only a total of six components loosening. Tanaka (Ref. 302) performed 37 surface replacements on 57 joints. The average followup was 2 years. Seventy-three percent of the hips were pain-free. Walking ability improved in 31 patients. In 1975, Amstutz (Ref. 303) developed a further variant of a cemented double cup prosthesis. In 100 procedures with an average followup of 8 months, only 3 cases required revision. Walking function, arc of flexion, and rotation improved after the operation.

FDA finds that hip joint metal/polymer semi-constrained resurfacing prostheses are implanted devices that are intended to be used in relieving disabling pain and in restoring or minimizing further loss of functional use of a joint or limb. FDA believes these uses are of substantial importance in preventing impairment of human health. FDA believes that insufficient clinical experience exists to fully establish the persons for whose use the devices are intended and the proper conditions of use. The agency believes that the probable benefit to health from use of these devices does not compare

favorably with the likelihood of injury or illness resulting from their use.

Because of the lack of adequate data to demonstrate the safety and effectivenesss of these implanted devices, FDA believes that uncontrolled use of the hip joint metal/polymer semi-constrained resurfacing prosthesis presents an unreasonable risk of illness or injury. Because these devices are intended to be implanted in the human body, the Federal Food, Drug, and Cosmetic Act requires that they be classified into class III unless FDA determines that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of these devices. On the basis of available information, FDA cannot make this determination. Moreover, FDA believes that insufficient information exists to support the conclusion that general controls or performance standards will provide reasonable assurance of the safety and effectiveness of these devices. Therefore, FDA is proposing that these devices be classified into class III.

§ 888.3480; Docket No. 78N–3082; Knee joint femorotibial metallic constrained prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of knee joint femorotibial metallic constrained prostheses:

1. Identification: A knee joint femorotibial metallic constrained prosthesis is an implanted device intended partially to replace a knee joint. The device prevents dislocation in more than one anatomic plane and has components that are linked together. The only knee joint movement allowed by the device is in the sagittal plane. This generic type of device includes prostheses that have an intramedullary stem at both the proximal and distal locations. The upper and lower components may be joined either by a solid bolt or pin, an internally threaded bolt with locking screw, or a bolt retained by circlip. The components of the device are made of alloys, such as cobalt-chromium-molybdenum. The stems of the device may be perforated, but are intended to be implanted with a polymethylmethacrylate luting agent (bone cement).

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that knee joint femorotibial metallic constrained prostheses be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent loss or reduction of joint function, adverse tissue reaction, or infection. The Panel believes that general controls alone will not provide sufficient control over these characteristics.

Although a knee joint femorotibial metallic constrained prosthesis is an implanted device, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that the labeling for the device include information on the dimensions and kinematics of the device and its strength and wear characteristics.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and experience with, the device, and its review of the medical literature. Results from using the device in more than 720 cases have been reported in the medical literature in the United States during the past 3 years (Refs. 304, 310, and 313). There are also reports in the medical literature documenting use of the device in several thousand cases worldwide during the past 10 years. The Panel believes that this extensive clinical use has revealed the usual mechanical problems, implant loosening and settling. The Panel determined that the overall risks resulting from use of the prosthesis were no worse than the risks associated with major knee surgery without implantation of a prosthesis.

5. Risks to health: (a) Loss or reduction of joint function: Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the Panel recommendation and is proposing that knee joint femorotibial metallic constrained prosthesis be classified into class II. The agency believes that there is sufficient information to establish a performance standard for this device. Of the 957 patients reviewed by the Panel who have had this prosthesis implanted and who were discussed in the worldwide medical literature (Refs. 304 through 314), 108 (11 percent) suffered implant failure, 233 (24 percent) of the cases had complications, and 104 (11 percent) had loosening of the prosthesis.

FDA has sought additional data on the safety and effectiveness of this device. Kettelkamp (Ref. 315) reported that the failure rate for the device ranges from 5 percent to 24 percent for the hinged metal knee prosthesis, with a short followup time. Kettlekamp (Ref. 315) and Chand (Ref. 316) both believe that excessive forces may be applied to the intramedullary stem bone cement interface because the constrained prosthesis hinge prevents medial/lateral joint movement. Kettlekamp believes that if the stem loosens the cement may rub away and destroy the surrounding bone, causing a larger cavity and making revision difficult or impossible.

Kettlekamp reviewed reports in the medical literature on use of 576 Walldius hinged knee prostheses. In one group of 144 implantations, complications occurred in 29 cases (13 percent). In the remaining 432 cases, 89 (20 percent) were classified as failures, 33 (7 percent) required reoperations, and 53 (12 percent) had loosening. Fractures occurred in 11 cases (2 percent) and deep infection was reported in 35 knees (8 percent). Kettlekamp reported that the incidence of complication increased with the length of reported followup. Brady (Ref. 313) reviewed results of implanting the Shiers design of this device in 288 knees. He reported poor results in 71 knees (24 percent), reoperation was required in 33 knees (11 percent), and loosening observed in 56 knees (19 percent). Brady states that the major problems involved with use of this prosthesis are the absence of axial (medial) rotation, the necessary resection of large amounts of bone, and the creation of physiologic dead space.

Kettlekamp (Ref. 315) and Deburge, et al. (Ref. 317), report that the major problem with the Shiers design prosthesis is loosening. Deburge reported a loosening rate of 15 percent (22 patients) during a 5-year followup of the request of implanting the Guepar contrained knee prosthesis in 152 patients. However, less than half of these instances of device loosening were

symptomatic (10 of 22 patients). Reoperations were peroformed on the 10 patients. Other authors (Ref. 310) believe that the rate of loosening of the prosthesis is higher, possibly around 80 percent, but that only a small percentage of those patients with device loosening are symptomatic.

Arden and Kamdar (Ref. 318) reported followup for 7 years on implantation of 193 Shiers design prostheses. They reported that 11 percent of the patients had aseptic loosening. Kaushal (Ref. 319) reported followup examination of a series of 30 knees about 42 months following implantation of the prosthesis. The examination revealed that 13 knees (46 percent) had phlebothrombosis, 8 knees (11 percent) and asymptomatic loosening, 4 knees (5.4 percent) had deep infections, and 3 knees (4.3 percent) had symptomatic loosening. The major problems with use of the prosthesis were settling, loosening, and limitation on the range of joint motion allowed. In preliminary data, Van Camp (Ref. 320) showed that stress loading appeared to cause mechancial loosening of the device.

Walker (Ref. 321) stated that the valgus angle of the knee was ignored in the older designs of this prosthesis. Walker said this design problem resulted in lateral stress on the intramedullary stems of the device. This theory was verified experimentally by Wagner and Bourgois (Ref. 322). Wagner and Bourgois also showed that, in both the Walldius and Shiers designs of the prosthesis, the prosthesis' axis of rotation was not equivalent to the axis of the anatomic joint it replaced. These researchers said the pin in the Shiers prosthesis was turned down on the axis and that it might loosen if the prosthesis were overstressed. Because the axle pin of the Walldius prosthesis is clamped on one side, the location of the axis causes localized wear.

Although infection immediately following implantation of a prosthesis is primarily a result of surgical technique, Swanson, et al. (Ref. 323), state that the design of the prosthesis may minimize the rate of infection associated with implantation. Swanson found that the infection rate was lower when less bone was removed for insertion of the device. Phillips and Taylor (Ref. 308) report that most groups of patients who have received this prosthesis have suffered about a 10 percent higher incidence of infection than patients in whom other generic types of knee prostheses have been implanted.

In cases of total failure of implantation of a joint prosthesis, the prosthesis may be removed and the joint fused (arthrodesis). The rate of success is performing arthrodesis is related to the amount of bone that was removed to implant the device. Arthrodesis is difficult following implantation of a constrained joint replacement device (Ref. 324).

Although knee joint femorotibial metallic constrained prostheses are implanted devices, FDA has determined that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the devices. In addition, FDA has indentified and assessed the major risks to health accompaning the use of the devices. FDA believes that the major risks, i.e., loosening, infection, and adverse tissue reaction, are related to biological responses of the human body to the presence of the device, the device design, and the underlying joint pathology, and not to physical failure(s) of the device. Clinical experience with these devices has established the persons for whose use the devices are intended and the proper conditions of use. FDA has determined that the probable benefit to health from proper use of these devices outweighs any likelihood of injury or illiness resulting from their use. FDA further believes that information labeling and compliance with general controls may greatly reduce the risks to health associated with the use of these devices. The agency believes that a performance standard is necesssary because general controls alone are insufficient to minimize the risks to health presented by these devices.

§ 888.3490; Docket No. 78N–3083; Knee joint femorotibial metal/composite non-constrained prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendations regarding the classification of knee joint femorotibial metal/composite non-constrained prostheses:

1. Identification: A knee joint femorotibial metal/composite non-constrained prosthesis is an implanted device intended partially to replace a knee joint. The device limits minimally (less than normal anatomic constraints) translation in one or more planes. It has no linkage across-the-joint. This generic type of device includes prostheses that have a femoral condylar resurfacing component or components made of alloys, such as cobalt-chromium-molybdenum, and a tibial condylar component or components made of ultra-high molecular weight polyethylene with carbon-fibers composite and are intended for implantation with a polymethylmethacrylate luting agent (bone cement).

2. Recommended classification: Class III. The Panel recommends that premarket approval of this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that knee joint femorotibial metal/composite non-constrained prostheses be classified into class III because these devices are implanted and are intended to be used in relieving disabling pain and in restoring or minimizing further loss of functional use of joint or limb. The Panel believes these uses are of substantial importance in preventing impairment of human health.

The Panel believes that general controls alone will not provide sufficient control over these characteristics. The Panel also believes that it is not possible to establish an adequate performance standard for the device. There is a lack of safety and effectiveness data to demonstrate the satisfactory performance of the device. The Panel has found that insufficient information exists to support the conclusion that general controls or performance standards will be adequate to provide reasonable assurance of the safety and effectiveness of the device. Therefore, the device must be subject to premarket approval to assure its safety and effectiveness.

The Panel also recommends that the labeling for the device include information on the dimensions and kinematics of the device and its strength and wear characteristics.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' clinical experience with similar devices and a series of presentations made to the Panel (Refs. 325 and 326). Dr. Robert Johnson (Rensselear Polytechnic Institute) compared the physical properties of the carbon-fiber-reinforced ultra-high molecular weight polyethylene composite material with the physical properties of conventional polyethylene material. He found that the reinforced material was superior to the conventional polyethylene material regarding compressive deformation, flexural stress, compressive creep, modulus of elasticity, and fatigue. Dr. Johnson also noted that the technology of composite materials such as carbon-fiber-reinforced polyethylene is in its infancy with regard to engineering in general.

Dr. Jack Lemons (University of Alabama) presented the results of

toxicity tests on the carbon-fiber-reinforced material. The results of in vitro tests showed the material, and extracts from the material, to be noncytotoxic to monolayers of cells and nonhemolytic to rabbit blood. The results of in vivo tests indicated that the material was nonirritating, nontoxic, and did not produce adverse effects after up to 15 months of implantation. The results of subacute toxicity tests indicated that intracutaneous extracts of the material were nonirritating when injected into rabbits; that systemic injections produced no adverse effects in mice; and that when the material was implanted along the backs of rabbits, it was nontoxic when it was evaluated at 6 and 12 weeks. The results of the chronic toxicity tests indicated that polyethylene material reinforced with carbon fibers was noncytotoxic, nontoxic, nonirritating, and produced no adverse effects when it was injected into the knee spaces of four rabbits and evaluated 15 months later. Dr. Lemons determined that these tests show that the carbon-fiber/reinforced material is biocompatible.

Dr. Joel Schilling (Portland, OR) presented a report on the histological examination of pieces of tissue removed from a patient who had received an untra-high molecular weight polyethylene prosthesis in one ankle and a carbon-fiber-reinforced ultra-high molecular weight polyethylene composite prosthesis in the other. Dr. Schilling found that there was minimal tissue reaction to either type of material and that there seemed to be very little reaction to the carbon fragments.

Dr. Robert Volz (University of Arizona) presented a comparison of the effect of temperature on the conventional ultra-high molecular weight polyethylene and on the carbon-fiber-reinforced material. Dr. Volz concluded that the carbon-fiber-reinforced material offered considerable improvement in its resistance to deformation at body temperatures (i.e., 37° C) and at 96° C, the temperature reached during polymerization of methylmethacrylate cement.

At the July Panel meeting (Ref. 326) Robert Fuson, M.D., (Zimmer-USA) summarized the clinical experiences with prostheses made from the carbon-fiber-reinforced material. A total of 86 acetabular components for total hip prostheses, 18 tibial components for total knees, and 23 tibial components for total ankles have been implanted. Of these, 65 hip, 18 knee, and 22 ankle components have been implanted for more than 6 months. Only 61 hip components, 11 knee components, and 12 ankle components have been implanted for over 1 year. Only five implantations (ankle) had been clinically followed for 2 years. No adverse reactions related to these prostheses were reported.

5. Risks to health: (a) Loss or reduction of joint function: Improper design, or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the Panel recommendation and is proposing that knee joint femorotibial metal/composite non-constrained prostheses be classified into class III. FDA finds that these implanted devices are intended to be used in relieving disabling pain and in restoring or minimizing further loss of functional use of a joint or limb. FDA believes these uses are of substantial importance in preventing impairment of human health. Because these devices have not been studied for more than 2 years, FDA believes insufficient clinical experience exists to fully establish the persons for whose use the devices are intended an the proper conditions of use. The agency believes that the probable benefit to health from use of the devices does not compare favorably with the likelihood of illness or injury resulting from their use.

Because of the lack of adequate data to demonstrate the safety and effectiveness of these implanted devices, FDA believes that use of the knee joint femorotibial metal/composite non-constrained prosthesis presents an unreasonable risk of illness or injury. Because these devices are intended to be implanted in the human body, the Federal Food, Drug, and Cosmetic Act requires that they be classified into class III unless FDA determines that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of these devices. On the basis of available information, FDA cannot make that determination. Moreover, FDA believes that insufficient information exists to support the conclusion that general controls or performance standards will provide reasonable assurance of the safety and effectiveness of the device. Therefore, FDA is proposing that these devices be classified into class III.

§ 888.3500; Docket No. 78N-3302; Knee joint femorotibial metal/composite semi-constrained prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of knee joint femorotibial metal/composite semi-constrained prostheses:

1. Identification: A knee joint femorotibial metal/composite semi-constrained prosthesis is an implanted two-part device intended partially to replace a knee joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that have a femoral component made of alloys, such as cobalt-chromium-molybdenum, and a tibial component with the articulating surfaces made of ultra-high molecular weight polyethylene with carbon-fiber composite and is limited to those devices intended for implantation with a polymethylmethacrylate luting agent (bone cement).

2. Recommended classification: Class III. The Panel recommends that premarket approval of this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that knee joint femorotibial metal/composite semi-constrained prostheses be classified into class III because these devices are implanted and are intended to be used in relieving disabling pain and in restoring or minimizing further loss of functional use of a joint or limb. The Panel believes these uses are of substantial importance in preventing impairment of human health. The Panel believes that general controls alone will not provide sufficient control over these characteristics. The Panel also believes that it is not possible to establish an adequate performance standard for the device. There is a lack of safety and effectiveness data to demonstrate the satisfactory performance of the device. The Panel has found that insufficient information exists to support the conclusion that performance standards will be adequate to provide reasonable assurance of the safety and effectiveness of the device. Therefore, the device must be subject to premarket approval to assure its safety and effectiveness.

The Panel also recommends that the labeling for the device include information on the dimensions and kinematics of the device and its strength and wear characteristics.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' clinical experience with similar devices and a series of presentations to the Panel (Refs. 325 and 326). A discussion of these presentations is given in this preamble under § 888.3490.

5. Risks to health: (a) Loss or reduction of joint function: Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to a dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the Panel recommendation and is proposing that knee joint femorotibial metal/composite semi-constrained prostheses be classified into class III. FDA finds that these implanted devices are intended to be used in relieving disabling pain and in restoring or minimizing further loss of functional use of a joint or limb. FDA believes these uses are of substantial importance in preventing impairment of human health. However, FDA believes insufficient clinical experience exists to fully establish the persons for whose use the devices are intended and the proper conditions of use. The agency believes that the probable benefit to health from use of the devices does not compare favorably with the likelihood of illness or injury resulting from their use.

Because of the lack of adequate data to demonstrate the safety and effectiveness of these implanted devices, FDA believes that use of the knee joint femorotibial metal/composite semi-constrained prosthesis presents a potential unreasonable risk of illness or injury. Because these devices are intended to be implanted in the human body, the Federal Food, Drug, and Cosmetic Act requires that they be classified into class III unless FDA determines that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of these devices. On the basis of available information, FDA cannot make that determination. Moreover, FDA believes that insufficient information exists to support the conclusion that general controls or performance standards will provide reasonable assurance of the safety and effectiveness of these devices. Therefore, FDA is proposing that these devices be classified into class III.

§ 888.3510; Docket No. 78N–3084; Knee joint femorotibial metal/polymer constrained prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of knee joint femorotibial metal/polymer constrained prostheses:

1. Identification: A knee joint femorotibial metal/polymer constrained prosthesis is an implanted device intended partially to replace a knee joint. The device limits translation or rotation in one or more planes and has components that are linked together or affined. This generic type of device includes prostheses composed of a ball-and-socket joint located between a stemmed femoral and a stemmed tibial component and a runner and track joint between each pair of femoral and tibial condyles. The ball-and-socket joint is composed of a ball at the head of a column rising from the stemmed tibial component. The ball, the column, the tibial plateau, and the stem for fixation of the tibial component are made of an alloy, such as cobalt-chromium-molybdenum. The ball of the tibial component is held within the socket of the femoral component by the femoral component's flat outer surface. The flat outer surface of the tibial component abuts both a reciprocal flat surface within the cavity of the femoral component and flanges on the femoral component designed to prevent distal displacement. The stem of the femoral component is made of an alloy, such as cobalt-chromium-molybdenum, but the socket of the component is made of ultra-high molecular weight polyethylene. The femoral component has metallic runners which align with the ultra-high molecular weight polyethylene tracks that press-fit onto the metallic tibial component. This generic type of device is limited to those devices intended to be implanted with a polymethylmethacrylate luting agent (bone cement).

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that knee joint femorotibial metal/polymer constrained prostheses be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent loss or reduction of joint function, adverse tissue reaction, or infection. The Panel believes that general controls alone will not provide sufficient control over these characteristics.

Although a knee joint femorotibial metal/polymer constrained prosthesis is an implanted device, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that the labeling for the device include information on the dimensions and kinematics of the device and its strength and wear characteristics.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and experience with, the device. Long-term followup data are not available for this generic device. The only clinical data available on use of this device is reported by Matthews, Kaufer, and Sonstegard, the inventors/developers (Ref. 327). These data have shown 22 patients having 25 prosthesis implanted with a followup of 1 to 1.5 years.

5. Risks to health: (a) Loss or reduction of joint function: Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the Panel recommendation and is proposing that knee joint femorotibial metal/polymer constrained prostheses be classified into class II. The agency believes that there

is sufficient information to establish a performance standard for this device. FDA notes that clinical results after long-term (5 or more years) implantation of the devices have not been reported. Matthers, et al. (Ref. 328), report that the recipients of the implants have only been followed for up to 2 years. FDA notes that the only available pertinent publications (Refs. 328 and 329) are those of the initial investigations of the new prosthesis design.

Despite the absence of published reports of long-term clinical followup, FDA has determined that premarket approval of knee joint femorotibial metal/polymer constrained prostheses is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of these devices. In addition, FDA has identified and assessed the major risks to health associated with the use of these devices. FDA believes that the major risks, i.e., loosening, infection, and adverse tissue reaction, are related to biological responses of the human body to the presence of the device, the device design, and the underlying joint pathology, and not to physical failure(s) of the device. Short-term clinical experience with these devices has established the persons for whose use the devices are intended and the proper conditions of use. FDA has determined that the probable benefit to health from proper use of these devices outweighs any likelihood of injury or illness resulting from their use. FDA believes that informative labeling and compliance with general controls may greatly reduce the risks to health accompanying the use of these devices. The agency believes that a performance standard is necessary because general controls alone are insufficient to minimize the risks to health presented by these devices.

§ 888.3520; Docket No. 78N–3085; Knee joint femorotibial metal/polymer non-constrained prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of knee joint femorotibial metal/polymer non-constrained prosthesis:

1. Identification: A knee joint femorotibial metal/polymer non-constrained prosthesis is an implanted device intended partially to replace a knee joint. The device limits minimally (less than normal anatomic constraints) translation in one or more planes. It has no linkage across-the-joint. This generic type of device includes prostheses that have a femoral condylar resurfacing component or components made of alloys, such as combalt-chromium-molybdenum, and a tibial component or components made of ultra-high molecular weight polyethylene, and are intended to be implanted with a polymethylmethacrylate luting agent (bone cement).

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that knee joint femorotibial metal/polymer non-constrained prostheses be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent loss or reduction of joint function, adverse tissue reaction, or infection. The Panel believes that general controls alone will not provide sufficient control over these characteristics.

Although knee joint femorotibial metal/polymer non-constrained prostheses are implanted devices, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that labeling for the device include information on the dimensions and kinematics of the device and its strength and wear characteristics.

4. Summary of data on which the recommendation is based: the Panel based its recommendation on the Panel members' personal knowledge of, and experience with, the device.

5. Risks to health: (a) Loss or reduction of joint function: Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the Panel recommendation and its proposing that knee joint femorotibial metal/polymer non-constrained prostheses be classified into class II. FDA has sought additional data and documentation of the safety and effectiveness of these devices. Marmor (Refs. 330 and 331) reported early results from use of the device. In 1977 (Ref. 332), Chand reported Marmor's results with 103 patients (21 bilateral) with a followup range of 24 to 42 months. The reported incidence of complications ranged from: general—none reported; remote—6 deaths (5.7 percent) from causes reportedly unrelated to the device; systemic—one thrombophlebitis (less than 1 percent); and local—at least 29 percent. The most frequent complication early in the series of patients was immediate postoperative infection with an incidence of 28.8 percent (21 of 73). The next most frequent complication was tibial component loosening, with a reported incidence of 11.6 percent (12 of 102). The reoperation rate for this series was reported as 12 of 123 knees or 9.8 percent.

FDA's review of available literature (Refs. 333 through 337) failed to disclose device experience which would significantly alter the trends already suggested, with the exception of the report of Sneppen, Fredensborg, et al. (Ref. 336), who reported 6 postoperative dislocations out of 50 implantations for a patellofemoral complication incidence of 12 percent.

It has been reported that hundreds of surgeons in the United States and many other parts of the world are implanting the generic knee joint femorotibial metal/polymer non-constrained prosthesis (Ref. 338). Reports of grating, dislocation, or pain associated with the device (Refs. 330, 334, 335, 336, and 339) are attributed by Carlova (Ref. 338) to an "inadvertent" design change of the most widely used size of femoral component. Marmor also recommended not using the 6-millimeter-thick hemitibial components because the polyethylene tended to buckle and loosen (Ref. 339).

As an example of a series of patients with intermediate-term followup, Cracchiolo, et al. (Ref. 340), reported on 118 Gunston/Cracchiolo prostheses that had been implanted in 93 patients. General complications reported were: 1 incidence each of hepatitis and drug allergy; remote complications consisted of 1 patient with cholecystitis and 26 cases of catheter-associated urinary tract infection. The principal systemic intraoperative complication reported was 9 arrhythmias or other

cardiopulmonary events. Local complications included 2 nerve palsies (presumably chronic), 1 femoral artery occlusion necessitating emergency reoperation, 6 prosthesis subluxations, 5 component loosenings, 1 bone fracture, 4 patients with persistent disabling pain, and 22 patients whose postoperative ability to walk unaided was less than fair. The presumed failure incidence during a mean followup of 40 months (range: 24 to 75 months) was 19.4 percent (18 of 93, excluding the "poor" status patients noted above) for this series; including at least a 12.9 percent reoperation incidence.

The following intermediate-term complications have been reported: device loosening/bone resorption (Refs. 341 and 342); design-associated recurrence of musculotendinous contractures or soft tissue deformities (Ref. 343); loss of function associated with pain or change in joint biomechanics (Refs. 334, 339, 343, and 344), and complications relating to tribologic properties, such as friction, lubrication, or wear (Refs. 345 through 359).

Although knee joint femorotibial metal/polymer nonconstrained prostheses are implanted devices, FDA has determined that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of these devices. In addition, FDA has identified and assessed the major risks to health associated with the use of these devices. FDA believes that the major risks, i.e., loosening, infection, and adverse tissue reaction, are related to biological responses of the human body to the presence of the device, the device design, and the underlying joint pathology, and not to physical failure(s) of the device. Clinical experience with these devices has established the persons for whose use the devices are intended and the proper conditions of use. FDA has determined that the probable benefit to health from proper use of these devices outweighs any likelihood of injury or illness resulting from their use. FDA further believes that informative labeling and compliance with general controls may greatly reduce the risks to health associated with the use of these devices. The agency believes that a performance standard is necessary because general controls alone are insufficient to minimize the risks to health presented by these devices.

§ 888.3530; Docket No. 78N–3086; Knee joint femorotibial metal/polymer semi-constrained prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of knee joint femorotibial metal/polymer semi-constrained prostheses:

1. Identification: A knee joint femorotibial metal/polymer semi-constrained prosthesis is an implanted device intended partially to replace a knee joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that consists of a femoral component made of alloys, such as cobalt-chromium-molybdenum, and a tibial component made of ultra-high molecular weight polyethylene, and is limited to those devices intended to be implanted with a polymethylmethacrylate luting agent (bone cement).

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that knee joint femorotibial metal/polymer semi-constrained prostheses be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent loss or reduction of joint function, adverse tissue reaction, or infection. The Panel belives that general controls alone will not provide sufficient control over these characteristics.

Although these are implanted devices, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that the labeling for the device include information on the dimensions and kineamatics of the device and its strength and wear characteristics.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and experience with, the device.

5. Risks to health: (a) Loss or reduction of joint function: Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the Panel recommendation and is proposing that knee joint femorotibial metal/polymer semi-constrained prostheses be classified into class II. FDA has sought additional data and information on the safety and effectiveness of these devices. The following data is representative of clinical experience within the immediate postoperative and short-term followup interval reported by users other than the inventor/developers of the prosthesis. The incidence of complications reported by Holman and Tyer (Ref. 360) was: remote—(2 percent); systemic—(5.7 percent); and local—(not determinable). The failure rate was approximately 15 percent (8 of 53) for this series of semi-constrained knee prostheses, with a followup range of 1 to 10 months. The incidence of complications reported by Insall, et al. (Ref. 361), was: remote—none reported; systemic—(7 percent); and local—(20 percent). The device failure rate was approximately 22 percent (11 of 50 cases) for this series, with a followup of less than 14 months. At least 6 of the clinical failures required a minimum of 1 reoperation and 4 required removal of the prosthesis. Fox (Ref. 362) reported that over a period of 33 months, 74 prostheses were implanted in 62 patients, of which 29 were included in the author's clinical statistics. Local complications included 6 tibial component loosenings, 2 loose tibial markers, and 8 malpositionings of components. Thirty-one knees in an unknown number of patients had at least 1 complication; 9 patients had 2 or more complications. The clinical failure rate was at a minimum of 16 percent (10 of 62) for this series, assuming that each reoperation not otherwise identified was performed upon a different patient, with a followup range of a few days up to 34 months.

Riley and Hungerford (Ref. 363) reported that care in patient selection combined with strict attention to

operative detail can minimize complications caused by surgical procedure. These authors reported that during a period of 41 months, 58 prostheses were implanted in 48, reheumatoid arthritic patients. Three patients died less than 24 months following implantation of the prosthesis and were excluded from the data tabulations. Systemic complications reported were one death from cardiac arrest. Local complications included 1 palsy (transient), 1 residual flexion contracture requiring reoperation, at least 2 confirmed component loosenings, 4 patients with persistent disabling pain, and 1 patient with prominent patellofemoral symptons requiring reoperation. The failure rate was 27.1 percent (13 of 48) for this series—including 8.3 percent reoperation incidence—with a median followup of 36 months (range: 2 weeks to 64 months).

Cracchiolo, et al. (Ref. 364), reported that 92 Geometric prostheses had been implanted in 81 patients. General complications reported were 1 incidence each of hepatitis and pneumonia and 5 of drug allergy; remote complications consisted of 30 cases of catheter-associated urinary tract infection (an incidence of 37 percent). The principal systemic intraoperative complication reported was 6 arrhythmias or other cardiopulmonary events. Local complications included 1 nerve palsy (presumably chronic), 4 deep wound infections (necessitating reoperation), 2 bone fractures, 1 presumed component fracture, 1 dislocation, 9 component loosenings, at least 3 patients with persistent, disabling pain (2 necessitating reoperation) and 25 patients whose postoperative ability to walk unaided was less than fair. The presumed failure incidence was 21 percent (17 of 81, excluding the patients with poor walking status noted above). Only 1 or 2 of the failures occurred later than the first postoperative year. There was at least an 18.5 percent reoperation incidence, with a mean followup of 41 months (range: 24 to 78 months).

Larsson and Ahlgren (Ref. 365) reported on 29 Geometric prostheses that had been implanted in 27 patients. General complications reported were limited to 1 incidence of pneumonia; no remote complications were identified. The principal systemic complication was 1 death attributed to cardiovascular disease sometime after a 12-month postoperative visit. Local complications included 3 deep-wound infections (1 immediate and 2 later than 6 months postoperatively), 3 tibial component loosenings (11.1 percent incidence at 2.5, 3, and 3.5 years postoperatively), 15 patients with less than a 90° flexion/extension arc, 4 patients with radiologic evidence of bone resorption around the tibial component, 5 with persistent swelling, and 6 patients who required support to enable walking.

The following intermediate-term complications have been reported: bony or soft-tissue necrosis (Refs. 9 and 89); design-induced recurrence of musculotendinous contractures or soft-tissue deformities (Refs. 343 and 96); device loosening/bone resorption (Refs. 89, 341, and 342); infection (Refs. 146, 148, 149, 183, 323, and 408); loss of function associated with pain or change in joint biomechanics (Refs. 344 and 360); and complications relating to tribologic properties, such as friction, lubrication, or wear (Refs. 241 through 243 and 345 through 359).

Although knee joint femorotibial metal/polymer semi-constrained prostheses are implanted devices, FDA has determined that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of these devices. In addition, FDA has identified and assessed the major risks to health associated with the use of these devices. FDA believes that the major risks, i.e., loosening, infection, and adverse tissue reaction, are related to biological responses of the human body to the presence of the device, the device design, and the underlying joint pathology, and not to physical failure(s) of the device. Clinical experience with these devices has established the persons for whose use the devices are intended and the proper conditions of use. FDA has determined that the probable benefit to health from proper use of these devices outweighs any likelihood of injury or illness resulting from their use. FDA further believes that informative labeling and compliance with general controls may greatly reduce the risks to health associated with the use of these devices. The agency believes that a performance standard is necessary because general controls alone are insufficient to minimize the risks to health presented by these devices.

§ 888.3540; Docket No. 78N–3087; Knee joint patellofemoral polymer/metal semi-constrained prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of knee joint patellofemoral polymer/metal semi-constrained prostheses:

1. Identification: A knee joint patellofemoral polymer/metal semi-constrained prosthesis is an implanted two-part device intended partially to replace a knee joint in the treatment of primary patellofemoral arthritis or chondromalcia. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It as no linkage across-the-joint. This generic type of device includes a component made of alloys, such as cobalt-chromium-molybdenum or austenitic steel, for resurfacing the intercondylar groove (femoral sulcus) on the anterior aspect of the distal femur, and a patellar component made of ultra-high molecular weight polyethylene. This generic type of device is limited to those devices intended for implantation with a polymethylmethacrylate luting agent (bone cement). The patellar component is designed to be implanted only with its femoral component.

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that knee joint patellofemoral polymer/metal semi-constrained prostheses be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent loss or reduction of joint function, adverse tissue reaction, or infection. The Panel has limited the indications for use of the device to treatment of primary patellofemoral arthritis or chondromalacia (Ref. 366). The Panel believes that general controls alone will not provide sufficient control over these characteristics.

Although a knee joint patellofemoral polymer/metal semi-constrained prosthesis is an implanted device, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Panel believes that, despite the risk of infection, the rate of clinical success associated with implantation of these prostheses surpasses that achieved with more established procedures.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and experience with, similar devices and a presentation made to the Panel (Ref.

366). James Fox reported on his clinical experience with this generic type of device. Fox stated that patellofemoral joint replacement was performed in more than 60 knees, with followup since 1974. He reported that he, as well as his patients, were pleased with the results.

5. Risks to health: (a) Loss or reduction of joint function: Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution of wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA disagrees with the Panel recommendation and is proposing that knee joint patellofemoral polymer/metal semi-constrained prostheses be classified into class III. Other than the presentation to the Panel made by James Fox (Ref. 366), FDA is not aware of any clinical data of this device. Moreover, because Dr. Fox provided no details regarding the device or its implantation procedure, FDA is not certain that the devices Dr. Fox implanted belong to this generic class.

FDA has reviewed the pertinent engineering and clinical literature to determine whether sufficient information exists to permit the establishment of a performance standard for this device. FDA has found that the literature discussing the most crucial information needed to establish a standard is inadequate. For example, the correlation between pertinent preclinical mechanical tests and clinical findings are unknown.

FDA finds that knee joint patellofemoral polymer/metal semi-constrained prostheses are implanted devices that are intended to be used in relieving disabling pain and in restoring or minimizing further loss of functional use of a joint of limb. FDA believes these uses are of substantial importance in preventing impairment of human health. However, FDA believes insufficient clinical experience exists to fully establish the persons for whose use the devices are intended and the proper conditions of use. The agency believes that the probable benefit to health from use of these devices does not compare favorably with the likelihood of illness or injury resulting from their use.

Because of the lack of adequate data to demonstrate the safety and effectiveness of these implanted devices, FDA believes that use of knee joint patellofemoral polymer/metal semi-constrained prostheses prevents an unreasonable risk of illness or injury. Because these devices are intended to be implanted in the human body, the Federal Food, Drug, and Cosmetic Act requires that they be classified into class III unless FDA determines that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of these devices. On the basis of available information, FDA cannot make that determination. FDA believes that insufficient information exists to support the conclusion that general controls or performance standards will provide reasonable assurance of the safety and effectiveness of the devices. Therefore, FDA is proposing that these devices be classified into class III.

§ 888.3550; Docket No. 78N–3088; Knee joint patellofemorotibial polymer/metal/metal constrained prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of knee joint patellofemorotibial polymer/metal/metal constrained prostheses:

1. Identification: A knee joint patellofemorotibial polymer/metal/metal constrained prosthesis is an implanted device intended to replace a knee joint. The device prevents dislocation in more than one anatomic plane and has components that are linked together. This generic type of device includes prostheses that have a femoral component, a tibial component, a cylindrical bolt and accompanying locking hardware that are all made of alloys, such as cobalt-chromium-molybdenum, and a retropatellar resurfacing component made of ultra-high molecular weight polyethylene. The retropatellar resurfacing component may be attached to the resected patella either with a metallic screw or luting agent. All stemmed metallic components within this generic class are intended to be implanted with a polymethylmethacrylate luting agent (bone cement).

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that knee joint patellofemorotibial polymer/metal/metal constrained prostheses be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent loss or reduction of joint function, adverse tissue reaction, or infection. The Panel believes that general controls alone will not provide sufficient control over these characteristics.

Although a knee joint patellofemorotibial polymer/metal/metal constrained prosthesis is an implanted device, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Panel believes that, despite the risk of infection, the rate of clinical success associated with implantation of these prostheses surpasses that achieved with more established procedures. The Panel recommends that the labeling for the device include information on the dimensions and kinematics of the device and its strength and wear characteristics.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and experience with, the device and a presentation made to the Panel. Dr. Roland Pritchard and Dr. James Fox (Ref. 366) described their experiences with various patellofemoral joint replacing devices including this generic type of device. Dr. Pritchard has implanted patellofemorotibial joint prostheses in at least 100 patients during the past 3 years. Also, Dr. Fox reported that he has achieved good results in over 60 cases since 1974.

5. Risks to health: (a) Loss or reduction of joint function: Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surface of the device and the release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence

of the prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the Panel recommendation and is proposing that knee joint patellofemorotibial polymer/metal/metal constrained prostheses be classified into class II. FDA has sought additional data and information on the safety and effectiveness of these devices.

In May 1962, Young (Ref. 368) reported on a series of 16 patients ranging in age from 31 to 70 years who had a Young design prosthesis implanted (two were bilateral implantations). With a followup time between 9 and 61 months (median of 20 months), 7 of these 16 experienced a clinical failure (43.8 percent) with a mean time of about 9 months before prosthesis removal and arthrodesis (joint fusion). In a later report in 1971, Young, (Ref. 373) stratified results by indication: at least 3 of 19 osteoarthrotic knees were failures (15.8 percent incidence); at least 17 of 45 rheumatoid knees failed (37.8 percent incidence); of 4 replacements for giant-cell tumor, 2 failed (50 percent incidence); and at least 6 of 10 traumatic arthritic kees failed (60 percent incidence). Young noted that 9 knees examined sometime after initial implantation demonstrated darkening in tissue adjacent to metallic components. Young believed that the darkening of tissue was caused by tissue contamination from corrosion products. Young also believed that similar tissue darkening was noted by Girzadas, Geens, et al. (Ref. 369). Young believed that the darkening was caused by the bolts used in his design that were made from a cobalt-based alloy, whereas the other components were made from a casting alloy. Young stated that, as a result of his survey of the clinical results of 85 physicians who had implanted the Young-design prosthesis, he was not optimistic about use of the hinged metal/metal knee prostheses and their furture for replacement arthroplasty.

In 1973, Hanslik (Ref. 374), reported results of using the device in 50 patients (two bilaterally implanted), principally for the indication of osteoarthrosis. Minimum followup was not given, while maximum followup was possibly 4 years. The patients ranged in age from 56 to 76 years. At least four failures (8 percent) were associated with restricted gliding of the patellofemoral articulation: one of these was attributed to polymethylmethacrylate-induced bony necrosis. Hanslik used the Young (Ref. 368) design of prosthesis and had made major modifications in implantation technique as recommended by Friedebold and Radloff (Refs. 367 and 370 through 372). Hanslik performed partial resection of the patella rather than total excision and used a polymethylmethacrylate luting agent to grout the medullary stems (presumably in addition to the cancellous bone screws recommended by Young). Friedebold and Radloff (Ref. 372) reported on use of the prosthesis in femorotibial replacement in 11 patients ranging in age from 50 to 80 years, with between 6 months and 5 years of followup. There were three failures (27.3 percent).

Although knee joint patellofemorotibial polymer/metal/metal constrained prostheses are implanted devices, FDA has determined that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of these devices. In addition, FDA has identified and assessed the major risks to health associated with the use of these devices. FDA believes that the major risks, i.e., loosening, infection, and adverse tissue reaction, are related to biological responses of the human body to the presence of the device, the device design, and the underlying joint pathology, and not to physical failure(s) of the device. Clinical experience with these devices has established the persons for whose use the devices are intended and the proper conditions of use. FDA has determined that the probable benefit to health from proper use of these devices outweighs any likelihood of injury or illness resulting from their use. FDA believes that informative labeling and compliance with general controls may greatly reduce the risks to health associated with the use of these devices. The agency believes that a performance standard is necessary because general controls alone are insufficient to minimize the risks to health presented by these devices.

§ 888.3560: Docket No. 78N–3090; Knee joint patellofemorotibial polymer/metal/ploymer semi-constrained prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of knee joint patellofemorotibial polymer/metal/polymer semi-constrained prostheses:

1. Identification: A knee joint patellofemorotibial polymer/metal/polymer semi-constrained prosthesis is an implanted device intended to replace a knee joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that have a femoral component made of alloys, such as cobalt-chromium-molybdenum, and a tibial component or components and a retropatellar resurfacing component made of ultra-high molecular weight polyethylene. This generic type of device is limited to those devices intended to be implanted with a polymethylmethacrylate luting agent (bone cement).

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that knee joint patellofemorotibial polymer/metal/polymer semi-constrained prostheses be classified into class II because the design, material composition, and mechancial properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent loss or reduction of joint function, adverse tissue reaction, or infection. The Panel believes that general controls will not provide sufficient control over these characteristics.

Although a knee joint patellofemorotibial polymer/metal/polymer semi-constrained prosthesis is an implanted device, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Panel believes that, while the risk of infection is greater, the rate of clinical success associated with implantation of this prosthesis surpasses that achieved with more established procedures. The Panel also believes that a performance standard will adequately control the risks associated with the device, such as problems relating to device geometry or mechanical design, and component loosening.

The Panel recommends that the labeling for the device include information on the dimensions and kinematics of the device and its strength and wear characteristics.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and experience with, the device.

5. Risks to health: (a) Loss or reduction of joint function: Improper design, or inadequate mechanical

properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the Panel recommendation and is proposing that knee joint patellofemorotibial polymer/metal/polymer semi-constrained prostheses be classified into class II. FDA has sought additional data and information on the safety and effectiveness of these devices. Insall, Ranawat, and coworkers (Refs. 375 through 379) reported on the implantation of the device in 183 patients (220 devices). Complications reported were: general—8 deaths (causes unspecified) reported within 3 years after implantation; remote—none reported; systemic—4 percent from clinical signs and symptoms, 35 percent with "positive" radiographic venograms (which imply blockage of a blood vessel), 11 percent with "positive" radiographic lung scans (direct evidence of clot in pulmonary artery); and local—greater than 23 percent. Of the 220 knees involved, 3 of 139 osteoarthritic knees and 1 of the 81 rheumatoid arthritic knees developed partial femorotibial dislocations.

The complications exhibiting the greatest incidence were: superficial infection (wound drainage) (22.9 percent); developing radiolucency in one or more components (22 percent); tibial component anteroposterior tilt greater than 5 degrees (8 percent); femoral component valgus tilt greater than 5 degrees (5 percent) delayed wound healing (3.8 percent); and pain persisting or originating postoperatively (3.6 percent).

Although knee joint patellofemorotibial polymer/metal/polymer semi-constrained prostheses are implanted devices, FDA has determined that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of these devices. In addition, FDA has identified and assessed the major risks to health accompanying the use of these devices. FDA believes that the major risks, i.e., loosening, infection, and adverse tissue reaction, are related to biological responses of the human body to the presence of the device, the device design, and the underlying joint pathology, and not to physical failure(s) of the device. Clinical experience with these devices has established the persons for whose use the devices are intended and the proper conditions of use. FDA has determined that the probable benefit to health from proper use of these devices outweighs any likelihood of injury or illness resulting from their use. FDA further believes that labeling and compliance with general controls may greatly reduce the risks to health associated with the use of these devices. The agency believes that a performance standard is necessary because general controls alone are insufficient to minimize the risks to health presented by these devices.

§ 888.3570; Docket No. 78N–3091; Knee joint femoral (hemi-knee) metallic uncemented prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of knee joint femoral (hemi-knee) metallic uncemented prostheses:

1. Identification: A knee joint femoral (hemi-knee) metallic uncemented prosthesis is an implanted device made of alloys, such as cobalt-chromium-molybdenum, that is intended to replace part of a knee joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that consist of a femoral component with or without protuberance(s) for the enhancement of fixation and is limited to those devices intended for implantation without use of polymethylmethacrylate luting agent (bone cement).

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that knee joint femoral (hemi-knee) metallic uncemented prostheses be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent loss or reduction of limb function, adverse tissue reaction, or infection. The Panel believes that general controls alone will not provide sufficient control over these characteristics. Although a knee joint femoral (hemi-knee) metallic uncemented prosthesis is an implanted device, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Panel also recommends that the labeling for the device include information on the dimensions and kinematics of the device and its strength and wear characteristics.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and experience with, the device.

5. Risks to health: (a) Loss or reduction of joint or limb function: Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in the loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and the systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection. (d) Death: Death may result from lipoembolic sequelae or thromboembolic complications during or immediately following implantation.

FDA disagrees with the Panel recommendation and is proposing that knee joint femoral (hemi-knee) metallic uncemented prostheses be classified into class III. FDA has sought additional data on the safety and effectiveness of the device. FDA is concerned about both the severity of the clinical complications resulting from use of the device and the rate at which these complications occur. The agency used the complication classification scheme developed by Fox (Ref. 380) and grouped complications by time periods following surgical implantation; immediate postoperative complications, within two weeks; short term, within 24 months; and long term, more than 24 months. Platt and Pepler reported in 1969 their clinical results on 55 patients who had this prosthesis implanted with up to 10 years followup

(Ref. 381). Their reported incidence of complications ranged from: (1) General—none reported, and (2) systemic—none reported; to (3) remote—1 late (2 years postoperatively) paranoid schizophrenia (1.8 percent); and (4) local—at least 45 percent. The most frequent complication was immediate postoperative infection with a presumed incidence of 25.5 percent. The reoperation rate for this series of patients was reported as 20 out of 62 knees or 32.4 percent; assuming only one reoperation per patient a 36.4 percent revision rate will result.

Aufranc and Jones, et al. (Refs. 382 through 384), made extensive modifications to M. Smith-Peterson's original "keeled" femoral condylar mold (Ref. 385) and commenced a series of device implantations employing a noncemented stemmed implant in 1952. Clinical results on 64 patients with a minimum of 1-year followup showed that the incidence of complications were, (1) zero for general and remote categories (2) 3.1 percent for systemic (2 thrombophlebitic episodes), and (3) a minimum of 25 percent for cumulated local complications. Matching Platt and Pepler's experience (Ref. 381), the most frequent complication observed was immediate postoperative infection with a presumed incidence of 20.3 percent. This series of patients, as of mid-1969, displayed a reoperation rate of 14 out of 79 knees (17.7 percent), assuming only one reoperation per patient. Considering this result, with their report of 16 clinical results rated at less than "fair," the failure rate is calculated as 38 percent with an average followup time of 87 months. Aufranc and Jones (Ref. 382) note that 6 of their initial 14 implantations were failures (42.9 percent) with a maximum followup of 5 years; apparently 10 more years of surgical experience reduced the overall failure rate by 5 percent, without altering the principal reported failure modes: infection and "poor" clinical result.

Further review of available literature (Refs. 386 through 395), failed to disclose device experience which would significantly alter the trends described above.

FDA finds that knee joint femoral (hemi-knee) metallic uncemented prostheses are implanted devices that are intended to be used in relieving disabling pain and in restoring or minimizing futher loss of functional use of a joint or a limb. FDA believes these uses are of substantial importance in preventing impairment of human health. However, FDA believes that insufficient clinical experience exists to fully establish the persons for whose use the devices are intended and the proper conditions of use. The agency believes that the probable benefit to health from use of the devices does not compare favorably with the likelihood of illness or injury resulting from their use.

Because of the lack of adequate data to demonstrate the safety and effectiveness of these implanted devices, FDA believes that use of the knee joint femoral (hemi-knee) metallic uncemented prosthesis presents an unreasonable risk of illness or injury. Because these devices are intended to be implanted in the human body, the Federal Food, Drug, and Cosmetic Act requires that they be classified into class III unless FDA determines that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of these devices. On the basis of available information, FDA cannot make this determination. Moreover, FDA believes that insufficient information exists to support the conclusion that general controls or performance standards will provide reasonable assurance of the safety and effectiveness of these devices. Therefore, FDA is proposing that these devices be classified into class III.

§ 888.3580; Docket No. 78N–3092; Knee joint patellar (hemi-knee) metallic resurfacing uncemented prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of knee joint patellar (hemi-knee) metallic resurfacing uncemented prostheses:

1. Identification: A knee joint patellar (hemi-knee) metallic resurfacing uncemented prosthesis is an implanted device made of alloys, such as cobalt-chromium-molybdenum, intended to replace the retropatellar articular surface of the patellofemoral joint. The device limits minimally (less than normal anatomic constraints) translation in one or more planes. It has no linkage across-the-joint. This generic type of device includes prostheses that have a retropatellar resurfacing component and an orthopedic screw to transfix the patellar remnant. This generic type of device is limited to those devices intended for implantation without use of polymethylmethacrylate luting agent (bone cement). The device is intended for use only in treatment of degenerative and posttraumatic patellar (osteo) arthritis.

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that knee joint patellar (hemi-knee) metallic resurfacing uncemented prostheses be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent loss or reduction of joint function, adverse tissue reaction, or infection. The Panel believes that general controls alone will not provide sufficient control over these characteristics. Although these are implanted devices, the Panel believes that premarket approval is not necessary because sufficient information exists to establish performance standards that will provide reasonable assurance of the safety and effectiveness of the device. The Panel recommended that the indications for use of the device be limited to degenerative and posttraumatic patellar arthritis (Ref. 396). The Panel recommends that the labeling for the device include information on the dimensions and kinematics of the device and its strength and wear characteristics.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Loss or reduction of joint function: Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the Panel recommendation and is proposing that knee joint pateller (hemi-knee) metallic resurfacing uncemented prostheses be classified into class II. FDA has sought additional data and information on the safety and effectiveness of these devices. In 1955, D. C. McKeever (Ref. 397) reported results obtained from implanting this device in 39 patients (4 bilaterally). The reported median

followup time was 54 months. Reported complications were limited to: 2 patients in which too large a prosthesis had been implanted, thus unnecessarily prolonging convalescence; 3 patients with short-term deep infection; 1 patient with a late developing deep infection; and 1 patient with bone necrosis. Four of these complication occurrences necessitated reoperation for removal of the device and 3 knees were arthrodesed as well, producing a cumulative failure rate of 10.3 percent for the series.

DePalma, et al, (Ref. 398), employed the McKeever design in a series of patients, 17 of which were discussed in 1960. With a median followup time of 35 months, they reported only three results that they considered less than good; two fair and one poor. No appearance of complications or reoperations were reported, producing a cumulative failure rate of 5.9 percent. In 1973, Levitt (Ref. 399) reviewed DePalma's series of patients when 68 devices had been implanted (including bilaterals). When a prosthesis was implanted, patients with degenerative joint diseases frequently had had one or more other surgical procedures performed concurrently on the same joint. Levitt noted a readily detectable continuing progression of arthritic degeneration with time as followups were extended. Levitt reexamined 10 out of 20 patients of DePalma's series and determined that 50 percent had unsatisfactory results. He concluded that it was impossible to determine the clinical success of the prosthesis in a joint involved with degenerative disease upon which one or more other surgical procedures had been carried out concurrently with implantation, i.e., a determination of whether the unsatisfactory result(s) was secondary to the continuation of the disease process or to the inefficacy of the prosthesis.

Vermeulen and coworkers in 1973 (Ref. 400) reported results in eight aged female patients with from 3 to 8 years followup. It was not possible to determine from the report the degree of individual clinical improvement.

In reviewing osteoarthrosis of the patellofemoral joint, I. S. Smillie remarked in 1975 that the McKeever prosthesis has not met with success in other surgeons' hands (Ref. 401). This view has been corroborated by a panel member, who noted that the devices did not demonstrate much clinical success and that many of them had to be removed (Ref. 402), and they have seen limited use since the decade of the fifties (Ref. 396).

In 1975, Hanslik (Ref. 403) reported on a series of implantations of the McKeever patellar resurfacing device accompanied by tibial plateau resection and stapling (proximal tibial osteotomy). Seventy-six patients (2 bilaterals) with from 1 to 4.5 years followup were reviewed; however, it was impossible to determine from the report the degree of individual clinical improvement. FDA notes that because the two procedures were done concurrently, it is not possible to attribute any degree of clinical success entirely to the patellar resurfacing device. FDA is unaware of any published data since 1975 showing use of this generic type of device.

Although knee joint patellar (hemi-knee) metallic resurfacing uncemented prostheses are implanted devices, FDA has determined that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of these devices. In addition, FDA has identified and assessed the major risks to health associated with the use of these devices. FDA believes that the major risks, i.e., loosening, infection, and adverse tissue reaction, are related to biological responses of the human body to the presence of the device, the device design, and the underlying joint pathology, and not to physical failure(s) of the device. Clinical experience with these devices has established the persons for whose use the devices are intended and the proper conditions of use. FDA has determined that the probable benefit to health from proper use of these devices outweighs any likelihood of injury or illness resulting from their use. FDA believes that informative labeling and compliance with general controls may greatly reduce the risks to health associated with the use of these devices. The agency believes that a performance standard is necessary because general controls alone are insufficient to minimize the risks to health presented by these devices.

§ 888.3590; Docket No. 78N–3093; Knee joint tibial (hemi-knee) metallic resurfacing uncemented prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of knee joint tibial (hemi-knee) metallic resurfacing uncemented prostheses:

1. Identification: A knee joint tibial (hemi-knee) metallic resurfacing uncemented prosthesis is an implanted device intended partially to replace a knee joint. The device limits minimally (less than normal anatomic constraints) translation in one or more planes. It has no linkage across-the-joint. This prosthesis is made of alloys, such as cobalt-chromium-molybdenum, and is intended to resurface one tibial condyle. The generic type of device is limited to those devices intended for implantation without the use of a polymethylmethacrylate luting agent (bone cement).

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that knee joint tibial (hemi-knee) metallic resurfacing uncemented prostheses be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent loss or reduction of joint function, adverse tissue reaction, or infection. The Panel believes that general controls alone will not provide sufficient control over these characteristics.

Although these are implanted devices, and Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. the Panel recommends that the labeling for the device include information on the dimensions and kinematics of the device and its strength and wear characteristics.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Loss or reduction of joint function: Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properities of the device such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the Panel recommendation and is proposing that

knee joint tibial (hemi-knee) metallic resurfacing uncemented prostheses be classified into class II. FDA has sought additional data and information on the safety and effectiveness of these devices.

Stauffer, et al. (Ref. 404), reported their results following implantation of the prosthesis in 28 patients (9 were bilaterally implanted) with a mean followup of 18 months (range: 7 to 34 months). The principal local complications included recurring valgus deformity, patellofemoral pain, and decreased patellar mobility. Seventeen of 37 knees were rated "poor" on the authors' evaluation scale, resulting in a 45.9 percent failure rate. The authors emphasized that the physical condition of a patient's patellofemoral joint before implantation was a major factor in the postoperative functional results. The authors suggested that the condition of a patient's patellofemoral joint be evaluated and reported at the time the prosthesis is implanted, to allow more accurate assessment of the safety and effectiveness of the prosthesis after implantation.

Burrough, et al. (Ref. 405), compared the implantation in the patient's tibia of one tibial condylar resurfacing prosthesis with the implantation of two of the prostheses. Twenty of their 22 patients were rheumatoid arthritics. Equal numbers of patients' knees had one or two tibial condyles resurfaced with the prosthesis, with a mean followup of 10.6 months (range: 2 through 14 months). No complications were reported. Burrough, et al., stated that implantation of two of the prostheses in a patient's tibia provided more improvement in walking and more pain reduction than implantation of one of the devices. However, Henderson and Peterson (Ref. 406) and Clary and Couk (Ref. 407) disagree. FDA reviewed other published reports of clinical studies of tibial resurfacing prostheses (Refs. 408 through 442). Two reports—that of Friedebold and Radloff (Ref. 422) and that of Lowe and coworkers (Ref. 425)—describe the use of a polymethylmethacrylate luting agent to fix the prosthesis into the surgically prepared cavity. The original developers of the prosthesis intended that the device not be cemented (Refs. 409, 410, 418, and 442). The identification of the knee joint tibial (hemi-knee) metallic resurfacing uncemented prosthesis excludes the use of a polymethylmethacrylate luting agent with this device, because FDA believes that insufficient information exists to establish a performance standard when a luting agent is used with the device.

Although knee joint tibial (hemi-knee) metallic non-constrained resurfacing uncemented prostheses are implanted devices, FDA has determined that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of these devices. In addition, FDA has identified and assessed the major risks to health associated with the use of these devices. FDA believes that the major risks, i.e., loosening, infection, and adverse tissue reaction, are related to biological responses of the human body to the presence of the device, the device design, and the underlying joint pathology, and not to physical failure(s) of the device. Clinical experience with these devices has established the persons for whose use the devices are intended and the proper conditions of use. FDA has determined that the probable benefit to health from proper use of these devices outweighs any likelihood of injury or illness resulting from their use. FDA further believes that informative labeling and compliance with general controls may greatly reduce the risks to health associated with the use of these devices.

§ 888.3640; Docket No. 78N–3094; Shoulder joint constrained prostheses.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of shoulder joint constrained prostheses:

1. Identification: A shoulder joint constrained prosthesis is an implanted device intended to replace a shoulder joint. The device prevents dislocation in more than one anatomic plane and has components that are linked together. This generic type of device includes prostheses that have a humeral component made of alloys, such as cobalt-chromium-molybdenum, and a glenoid component made of this alloy or a combination of this alloy and ultra-high molecular weight polyethylene. This generic type of device is limited to those devices intended for implantation with a polymethylmethacrylate luting agent (bone cement).

2. Recommended classification: Class III. The Panel recommend that premarket approval of this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that shoulder joint constrained prostheses be classified into class III because the device is implanted and is intended to be used in relieving disabling pain and in restoring or minimizing further loss of functional use of a joint or limb. The Panel believes these uses are of substantial importance in preventing impairment of human health.

The Panel believes that general controls alone will not provide sufficient control over these characteristics. The Panel also believes that it is not possible to establish an adequate performance standard for the device. There is a lack of safety and effectiveness data to demonstrate the satisfactory performance of the device. The Panel has found that insufficient information exists to support the conclusion that general controls or performance standards will be adequate to provide reasonable assurance of the safety and effectiveness of the device. Therefore, the device must be subject to premarket approval to assure its safety and effectiveness.

The Panel also recommends that the labeling for the device include information on the dimensions and kinematics of the device and its strength and wear characteristics.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of the device and on their knowledge of the medical literature (Refs. 443 through 446). Two of these references (Refs. 443 and 444) describe a shoulder joint constrained prosthesis (Fenlin and Zippel designs) and report that implantation of the device relieved pain in 16 of 17 patients. In the patient with the painful prosthesis, the authors believed that the device had loosened. The times of implantation were not reported.

Fenlin (Ref. 445) reported that the Fenlin design prosthesis had been implanted in five patients. The results in three of these patients were discussed. One patient was described as being free of pain, and able to use the operated shoulder for all normal activities, except those requiring elevation of the arm above 80°. The length of followup in this patient was 20 months. Complications were reported in the other two patients. In one patient, the device had loosened at 3 months postoperatively, due to abnormal anatomy of the glenoid. The second patient suffered partial nerve palsy due to damage of the axillary nerve during surgery. Linscheid and Cofield (Ref. 446) reported on the implantation of 13 constrained shoulder joint prostheses (6 of the Stanmore design, and 7 of the Bickel design). The average time of followup was reported as 13 months and ranged from 2 to 26 months. There were two cases of dislocations of the Stanmore design

prosthesis and one case of dislocation of the Bickel design prosthesis. There were two additional complications reported with the Bickel design device; one case of fracture of the humeral component and one case of loosening of the glenoid component.

5. Risks to health: (a) Loss or reduction of joint function: Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or lossening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the recommendation of the Panel and is proposing that shoulder joint constrained prostheses be classified into class III. FDA has sought additional data and information on the safety and effectiveness of these devices. Cofield (Ref. 447) reported that prosthetic replacement of the shoulder joint is an experimental, investigational procedure. This author noted that basic knowledge about shoulder biomechanics is limited and that current knowledge of shoulder prostheses is not sufficient to establish the requirements of a prosthetic replacement. Buechel, et al. (Ref. 448), noted that complications with current shoulder prostheses have been associated with the designs of the devices: (1) The Bickel design shoulder joint prosthesis was reported to dislocate and loosen due to the limited motion of the prosthesis; (2) the prosthesis design used by Lettin and Scales (presumably the Stanmore design shoulder prosthesis) was reported to significantly limit joint motion, then sublux, and eventually dislocate at the extremes of normal joint motion. Clinical results with several prosthesis designs were reported by Cofield (Ref. 447, 449, and 450). Eleven persons in whom Bickel design prostheses had been implanted were evaluated 18 months to 39 months postoperatively (Ref. 449). Three (27 percent) were experiencing significant pain. The components of the Bickel device had dislocated in two cases. The glenoid component had dislodged from the scapula in two cases and loosened in one. The humeral component had fractured in two other cases. Reoperation was required in four patients and was needed in two or three others. Cofield reported that further clinical and mechanical deterioration in these patients was anticipated due to progressive loosening of the glenoid components and fatigue fracture of the neck of the humeral component, which was not believed to be strong enough. These authors concluded that this type of shoulder joint replacement (i.e., the Bickel design) is not justified. Cofield (Refs. 447 and 450) also reported clinical results in nine patients who had received Stanmore prostheses. After an average postoperative time of 1 year (ranging between 4 and 18 months), six patients had satisfactory relief of pain and three had significant pain. The glenoid component had loosened in two patients. FDA concurs with the Panel that the reported clinical experience with these devices does not establish their long-term safety and effectiveness.

FDA finds that shoulder joint constrained prostheses are implanted devices that are intended to be used in relieving disabling pain and in restoring or minimizing further loss of functional use of a joint or a limb. FDA believes these uses are of substantial importance in preventing impairment of human health. FDA believes that insufficient clinical experience exists to fully establish the persons for whose use the devices are intended and the proper conditions of use. The agency believes that the probable benefit to health from use of the devices does not compare favorably with the likelihood of illness or injury resulting from their use.

Because of the lack of adequate data to demonstrate the safety and effectiveness of these implanted devices, FDA believes that use of the shoulder joint constrained prosthesis presents an unreasonable risk of illness or injury. Because these devices are intended to be implanted in the human body, the Federal Food, Drug, and Cosmetic Act requires that they be classified into class III unless FDA determines that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of these devices. On the basis of available information, FDA cannot make that determination. FDA believes that insufficient information exists to support the conclusion that general controls or performance standards will provide reasonable assurance of the safety and effectiveness of these devices. Therefore, FDA is proposing that these devices be classified into class III.

§ 888.3650; Docket No. 78N–3095; Shoulder joint non-constrained prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of shoulder joint non-constrained prostheses:

1. Identification: A shoulder joint non-constrained prosthesis is an implanted device intended to replace a shoulder joint. The device limits minimally (less than normal anatomic constraints) translation in one or more planes. It has no linkage across-the-joint. This generic type of device includes prostheses that have a humeral component made of alloys, such as cobalt-chromium-molybdenum, and a glenoid resurfacing component made of ultra-high molecular weight polyethylene, and is limited to those devices intended for implantation with a polymethylmethacrylate luting agent (bone cement).

2. Recommended classification: Class III. The Panel recommends that premarket approval of this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that shoulder joint non-constrained prostheses be classified into class III because the devices are implanted and are intended to be used in relieving disabling pain and in restoring or minimizing further loss of functional use of a joint or limb. The Panel believes these uses are of substantial importance in preventing impairment of human health. The Panel believes that general controls alone will not provide sufficient control over these characteristics. The Panel believes that it is not possible to establish an adequate performance standard for the device. There is a lack of safety and effectiveness data to demonstrate the satisfactory performance of the device. The Panel also believes that insufficient information exists to support the conclusion that general controls or performance standards will be adequate to provide reasonable assurance of the safety and effectiveness of the device. Therefore, the device must be subject to premarket approval to assure its safety and effectiveness.

The Panel recommends that the labeling for the device include information on the dimensions and kinematics of the device and its strength and wear characteristics.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of the

device and on their knowledge of the medical literature.

5. Risks to health: (a) Loss or reduction of joint function: Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss of reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the Panel recommendation and is proposing that shoulder joint non-constrained prostheses be classified into class III. FDA has reviewed the Panel recommendation and has sought additional information on the safety and effectiveness of the device. After reviewing the clinical experience with the device, Cofield (Ref. 451) reported that clinical results from implantation of four of these prostheses had been presented. Published clinical reports were available for only one of these implantations. Neer (Ref. 452) reported that the early results were good with the device he implanted. Cofield (Ref. 451) also presented his clinical experience with the device. Cofield discussed 40 of his patients, 33 of whom have had shoulder joint non-constrained prostheses implanted for more than 3 months. He did not report the maximum or average times of implantation. Complications included one infection requiring removal of the device, one postoperative dislocation of the joint which required reoperation, one axillary nerve injury which also required reoperation, one case of heterotopic bone formation, and one retearing of a muscle cuff repair.

FDA finds that shoulder joint non-constrained prostheses are implanted devices that are intended to be used in relieving disabling pain and in restoring or minimizing further loss of functional use of a joint or limb. FDA believes these uses are of substantial importance in preventing impairment of human health. FDA believes that insufficient clinical experience exists to fully establish the persons for whose use the devices are intended and the proper conditions of use. The agency believes that the probable benefit to health from use of the devices does not compare favorably with the likelihood of illness or injury resulting from their use.

Because of the lack of adequate data to demonstrate the safety and effectiveness of these implanted devices, FDA believes that use of the shoulder joint non-constrained prosthesis presents an unreasonable risk of illness or injury. Because these devices are intended to be implanted in the human body, the Federal Food, Drug, and Cosmetic Act requires that they be classified into class III unless FDA determines that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of these devices. On the basis of available information, FDA cannot make this determination. FDA believes that insufficient information exists to support the conclusion that general controls or performance standards will provide reasonable assurance of the safety and effectiveness of these devices. Therefore, FDA is proposing that these devices be classified into class III.

§ 888.3660; Docket No. 78N–3096; Shoulder joint semi-constrained prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of shoulder joint semi-constrained prostheses:

1. Identification: A shoulder joint semi-constrained prothesis is an implanted device intended to replace a shoulder joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that have a humeral resurfacing component made of alloys, such as cobalt-chromium-molybdenum, and a glenoid resurfacing component made of ultra-high molecular weight polyethylene, and is limited to those devices intended for implantation with a polymethyl-methacrylate luting agent (bone cement).

2. Recommended classification: Class III. The Panel recommends that premarket approval of this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that shoulder joint semi-constrained prostheses be classified into class III because the devices are implanted and are intended to be used in relieving disabling pain and in restoring or minimizing further loss of functional use of a joint or limb. The Panel believes these uses are of substantial importance in preventing impairment of human health.

The Panel believes that general controls alone will not provide sufficient control over these characteristics. The Panel believes that it is not possible to establish an adequate performance standard for the device. There is a lack of safety and effectiveness data to demonstrate the satisfactory performance of the device. The Panel has found that insufficient information exists to support the conclusion that general controls or performance standards will be adequate to provide reasonable assurance of the safety and effectiveness of the device. Therefore, the device must be subject to premarket approval to assure its safety and effectiveness.

The Panel recommends that the labeling for the device include information on the dimensions and kinematics of the device and its strength and wear characteristics.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of the device and on their knowledge of the medical literature.

5. Risks to health; (a) Loss or reduction of joint function: Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA agress with the Panel recommendation and is proposing that shoulder joint semi-constrained prostheses be classified into class III. FDA has sought additional data and information on the safety and effectiveness of the device. Preliminary clinical results with the device were reported by Siegel, et al. (Ref. 453). The authors implanted the St. George design shoulder prosthesis in 28 patients. Postoperative evaluation of 24 patients early in the series revealed that the best results, including pain relief and increased joint range of motion, were obtained on rheumatoid patients.

Complications included infection in one patient and dislocation of the device in two others. The authors stated that longer periods of observation were needed to determine the indications for use of a total shoulder prosthesis of this design.

FDA believes that Siegel, et al.'s, data are insufficient to establish the safety and effectiveness of the prostheses. Additional studies with longer followup times are needed. FDA finds that shoulder joint semi-constrained prostheses are implanted devices that are intended to be used in relieving disabling pain and in restoring or minimizing further loss of functional use of a joint or limb. FDA believes these uses are of substantial importance in preventing impairment of human health. FDA believes that insufficient clinical experience exists to fully establish the persons for whose use the devices are intended and the proper conditions of use. The agency believes that the probable benefit to health from use of the devices does not compare favorably with the likelihood of illness or injury resulting from their use.

Because of the lack of adequate data to demonstrate the safety and effectiveness of these implanted devices, FDA believes that use of the shoulder joint semi-constrained prosthesis presents an unreasonable risk of illness or injury. Because these devices are intended to be implanted in the human body, the Federal Food, Drug, and Cosmetic Act required that they be classified into class III unless FDA determines that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of these devices. On the basis of available information, FDA cannot make that determination. Moreover, FDA believes that insufficient information exists to support the conclusion that general controls or performance standards will provide reasonable assurance of the safety and effectiveness of these devices. Therefore, FDA is proposing that these devices be classified into class III.

§ 888.3680; Docket No. 78N–3058; Shoulder joint glenoid (hemi-shoulder) prosthesis.

The Orthopedic Device Classification Panel, and FDA advisory committee, made the following recommendations regarding the classification of shoulder joint glenoid (hemi-shoulder) prostheses:

1. Identification: A shoulder joint glenoid (hemi-shoulder) prosthesis is an implanted device that has a glenoid (socket) component made of alloys, such as cobalt-chromium-molybdenum, and that is intended to replace a portion of the shoulder joint. This generic type of device is limited to those devices intended for implantation with a ploymethylethacrylate luting agent (bone cement).

2. Recommended classification: Class III. The Panel recommends that premarket approval of this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that shoulder joint glenoid (hemi-shoulder) prostheses be classified into class III because the device is implanted and is intended to be used in relieving disabling pain and in restoring or minimizing further loss of functional use of a joint or limb. The Panel believes these uses are of substantial importance in preventing impairment of human health.

The Panel believes that general controls alone will not provide sufficient control over these characteristics. The Panel also believes that it is not possible to establish an adequate performance standard for the device. There is a lack of safety and effectiveness data to demonstrate the satisfactory performance of the device. The Panel has found that insufficient information exists to support the conclusion that general controls or performance standards will be adequate to provide reasonable assurance of the safety and effectiveness of the device. Therefore, the device must be subject to premarket approval to assure its safety and effectiveness.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Loss or reduction of joint function: Inproper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the Panel recommendation and is proposing that shoulder joint glenoid (hemi-shoulder) prostheses be classified into class III. FDA finds that these implanted devices are intended to be used in relieving disabling pain and in restoring or minimizing further loss of functional use of a joint or limb. FDA believes these uses are of substantial importance in preventing impairment of human health. FDA believes that insufficient clinical experience exists to fully establish the persons for whose use these devices are intended and the proper conditions of use. The agency believes that the probable benefit to health from use of these devices does not compare favorable with the likelihood of injury or illness resulting from their use.

Because of the lack of adequate data to demonstrate the safety and effectiveness of these implanted devices, FDA believes that use of the shoulder joint glenoid (hemi-shoulder) prosthesis presents an unreasonable risk of illness or injury. Because these devices are intended to be implanted in the human body, the Federal Food, Drug, and Cosmetic Act requires that they be classified into class III unless FDA determines that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of these devices. On the basis of available information, FDA cannot make this determination. Moreover, FDA believes that insufficient information exists to support the conclusion that general controls or performance standards will provide reasonable assurance of the safety and effectiveness of these devices. Therefore, FDA is proposing that these devices be classified into class III.

§ 888.3690; Docket No. 78N–3097; Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis.

The orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of shoulder joint humeral (hemi-shoulder) metallic uncemented prostheses:

1. Identification: A shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis is an implanted intramedullary stemmed device made of alloys, such as cobalt-chromium-molybdenum. It is intended to replace the articular surface of the proximal end of the humerus and to be fixed without a polymethylmethacrylate luting agent (bone cement).

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that shoulder joint humeral

(hemi-shoulder) metallic uncemented prostheses be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent loss or reduction of joint function, adverse tissue reaction, or infection. The Panel believes that general controls will not provide sufficient control over these characteristics.

Although a shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis is an implanted device, the Panel believes that premarket approval is not necessary because there is sufficient information to establish a standard that will provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that labeling for the device include information on the dimensions and kinematics of the device and its strength and wear characteristics.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and their knowledge of the medical literature.

5. Risks to health: (a) Loss or reduction of joint function: Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequte biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away of the articulating surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the Panel recommendation and is proposing that shoulder joint humeral (hemi-shoulder) metallic uncemented prostheses be classified into class II. FDA has sought additional data and documentation on the safety and effectiveness of this device. Four surgeons reported clinical use of this device (Refs. 454 through 457). In 1955, the Neer device was described (Ref. 454), and clinical results were presented on 12 patients with a time of followup from 2 months to 23 months. Eleven were free from pain, and in the remaining patient, the pain was believed to be caused by improper seating of the device. In 1969, Oster (Ref. 455) reported on four patients who received the Neer prostheses for the treatment of fracture dislocations. The time of followup ranged from 4 months to 18 months, with an average time of 10 months. Two patients had the devices implanted for 1 year or more. The range of motion was reported as limited in two and poor in one. In the fourth patient, the prosthesis had dislocated, reoperation was required, and the prosthesis was removed later due to infection. The author commented that satisfactory results had been obtained in two of the four cases and that the unsatisfactory results in two patients were due to one patient's refusal to cooperate during rehabilitation and the other patient's delay in seeking treatment.

In 1975, Clayton and Ferlic (Ref. 456) reported on the use of the device in eight patients with rheumatoid arthritis. The time of followup ranged from 2 months to 20 months, with an average time of 8 months. All eight patients had pain preoperatively. Postoperative improvements were reported in seven of the eight patients, with four patients having complete relief of pain. Postoperative improvements in range of motion were reported in six patients.

Neer (Ref. 457), the originator of the prosthesis, reported on the long-term results with this device. The devices had been implanted in 21 patients for 5 or more years and the average followup in this series of patients was 6 years, ranging from 8 months to 20 years. Neer reported that excellent results were obtained in 10 of these patients, satisfactory results in 8, and unsatisfactory results in 3. There was no radiologic evidence of loosening of the stem of the prosthesis in the medullary canal and no instance of settling of the prosthesis in the humerus. Neer reported that there were no postoperative complications or significant local complications and only one instance of dislocation, this occurring in a patient with poliomyelitis.

FDA reviewed several reports (Refs. 458 through 461) on the use of custom-made humeral prostheses that are not the same generic type of device as that classified herein. The custom-made devices, which were made of polymeric materials rather than metal, were attached to the bone by bone plates rather than through an intramedullary stem and were designed to replace portions of the long bone of the humerus rather than the articular head. Because of these differences, the clinical experience with these custom-made devices cannot be compared to the experience reported for the shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis.

Although shoulder joint humeral (hemi-shoulder) metallic uncemented prostheses are implanted devices, FDA has determined that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of these devices. In addition, FDA has identified and assessed the major risks to health associated with the use of these devices. FDA believes that the major risks, i.e., loosening, infection, and adverse tissue reaction, are related to biological responses of the human body to the presence of the device, the device design, and the underlying joint pathology, and not to physical failure(s) of the device. Clinical experience with these devices has established the persons for whose use the devices are intended and the proper conditions of use. FDA has determined that the probable benefit to health from proper use of these devices outweighs any likelihood of injury or illness resulting from their use. FDA further believes that informative labeling and compliance with general controls may greatly reduce the risks to health associated with the use of these devices. The agency believes that a performance standard is necessary because general controls alone are insufficient to minimize the risks to health presented by these devices.

§ 888.3720; Docket No. 78N–3099; Toe joint constrained uncemented prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of toe joint constrained uncemented prostheses:

1. Identification: A toe joint constrained uncemented prosthesis is an implanted device made of silicone elastomer or polyester reinforced silicone elastomer. It is intended to be used without a polymethylmethacrylate luting agent (bone cement) to replace the first metatarsophalangeal (big toe) joint. This generic type of device consists of a single flexible across-the-joint component that prevents dislocation in more than one anatomic plane.

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that toe jont constrained

uncemented prostheses be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent loss or reduction of joint function, adverse tissue reaction, or infection. The Panel believes that general controls alone will not provide sufficient control over these characteristics.

Although these are implanted devices, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that the labeling for the device include information on the dimensions and kinematics of the device and its strength and wear characteristics.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on their knowledge of the medical literature.

5. Risks to health: (a) Loss or reduction of joint function: Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the Panel recommendation and is proposing that toe joint constrained uncemented prostheses be classified into class II. FDA has sought additional data and information on the safety and effectiveness of the toe joint constrained uncemented prostheses. Several reports described the use of the prostheses in the metatarsophalangeal (MTP) joints of the foot (Refs. 462 through 467).

Although toe joint constrained uncemented prostheses are implanted devices, FDA has determined that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of these devices. In addtion, FDA has identified and assessed the major risks to health associated with the use of these devices. FDA believes that the major risks, i.e., loosening, infection, and adverse tissue reaction, are related to biological responses of the human body to the presence of the device, the device design, and the underlying joint pathology, and not to physical failure(s) of the device. Clinical experience with these devices has established the persons for whose use the devices are intended and the proper conditions of use. FDA had determined that the probable benefit to health from proper use of these devices outweighs any likelihood of injury or illness resulting from their use. FDA further believes that informative labeling and compliance with general controls may greatly reduce the risks to health associated with the use of these devices. The agency believes that a performance standard is necessary because general controls alone are insufficient to minimize the risks to health presented by these devices.

§ 888.3730; Docket No. 78N–3100; Toe joint phalangeal (hemi-toe) prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of toe joint phalangeal (hemi-toe) prostheses:

1. Identification: A toe joint phalangeal (hemi-toe) prosthesis is an implanted device made of silicone elastomer intended to replace the base of the proximal phalanx of the toe.

2. Recommended classification: Class II. The Panel recommends that establishing a peformance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that toe joint phalangeal (hemi-toe) prostheses be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent loss or reduction of joint function, adverse tissue reaction, or infection. The Panel believes that general controls alone will not provide sufficient control over these characteristics.

Although these are implanted devices, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that the labeling for the device include information on the dimensions and kinematics of the device and its strength and wear characteristics.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and their knowledge of the medical literature.

5. Risks to health: (a) Loss or reduction of joint function: Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the Panel recommendation and its proposing that toe joint phalangeal (hemi-toe) prostheses be classified into class II. The agency has reviewed the Panel recommendation and has obtained additional data and information describing the use of toe joint phalangeal (hemi-toe) prostheses (Refs. 468 through 472). Swanson, et al. (Refs. 468 and 469), described the development of the prostheses and the surgical technique and reported on 55 patients who received the prostheses. The average range of postoperative joint motion was reported to be 60 degrees in extension and 5 degrees in flexion.

La Porta, et al. (Ref. 470), reported on 536 devices which had been implanted over a 4-year period with excellent postoperative results in 150 out of 536 joints (27.9 percent), good results in 39.1 percent, fair results in 22.9 percent, and poor results in 10.1 percent.

Albin and Weil (Ref. 471) reported that silicone implant arthroplasty had been performed on 1,000 feet at Northlake Community Hospital. Of those 1,000, 150 feet, all of which were operated on by, or under the direct supervision of two surgeons, were selected for evaluation of this procedure. They reported that clinical examinations were made of 50 feet and that radiographic examinations were made of 100 feet with an average followup time of 12.5 months. These

authors reported that the postoperative average active range of joint motion was 43 degrees and that the average passive range of motion was 60 degrees. They reported that there was a recurrence of abduction deviation in 70 percent of the cases and a recurrence of valgus rotation in 48 percent. They reported that while 62 percent of the patients had a good distribution of body weight over the operated joint, this percentage may be improved by a modification of the surgical technique.

Recently, Caneva (Ref. 472) recommended cautious use of this prosthesis in young, extremely active individuals. This author reported that degenerative changes in the bone opposing the prostheses had occurred in four young active male patients about 6 months after surgery. These patients experienced pain, edema, and restricted joint motion.

Although toe joint phalangeal (hemi-toe) prostheses are implanted devices, FDA has determined that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of these devices. In addition, FDA has identified and assessed the major risk to health associated with the use of these devices. FDA believes that the major risk, bone resorption, is related to biological responses of the human body to the presence of the device, the device design, and the underlying joint pathology, and not to physical failure(s) of the device. Clinical experience with these devices has established the persons for whose use the devices are intended and the proper conditions of use. FDA has determined that the probable benefit to health from proper use of these devices outweighs any likelihood of injury or illness resulting from their use. FDA further believes that informative labeling and compliance with general controls may greatly reduce the risks to health associated with the use of these devices. The agency believes that a performance standard is necessary because general controls alone are insufficient to minimize the risks to health presented by these devices.

§ 888.3750; Docket No. 78N-3101; Wrist joint carpal lunate prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of wrist joint carpal lunate prostheses:

1. Identification: A wrist joint carpal lunate prosthesis is a one-piece implanted device made of silicone elastomer. It is intended to replace the carpal lunate bone of the wrist.

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that wrist joint carpal lunate prostheses be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent loss or reduction of joint function, adverse tissue reaction, or infection. The Panel believes that general controls alone will not provide sufficient control over these characteristics.

Although carpal lunate prostheses are implanted devices, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that the labeling of the device describe its dimensions.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Loss or reduction of joint function: Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility or resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the Panel recommendation and is proposing that wrist joint carpal lunate prostheses be classified into class II. FDA has sought additional data and information on the safety and effectiveness of these devices. The agency has reviewed the available medical literature pertaining to silicone wrist joint carpal lunate prostheses. Roca, et al. (Ref. 473), reported clinical results obtained in 10 patients in whom the prosthesis had been implanted for 2 years. The results were rated as satisfactory in seven patients and unsatisfactory in three. The unsatisfactory results were due to disclocation of the device in two cases and medial nerve paresthesia of unexplained origin in the other patient. Lichtman, et al. (Ref. 474), compared the results of implantation of the prosthesis with plaster immobilization of the joint—a nonsurgical alternative treatment in patients with Kienbock's disease (degeneration of the carpal lunate bone)—to establish more clearly the indications for the prosthesis and the timing for the procedure. These investigators concluded that plaster immobilization gave unsatisfactory results, particularly when compared to results obtained from implantation of the device before the carpal lunate bone had collapsed. Twenty devices had been implanted, 14 of which produced satisfactory results when evaluated at 10 through 54 months postoperatively (average was 27 months). The device was noted to have dislocated in 8 patients: in 5 of the 6 patients with unsatisfactory results and in 3 of the 14 patients with satisfactory results. These authors also reported that the original design of the device was modified by deepening the concavities on its surface to provide a more secure articulation between the device and the carpal bones and to reduce the incidence of device dislocation.

Although wrist joint carpal lunate prostheses are implanted devices, FDA has determined that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of these devices. In addition, FDA has identified and assessed the major risks to health associated with the use of these devices. FDA believes that the major risks, i.e., loosening, infection, and adverse tissue reaction, are related to biological responses of the human body to the presence of the device, the device-design, and the underlying joint pathology, and not to physical failure(s) of the device. Clinical experience with these devices has established the persons for whose use the devices are intended and the proper conditions of use. FDA has determined that the probable benefit to health from proper use of these devices outweighs any likelihood of injury or illness resulting from their use. FDA further believes that informative labeling and compliance with general controls may greatly reduce the risks to health associated with the use of these devices. The agency believes that a performance

standard is necessary because general controls alone are insufficient to minimize the risks to health presented by these devices.

§ 888.3760; Docket No. 78N–3102; Wrist joint carpal scaphoid prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of wrist joint carpal scaphoid prostheses:

1. Identification: A wrist joint carpal scaphoid prosthesis is a one-piece implanted device made of silicone elastomer intended to replace the carpal scaphoid bone of the wrist.

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that wrist joint carpal scaphoid prostheses be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent loss or reduction of joint function, adverse tissue reaction, or infection. The Panel believes that general controls alone will not provide sufficient control over these characteristics.

Although these are implanted devices, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that the labeling of the device describe its dimensions.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Loss or reduction of joint function: Improper design or inadequate mechanical properties of the device, such as its lack of strength or resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of a prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the Panel recommendation and is proposing that wrist joint carpal scaphoid prostheses be classified into class II. The agency obtained additional data and information describing the use of wrist joint carpal scaphoid prostheses. Swanson (Ref. 475) reported that development of the wrist joint carpal scaphoid prosthesis was prompted by the shortcomings of most other current procedures, such as replacement of the carpal scaphoid with a metallic or an acrylic prosthesis. Swanson noted that investigators of these other devices reported problems concerning implant loosening and bone resorption due to the hardness of the implanted material. A recent publication (Ref. 476) cites problems associated with silicone carpal scaphoid prostheses that included fracture of the stem of the prosthesis and implant loosening.

Although wrist joint carpal scaphoid prostheses are implanted devices, FDA has determined that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of these devices. In addition, FDA has identified and assessed the major risks to health associated with the use of these devices. FDA believes that the major risks, i.e., loosening, infection, and adverse tissue reaction, are related to biological responses of the human body to the presence of the device, the device design, and the underlying joint pathology, and not to physical failure(s) of the device. Clinical experience with these devices has established the persons for whose use the devices are intended and the proper conditions of use. FDA has determined that the probable benefit to health from proper use of these devices outweighs any likelihood of injury or illness resulting from their use. FDA further believes that informative labeling and compliance with general controls may greatly reduce the risks to health associated with the use of these devices. The agency believes that a performance standard is necessary because general controls alone are insufficient to minimize the risks to health presented by these devices.

§ 888.3770; Docket No. 78N–3304; Wrist joint carpal trapezium prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of wrist joint carpal trapezium prostheses:

1. Identification: A wrist joint carpal trapezium prosthesis is a one-piece implanted device made of silicone elastomer or silicone elastomer/polyester material intended to replace the carpal trapezium bone of the wrist.

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that wrist joint carpal trapezium prostheses be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent loss or reduction of joint function, adverse tissue reaction, or infection. The Panel believes that general controls alone will not provide sufficient control over these characteristics.

Although wrist joint carpal trapezium prostheses are implanted devices, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Loss or reduction of joint function: Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the Panel recommendation and is proposing that wrist joint carpal trapezium prostheses be classified into class II. The agency has sought additional data and information on the safety and effectiveness of these devices. Three types of implant arthroplasty concerning the trapezium are discussed in the medical literature: resurfacing of the

metacarpal surface as described by Kessler and Crawford (Refs. 477 and 478); resurfacing of the trapezial surface as described by Ashworth (Ref. 479); and complete excision and replacement of the trapezium bone with a Swanson-type silicone elastomer or Niebauer-type silicone elastomer/polyester prosthesis (Refs. 480 through 487).

Kessler (Ref. 477) reported that 11 of the 18 patients treated by resurfacing the metacarpal surface with a silicone prosthesis were free from pain 2 years postoperatively. Crawford (Ref. 478) reported that of nine patients receiving this resurfacing prosthesis, improved function was encountered initially, but that within 4 to 8 weeks signs of chronic synovitis were present in all patients. The prosthesis had also subluxated and dislocated in five cases (55 percent). When three of these resurfacing prostheses were removed and replaced with Swanson or Niebauer prostheses, all of the resurfacing prostheses were found to be badly torn. Microsilastic particles were found within the synovium of all joints, with abundant foreign body giant cell reaction. The author concluded that the base of the resurfacing prosthesis was much too weak to allow normal thumb function and that the results obtained with the resurfacing prosthesis did not compare well with the results expected after excision of the trapezium (an alternative treatment), with or without prosthetic replacement of the trapezium.

Ashworth (Ref. 479) reported the results of resurfacing of the trapezium in 42 patients. The trapezium was resurfaced with a silicone prosthesis, using a neurosurgical burr-hole cover that had been adapted by reshaping. The prosthesis was inserted in a hole drilled into the trapezium. Patients were evaluated 1 to 75 months (average 31 months) postoperatively. The results were considered excellent if pain was absent and there had been no decrease in abduction or grip strength. Forty patients were evaluated as having excellent results using these criteria. In the other two patients, the operation was considered to be a failure because the device fractured. The authors believed that, in both cases, the failure was due to error in surgical technique.

A number of authors reported on the use of Swanson (Refs. 480, and 482 through 487) and Niebauer (Refs. 481 and 483) prostheses to replace the entire trapezium. Haffajee (Ref. 480) reported on the implantation of the Swanson prosthesis in 100 hands with a postoperative followup of 1 to 5 years. He found that pain was relieved in all but five hands. While there were no device fractures, there were 19 device dislocations. Swanson (Ref. 486) reported on the implantation of the Swanson prosthesis in 46 patients. The postoperative followup ranged from 6 months to 5½ years, with a followup of 2 or more years in 32 patients. Pain was completely relieved in all 46, but the device had subluxated in 8 patients. Ferlic (Ref. 481) evaluated postoperative results in 11 patients 1 to 3 years after they received Niebauer prostheses. Ferlic found that all patients were satisfied, principally because of relief of pain. There were no device dislocations.

Weilby (Ref. 482) reported that of 100 consecutive patients receiving the Swanson prosthesis, 32 (32 percent) showed implant subluxation with varying degrees of disfunction and complaints. Reoperation for removal of the implant was advised in 16 cases (16 percent). Haffajee (Ref. 480) reported a dislocation rate of 19 percent (9 occurring with the original Swanson design prosthesis and 10 with the newer design). Dislocation of the prosthesis affected the range of thumb abduction, and was noted in 13 of the 15 hands, in the series in which abduction was not improved. Lister (Ref. 484) reported a subluxation rate of 25 percent. Two-thirds of these patients complained of instability and persistent loss of strength and reoperations were necessary for removal of the prosthesis. Sarkin (Ref. 485) reported that of five patients receiving a silicone implant, the prosthesis had subluxated in two (40 percent) and had dislocated in another, requiring surgical removal.

The causes of subluxation and dislocation of the prostheses were considered by several authors. Swanson (Ref. 486) reported that the 8 cases of subluxation which occurred in his series of 46 patients were due to: incomplete removal of the trapezium in 3 patients; uncorrected hyperextension deformity in 4 patients; and inadequate capsular repair around the implant in 1 patient. He reported a mild subluxation in one patient due to a capsular tear unrecognized during surgery. Weilby (Ref. 482) identified several other reasons for dislocation: the use of too large an implant; incomplete removal of osteophytes; damage to the ligaments and joint capsule by previous surgical procedures; and use of an incorrect postoperative dressing. Haffajee (Ref. 480) believed that positioning the base of the implant in the shaft of the bone so that the base/shaft angle was 80° or less might reduce bone implant dislocations. Several authors (Refs. 480, 483, 484, and 485) discussed the effects of a variety of surgical procedures, particularly the use of tendons to stabilize the implant, on the incidence of implant subluxation. Others (Refs. 480 and 484) believed that the design of the Swanson implant encouraged subluxation and one (Ref. 484) recommended that the design be modified.

Although wrist joint carpal trapezium prostheses are implanted devices, FDA has determined that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of these devices. In addition, FDA has identified and assessed the major risks to health associated with the use of these devices. FDA believes that the major risks, i.e., loosening, infection, and adverse tissue reaction, are related to biological responses of the human body to the presence of the device, the device design, and the underlying joint pathology, and not to physical failure(s) of the device. Clinical experience with these devices has established the persons for whose use the devices are intended and the proper conditions of use. FDA has determined that the probable benefit to health from proper use of these devices outweighs any likelihood of injury or illness resulting from their use. FDA further believes that informative labeling and compliance with general controls may greatly reduce the risks to health associated with use of these devices. The agency believes that a performance standard is necessary because general controls alone are insufficient to minimize the risks to health presented by these devices.

§ 888.3780; Docket No. 78N-3103; Wrist joint polymer constrained uncemented prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of wrist joint polymer constrained uncemented prostheses:

1. Identification: A wrist joint polymer constrained uncemented prosthesis is an implanted device made of polyester-reinforced silicone elastomer. It is intended to be used without a polymethylmethacrylate luting agent (bone cement) to replace a wrist joint. This generic type of device consists of a single flexible across-the-joint component that prevents dislocation in more than one anatomic plane.

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that wrist joint polymer constrained uncemented prostheses be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent loss or reduction of joint function, adverse tissue reaction, or infection. The Panel believes that general controls alone will not provide sufficient control over these characteristics.

Although wrist joint polymer constrained uncemented prostheses are implanted devices, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommenation on the Panel members' personal knowledge of the device; oral presentations made to the Panel on November 14, 1977 (Ref. 488) and March 21, 1978 (Ref. 489); written reports prepared by physicians using the devices (Refs. 490 and 491); and the Panel members' knowledge of the medical literature.

On November 14, 1977, Dr. Alfred Swanson presented clinical results on use of the device in 59 patients (Ref. 488). A total of 76 devices had been implanted. Thirty of these prostheses were made from "conventional" medical grade silicone elastomer and 46 were made from a "high performance" silicone elastomer, a new formulation which was developed to provide increased resistance to tearing and implant fracture. Fifty-six devices had been implanted for over 1 year (range was 12 months to 91 months). Twenty-one devices had been implanted for 1 to 2 years, 17 for 2 to 3 years and 18 for over 3 years. Pain, range of motion, and grasp strength were evaluated pre- and postoperatively. The average range of joint motion had increased from 38 degrees flexion and 6 degrees extension to 41 degrees flexion and 21 degrees extension. Grasp strength had increased from an average of 7 pounds to an average of 12 pounds. The percentage of patients who were pain free increased from 16 percent preoperatively to 89 percent postoperatively. The following complications were reported: four cases of recurrent synovitis, three implant fractures, and one case of severe tendon imbalance.

On March 21, 1978, Mr. Eldon Frisch presented a summary of the postoperative results that had been obtained during clinical testing of the prosthesis (Ref. 489). Postoperative clinical results had been provided by 32 physicians on 101 prostheses made of "conventional" silicone elastomer, and on 200 prostheses made from the "high performance" elastomer. Mr. Frisch reported that good and fair results had been obtained in over 90 percent of the cases with regard to pain relief, joint stability and joint range of motion. The following complications had been reported: seven fractures of implants made of the "conventional" elastomer and one fracture of an implant made of the "high performance" elastomer.

The following additional data on the "high performance" elastomer implants were presented at the March 21, 1978 Panel meeting: two oral presentations and two written reports prepared by physicians who had used the device (Refs. 489 through 491). Drs. John Madden and Edward Nalebuff made oral presentations to the Panel (Ref. 489). Dr. Nalebuff had implanted 37 devices with an average postoperative followup time of 13 months (range 4 through 25 months) and Dr. Madden had implanted 5 devices with an average postoperative followup of 8 months (range 6 months through 1 year). Based on their short-term clinical experience with the device, both surgeons reported that they were satisfied with the results. Dr. Nalebuff reported that the device: (1) Relieved pain in a significant number of patients; (2) provided satisfactory stability; and (3) made it possible to correct joint deformity, maintaining an average of 64 degrees of motion.

Drs. Edward Hay, Alonzo Kornegay, and Spencer Rowland submitted written reports of their short-term clinical results with the device (Refs. 490 and 491). Drs. Hay and Kornegay reported that devices had been implanted in 11 patients with an average postoperative followup of 11½ months (range 3 to 22 months). Pain relief was excellent and wrist joint motion was improved in eight patients. Dr. Rowland reported that 18 devices (15 of the "high performance" elastomer, and 3 of the "conventional" elastomer) had been implanted in 14 patients for at least 1 year (maximum of 30 months). It was reported that all patients had pain-free wrists at the time of evaluation and that none of the patients had lost wrist joint motion.

5. Risks to health: (a) Loss or reduction of joint function: Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and the systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the Panel recommendation and is proposing that wrist joint polymer constrained uncemented prostheses be classified into class II. In proposing to classify this device into class II, the agency is relying on the same data discussed by the Panel in support of its recommendation that the device be classified into class II. Although wrist joint polymer constrained uncemented prostheses are implanted devices, FDA has determined that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of these devices. In addition, FDA has identified and assessed the major risks to health accociated with use of these devices. FDA believes that the major risks, i.e., loosening, infection, and adverse tissue reaction, are related to biological responses of the human body to the presence of the device, the device design and the underlying joint pathology, and not to physical failure(s) of the device. Clinical experience with these devices has established the persons for whose use the devices are intended and the proper conditions of use. FDA has determined that the probable benefit to health from proper use of these devices outweighs any likelihood of injury or illness resulting from their use. FDA further believes that informative labeling and compliance with general controls may greatly reduce the risks to health associated with use of these devices. The agency believes that a performance standard is necessary because general controls alone are insufficient to minimize the risks to health presented by these devices.

§ 888.3790; Docket No. 78N-3305; Wrist joint mental constrained prosthesis.

The Orthopedic Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of wrist joint metal contrained prostheses:

1. Identification: A wrist joint metal constrained prosthesis is an implanted

device intended to replace a wrist joint. The device prevents dislocation in more than one anatomic plane and consists of either a single flexible across-the-joint component or two components linked together. This generic type of device is limited to a device which is made of alloys, such as cobalt-chromium-molybdenum, and is limited to those devices intended for implantation with a polymethylmethacrylate luting agent (bone cement).

2. Recommended classification: Class III. The Panel recommends that premarket approval of this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that wrist joint metal constrained prostheses be classified into class III because the device is implanted and is intended to be used in relieving disabling pain and in restoring or minimizing further loss of functional use of a joint or limb. The Panel believes these uses are of substantial importance in preventing impairment of human health.

The Panel believes that general controls alone will not provide sufficient control over these characteristics. The Panel also believes that it is not possible to establish an adequate performance standard for the device. There is a lack of safety and effectiveness data to demonstrate the satisfactory performance of the device. The Panel has found that insufficient information exists to support the conclusion that general controls or performance standards will be adequate to provide reasonable assurance of the safety and effectiveness of the device. Therefore, the device must be subject to premarket approval to assure its safety and effectiveness.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of the device and on the available medical literature. Gschwend, et al. (Ref. 492), used this prosthesis in 15 cases from 1971–1975. Fixation was reported to be inadequate and not correlated to loads imposed on the wrist joint. In three cases (20 percent), the distal stem became loose. The stem fractured in two cases (13 percent). On one occasion (6.6 percent) the metacarpal bone broke. In another case, as a result of a disturbance of muscle balance, the investigators observed a fixed ulnar deviation of the wrist joint with a tendency toward radial penetration of the medullary canal of the third metacarpal bone. The investigators also described three cases (20 percent) of a sinking of the prosthesis into the capitate through the third metacarpal.

5. Risks to health: (a) Loss or reduction of joint function: Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistence to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the Panel recommendation and is proposing that wrist joint metal constrained prostheses be classified into class III. FDA finds that these implanted devices and intended to be used in relieving disabling pain and in restoring or minimizing further loss of functional use of a joint or limb. FDA believes these uses are of substantial importance in preventing impairment of human health. FDA believes that insufficient clinical experience exists fully establish the persons for use the devices are intended and the proper conditions of use. The agency believes that the probable benefit to health from use of these devices does not compare favorably with the likelihood of illness or injury resulting from their use.

Because of the lack of adequate data to demonstrate the safety and effectiveness of these implanted devices, FDA believes that use of wrist joint metal constrained prostheses presents an unreasonable risk of illness or injury. Because these devices are intended to be implanted in the human body, the Federal Food, Drug, and Cosmetic Act requires that they be classified into class III unless FDA determines that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of these devices. On the basis of available information, FDA cannot make that determination. FDA believes that insufficient information exists to support the conclusion that general controls or performance standards will provide reasonable assurance of the safety and effectiveness of these devices. Therefore, FDA is proposing that these devices be classified into class III.

§ 888.3800; Docket No. 78N–3104; Wrist Joint Semi-Constrained Prosthesis

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of wrist joint semi-constrained prostheses:

1. Identification: A wrist joint semi-constrained prosthesis is an implanted device intended to replace a wrist joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that have either (a) a one-part radial component made of alloys, such as cobalt-chromium-molybdenum, with an ultra-high molecular weight polyethylene bearing surface, or (b) a two-part radial component made of alloys and an ultra-high molecular weight polyethylene ball that is mounted on the radial component with a trunnion bearing. The metallic portion of the two-part radial component is inserted into the radius. These devices have a metacarpal component(s) made of alloys, such as cobalt-chromium-molybdenum. This generic type of device is limited to those devices intended to be implanted with a polymethylmethacrylate luting agent (bone cement).

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that wrist joint semi-constrained prostheses be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent loss or reduction of joint function, adverse tissue reaction, or infection. The Panel believes that general controls alone will not provide sufficient control over these characteristics.

Although wrist joint semi-constrained prostheses are implanted devices, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that the labeling for the device include information on the dimensions and kinematics of the device and its strength and wear characteristics.

4. Summary of data on which the recommendation is based: The Panel

based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device, and on several oral presentations made to the Panel. On April 15, 1977, Dr. Robert Volz (Ref. 493) discussed the clinical results obtained following implantation of the AMC-type wrist joint semi-constrained prosthesis. Fifty prostheses had been implanted, 21 by Dr. Volz and 29 by 15 other surgeons participating in the clinical study. The minimum and maximum times the devices had been implanted were reported as 6 months and 33 months, respectively. Dr. Volz noted that the most consistent complication was a tendency of the wrist to drift into an abnormal position (ulnar deviation). At the time of evaluation, about 75 percent of the patients were pain free while 25 percent experienced mild pain. On July 15, 1977, Dr. Robert Beckenbaugh (Ref. 494) made a presentation to the Panel on his clinical experience with the Meuli wrist joint semi-constrained prosthesis. Eighty-four prostheses had been implanted. The average time of implantation was reported as 14 months, with over half of the patients having had the prostheses implanted for 18 months. Dr. Beckenbaugh reported that there had been some problems with positioning of the prosthesis, resulting in a tendency of the wrist to drift into ulnar deviation. These problems required reoperation in 36 percent of the patients receiving the prosthesis in the surgeon's first year of experience with the devices, 20 percent of those implanted received reoperation in his second year of experience with it and 4 percent in his third year. This reduction in the rates of reoperation were related to increased experience with the procedure and the bending and cutting of the intramedullary stems of the metacarpal component of the device. Ninety-three percent of the patients were pain free at the time of the last evaluation. Dr. Frank R. Noyes, a consultant to the Panel, noted that long-term results of the use of wrist joint semi-constrained prostheses were not available and that these results would be required in the future to ascertain whether the Panel's classification recommendation is still appropriate.

5. Risks to health: (a) Loss or reduction of joint function: Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the Panel recommendation and is proposing that wrist joint semi-constrained prostheses be classified into class II. The agency has sought additional information on the use of wrist joint semi-constrained prostheses. The data presented to the Panel by Drs. Beckenbaugh and Volz (Refs. 493 and 494) contained early clinical studies regarding the series of patients involved (Refs. 495 through 498). The only other available published clinical data on wrist joint semi-constrained prostheses are reports from the originator of the Meuli design of the prosthesis (Ref. 499). Meuli reported the clinical results of a series of 21 patients in whom 26 prostheses had been implanted over 5.5 year period. There were nine failures: two infections, one case of device loosening, four cases of ankylosis, and two cases of severe synovitis due to the use of polyester material in an earlier design of the device. On final analysis, however, 18 of the 21 patients were satisfied with the results.

Although wrist joint semi-constrained prostheses are implanted devices, FDA has determined that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of these devices. In addition, FDA has identified and assessed the major risks to health associated with the use of these devices. FDA believes that the major risks, i.e., loosening, infection, and adverse tissue reaction, are related to biological responses of the human body to the presence of the device, the device design, and the underlying joint pathology, and not to physical failure(s) of the device. Clinical experience with these devices has established the persons for whose use the devices are intended and the proper conditions of use. FDA has determined that the probable benefit to health from proper use of these devices outweighs any likelihood of injury or illness resulting from their use. FDA further believes that informative labeling and compliance with general controls may greatly reduce the risks to health associated with use of these devices. The agency believes that a performance standard is necessary because general controls alone are insufficient to minimize the risks to health presented by these devices.

§ 888.3810; Docket No. 78N–3105; Wrist joint ulnar (hemi-wrist) prosthesis.

The Orthopedic Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of wrist joint ulnar (hemi-wrist) prostheses:

1. Identification: A wrist joint ulnar (hemi-wrist) prosthesis is a mushroom-shaped implanted device that is made of a medical grade silicone elastomer or ultra-high molecular weight polyethylene. It is intended to be inserted into the intramedullary canal of the bone and held in place by a suture. Its purpose is to cover the resected end of the distal ulna to control bone overgrowth and to provide an articular surface for the radius and carpus.

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that wrist joint ulnar (hemi-wrist) prostheses be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent loss or reduction of joint function, adverse tissue reaction, or infection. The Panel believes that general controls alone will not provide sufficient control over these characteristics.

Although wrist joint ulnar (hemi-wrist) postheses are implanted devices, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Panel also recommends that the labeling of the device describe its dimensions.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Loss or reduction of joint function: Improper design or inadequate mechanical properties of the device, such as its lack of strength or resistance to wear, may result in a loss or reduction of joint function due to fracture or deformation of the device, or migration of the device in the surgical cavity. (b) Adverse tissue

reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the Panel recommendation and is proposing that wrist joint ulnar (hemi-wrist) prostheses be classified into class II. The agency has sought additional information on the safety and effectiveness of these devices. Two publications (Refs. 500 and 501) presented reports of clinical uses of the devices. Swanson (Ref. 500) presented results on a series of 54 patients. Bilateral implantations were perfrmed in 19 cases providing a total of 73 device implantations. Improvement was reported in the average postoperative values for pronation and supination, extension and flexion, and ulnar and radial deviation. Two types of complications were reported: (1) Migration of the implant in five cases in which the implant was not sutured in place; and (2) significant amounts of bone resorption in the distal centimeter of the ulnar in two other cases. Bone resorption was attributed to the design of the cuff of the device which was reported to have produced an excessively tight fit on the bone. The device and the surgical implantation procedure were reported to have been modified as a result of the adverse effects.

Three years after the initial results were presented by Swanson (Ref. 500), Berg (Ref. 501) reported his clinical results from four patients. The length of postoperative followup ranged from 8 months to 2½ years (average 20 months). Bone resorption was noted to have occurred beneath the cuff of the device in the patient with the longest followup. The author noted that while the followup periods were short, the early results were promising. It was reported that all four patients had relief of pain and that in no case was there a decrease of function, motion, or grip strength after the procedure.

Although wrist joint ulnar (hemi-wrist) prostheses are implanted devices, FDA has determined that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of these devices. In addition, FDA has identified and assessed the major risks to health associated with use of these devices. FDA believes that the major risks, i.e., loosening, infection, and adverse tissue reaction, are related to biological responses of the human body to the presence of the device, the device design, and the underlying joint pathology, and not to physical failure(s) of the device.

Clinical experience with these devices has established the persons for whose use the devices are intended and the proper conditions of use. FDA has determined that the probable benefit to health from proper use of the devices outweighs any likelihood of injury or illness resulting from their use. FDA further believes that informative labeling and compliance with general controls may greatly reduce the risks to health associated with use of these devices. The agency believes that performance standard is necessary because general controls alone are insufficient to minimize the risks to health presented by these devices.

§ 888.4150; Docket No. 78N-3106; Calipers for clinical use.

The Orthopedic Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of calipers for clinical use:

1. Identification: A caliper for clinical use is a compass-like device intended for use in measuring the thickness or diameter of a part of the body or the distance between two body surfaces, such as for measuring an excised skeletal specimen to determine the proper replacement size of a prosthesis.

2. Recommended classification: Class I. The Panel recommends that the device be exempt from the premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)) and the good manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The panel recommends that calipers for clinical use be classified into class I because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel believes that manufacturers of the device should not be required to comply with premarket notification procedures or with the GMP regulation in manufacturing the device because this simple device presents no risks to health and all possible defects are readily detectable before use. The Panel noted that this device must be sterilizable.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

FDA agrees with the Panel recommendation and is proposing that calipers for clinical use be classified into class I. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

In response to the Panel's recommendation that manufacturers of calipers for clinical use be exempt from sections 510(k) and 520(f) of the act, FDA is proposing that these manufacturers be subject to registration and device listing under section 510 (a) through (j) of the act, but exempt from premarket notification under section 510(k) of the act and Subpart E of Part 807 of the regulations. FDA disagrees with the Panel's recommendation that manufacturers of calipers for clinical use be exempt from the GMP regulation under section 520(f) of the act. The agency believes that compliance with this regulation is necessary to assure the quality of this device and thus its safety, effectiveness, and compliance with the adulteration and misbranding provisions of the act. Compliance with the GMP regulation will help prevent defects in calipers for clinical use that could harm users. See § 888.1250 *Nonpowered dynamometer* in an earlier section of the preamble and the discussion under the heading "Exemptions for Class I Devices" for further explanation of the agency's policies concerning exemptions.

§ 888.4200; Docket No. 78N-3107; Cement dispenser.

The Orthopedic Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of cement dispensers:

1. Identification: A cement dispenser is a nonpowered syringe like device intended for use in placing bone cement into surgical sites.

2. Recommended classification: Class I. The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that cement dispensers be classified into class I because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This is a relatively simple device with few risks associated with its use. The Panel does not believe that this device requires

performance standards to control the identified risks to health.

4. Summary of data on which the recommendation is based: Cement dispensers are routinely used for a variety of surgical procedures, such as fixation of prostheses and repair of bone fractures. The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: Adverse tissue reaction: The chemically reactive materials present in bone cement may dissolve or leach substances from the device and cause the patient to have an adverse tissue reaction.

FDA agrees with the Panel recommendation and is proposing that cement dispensers be classified into class I with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

§ 888.4210; Docket No. 76N–3108; Cement mixer for clinical use.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of cement mixers for clinical use:

1. Identification: A cement mixer for clinical use is a device consisting of a container intended for use in mixing bone cement.

2. Recommended classification: Class I. The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recomends that cement mixers for clinical use be classified into class I because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This is a relatively simple device with few risks associated with its use. The Panel does not believe that this device requires performance standards to control the identified risk to health. The Panel also recommends that the material from which the device is fabricated be identified in the device labeling.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: Adverse tissue reaction: The chemically reactive materials present in bone cement may dissolve or leach substances from the device and cause the patient to have an adverse tissue reaction.

FDA agrees with the Panel recommendation and is proposing that cement mixers for clinical use be classified into class I with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

§ 888.4220; Docket No. 78N–3109; Cement monomer vapor evacuator.

The Orthopedic Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of cement monomer vapor evacuators:

1. Identification: A cement monomer vapor evacuator is a device intended for use during surgery for the containment or removal of bone cement monomer vapor or the removal of other undesirable fumes.

2. Recommended clasification: Class I. The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that cement monomer vapor evacuators be classified into class I because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

FDA agrees with the Panel recommendation and is proposing that cement monomer vapor evacuators be classified into class I with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

§ 888.4230; Docket No. 78N–3110; Cement ventilation tube.

The Orthopedic Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of cement ventilation tubes:

1. Identification: A cement ventilation tube is a device, usually made from plastic, that consists of a segment of tubing that is intended to be inserted into a surgical cavity to allow the release of air or fluid from the cavity as it is being filled with bone cement.

2. Recommended classification: Class I. The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that cement ventilation tubes be classified into class I because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This is a relatively simple device with few risks associated with its use. The Panel does not believe that this device requires performance standards to control the identified risk to health.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: Adverse tissue reaction: The chemically reactive materials present in bone cement may dissolve or leach substances from the device and cause the patient to have an adverse tissue reaction.

FDA agrees with the Panel recommendation and is proposing that cement ventilation tubes be classified into class I with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

§ 888.4300; Docket No. 78N–3111; Depth gauge for clinical use.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of depth gauges for clinical use:

1. Identification: A depth gauge for clinical use is a device consisting of an instrument with a graduated scale intended for various uses, such as to determine the proper length of screws for fastening the ends of a fractured bone.

2. Recommended classification: Class I. The Panel recommends that this device be exempt from the premarket notification procedures under section 510(k) of the act and the GMP regulation under section 520(f) of the act.

3. Summary of reasons for recommendation: The Panel recommends that depth gauges for clinical use be classified into class I because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel believes that manufacturers of the device should not be required to comply with premarket notification procedures or with the good manufacturing practice regulation because this simple device presents no risks to health and all possible defects are readily detectable before use.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

FDA agrees with the Panel recommendation and is proposing that gauges that clinical use be classified

into class I. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

In response to the Panel's recommendation that manufacturers of depth gauges for clinical use be exempt from sections 510(k) and 520(f) of the act, FDA is proposing that these manufacturers be exempt from premarket notification under section 510(k) of the act and Subpart E of Part 807 of the regulations. FDA disagrees with the Panel's recommendation that manufacturers of depth gauges for clinical use be exempt from the GMP regulation under section 520(f) of the act. The agency believes that compliance with this regulation is necessary to assure the quality of this device and thus its safety, effectiveness, and compliance with the adulteration and misbranding provisions of the act. Compliance with the GMP regulation will help prevent defects in depth gauges for clinical use that could harm users. See § 888.1250 *Nonpowered dynamometer* in an earlier section of the preamble and the discussion under the heading "Exemptions for Class I Devices" for further explanation of the agency's policies concerning exemptions.

§ 888.4540; Docket No. 78N–3114; Orthopedic manual surgicial instrument.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of orthopedic manual surgical instruments:

1. Identification: An orthopedic manual surgical instrument is a nonpowered handheld device intended for medical purposes to manipulate tissue, or for use with other devices in orthopedic surgery. This generic type of device includes the cerclage applier, awl, bender, drill brace, broach, burr, corkscrew, countersink, pin crimper, wire cutter, prosthesis driver, extractor, file, fork, needle holder, impactor, bending or contouring instrument, compression instrument, passer, socket positioner, probe, femoral neck punch, socket pusher, reamer, rongeur, scissors, screwdriver, bone skid, staple driver, bone screw starter, surgical stripper, tamp, bone tap, trephine, wire twister, and wrench.

2. Recommended classification: Class I. The Panel recommends that these devices be exempt from premarket notification procedures under section 510(k) of the act and the GMP regulation under section 520(f) of the act, except those requirements pertaining to quality control.

3. Summary of reasons for recommendation: The Panel recommends that orthopedic manual surgical instruments be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. Orthopedic manual surgical instruments have been used for many years in a variety of surgical procedures. These are simple, nonpowered devices that present no undue hazards when used for the purposes for which they were designed.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members, personal knowledge of, and clinical experience with, the device.

5. Risks to health: Tissue damage and adverse tissue reaction: Inadequate mechanical properties, such as lack of material strength of the device, may result in device fracture and possible tissue damage and, if fragments of the fractured device remain in the tissue, an adverse tissue reaction may result.

FDA agrees with the Panel recommendation and is proposing that orthopedic manual surgical instruments be classified into class I. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the devices.

In response to the Panel's recommendation that manufacturers of orthopedic manual surgical instruments be exempt from sections 510(k) and 520(f) of the act, FDA is proposing that these manufacturers be exempt from premarket notification under section 510(k) of the act and Subpart E of Part 807 of the regulations. FDA disagrees with the Panel's recommendation that manufacturers of orthopedic manual surgical instruments be exempt from the GMP regulation under section 520(f) of the act. The agency believes that compliance with this regulation is necessary to assure the quality of these devices and thus their safety, effectiveness, and compliance with the adulteration and misbranding provisions of the act. Compliance with the GMP regulation will help prevent defects in orthopedic manual surgical instruments that could harm users. See § 888.1250 *Nonpowered dynamometer* in an earlier section of the preamble and the discussion under the heading "Exemptions for Class I Devices" for further explanation of the agency's policies concerning exemptions.

§ 888.4580; Docket No. 78N–3116; Sonic surgical instrument and accessories/ attachments.

The Orthopedic Device Classification Panel and the Neurological Device Classification Panel, FDA advisory committees, made the following recommendations regarding the classification of sonic surgical instruments and accessories/ attachments:

1. Identification: A sonic surgical instrument is a hand-held device with various accessories or attachments, such as a cutting tip that vibrates at high frequencies, and is intended for medical purposes to cut bone or other materials, such as acrylic.

2. Recommended classification: Class II. Both Panels recommend that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: Both Panels recommend that the device be classified into class II because certain characteristics of this device, such as its electrical properties, must be controlled by a performance standard. The Panels believe that general controls alone would not provide sufficient safeguards over the dangers associated with use of the device. The Panels believe that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that sufficient information exists to establish a standard.

4. Summary of data on which the recommendation is based: Both Panels based their recommendations on the potential hazards associated with the device and on the Panel members' clinical experience with the device. The Panel members believe that the data indicate that the device will cut bone as safely as other techniques without apparent damage to surrounding tissue or bone.

5. Risks to health: (a) Electrical shock: Excessive current leakage from the device may cause electrical shock to the patient or operator. (b) Hard or soft tissue injury: Excessive sonic energy may result in injury to the hard or soft tissue being cut.

FDA agrees with the recommendations of both Panels and is proposing that sonic surgical instruments and accessories or attachments be classified into class II. The agency believes that a performance standard is necessary for these devices because general controls alone are insufficient to minimize the risks to health presented by these devices. A performance standard will provide

reasonable assurance of the safety and effectiveness of these devices. The agency also believes that sufficient information exists to establish a performance standard for these devices. FDA has reviewed the recommendations of the Orthopedic Device Classification Panel and of the Neurological Device Classification Panel for sonic surgical instruments and accessories or attachments and has determined that the classification of these devices should be published in the part of the Code of Federal Regulations for orthopedic devices.

§ 888.4600; Docket No. 78N–3117; Protractor for clinical use.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of protractors for clinical use:

1. Identification: A protractor for clinical use is a device intended for use in measuring the angles of bones, such as on X-rays or in surgery.

2. Recommended classification: Class I. The Panel recommends that the device be exempt from the premarket notification procedures under section 510(k) of the act and the GMP regulation under section 520(f) of the act.

3. Summary of reasons for recommendation: The Panel recommends that protractors for clinical use be classified into class I because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel believes that manufacturers of the device should not be required to comply with premarket notification procedures or with the good manufacturing practice regulation in manufacturing the device because this simple device presents no risks to health and all possible defects are readily detectable before use.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

FDA agrees with the Panel recommendation and is proposing that protractors for clinical use be classified into class I. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

In response to the Panel's recommendation that manufacturers of protractors for clinical use be exempt from sections 510(k) and 520(f) of the act, FDA is proposing that these manufacturers be exempt from premarket notification under section 510(k) of the act and Subpart E of Part 807 of the regulations. FDA disagrees with the Panel's recommendation that manufacturers of protractors for clinical use be exempt from the GMP regulation under section 520(f) of the act. The agency believes that compliance with this regulation is necessary to assure the quality of this device and thus its safety, effectiveness, and compliance with the adulteration and misbranding provisions of the act. Compliance with the GMP regulation will help prevent defects in protractors for clinical use that could harm users. See § 888.1250 *Nonpowered dynamometer* in an earlier section of the preamble and the discussion under the heading "Exemptions for Class I Devices" for further explanation of the agency's policies concerning exemptions.

§ 888.4800; Docket No. 78N–3118; Template for clinical use.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of templates for clinical use:

1. Identification: A template for clinical use is a device that consists of a pattern or guide intended for medical purposes, such as selecting or positioning orthopedic implants or guiding the marking of tissue before cutting.

2. Recommended classification: Class I. The Panel recommends that the device be exempt from the premarket notification procedures under section 510(k) of the act and the GMP regulation under section 520(f) of the act.

3. Summary of reasons for recommendation: The Panel recommends that templates for clinical use be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel believes that manufacturers of the device should not be required to comply with the premarket notification procedures or with the good manufacturing practice regulation because all possible defects are readily detectable before use.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: Tissue damage and adverse tissue reaction: Fracture of the device could injure surrounding tissue and, if device fragments remain in the tissue, could cause an adverse tissue reaction.

FDA agrees with the Panel recommendation and is proposing that templates for clinical use be classified into class I. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

In response to the Panel's recommendations that manufacturers of protractors for clinical use be exempt from sections 510(k) and 520(f) of the act, FDA is proposing that these manufacturers be exempt from premarket notification under section 510(k) of the act and Subpart E of Part 807 of the regulations. FDA disagrees with the Panel's recommendation that manufacturers of templates for clinical use be exempt from the GMP regulation under section 520(f) of the act. The agency believes that compliance with this regulation is necessary to control the risk to health identified by the Panel. Compliance with the GMP regulation will help prevent defects in templates for clinical use that could harm patients. See § 888.1250 *Nonpowered dynamometer* in an earlier section of the preamble and the discussion under the heading "Exemptions for Class I Devices" for further explanation of the agency's policies concerning exemptions.

§ 888.5850; Docket No. 78N–3120; Nonpowered orthopedic traction apparatus and accessories.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of nonpowered orthopedic traction apparatus and accessories:

1. Identification: A nonpowered orthopedic traction apparatus is a device that consists of a rigid frame with nonpowered traction accessories, such as cords, pulleys, or weights, and that is intended to apply a therapeutic pulling force to the skeletal system.

2. Recommended classification: Class I. The Panel recommends that the device be exempt from the premarket notification procedures under section 510(k) of the act and the GMP regulation under section 520(f) of the act.

3. Summary of reasons for recommendation: The Panel recommends that nonpowered orthopedic traction apparatus and accessories be classified into class I because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel believes that manufacturers of the device should not be required to comply with the premarket notification procedures or with the good manufacturing practice regulation because these simple devices present no

risks to health and all possible defects are readily detectable before use.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and experience with, nonpowered orthopedic traction apparatus and accessories.

5. Risks to health: None identified.

FDA agrees with the panel recommendation and is proposing that nonpowered orthopedic traction apparatus and accessories be classified into class I.

In response to the Panel's recommendation that manufacturers of nonpowered orthopedic traction apparatus and accessories be exempt from sections 510(k) and 520(f) of the act, FDA is proposing that these manufacturers be exempt from premarket notification under section 510(k) of the act and Subpart E of Part 807 of the regulations. FDA is proposing that manufacturers of these devices be exempt from all requirements of the GMP regulation with the exception of § 820.180, regarding general requirements concerning records, and § 820.198, regarding maintenance of complaint files. See § 888.1250 *Nonpowered dynamometer* in an earlier section of the preamble and the discussion under the heading "Exemptions for Class I Devices" for further explanation of the agency's policies concerning exemptions.

§ 888.5890; Docket No. 78N–3122; Noninvasive traction component.

The Orthopedic Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of noninvasive traction components:

1. Identification: A noninvasive traction component is a device, such as a head halter, pelvic belt, or a traction splint, that does not penetrate the skin and is intended to assist in connecting a patient to a traction apparatus so that a therapeutic pulling force may be applied to the patient's body.

2. Recommended classification: Class I. The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that noninvasive traction components be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

FDA agrees with the Panel recommendation and is proposing that noninvasive traction components be classified into class I with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

§ 888.5940; Docket No. 78N–3123; Cast component.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of cast components:

1. Identification: A cast component is a device intended for medical purposes to protect or support a cast. This generic type of device includes the cast heel, toe cap, cast support, and walking iron.

2. Recommended classification: Class I. The Panel recommends that the device be exempt from the GMP regulation under section 520(f) of the act.

3. Summary of reasons for recommendation: The Panel recommends that cast components be classified into class I because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel does not believe that this device requires performance standards. The Panel recommends that the manufacturer be exempt from the good manufacturing practice requirements because adherence to the good manufacturing practice regulation would not improve the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

FDA agrees with the Panel recommendation and is proposing that cast components be classified into class I. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the devices.

In response to the Panel's recommendation that manufacturers of cast components be exempt from section 520(f) of the act, FDA is proposing that a manufacturer of these devices be exempt from all requirements of the GMP regulation with the exception of § 820.180, regarding general requirements concerning records, and § 820.198, regarding maintenance of complaint files. See § 888.1250 *Nonpowered dynamometer* in an earlier section of the preamble and the discussion under the heading "Exemptions for Class I Devices" for further explanation of the agency's policies concerning exemptions.

§ 888.5960; Docket No. 78N–3124; AC-powered cast removal instrument.

The Orthopedic Device Classification Panel, an FDA advisory committee made the following recommendation regarding the classficiation of AC-powered cast removal instruments:

1. Identification: An AC-powered cast removal instrument is an AC-powered hand-held device intended to remove a cast from a patient. This generic type of device includes the electric cast cutter and cast vacuum.

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that AC-powered cast removal instruments be classified into Class II because the electrical properties of the device must be controlled to prevent electrical injury to the patient or operator. The Panel believes that general controls alone will not provide sufficient safeguards over the dangers associated with use of the device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that sufficient information exists to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: Electrical injury: Excessive current leakage from this device may cause electrical injury to the patient or operator.

FDA agrees with the Panel recommendation and is proposing that AC-powered cast removal instruments be classified into class II. The agency believes that a performance standard is necessary for these devices because general controls alone are insufficient to minimize the risks to health presented by these devices. A performance standard will provide reasonable assurance of the safety and effectiveness of these devices. The agency also believes that there is sufficient information to establish a performance standard for these devices.

§ 888.5980; Docket No. 78N–3125; Manual cast application and removal instrument.

The Orthopedic Device Classification Panel, an FDA advisory committee,

made the following recommendation regarding the classification of manual cast application and removal instruments:

1. Identification: A manual cast application and removal instrument is a nonpowered hand-held device intended to be used in applying or removing a cast. This generic type of device includes the cast knife, cast spreader, plaster saw, plaster dispenser, and casting stand.

2. Recommended classification: Class I. The Panel recommends that the device be exempt from the GMP regulation under section 520(f) of the act.

3. Summary of reasons for recommendation: The Panel recommends that manual cast application and removal instruments be classified into class I because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel does not believe that these devices require performance standards. The Panel recommends that the manufacturer be exempt from the good manufacturing practice requirements because adherence to the good manufacturing practice regulation would not improve the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

FDA agrees with the Panel recommendation and is proposing that manual cast application and removal instruments be classified into class I. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices.

In response to the Panel's recommendation that manufacturers of manual cast application and removal instruments be exempt from section 520(f) of the act, FDA is proposing that a manufacturer of these devices be exempt from all requirements in the GMP regulation, with the exception of § 820.180, regarding general requirements concerning records, and § 820.198, regarding maintenance of complaint files. See § 888.1250 *Nonpowered dynamometer* in an earlier section of the preamble and the discussion under the heading "Exemptions for Class I Devices" for further explanation of the agency's policies concerning exemptions.

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The following information has been placed in the Dockets Management Branch (address above) and may be seen by interested persons from 9 a.m. to 4 p.m., Monday through Friday.

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Environmental Impact

The agency has determined pursuant to 21 CFR 25.24(b)(12) (proposed December 11, 1979; 44 FR 71742) that this proposed action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 888

Medical devices, Orthopedic devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10 (formerly 5.1; see 46 FR 26052; May 11, 1981)), it is proposed that Chapter I of Title 21 of the Code of Federal Regulations be amended by adding new Part 888, to read as follows:

PART 888—ORTHOPEDIC DEVICES

Subpart A—General Provisions

Sec.
888.1 Scope.

Subpart B—Orthopedic Diagnostic Devices

888.1100 Arthoscope.
888.1240 AC-powered dynamometer.
888.1250 Nonpowered dynamometer.
888.1500 AC-powered goniometer.
888.1520 Nonpowered goniometer.

Subpart D—Orthopedic Prosthetic Devices

888.3000 Bone cap.
888.3010 Bone fixation cerclage.
888.3020 Intramedullary fixation rod.
888.3025 Passive tendon prosthesis.
888.3030 Single/multiple component metallic bone fixation appliances and accessories.
888.3040 Smooth or threaded metallic bone fixation fastener.
888.3050 Spinal interlaminal fixation orthosis.
888.3060 Spinal intervertebral body fixation orthosis.
888.3100 Ankle joint metal/composite semi-constrained prosthesis.
888.3110 Ankle joint metal/polymer semi-constrained prosthesis.
888.3120 Ankle joint metal/polymer non-constrained prosthesis.
888.3150 Elbow joint constrained prosthesis.
888.3160 Elbow joint semi-constrained prosthesis.
888.3170 Elbow joint radial (hemi-elbow) prosthesis.
888.3180 Elbow joint humeral (hemi-elbow) uncemented prosthesis.
888.3200 Finger joint metal/metal constrained uncemented prosthesis.
888.3210 Finger joint metal/metal contrained prosthesis.
888.3220 Finger joint metal/polymer constrained prosthesis.
888.3230 Finger joint polymer constrained prosthesis.
888.3300 Hip joint metal constrained prosthesis.
888.3310 Hip joint metal/polymer constrained prosthesis.
888.3320 Hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis.
888.3330 Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis.
888.3340 Hip joint metal/composite semi-constrained prosthesis.
888.3350 Hip joint metal/polymer semi-constrained prosthesis.
888.3360 Hip joint femoral (hemi-hip) metallic prosthesis.
888.3370 Hip joint (hemi-hip) acetabular metal prosthesis.
888.3380 Hip joint femoral (hemi-hip) trunnion-bearing metal/polyacetal prosthesis.
888.3390 Hip joint femoral (hemi-hip) metal/polymer prosthesis.
888.3400 Hip joint femoral (hemi-hip) resurfacing prosthesis
888.3410 Hip joint metal/polymer semi-constrained resurfacing prosthesis
888.3480 Knee joint femorotibial metallic constrained prosthesis.
888.3490 Knee joint femorotibial metal/composite non-constrained prosthesis.
888.3500 Knee joint femorotibial metal/composite semi-constrained prosthesis.
888.3510 Knee joint femorotibial metal/polymer constrained prosthesis.
888.3520 Knee joint femorotibial metal/polymer non-constrained prosthesis.
888.3530 Knee joint femorotibial metal/polymer semi-constrained prosthesis.
888.3540 Knee joint patellofemoral polymer/metal semi-constrained prosthesis.
888.3550 Knee joint patellofemorotibial polymer/metal/metal constrained prosthesis.
888.3560 Knee joint patellofemorotibial polymer/metal/polymer semi-constrained prosthesis.
888.3570 Knee joint femoral (hemi-knee) metallic uncemented prosthesis.
888.3580 Knee joint patellar (hemi-knee) metallic resurfacing uncemented prosthesis.
888.3590 Knee joint tibial (hemi-knee) metallic resurfacing uncemented prosthesis.
888.3640 Shoulder joint constrained prosthesis.
888.3650 Shoulder joint non-constrained prosthesis.
888.3660 Shoulder joint semi-constrained prosthesis.
888.3680 Shoulder joint glenoid (hemi-shoulder) prosthesis.
888.3690 Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis.
888.3720 Toe joint constrained uncemented prosthesis.
888.3730 Toe joint phalangeal (hemi-toe) prosthesis.
888.3750 Wrist joint carpal lunate prosthesis.
888.3760 Wrist joint carpal scaphoid prosthesis.
888.3770 Wrist joint trapezium prosthesis.
888.3780 Wrist joint polymer constrained uncemented prosthesis.
888.3790 Wrist joint metal constrained prosthesis.
888.3800 Wrist joint semi-constrained prosthesis.
888.3810 Wrist joint ulnar (hemi-wrist) prosthesis.
888.4150 Calipers for clinical use.
888.4200 Cement dispenser.
888.4210 Cement mixer for clinical use.
888.4220 Cement monomer vapor evacuator.
888.4230 Cement ventilation tube.
888.4300 Depth gauge for clinical use.
888.4540 Orthopedic manual surgical instrument.
888.4580 Sonic surgical instrument and accessories/attachments.
888.4600 Protractor for clinical use.
888.4800 Template for clinical use.
888.5850 Nonpowered orthopedic traction apparatus and accessories.
888.5890 Noninvasive traction components.
888.5940 Cast components.
888.5960 AC-powered cast removal instruments.
888.5980 Manual cast application/removal instruments.

Authority: Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).

Subpart A—General Provisions

§ 888.1 Scope.

(a) This part sets forth the classification of orthopedic devices intended for human use that are in commercial distribution.

(b) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a premarket notification submission for a device under Part 807 cannot show merely that the device is accurately described by the section title and identification provision of a regulation in this part, but shall state why the device is substantially equivalent to other devices, as required by § 807.87.

(c) To avoid duplicative listings, an orthopedic device that has two or more types of uses (e.g., used both as a diagnostic device and as a surgery device) is listed on one subpart only.

(d) References in this part to regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21 unless otherwise noted.

Subpart B—Orthopedic Diagnostic Devices

§ 888.1100 Arthroscope.

(a) *Identification.* An arthroscope is a type of electrically powered endoscope that is intended to make visible the interior of a joint. The arthroscope may be combined with accessories to permit surgery in selected anatomic locations.

(b) *Classification.* Class II (performance standards).

§ 888.1240 AC-powered dynamometer.

(a) *Identification.* An AC-powered dynamometer is an electrically powered device intended for medical purposes to assess neuromuscular function or degree of neuromuscular blockage by measuring, with a force transducer (a device that translates force into electrical impulses), the grip-strength of a patient's hand.

(b) *Classification.* Class II (performance standards).

§ 888.1250 Nonpowered dynamometer.

(a) *Identification.* A nonpowered dynamometer is a mechanical device intended for medical purposes to measure the pinch and grip muscle strength of a patient's hand.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in Subpart E of Part 807. The device also is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, regarding general requirements concerning records, and § 820.198, regarding complaint files.

§ 888.1500 AC-powered goniometer.

(a) *Identification.* An AC-powered goniometer is an AC-powered measuring and recording device intended to evaluate joint function by measuring ranges of motion, acceleration, or forces exerted by a joint.

(b) *Classification.* Class II (performance standards).

§ 888.1520 Nonpowered goniometer.

(a) *Identification.* A nonpowered goniometer is a mechanical device intended for medical purposes to measure the range of motion of joints.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in Subpart E of Part 807. The device also is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, regarding general requirements concerning records, and § 820.198, regarding complaint files.

Subpart D—Orthopedic Prosthetic Devices

§ 888.3000 Bone cap.

(a) *Identification.* A bone cap is a mushroom-shaped implanted device made of either silicone elastomer or ultra-high molecular weight polyethylene. It is intended to cover the severed end of a long bone, such as the humerus or tibia, to control bone overgrowth in juvenile amputees.

(b) *Classification.* Class II (performance standards).

§ 888.3010 Bone fixation cerclage.

(a) *Identification.* A bone fixation cerclage is an implanted device that is made of alloys such as cobalt-chromium-molybdenum, and that consists of a metallic ribbon or flat sheet or a wire. When implanted, the device is wrapped around the shaft of a long bone, anchored to the bone with wire or screws, and used in the fixation of fractures.

(b) *Classification.* Class II (performance standards).

§ 888.3020 Intramedullary fixation rod.

(a) *Identification.* An intramedullary fixation rod is an implanted device that consists of a rod made of alloys, such as cobalt-chromium-molybdenum and stainless steel. It is inserted into the medullary (bone marrow) canal of long bones for the fixation of fractures.

(b) *Classification.* Class II (performance standards).

§ 888.3025 Passive tendon prosthesis.

(a) *Identification.* A passive tendon prosthesis is an implanted device made of silicone elastomer or a polyester reinforced medical grade silicone elastomer intended for use in the surgical reconstruction of a flexor tendon of the hand. The device is implanted for a period of 2 to 6 months to aid growth of a new tendon sheath. The device is not intended as a permanent implant nor to function as a replacement for the ligament or tendon nor to function as a scaffold for soft tissue ingrowth.

(b) *Classification.* Class II (performance standards).

§ 888.3030 Single/multiple component metallic bone fixation appliances and accessories.

(a) *Identification.* Single/mutliple component metallic bone fixation appliances and accessories are implanted devices, consisting of one or more metallic components and their metallic fasteners. The devices contain a plate, a nail/plate combination, or a blade/plate combination that is made of alloys, such as cobalt-chromium-molybdenum, stainless steel, and titanium, that is intended to be held in position with fasteners, such as screws and nails, or bolts, nuts, and washers. These devices are intended to be used for fixation of fractures of the proximal or distal end of long bones, such as intracapsular, intertrochanteric, intercervical, supracondylar, or condylar fractures of the femur; for fusion of a joint; or for surgical procedures that involve cutting a bone. The device is intended to be implanted or attached through the skin so that a pulling force (traction) may be applied to the skeletel system.

(b) *Classification.* Class II (performance standard).

§ 888.3040 Smooth or threaded metallic bone fixation fastener.

(a) *Identification.* A smooth or threaded metallic bone fixation fastener is an implanted device that consists of a stiff wire segment or rod made of alloys, such as cobalt-chromium-molybdenum and stainless steel, and that may be smooth on the outside, fully or partially threaded, straight or U-shaped; and may be either blunt pointed, sharp pointed or have a formed, slotted head on the end. It is intended to be used for fixation of bone fractures, bone reconstructions, as a guide pin for insertion of other implants, or to be implanted through the skin so that a pulling force (traction) may be applied to the skeletal system.

(b) *Classification.* Class II (performance standards).

§ 888.3050 Spinal interlaminal fixation orthosis.

(a) *Identification.* A spinal interlaminal fixation orthosis is an implanted device made of an alloy, such as stainless steel, that consists of various hooks and a posteriorly placed compression or distraction rod. The device is implanted, usually across three adjacent vertebrae, to straighten and immobilize the spine to allow bone grafts to unite and fuse the vertebrae together. The device is used primarily in the treatment of scoliosis (a lateral curvature of the spine), but it also has been used in the treatment of fracture or dislocation of the spine, grades 3 and 4 of spondylolisthesis (a dislocation of the spinal column), and lower back syndrome.

(b) *Classification.* Class II (performance standards).

§ 888.3060 Spinal intervertebral body fixation orthosis.

(a) *Identification.* A spinal intervertebral body fixation orthosis is an implanted device made of titanium. It consists of various vertebral plates that are punched into each of a series of vertebral bodies. An eye-type screw is inserted in a hole in the center of each of the plates. A braided cable is threaded through each eye-type screw. The cable is tightened with a tension device and it is fastened or crimped at each eye-type screw. The device is intended to apply force to a series of vertebrae to correct "sway back", scoliosis (lateral curvature of the spine), or other conditions.

(b) *Classification.* Class II (performance standards).

§ 888.3100 Ankle joint metal/composite semi-constrained prosthesis.

(a) *Identification.* An ankle joint metal/composite semi-constrained prosthesis is an implanted device intended to replace an ankle joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that consist of a talar resurfacing component made of alloys, such as cobalt-

chromium-molybdenum, and a tibial resurfacing component fabricated from a carbon fiber reinforced ultra-high molecular weight polyethylene composite, and is limited to those devices intended for implantation with a polymethylmethacrylate luting agent (bone cement).

(b) *Classification.* Class III (premarket approval).

§ 888.3110 Ankle joint metal/polymer semi-constrained prosthesis.

(a) *Identification.* An ankle joint metal/polymer semi-constrained prosthesis is an implanted device intended to replace an ankle joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces and has no linkage across-the-joint. This generic type of device includes prostheses that have a talar resurfacing component made of alloys, such as cobalt-chromium-molybdenum, and a tibial resurfacing component made of ultra-high molecular weight polyethylene, and is limited to those devices intended for implantation with a polymethylmethacrylate luting agent (bone cement).

(b) *Classification.* Class II (performance standards).

§ 888.3120 Anke joint metal/polymer non-constrained prostheses.

(a) *Identification.* An ankle joint metal/polymer non-constrained prosthesis is an implanted device intended to replace an ankle joint. The device limits minimally (less than normal anatomic constraints) translation in one or more planes. It has no linkage across-the-joint. This generic type of device includes prostheses that have a tibial component made of alloys, such as cobalt-chromium-molybdenum, and a talar component made of ultra-high molecular weight polyethylene, and is limited to those devices intended for implantation with a polymethylmethacrylate luting agent (bone cement).

(b) *Classification.* Class III (premarket approval).

§ 888.3150 Elbow joint constrained prosthesis.

(a) *Identification.* An elbow joint constrained prosthesis is an implanted device made exclusively of alloys, such as cobalt-chromium-molybdenum, or made from these alloys and ultra-high molecular weight polyethylene, that is intended to replace an elbow joint. The device prevents dislocation in more than one anatomic plane and consists of two components which are linked together (or affined). The generic type of device is limited to those prostheses intended for implantation with a polymethylmethacrylate luting agent (bone cement).

(b) *Classification.* Class III (premarket approval).

§ 888.3160 Elbow joint semiconstrained prosthesis.

(a) *Identification.* An elbow joint semi-constrained prosthesis is an implanted device intended to replace an elbow joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that consist of a humeral resurfacing compoonent made of alloys, such as cobalt-chromium-molybdenum, and a radial resurfacing component made of ultra-high molecular weight polyethylene. This generic type of device is limited to those devices intended for implantation with a polymethylmethacrylate luting agent (bone cement).

(b) Classification. Class II (performance standards).

§ 888.3170 Elbow joint radial (hemi-elbow) prosthesis.

(a) *Identification.*An elbow joint radial (hemi-elbow) prosthesis is an implanted device made of medical grade silicone elastomer intended to replace the proximal end of the radius. The device is intended for implantation without a polymethylmethacryate luting agent (bone cement).

(b) Classification. Class II (performance standards).

§ 888.3180 Elbow joint humeral (hemi-elbow) uncemented prosthesis.

(a) *Identification.*An elbow joint humeral (hemi-elbow) uncemented prosthesis is an implanted device made of alloys, such as cobalt-chromium-molybdenum, that is intended to replace the distal end of the humerus formed by the trochlea humeri and the capitulum humeri. The device is intended for implantation without a polymethylmethacrylate luting agent (bone cement).

(b) Classification. Class III (premarket approval).

§ 888.3200 Finger joint metal/metal constrained uncemented prosthesis.

(a) *Identification.* A finger joint metal/metal constrained uncemented prosthesis is an implanted device intended to replace a metacarpophalangeal or proximal interphalangeal (finger) joint. The device prevents dislocation in more than one anatomic plane and consists of two components which are linked together. This generic type of device includes prostheses made of alloys, such as cobalt-chromium-molybdenum, or prostheses made from alloys and ultrahigh molecular weight polyethylene. This generic type of device is limited to prostheses intended to be implanted without a polymethylmethacrylate luting agent (bone cement).

(b) Classification. Class III (premarket approval).

§ 888.3210 Finger joint metal/metal constrained prosthesis.

(a) *Identification.* A finger joint metal/metal constrained uncemented prosthesis is an implanted device intended to replace a metacarpophalangeal (finger) joint. This device prevents dislocation in more than one anatomic plane and has components which are linked together. This generic type of device includes prostheses made of alloys, such as cobalt-chromium-molybdenum, and is limited to those to those devices intended for implantation with a polymethylmethacrylate luting agent (bone cement).

(b) Classification. Class III (premarket approval).

§ 888.3220 Finger joint metal/metal constrained prosthesis.

(a) *Identification.* A finger joint metal/polymer constrained prosthesis is an implanted device intended to replace a metacarpophalangeal or proximal interphalangeal (finger) joint. The device prevents dislocation in more than one anatomic plane, and consists of two components which are linked together. This generic type of device includes prostheses made of alloys, such as cobalt-chromium-molybdenum, an ultra-high molecular weight polyethylene, and is limited to those devices that are intended for implantation with a polymethylmethacrylate luting agent (bone cement).

(b) *Classification.* Class III (premarket approval).

§ 888.3230 Finger joint polymer constrained prosthesis.

(a) *Identification.* A finger joint polymer constrained prosthesis is an implanted device intended to replace a metacarpophalangeal or proximal interphalangeal (finger) joint. This generic type of device includes prostheses that consist of a single flexible across-the-joint component made from either a silicone elastomer or a combination of polypropylene and polyester material. The flexibile across-the-joint component may be covered with a silicone rubber sleeve. These prostheses are intended to be implanted

without a polymethylmethacrylate luting agent (bone cement).

(b) *Classification.* Class II (performance standards).

§ 888.3300 Hip joint metal constrained prosthesis.

(a) *Identification.* A hip joint metal constrained prosthesis is an implanted device intended to replace a hip joint. The device prevents dislocation in more than one anatomic plane and has components that are linked together. This generic type of device includes prostheses that have a femoral component made of alloys, such as cobalt-chromium-molybdenum, and an acetabular component made of an alloy with an ultra-high molecular weight polyethylene insert, and is limited to those devices intended for implantation with a polymethylmethacrylate luting agent (bone cement).

(b) *Classification.* Class III (premarket approval).

§ 888.3310 Hip joint metal/polymer constrained prosthesis.

(a) *Identification.* A hip joint metal/polymer contrained prosthesis is an implanted device intended to replace a hip joint. The device prevents dislocation in more than oen anatomic plane and has components that are linked together. This generic type of device includes prostheses that have a femoral component made of alloys, such as cobalt-chromium-molybdenum, and an acetabular component made of ultra-high molecular weight polyethylene. This generic type of device is limited to those devices intended for implantation with a polymethylmethacrylate luting agent (bone cement).

(b) *Classification.* Class III (premarket approval).

§ 888.3320 Hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis.

(a) *Identification.* A hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis is an implanted two-part device intended to replace a hip joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that consist of a femoral and an acetabular component, both made of alloys such as cobalt-chromium-molybdenum. This generic type of device is limited to those devices intended for implantation with a polymethylmethacrylate luting agent (bone cement).

(b) *Classification.* Class III (premarket approval).

§ 888.3330 Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis.

(a) *Identification.* A hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis is an implanted two-part device intended to replace a hip joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that consist of a femoral and an acetabular component, both made of alloys, such as cobalt-chromium-molybdenum. The femoral component is intended to be fixed with bone cement. The acetabular component is intended to be used without a polymethylmethacrylate luting agent (bone cement).

(b) *Classification.* Class III (premarket approval).

§ 888.3340 Hip joint metal/composite semi-constrained prosthesis.

(a) *Identification.* A hip joint metal/composite semi-constrained prosthesis is an implanted two-part device intended to replace a hip joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that consist of a femoral component made of alloys such as cobalt-chromium-molybdenum, and an acetabular component made of carbon fiber reinforced ultra-high molecular weight polyethylene. Both components are intended to be implanted with a polymethylmethacrylate luting agent (bone cement).

(b) *Classification.* Class III (premarket approval).

§ 888.3350 Hip joint metal/polymer semi-constrained prosthesis.

(a) *Identification.* A hip joint metal/polymer semi-constrained prosthesis is an implanted device intended to replace a hip joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that have a femoral component made of alloys, such as cobalt-chromium-molybdenum, and an acetabular resurfacing component made of ultra-high molecular weight polyethylene, and is limited to those devices intended for implantation with a polymethylmethacrylate luting agent (bone cement).

(b) *Classification.* Class II (performance standards).

§ 888.3360 Hip joint femoral (hemi-hip) metallic prosthesis.

(a) *Identification.* A hip joint femoral (hemi-hip) metallic prosthesis is an implanted device intended to replace a portion of the hip joint. This generic type of device includes prostheses that have a femoral component made of alloys, such as cobalt-chromium-molybdenum. This generic type of device includes designs which are intended to be fixed to the bone with a polymethylmethacrylate luting agent (bone cement), as well as designs which have large window-like holes in the stem of the device and which are intended to be used without bone cement. However, in these latter designs, fixation of the device is not achieved by means of bone ingrowth.

(b) *Classification.* Class II (performance standards).

§ 888.3370 Hip joint (hemi-hip) acetabular metal prosthesis.

(a) *Identification.* A hip joint (hemi-hip) acetabular metal prosthesis is an implanted device intended to replace a portion of the hip joint. This generic type of device includes prostheses that have an acetabular component made of alloys, such as cobalt-chromium-molybdenum. This generic type of device is limited to those devices intended for implantation with a polymethylmethacrylate luting agent (bone cement).

(b) *Classification.* Class III (premarket approval).

§ 888.3380 Hip joint femoral (hemi-hip) trunnion-bearing metal/polyacetal prosthesis.

(a) *Identification.* A hip joint femoral (hemi-hip) trunnion-bearing metal/polyacetal prosthesis is an implanted two-part device intended to replace the head and neck of the femur. This generic type of device includes prostheses that consist of a metallic stem made of alloys, such as cobalt-chromium-molybdenum, with an integrated cylindrical trunnion bearing at the upper end of the stem that fits into a recess in the head of the device. The head of the device is made of polyacetal (polyoxymethylene) and it is covered by a metallic alloy, such as cobalt-chromium-molybdenum. The trunnion bearing allows the head of the device to rotate on its stem. The prosthesis stem is intended for implantation with a polymethylmethacrylate luting agent (bone cement).

(b) *Classification.* Class III (premarket approval).

§ 888.3390 Hip joint femoral hemi-hip metal/polymer prosthesis.

(a) *Identification.* A hip joint femoral hemi-hip metal/polymer prosthesis is an implanted two-part device intended to replace the head and neck of the femur. This generic type of device includes prostheses that have a femoral component made of alloys, such as cobalt-chromium-molybdenum, and a snap-fit acetabular component made of an alloy, such as cobalt-chromium-molybdenum, and ultra-high molecular weight polyethylene. This generic type of device may be fixed to the bone with a polymethylmethacrylate luting agent (bone cement) or implanted by impaction.

(b) *Classification.* Class II (performance standards).

§ 888.3400 Hip joint femoral (hemi-hip) resurfacing prosthesis.

(a) *Identification.* A hip joint femoral (hemi-hip) resurfacing prosthesis is an implanted device intended to replace a portion of the hip joint. This generic type of device includes prostheses that have a femoral resurfacing component made of alloys, such as cobalt-chromium-molybdenum.

(b) *Classification.* Class II (performance standards).

§ 888.3410 Hip joint metal/polymer semi-constrained resurfacing prosthesis.

(a) *Identification.* A hip joint metal/polymer semi-constrained resurfacing prosthesis is an implanted two-part device intended to replace the articulating surfaces of the hip while preserving the femoral head and neck. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that consist of a femoral cap component made of alloy, such as cobalt-chromium-molybdenum, that is placed over a surgically prepared femoral head, and an acetabular resurfacing polymer component. Both components are intended for implantation with a polymethylmethacrylate luting agent (bone cement).

(b) *Classification.* Class III (premarket approval).

§ 888.3480 Knee joint femorotibial metallic constrained prosthesis.

(a) *Identification.* A knee joint femorotibial metallic constrained prosthesis is an implanted device intended partially to replace a knee joint. The device prevents dislocation in more than one anatomic plane and has components that are linked together. The only knee joint movement allowed by the device is in the sagittal plane. This generic type of device includes prostheses that have an intramedullary stem at both the proximal and distal locations. The upper and lower components may be joined either by a solid bolt or pin, and internally threaded bolt with locking screw, or a bolt retained by circlip. The components of the device are made of alloys, such as cobalt-chromium-molybdenum. The stems of the device may be perforated, but are intended to be implanted with a polymethylmethacrylate luting agent (bone cement).

(b) *Classification.* Class II (performance standards).

§ 888.3490 Knee joint femorotibial metal/composite non-constrained prosthesis.

(a) Identification. A knee joint femorotibial metal/composite non-constrained prosthesis is an implanted device intended partially to replace a knee joint. The device limits minimally (less than normal anatomic constraints) translation in one or more planes. It has no linkage across-the-joint. This generic type of device includes prostheses that have a femoral condylar resurfacing component or components made of alloys, such as cobalt-chromium-molybdenum, and a tibial condylar component or components made of ultra-high molecular weight polyethylene with carbon-fibers composite and are intended for implantation with a polymethylmethacrylate luting agent (bone cement).

(b) *Classification.* Class III (premarket approval).

§ 888.3500 Knee joint femorotibial metal/composite semi-constrained prosthesis.

(a) *Identification.* A knee joint femorotibial metal/composite semi-constrained prosthesis is an implanted two-part device intended partially to replace a knee joint. The device limits translation and rotation in one or more plans via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that have a femoral component made of alloys, such as cobalt-chromium-molybdenum and a tibial component with the articulating surfaces made of ultra-high molecular weight polyethylene with carbon-fibers composite and is limited to those devices intended for implantation with a polymethylmethacrylate luting agent (bone cement).

(b) *Classification.* Class III (premarket approval).

§ 888.3510 Knee joint femorotibial metal/polymer constrained prosthesis.

(a) *Identification.* A knee joint femorotibial metal/polymer constrained prosthesis is an implanted device intended partially to replace a knee joint. The device limits translation or rotation in one or more planes and has components that are linked together or affined. This generic type of device includes prostheses composed of a ball-and-socket joint located between a stemmed femoral and a stemmed tibial component and a runner and track joint between each pair of femoral and tibial condyles. The ball-and-socket joint is composed of a ball at the head of a column rising from the stemmed tibial component. The ball, the column, the tibial plateau, and the stem for fixation of the tibial component are made of an alloy, such as cobalt-chromium-molybdenum. The ball of the tibial component is held within the socket of the femoral component by the femoral component's flat outer surface. The flat outer surface of the tibial component abuts both a reciprocal flat surface within the cavity of the femoral component and flanges on the femoral component designed to prevent distal displacement. The stem of the femoral component is made of an alloy, such as cobalt-chronium-molybdenum, but the socket of the component is made of ultra-high molecular weight polyethylene. The femoral component has metallic runners which align with the ultra-high molecular weight polyethylene tracks that press-fit into the metallic tibial component. This generic type of device is limited to those devices intended to be implanted with a polymethylmethacrylate luting agent (bone cement).

(b) *Classification.* Class II (performance standards).

§ 888.3520 Knee joint femorotibial metal/polymer nonconstrained prosthesis.

(a) *Identification.* A knee joint femorotibial metal/polymer non-constrained prosthesis is an implanted device intended partially to replace a knee joint. The device limits minimally (less than normal anatomic constraints) translation in one or more planes. It has no linkage across-the-joint. This generic type of device includes prostheses that have a femoral condylar resurfacing component or components made of alloys, such as cobalt-chromium-molybdenum, and a tibial component or components made of ultra-high molecular weight polyethylene, and are intended to be implanted with a polymethylmethacrylate luting agent (bone cement).

(b) *Classification.* Class II (performance standards).

§ 888.3530 Knee joint femorotibial metal/polymer semi-constrained prosthesis.

(a) *Identification.* A knee joint femorotibial metal/polymer semi-constrained prosthesis is an implanted device intended partially to replace a knee joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that consists of a femoral component made of alloys, such as cobalt-chronium-molybdenum, and a tibial component made of ultra-high molecular weight polyethylene, and is limited to those devices intended to be implanted with a polymethylmethacrylate luting agent (bone cement).

(b) *Classification.* Class II (performance standards).

§ 888.3540. Knee joint patellofemoral polymer/metal semi-constrained prosthesis.

(a) *Identification.* A knee joint patellofemoral polymer/metal semi-constrained prosthesis is an implanted two-part device intended partially to replace a knee joint in the treatment of primary patellofemoral arthritis or chondromalacia. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes a component made of alloys, such as cobalt-chromium-molybdenum or austenitic steel, for resurfacing the intercondylar groove (femoral sulcus) on the anterior aspects of the distal demur, and a patellar component made of ultra-high molecular weight polyethylene. This generic type of device is limited to those devices intended for implantation with a polymethylmethacrylate luting agent (bone cement). The patellar component is designed to be implanted only with its femoral component.

(b) *Classification.* Class III (premarket approval).

§ 888.3550 Knee joint patellofemorotibial polymer/metal/metal constrained prosthesis.

(a) *Identification.* A knee joint patellofemorotibial polymer/metal/metal constrained prosthesis is an implanted device intended to replace a knee joint. The device prevents dislocation in more than one anatomic plane and has components that are linked together. This generic type of device includes prostheses that have a femoral component, a tibial component, a cylindrical bolt and accompanying locking hardware that are all made of alloys, such as cobalt-chromium-molybdenum, and a retropatellar resurfacing component made of ultra-high molecular weight polyethylene. The retropatellar resurfacing component may be attached to the resected patella either with a metallic acrew or luting agent. All stemmed metallic components within this generic class are intended to be implanted with a polymethylmethacrylate luting agent (bone cement).

(b) *Classification.* Class II (performance standards).

§ 888.3560 Knee joint patellofemorotibial polymer/metal/polymer semi-constrained prosthesis.

(a) *Identification.* A knee joint patellofemorotibial polymer/metal/polymer semi-constrained prosthesis is an implanted device intended to replace a knee joint. The device limits translation and rotation in one or more plans via the geometry of its articulating surfaces. It has no linkage across-the-joint.

This generic type of device includes prostheses that have a femoral component made of alloys, such as cobalt-chromium-molybdenum, and a tibial component or components and a retropatellar resurfacing component made of ultra-high molecular weight polyethylene. This generic type of device is limited to those devices intended to be implanted with polymethylmethacrylate luting agent (bone cement).

(b) *Classification.* Class II (performance standards).

§ 888.3570 Knee joint femoral (hemi-knee) metallic uncemented prosthesis.

(a) *Indentification.* A knee joint femoral (hemi-knee) metallic uncemented prosthesis is an implanted device made of alloys, such as cobalt-chromium-molybdenum, that is intended to replace part of a knee joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that consist of a femoral component with or without protuberance(s) for the enhancement of fixation and is limited to those devices intended for implantation without use of polymethylmethacrylate luting agent (bone cement).

(b) *Classification.* Class III (premarket approval).

§ 888.3580 Knee joint patellar (hemi-knee) metallic resurfacing uncemented prosthesis.

(a) *Identification.* A knee joint patellar (hemi-knee) metallic resurfacing uncemented prosthesis is an implanted device made of alloys, such as cobalt-chromium-molybdenum, intended to replace the retropatellar articular surface of the patellofemoral joint. The device limits minimally (less than normal anatomic constraints) translation in one or more planes. It has no linkage across-the-joint. This generic type of device includes prostheses that have a retropatellar resurfacing component and an orthopedic screw to transfix the patellar remnant. This generic type of device is limited to those devices intended for implantation without use of polymethylmethacrylate luting agent (bone cement). The device is intended for use only in treatment of degenerative and posttraumatic patellar (osteo) arthritis.

(b) *Classification.* Class II (performance standards).

§ 888.3590 Knee joint tibial (hemi-knee) metallic resurfacing uncemented prostheses.

(a) *Identification.* A knee joint tibial (hemi-knee) metallic resurfacing uncemented prosthesis is an implanted device intended partially to replace a knee joint. The device limits minimally (less than normal anatomic constraints) translation in one or more planes. It has no linkage across-the-joint. This prosthesis is made of alloys, such as cobalt-chromium-molybdenum, and is intended to resurface one tibial condyle. The generic type of device is limited to those devices intended for implantation without the use of a polymethylmethacrylate luting agent (bone cement).

(b) *Classification.* Class II (performance standards).

§ 888.3640 Shoulder joint constrained prosthesis.

(a) *Identification.* A shoulder joint constrained prosthesis is an implanted device intended to replace a shoulder joint. The device prevents dislocation in more than one anatomic plane and has components that are linked together. This generic type of device includes prostheses that have a humeral component made of alloys, such as cobalt-chromium-molybdenum, and a glenoid component made of this alloy or a combination of this alloy and ultra-high molecular weight polyethylene. This generic type of device is limited to those devices intended for implantation with a polymethylmethacrylate luting agent (bone cement).

(b) *Classification.* Class III (premarket approval).

§ 888.3650 Shoulder joint non-constrained prosthesis.

(a) *Identification.* A shoulder joint non-constrained prosthesis is an implanted device intended to replace a shoulder joint. The device limits minimally (less than normal anatomic constraints) translation in one or more planes. It has no linkage across-the-joint. This generic type of device includes prostheses that have a humeral component made of alloys, such as cobalt-chromium-molybdenum, and a glenoid resurfacing component made of ultra-high molecular weight polyethylene, and is limited to those devices intended for implantation with a polymethylmethacrylate luting agent (bone cement).

(b) *Classification.* Class III (premarket approval).

§ 888.3660 Shoulder joint semi-constrained prosthesis.

(a) *Identification.* A shoulder joint semi-constrained prosthesis is an implanted device intended to replace a shoulder joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that have a humeral resurfacing component made of alloys, such as cobalt-chromium-molybdenum, and a glenoid resurfacing component made of ultra-high molecular weight polyethylene, and is limited to those devices intended for implantation with a polymethylmethacrylate luting agent (bone cement).

(b) *Classification.* Class III (premarket approval).

§ 888.3680 Shoulder joint glenoid (hemi-shoulder) prosthesis.

(a) *Identification* . A shoulder joint glenoid (hemi-shoulder) prosthesis is an implanted device that has a glenoid (socket) component made of alloys, such as cobalt-chromium-molybdenum, and that is intended to replace a portion of the shoulder joint. This generic type of device is limited to those devices intended for implantation with a polymethylmethacrylate luting agent (bone cement).

(b) *Classification.* Class III (premarket approval).

§ 888.3690 Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis.

(a) *Identification.* A shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis is an implanted intramedullary stemmed device made of alloys, such as cobalt-chromium-molybdenum.

It is intended to replace the articular surface of the proximal end of the humerus and to be fixed without a polymethylmethacrylate luting agent (bone cement).

(b) *Classification.* Class II (performance standards).

§ 888.3720 Toe joint constrained uncemented prosthesis.

(a) *Identification.* A toe joint constrained uncemented prosthesis is an implanted device made of silicone elastomer or polyester reinforced silicone elastomer. It is intended to be used without a polymethylmethacrylate luting agent (bone cement) to replace the first metatarsophalangeal (big toe) joint. This generic type of device consists of a single flexible across-the-joint component that prevents dislocation in more than one anatomic plane.

(b) *Classification.* Class II (performance standards).

§ 888.3730 Toe joint phalangeal (hemi-toe) prosthesis.

(a) *Identification.* A toe joint phalangeal (hemi-toe) prosthesis is an implanted device made of silicone elastomer intended to replace the base of the proximal phalanx of the toe.

(b) *Classification.* Class II (performance standards).

§ 888.3750 Wrist joint carpal lunate prosthesis.

(a) *Identification.* A wrist joint carpal lunate prosthesis is a one-piece implanted device made of silicone elastomer. It is intended to replace the carpal lunate bone of the wrist.

(b) *Classification.* Class II (performance standards).

§ 888.3760 Wrist joint carpal scaphoid prosthesis.

(a) *Identification.* A wrist joint carpal scaphoid prosthesis is a one-piece implanted device made of silicone elastomer or silicone elastomer intended to replace the carpal scaphoid bone of the wrist.

(b) *Classification.* Class II (performance standards).

§ 888.3770 Wrist joint carpal trapezium prosthesis.

(a) *Identification.* A wrist joint carpal trapezium prosthesis is a one-piece implanted device made of silicone elastomer/polyester material intended to replace the carpal trapezium bone of the wrist.

(b) *Classification.* Class II (performance standards).

§ 888.3780 Wrist joint polymer constrained uncemented prosthesis.

(a) *Identification.* A wrist joint polymer constrained uncemented prosthesis is an implanted device made of polyester-reinforced silicone elastomer. It is intended to be used without a polymethylmethacrylate luting agent (bone cement) to replace a wrist joint. This generic type of device consists of a single flexible across-the-joint component that prevents dislocation in more than one anatomic plane.

(b) *Classification.* Class II (performance standards).

§ 888.3790 Wrist joint metal constrained prosthesis.

(a) *Identification.* A wrist joint metal constrained prosthesis is an implanted device intended to replace a wrist joint. The device prevents dislocation in more than one anatomic plane and consists of either a single flexible across-the-joint component or two components linked together. This generic type of device is limited to a device which is made of alloys, such as cobalt-chromium-molybdenum, and is limited to those devices intended for implantation with a polymethylmethacrylate luting agent (bone cement).

(b) *Classification.* Class II (premarket approval).

§ 888.3800 Wrist joint semi-constrained prosthesis.

(a) *Identification.* A wrist joint semi-constrained prosthesis is an implanted device intended to replace a wrist joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prosthesis that have either (1) a one-part radial component made of alloys, such as cobalt-chromium-molybdenum, with an ultra-high molecular weight polyethylene bearing surface, or (2) a two-part radial component made of alloys and an ultra-high molecular weight polyethylene ball that is mounted on the radial component with a trunnion bearing. The metallic portion of the two-part radial component is inserted into the radius. These devices have a metacarpal component(s) made of alloys, such as cobalt-chromium-molybdenum. This generic type of device is limited to those devices intended to be implanted with a polymethylmethacrylate luting agent (bone cement).

(b) *Classification.* Class II (performance standards).

§ 888.3810 Wrist joint ulnar (hemi-wrist) prosthesis.

(a) *Identification.* A wrist joint ulnar (hemi-wrist) prosthesis is a mushroom-shaped implanted device that is made of a medical grade silicone elastomer or ultra-high molecular weight polyethylene. It is intended to be inserted into the intramedullary canal of the bone and held in place by a suture. Its purpose is to cover the resected end of the distal ulna to control bone overgrowth and to provide an articular surface for the radius and carpus.

(b) *Classification.* Class II (performance standards).

Subpart E—Orthopedic Surgery Devices

§ 888.4150 Calipers for clinical use.

(a) *Identification.* A caliper for clinical use is a compass-like device intended for use in measuing the thickness or diameter of a part of the body or the distance between two body surfaces, such as for measuring an excised skeletal specimen to determine the proper replacement size of a prosthesis.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in Subpart E of Part 807.

§ 888.4200 Cement dispenser.

(a) *Identification.* A cement dispenser is a nonpowered syringe like device intended for use in placing bone cement into surgical sites.

(b) *Classification.* Class I (general controls).

§ 888.4210 Cement mixer for clinical use.

(a) *Identification.* A cement mixer for clinical use is a device consisting of a container intended for use in mixing bone cement.

(b) *Classification.* Class I (general controls).

§ 888.4220 Cement monomer vapor evacuator.

(a) *Identification.* A cement monomer vapor evacuator is a device intended for use during surgery for the containment or removal of bone cement monomer vapor or the removal of other undesirable fumes.

(b) *Classification.* Class I (general controls).

§ 888.4230 Cement ventilation tube.

(a) *Identification.* A cement ventilation tube is a device usually made of plastic, that consists of a segment of tubing that is intended to be inserted into a surgical cavity to allow the release of air or fluid from the cavity as it is being filled with bone cement.

(b) *Classification.* Class I (general controls).

§ 888.4300 Depth gauge for clinical use.

(a) *Identification.* A depth gauge for clinical use is a device consisting of an instrument with a graduated scale intended for various uses, such as to determine the proper length of screws for fastening the ends of a fractured bone.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in Subpart E of Part 807.

§ 888.4540 Orthopedic manual surgical instrument.

(a) *Identification.* An orthopedic manual surgical instrument is a nonpowered hand-held device intended for medical purposes to manipulate tissue, or for use with other devices in orthopedic surgery. This generic type of device includes the cerclage applier, awl, bender, drill brace, broach, burr, corkscrew, countersink, pin crimper, wire cutter, prosthesis driver, extractor, file, fork, needle holder, impactor, bending or contouring instrument, compression instrument, passer, socket positioner, probe, femoral neck punch, socket pusher, reamer, rongeur, scissors, screwdriver, bone skid, staple driver, bone screw starter, surgical stripper, tamp, bone tap, trephine, wire twister, and wrench.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in Subpart E of Part 807.

§ 888.4580 Sonic surgical instrument and accessories/attachments.

(a) *Identification.* A sonic surgical instrument is a hand-held device with various accessories or attachments, such as a cutting tip that vibrates at high frequencies, and is intended for medical purposes to cut bone or other materials, such as acrylic.

(b) *Classification.* Class II (performance standards).

§ 888.4600 Protractor for clinical use.

(a) *Identification.* A protractor for clinical use is a device intended for use in measuring the angles of bones, such as on x-rays or in a surgery.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in Subpart E of Part 807.

§ 888.4800 Template for clinical use.

(a) *Identification.* A template for clinical use is a device that consists of a pattern or guide intended for medical purposes, such as selecting or positioning orthopedic implants or guiding the marking of tissue before cutting.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in Subpart E of Part 807.

§ 888.5850 Nonpowered orthopedic traction apparatus and accessories.

(a) *Identification.* A nonpowered orthopedic traction apparatus is a device that consists of a rigid frame with nonpowered traction accessories, such as cords, pulleys, or weights, and that is intended to apply a therapeutic pulling force to the skeletal system.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in Subpart E of Part 807. The device also is exempt from the good manufacturing practices regulation in Part 820 with the exception of § 820.180, regarding general requirements concerning records, and § 820.198, regarding complaint files.

§ 888.5890 Noninvasive traction component.

(a) *Identification.* A noninvasive traction component is a device, such as a head halter, pelvic belt, or a traction splint, that does not penetrate the skin and is intended to assist in connecting a patient to a traction apparatus so that a therapeutic pulling force may be applied to the patient's body.

(b) *Classification.* Class I (general controls).

§ 888.5940 Cast component.

(a) *Identification.* A cast component is a device intended for medical purposes to protect or support a cast. This generic type of device includes the cast heel, top cap, cast support, and walking iron.

(b) *Classification.* Class I (general controls). The device is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, regarding general requirements concerning records, and § 820.198, regarding complaint files.

§ 888.5960 AC-powered cast removal instrument.

(a) *Identification.* An AC-powered cast removal instrument is an AC-powered hand-held device intended to remove a cast from a patient. This generic type of device includes the electric cast cutter and cast vacuum.

(b) *Classification.* Class II (performance standards).

§ 888.5980 Manual cast aplication and removal instrument.

(a) *Identification.* A manual cast application and removal instrument is a nonpowered hand-held device intended

to be used in applying or removing a cast. This generic type of device includes the cast knife, cast spreader, plaster saw, plaster dispenser, and casting stand.

(b) *Classification.* Class I (general controls). The device is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, regarding general requirements concerning records, and § 820.198, regarding complaint files.

Because FDA believes that more time is needed for interested persons to submit comments on the classification of the numerous devices in this proposed regulation and the need to stagger the comment periods to allow an orderly review of all of the outstanding proposed classification regulations, FDA is providing a period through October 1, 1982 for interested persons to comment on this proposal. FDA finds in accordance with section 520(d)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(d)(2)) that good cause exists to extend the comment period beyond 90 days. Similar extensions of comment periods were granted for good cause for other proposed classification regulations. (See the **Federal Register** of March 19, 1982 (47 FR 11879).)

Interested persons may, on or before October 1, 1982 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 regarding the general provisions are to be identified with the docket number found in brackets in the heading of this document. Comments regarding a particular device are to be identified with the docket number for that device found in the "Panel Recommendations and FDA's Proposed Classifications" sections. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

The Food and Drug Administration has carefuly analyzed the economic effects of this proposed rule and certifies that, if promulgated, the rule will not have a significant economic impact on a substantial number of small entities as defined by the Regulatory Flexibility Act. In accordance with section 3(g)(1) of Executive Order 12291, the impact of this proposed rule has been carefully analyzed, and it has been determined that this proposal does not constitute a major rule as defined in section 1(b) of the Executive Order. Rules proposing classification of devices into class I generally maintain the status quo: These devices are now subject to only the general controls provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 352, 360, 360f, 360h, 360i, and 360j) and, under the proposed rules, would remain subject only to such controls either in their entirety or with certain exemptions. Devices classified into class II would also remain subject only to the general controls provisions of the act unless and until an applicable performance standard were established. Similarly, devices classified into class III remain subject only to the general controls provisions of the act until an additional regulation is promulgated pursuant to section 515(b) of the act (21 U.S.C. 360e(b)) requiring that such devices have in effect approved applications for premarket approval. In accordance with section 501(f)(2)(B) of the act (21 U.S.C. 351(f)(2)(B)), devices classified by regulation into class III may remain in commercial distribution without an approved premarket aproval application for 30 months following the effective date of classification of the device into class III, or for 90 days following the promulgation of a regulation under section 515(b) of the act (21 U.S.C. 360e(b)), whichever occurs later. In sum, device classification rules do not have a significant impact on a substantial number of small entities and are not major rules.

Dated: June 7, 1982.

Arthur Hull Hayes, Jr.,

Commissioner of Food and Drugs.

[FR Doc. 82-17576 Filed 7-1-82; 8:45 am]

BILLING CODE 4160-01-M

federal register

Friday
July 2, 1982

Part III

Department of Labor

Employment Standards Administration, Wage and Hour Division

Minimum Wages for Federal and Federally Assisted Construction; General Wage Determination Decisions

DEPARTMENT OF LABOR

Employment Standards Administration, Wage and Hour Division

Minimum Wages for Federal and Federally Assisted Construction; General Wage Determination Decisions

General wage determination decisions of the Secretary of Labor specify, in accordance with applicable law and on the basis of information available to the Department of Labor from its study of local wage conditions and from other sources, the basic hourly wage rates and fringe benefit payments which are determined to be prevailing for the described classes of laborers and mechanics employed on construction projects of the character and in the localities specified therein.

The determinations in these decisions of such prevailing rates and fringe benefits have been made by authority of the Secretary of Labor pursuant to the provisions of the Davis-Bacon Act of March 3, 1931, as amended (46 Stat. 1494, as amended, 40 U.S.C. 276a) and of other Federal statutes referred to in 29 CFR 1.1 (including the statutes listed at 36 FR 306 following Secretary of Labor's Order No. 24–70) containing provisions for the payment of wages which are dependent upon determination by the Secretary of Labor under the Davis-Bacon Act; and pursuant to the provisions of part 1 of subtitle A of title 29 of Code of Federal Regulations, Procedure for Predetermination of Wage Rates (37 FR 21138) and of Secretary of Labor's Orders 12–71 and 15–71 (36 FR 8755, 8756). The prevailing rates and fringe benefits determined in these decisions shall, in accordance with the provisions of the foregoing statutes, constitute the minimum wages payable on Federal and federally assisted construction projects to laborers and mechanics of the specified classes engaged on contract work of the character and in the localities described therein.

Good cause is hereby found for not utilizing notice and public procedure thereon prior to the issuance of these determinations as prescribed in 5 U.S.C. 553 and not providing for delay in effective date as prescribed in that section, because the necessity to issue construction industry wage determination frequently and in large volume causes procedures to be impractical and contrary to the public interest.

General wage determination decisions are effective from their date of publication in the **Federal Register** without limitation as to time and are to be used in accordance with the provisions of 29 CFR Parts 1 and 5. Accordingly, the applicable decision together with any modifications issued subsequent to its publication date shall be made a part of every contract for performance of the described work within the geographic area indicated as required by an applicable Federal prevailing wage law and 29 CFR, Part 5. The wage rates contained therein shall be the minimum paid under such contract by contractors and subcontractors on the work.

Modifications and Supersedeas Decisions to General Wage Determination Decisions

Modifications and supersedeas decisions to general wage determination decisions are based upon information obtained concerning changes in prevailing hourly wage rates and fringe benefit payments since the decisions were issued.

The determinations of prevailing rates and fringe benefits made in the modifications and supersedeas decisions have been made by authority of the Secretary of Labor pursuant to the provisions of the Davis-Bacon Act of March 3, 1931, as amended (46 Stat. 1494, as amended, 40 U.S.C. 276a) and of other Federal statutes referred to in 29 CFR 1.1 (including the statutes listed at 36 FR 306 following Secretary of Labor's Order No. 24–70) containing provisions for the payment of wages which are dependent upon determination by the Secretary of Labor under the Davis-Bacon Act; and pursuant to the provisions of part 1 of subtitle A of title 29 of Code of Federal Regulations, Procedure for Predetermination of Wage Rates (37 FR 21138) and of Secretary of Labor's orders 13–71 and 15–71 (36 FR 8755, 8756). The prevailing rates and fringe benefits determined in foregoing general wage determination decisions, as hereby modified, and/or superseded shall, in accordance with the provisions of the foregoing statutes, constitute the minimum wages payable on Federal and federally assisted construction projects to laborers and mechanics of the specified classes engaged in contract work of the character and in the localities described therein.

Modifications and supersedeas decisions are effective from their date of publication in the **Federal Register** without limitation as to time and are to be used in accordance with the provisions of 29 CFR Parts 1 and 5.

Any person, organization, or governmental agency having an interest in the wages determined as prevailing is encouraged to submit wage rate information for consideration by the Department. Further information and self-explanatory forms for the purpose of submitting this data may be obtained by writing to the U.S. Department of Labor, Employment Standards Administration, Wage and Hour Division, Office of Government Contract Wage Standards, Division of Government Contract Wage Determinations, Washington, D.C. 20210. The cause for not utilizing the rulemaking procedures prescribed in 5 U.S.C. 553 has been set forth in the original General Determination Decision.

Modifications to General Wage Determination Decisions

The numbers of the decisions being modified and their dates of publication in the **Federal Register** are listed with each State.

Florida:	
FL82-1005	Feb. 19, 1982.
FL82-1019	Mar. 12, 1982.
FL82-1015	Mar. 5, 1982.
Washington, D.C.: DC81-3040	June 5, 1981.
Maryland: DC81-3040	June 5, 1981.
Virginia: DC81-3040	June 5, 1981.
Colorado:	
CO82-5103	Feb. 12, 1982.
CO82-5104	Feb. 26, 1982.
Idaho: ID81-5157	Oct. 9, 1981.
Pennsylvania:	
PA79-3020	July 20, 1979.
PA81-3027	July 17, 1981.
PA81-3041	July 6, 1981.
PA81-3051	Sept. 4, 1981.
PA81-3058	Aug. 28, 1981.
PA81-3066	Oct. 23, 1981.
PA81-3068	Sept. 25, 1981.
PA81-3069	Sept. 25, 1981.
PA81-2072	Oct. 2, 1981.
PA81-3073	Oct. 2, 1981.
PA81-3081	Oct. 23, 1981.
PA81-3090	Dec. 18, 1981.
PA82-3010	Mar. 5, 1982.
PA82-3011	Mar. 12, 1982.
PA82-3012	Mar. 5, 1982.
PA82-3016	May 14, 1982.
PA82-3017	Mar. 26, 1982.
PA81-3076	Oct. 9, 1981.
PA81-3077	Oct. 9, 1981.
PA81-3080	Oct. 23, 1981.
Indiana: IN80-2015	Apr. 11, 1980.
Tennessee: TN81-1202	May 1, 1981.
South Dakota: SD81-5150	Sept. 4, 1981.
SD81-5151	Sept. 4, 1981.

Supersedeas Decisions to General Wage Determination Decisions

The numbers of the decisions being superseded and their dates of publication in the **Federal Register** are listed with each State. Supersedeas decision numbers are in parentheses following the numbers of the decisions being superseded.

Georgia: GA82-107(GA82-1033)	Feb. 19, 1982.

Please note that we are changing the format for **Federal Register** wage decisions to coincide with the provisions of All Agency Memorandum No. 132

dated January 29, 1980, which provides that the Department of Labor will discontinue identifying fringe benefits separately. Rather, they will be stated as a composite figure which is the total hourly equivalent value of fringe benefits found to be prevailing. Fringe benefits which can not be stated in monetary terms will be shown in footnotes. This procedure is being phased in gradually.

Signed at Washington, D.C., this 25th day of June 1982.

Dorothy P. Come,

Assistant Administrator, Wage and Hour Division.

BILLING CODE 4510-27-M

MODIFICATION PAGE 1

DECISION NO. FL82-1005 - MOD. # 1
(47 FR 7596 - February 19, 1982)
Duval County, Florida
Building Construction

CHANGE:

	Basic Hourly Rates	Fringe Benefits
ASBESTOS WORKERS	$14.21	1.88
BOILERMAKERS	14.50	3.015
BRICKLAYERS	11.65	1.41
IRONWORKERS	12.75	1.78
LABORERS:		
Gunnite Workers, Mechanical Tool Oper., Power Buggy Oper., & Pipelayers	7.92	.70
Unskilled	7.72	.70
LINEMEN:		
Lineman	12.60	3.228
Cable Splicer	12.80	3.234
Heavy Equipment Operator	11.00	2.37
Winch Truck Operator	8.75	2.003
Groundmen	6.50	1.625
POWER EQUIPMENT OPERATORS:		
Group I	12.84	1.70
Group II	11.56	1.70
Group III	9.26	1.70

DECISION NO. FL82-1019 - MOD. #2
(47 FR 10946 - March 12, 1982)
BUILDING CONSTRUCTION
VOLUSIA COUNTY, FLORIDA
(except Cape Kennedy Space Flight Center & Cape Canaveral Air Force Station)

CHANGE:

	Basic Hourly Rates	Fringe Benefits
ASBESTOS WORKERS	$14.21	3.10
CARPENTERS	11.07	1.50
IRONWORKERS	12.78	3.10
POWER EQUIPMENT OPERATORS:		
Group I	12.84	1.70
Group II	11.56	1.70
Group III	9.26	1.70

Decision No. FL82-1015 - Mod. #2
(45 FR 9654 - 3/5/82)
BUILDING CONSTRUCTION
ORANGE COUNTY, FLORIDA

CHANGE:

	Basic Hourly Rates	Fringe Benefits
IRONWORKERS	$12.78	3.10

DECISION NO. DC81-3040 - MOD. #11
(46 FR 30290 - June 5, 1981)
DISTRICT OF COLUMBIA; MARYLAND-MONTGOMERY AND PRINCE GEORGES; D.C TRAINING SCHOOL; Virginia-INDEPENDENT CITY OF ALEXANDRIA, ARLINGTON AND FAIRFAX COUNTIES

CORRECTION TO MOD. #9 PUBLISHED IN THE FEDERAL REGISTER MAY 28, 1982:
"Marble Setters" should read "Stone Masons and Marble Setters"

CHANGE:

	Basic Hourly Rates	Fringe Benefits
LABORERS (EXCLUDING HEAVY CONSTRUCTION)		
Plumbers' Laborers	10.52	2.84

DECISION NO. CO82-5103 - Mod. #5
(47 FR 6549 - February 12, 1982)
Adams, Arapahoe, Boulder, Clear Creek, Denver, Douglas, Eagle, Elbert, Gilpin, Grand, Jefferson, Lake, Larimer, Morgan, Park, Summit, and Weld Counties, Colorado

Change:

Asbestos Workers	$17.49	$2.52

DECISION NO. CO82-5104 - Mod. #6
(47 FR 8497 - February 26, 1982)
El Paso County, Colorado

Change:

Asbestos Workers	$17.49	$2.52

MODIFICATION PAGE 2

DECISION NO. ID81-5157 - Mod #11
(46 FR 50223 - Oct. 9, 1981)
Statewide Idaho

CHANGE:

CEMENT MASONS (AREA 1)

GROUP	BASE RATE (Zone 1)
1	$15.50
2	16.00
3	16.50

ZONE DIFFERENTIAL (Add to Base Rate)
Zone 2 $1.15
Zone 3 1.60
Zone 4 2.30
Zone 5 2.95

FRINGE BENEFITS:
Health and Welfare $1.05
Pension 2.00
Apprenticeship Training .15

LABORERS (AREA 1):

GROUP	BASE RATE (Zone 1) (Building, Heavy, and Highway Projects)
1	$13.72
2	13.97
3	14.22
4	14.47

ZONE DIFFERENTIAL (Add to Base Rate) (Heavy & Highway projects only, does not apply to Building Projects)
Zone 2 $1.15
Zone 3 1.60
Zone 4 2.30
Zone 5 2.95

FRINGE BENEFITS:
Health and Welfare $1.62
Pension 1.30
Apprenticeship Training .20

POWER EQUIPMENT OPERATORS (AREA 1):

GROUP	BASE RATE (Zone 1)
1	$13.65
2	13.95
3	14.50
4	14.65
5	14.80
6	15.05
7	15.30
8	16.30

ZONE DIFFERENTIAL (Add to Base Rate)
Zone 2 $1.25
Zone 3 1.75
Zone 4 2.50
Zone 5 3.05

FRINGE BENEFITS:
Health and Welfare $1.50
Pension 2.50
Apprenticeship Training .10

TRUCK DRIVERS (AREA 1):

GROUP	BASE RATE (Zone 1)
1	$15.19
2	15.23
3	15.29
4	15.38
5	15.59
6	15.63
7	15.69
8	15.73
9	15.84
10	15.88
11	16.19
12	16.33
13	16.49
14	16.63

ZONE DIFFERENTIAL (Add to Base Rate)
Zone 2 $1.25
Zone 3 1.75
Zone 4 2.50
Zone 5 3.05

FRINGE BENEFITS:
Health and Welfare $1.73
Pension 1.61
Apprenticeship Training .09

DECISION NO. PA79-3020	Basic Hourly Rates	Fringe Benefits
MOD. NO. 9		
(44 FR 42880 - July 20, 1979)		
Carbon, Monroe County, including Tobyhanna Army Depot and Pike County, Pa.		
CHANGE:		
Electricians:		
Carbon County: Penn Forest, Lehigh, Lausane, Banks, Packer, Mauch Chunk, Franklin, Mahoning Townships and East Side Borough in their entirety, and that portion of Kidder Township South of State Highway 940, but excluding Perryville Borough	$14.07	1.95+3%
Glaziers		
Zone 2	13.10	1.95
Ironworkers:		
Zone 1	16.95	3.20
Millwrights		
Zone 3	15.77	1.95
Piledrivermen	13.67	5.31+g
Plumbers		
Zone 1	14.59	3.10

DECISION NO. PA81-3027		
MOD. NO. 6		
(46 FR 37212 - July 17, 1981)		
Franklin County, Pennsylvania		
Electricians	14.21	1.67 +3½%
Ironworkers	15.765	3.245
Sheet Metal Workers	15.01	3.04

DECISION NO PA81-3041	Basic Hourly Rates	Fringe Benefits
MOD. NO. 7		
(46 FR 34934 - July 6, 1981)		
Allegheny, Armstrong, Beaver, Bedford, Blair, Butler, Cambria, Cameron, Centre, Clarion, Clearfield, Clinton Crawford, Elk, Erie, Fayette Forest, Franklin, Fulton, Greene, Huntingdon, Indiana, Jefferson, Mercer, Lawrence, McKean, Mifflin, Potter, Somerset, Venango, Warren, Washington, & Westmoreland, Counties, Pennsylvania		
CHANGE:		
Ironworkers		
Zone 2		
Structural, Ornamental & Reinforcing	$15.765	3.245

DECISION NO. PA81-3051		
MOD. NO. 6		
(46 FR 44653 - Sept. 4, 1981)		
Luzerne County, Pennsylvania		
CHANGE:		
Carpenters:		
Black Creek, Butler, Dennison, Foster, Hazle, Hollenback, Nescopeck, Sugarloaf, and Lower Salem Township	13.40	1.95
Electricians:		
Hazleton, Nescopeck, Hollenbach, Black Creek, Sugar Loaf, Hazle, Butler, Foster Twps., and the Borough of White Haven in their entirety and that portion of Dennison Twp., south and west of the Central Railroad of New Jersey line between Wright Township and White Haven	14.07	1.95 +3%

DECISION NO. PA81-3051, CONT'D	Basic Hourly Rates	Fringe Benefits
Ironworkers:		
Structural & Ornamental	$16.35	3.30
Reinforcing	16.25	3.30
Millwrights	15.77	1.95
Piledrivermen	13.67	5.31+g
Plumbers	14.59	3.10

DECISION NO. PA81-3058		
MOD. NO. 10		
(46 FR 43596 - August 28, 1981)		
Adams, Berks, Bradford, Carbon Columbia, Cumberland, Dauphin, Juniata, Lackawanna, Lancaster Lebanon, Lehigh, Luzerne, Lycoming, Monroe, Montour, Northampton, Northumberland, Perry, Pike, Schuylkill, Snyder, Sullivan, Susquehanna, Tioga, Union, Wayne, Wyoming & York Counties, Pa.		
CHANGE:		
Ironworkers:		
Structural, Ornamental & Reinforcing		
Adams, Cumberland, Dauphin, Lancaster, Lebanon, Lycoming, Montour, Northumberland, Juniata, Perry, Snyder, Union & York Counties	15.765	3.245
LINE CONSTRUCTION:		
Northampton County:		
Linemen	16.94	.60 +3-3/8%
Winch truck operator	11.86	.60 +3-3/8%
Truck Drivers	11.01	.60 +3-3/8%
Groundman	10.16	.60 +3-3/8%

DECISION NO. PA81-3066	Basic Hourly Rates	Fringe Benefits
MOD. NO. 4		
(46 FR 52082 - October 23, 1981)		
Dauphin, Cumberland, Perry, Juniata, New Cumberland Depot, in York County, Pennsylvania		
CHANGE:		
Carpenters	13.40	1.95
Electricians	14.21	1.67+ 3½%
Ironworkers:		
Structural, Ornamental & Reinforcing	15.765	3.245
Lathers	13.40	1.95
Millwrights	15.77	1.95
Piledrivermen	13.67	5.31+d
Sheet Metal Workers	15.01	3.04

DECISION NO. PA81-3068		
MOD. NO. 7		
(46 FR 47403 - September 25, 1981)		
Lebanon County, Pennsylvania		
CHANGE:		
Carpenters	13.40	1.95
Ironworkers	15.765	3.245
Lathers	13.40	1.95
Millwrights	15.77	1.95
Piledrivermen	13.67	5.31+d
OMIT:		
Electricians:		
That portion of Lebanon County that is North and West of Interstate Route 81, incl. all of the Fort Indiantown Gap Military Reservation	13.56	1.32+3½%
That portion of Lebanon Co. which extends South and East of Interstate Route 81	13.09	1.32+3½%
ADD:		
Electricians	14.21	1.67+3½%

MODIFICATION PAGE 5

DECISION NO. PA81-3069 MOD. NO. 5 (46 FR 47401 - September 25, 1981) Berks County, Pennsylvania	Basic Hourly Rates	Fringe Benefits
CHANGE:		
Electricians:		
Marion, Tulpehocken & Bethel Townships	$14.21	1.67+3½%
Ironworkers:		
Structural & Ornamental, bridge	15.90	3.25
Reinforcing	15.90	3.25
Piledrivermen	13.67	5.31+e

DECISION NO. PA81-2072 MOD. NO. 4 (46 FR 48851 - October 2, 1981) Adams & York Counties, Pennsylvania	Basic Hourly Rates	Fringe Benefits
CHANGE:		
Carpenters:		
Adams County	13.40	1.95
Electricians:		
Franklin, Carrol, Monoghan and Fairview Twps.	14.21	1.67 +3½%
Ironworkers	15.765	3.245
Lathers	13.40	1.95
Millwrights:		
Adams County	15.77	1.95
York County	13.29	1.68
Piledrivermen	13.67	5.31+c
Roofers, Composition	12.75	1.61
Sheet Metal Workers	15.01	3.04

DECISION NO. PA81-3073 MOD. NO. 3 (46 FR 48853 - October 2, 1981) Northumberland County, Pennsylvania	Basic Hourly Rates	Fringe Benefits
CHANGE:		
Carpenters	$12.72	1.95
Electricians:		
Delaware, Lewis & Trubut Twps.	12.21	3.18+3%
Ironworkers	15.765	3.245
Lathers	12.72	1.95
Millwrights	15.77	1.95
Piledrivermen	13.67	5.31+a

DECISION NO. PA81-3081 - MOD. #3 (46 FR 52080 - October 23, 1981) SULLIVAN COUNTY, PA.	Basic Hourly Rates	Fringe Benefits
CHANGE:		
ELECTRICIANS:		
Western part of County	12.21	3.18+3%
GLAZIERS	13.10	1.95
IRONWORKERS:		
Structural	16.35	3.30
Reinforcing	16.25	3.30
MILLWRIGHTS	15.77	1.95
PILEDRIVERMEN	13.67	5.31+b
PLUMBERS & STEAMFITTERS	15.81	2.19
CARPENTERS		
Remainder of County	12.72	1.95

DECISION NO. PA81-3090 - MOD. #4 (46 FR 61813 - December 18, 1981) LYCOMING COUNTY, PA.	Basic Hourly Rates	Fringe Benefits
CHANGE:		
CARPENTERS	12.72	1.95
IRONWORKERS	15.765	3.245
LATHERS	12.72	1.95
MILLWRIGHTS	15.77	1.95
PILEDRIVERMEN	13.67	5.31+d

MODIFICATION PAGE 6

DECISION NO. PA82-3010 - MOD. #2 (47 FR 9684 - March 5, 1982) CLINTON, CENTRE, HUNTINGDON, FULTON & MIFFLIN COUNTIES, PENNSYLVANIA	Basic Hourly Rates	Fringe Benefits
CHANGE:		
ELECTRICIANS:		
Clinton County in its entirety; Townships in Centre County; Burnside, Curtin, Liberty, Howard, Marion, Walker, Miles and Haines	12.21	3.18+3%
IRONWORKERS:		
Huntingdon & Mifflin Cos.	15.765	3.245
PLUMBERS & STEAMFITTERS:		
Clinton County	15.81	2.19
SHEET METAL WORKERS		
Centre, Huntingdon, Fulton & Mifflin Cos., Pennsylvania	15.01	3.04

DECISION NO. PA82-3011 - MOD. #2 (47 FR 10963 - March 12, 1982) BRADFORD, TIOGA & UNION COUNTIES, PENNSYLVANIA	Basic Hourly Rates	Fringe Benefits
CHANGE:		
ELECTRICIANS:		
Tioga County in its entirety; remainder of Union and Bradford Cos. Bradford County; Town of Towanda, that portion of the County West of the Susquehanna River South of Towanda and West of U.S. Highway 309, North of Towanda	12.21	3.18+3%
	14.15	2.75+3%
GLAZIERS:		
Bradford & Tioga Cos.	13.10	1.95
IRONWORKERS:		
Structural, ornamental & Reinforcing Union Co.	15.765	3.245
MILLWRIGHTS	15.77	1.95
PILEDRIVERMEN	13.67	5.31+d
PLUMBERS & STEAMFITTERS:		
Western half of Bradford County	14.59	3.10

DECISION NO. PA82-3012 - MOD. #3 (47 FR 9681 - March 5, 1982) COLUMBIA, MONTOUR & SNYDER COUNTIES, PA.	Basic Hourly Rates	Fringe Benefits
CHANGE:		
CARPENTERS	12.72	1.95
ELECTRICIANS:		
Berwick Borough in Columbia County	14.07	1.95+3%
South of U.S. Highway #522 in Snyder County	14.21	1.67+3 ⅛%
IRONWORKERS:		
Montour & Snyder	15.765	3.245
Structural & Ornamental:		
Columbia County	16.35	3.30
Reinforcing		
Columbia County	16.25	3.30
LATHERS	12.72	1.95
MILLWRIGHTS	15.77	1.95
PILEDRIVERMEN	13.67	5.31+d

DECISION NO. PA82-3016 - MOD. #1 (47 FR 20990 - May 14, 1982) NORTHAMPTON COUNTY, PA.	Basic Hourly Rates	Fringe Benefits
CHANGE:		
ELECTRICIANS:		
Remainder of County	16.00	3%+2.69
LABORERS:		
Laborers & Window Cleaners	9.44	1.81
Operator of jackhammer, paving breaking and other pneumatic and mechanical tools coming under the jurisdiction of laborers, laying of all clay, terra cotta, ironstone, vitrified concrete or non-metallic pipe and the making of joints for the same and cofferdams (below 10')	9.69	1.81
Wagon drills and men handling burning torches in the wrecking of buildings	10.19	1.81

DECISION NO. PA82-3016 - (CONT'D)	Basic Hourly Rates	Fringe Benefits
Plaster and mason tenders scaffold builders and handling of all materials to be used by plasterers and masons, brick and block loaded on pallets, cement finishers tenders, gunniting and molded-D and sandblaster helpers, power buggies, all floor hardner and "cure" application shall be the work of the mason tender. All pump such as the concrete, plasterer, mortar and water, installing plastic or other non-solid refactory materials in connection with the boiler work	9.94	1.81
Barko Tamper Operator	10.46	1.81
IRONWORKERS	16.95	3.20
LINE CONSTRUCTION:		
Linemen	16.94	.60+3 3/8%
Cable Splicer	16.94	"
Groundmen	10.16	"
Winch Truck Operator	11.86	"
PAINTERS (BETHLEHEM):		
Brush	14.70	2.28
Structural Steel	15.00	2.28
Spray	15.70	2.28
GLAZIERS	12.79	1.465
PILEDRIVERMEN	13.67	5.31+a
SHEET METAL WORKERS	15.01	3.04
SOFT FLOOR LAYERS	12.80	2.95

DECISION NO. PA82-3017 - MOD. #2 (47 FR 13108 - March 26, 1982) LACKAWANNA, SUSQUEHANNA, WAYNE & WYOMING COUNTIES, PENNSYLVANIA	Basic Hourly Rates	Fringe Benefits
CHANGE:		
GLAZIERS	13.10	1.95
IRONWORKERS:		
Lackawanna, Wayne and Wyoming Cos.		
Structural and ornamental	16.35	3.30
Reinforcing	16.25	3.30
MILLWRIGHTS:		
Wyoming County:		
East of Susquehanna River	15.77	1.95
PILEDRIVERMEN	13.67	5.31+d
PLUMBERS	14.59	3.10

DECISION NO. PA81-3076 - MOD. #5 (46 FR 50263 - October 9, 1981) SCHUYLKILL COUNTY, PA	Basic Hourly Rates	Fringe Benefits
CHANGE:		
CARPENTERS	13.40	1.95
ELECTRICIANS:		
North Union, East Union, West Mahony, (excluding Frackvill Borough), Mahony, Delano, Kline, Rush, Ryan, Blythe, Schuylkill, Walker, Rahn, East Brunswick and Wes: Penn. Twps.	14.07	3%
Tremont and Pine Grove Townships	14.21	1.67+ 3⅛%
IRONWORKERS	15.90	3.25
LATHERS	13.40	1.95
PILEDRIVERMEN	13.67	5.31+d
MILLWRIGHTS	15.77	1.95

DECISION NO. PA81-3077 - MOD. #5 (46 FR 50265 - October 9, 1981) LANCASTER COUNTY, PA	Basic Hourly Rates	Fringe Benefits
CHANGE:		
CARPENTERS	13.40	1.95
ELECTRICIANS:		
That portion northwest of a line extending from the Susquehanna River to the intersection of State Highways 441 and 241 along 241 to the Borough of Elizabethtown, around the limits of Elizabethtown on the west and north side, but including the Masonic Homes		

DECISION NO. PA82-3077 - (CONT'D)	Basic Hourly Rates	Fringe Benefits
in Elizabeth town, continuing along State Highway 241 to Lebanon County and that portion north of the Pennsylvania Turnpike, but including all Buildings on the Turnpike, from Lebanon County line to West Cocalico Tw	14.21	1.67+3 ⅛%
IRONWORKERS	15.765	3.245
LATHERS	13.40	1.95
MILLWRIGHTS	15.77	1.95
PILEDRIVERMEN	13.67	5.31+d

DECISION NO. PA81-3080 - MOD. #3 (46 FR 52078 - October 23, 1981) LEHIGH COUNTY, PA	Basic Hourly Rates	Fringe Benefits
CHANGE:		
BRICKLAYERS & STONEMASONS	13.45	3.00
CARPENTERS	14.01	2.35
CEMENT MASONS	14.68	1.60
ELECTRICIANS	14.55	3%+1.84
GLAZIERS	12.79	1.465
LABORERS:		
Laborers & window cleaner	9.44	1.81
Operator of jackhammer, paving breaking and other pneumatic and mechanical tools coming under the jurisdiction of laborers, laying of all clay terra cotta, ironstone, vitrified concrete or non-metallic pipe and the making of joints for same and cofferdams (below 10')	9.69	1.81
Wagon drills and men handling burning torches in the wrecking of buildings	10.19	1.81
Plasterer and mason tenders, scaffold builders and handling of all material to be used by plasterers and masons, brick and block loaded on pallets, cement finisher tenders, gunniting and molde -D and sandblaster helper power buggies, all floor hardner and "cure" application shall be work of the mason tender, all pumps such as the concrete, plasterer mortar and water, installing plastic or other nonsolid rafractory materials in connection with the boiler work	9.94	1.81
Barko tamper operator	10.46	1.81
MARBLE SETTERS	12.50	3.00
MILLWRIGHTS	14.41	2.35
PAINTERS:		
Brush	14.70	2.28
Structural Steel	15.00	2.28
Spray	15.70	2.28
PILEDRIVERMEN	13.67	5.31+d
PLASTERERS	14.63	1.50
PLUMBERS	18.33	2.65
POWER EQUIPMENT OPERATORS:		
Group 1	14.85	25.6%+ a
Group 2	14.56	"
Group 3	13.69	"
Group 4	12.92	"
Group 5	12.45	"
Group 6	11.54	"
Group 7	15.10	"
Group 7-A	15.35	"
Group 7-B	15.59	"
SHEET METAL WORKERS	15.01	3.04
SOFT FLOOR LAYERS	12.80	2.95
SPRINKLER FITTERS	16.92	2.95
STEAMFITTERS	17.86	3.11

DECISION NO. IN80-2015 -
MOD. #3
(45 FR 24985 - April 11, 1980)
Statewide, Except Lake, LaPorte, Porter and St. Joseph Counties, Ind.

Change:

	Basic Hourly Rates	Fringe Benefits
POWER EQUIPMENT OPERATORS: (Tunnel & Sewer Construction)		
Benton, Carroll, Cass, Clinton, Delaware, Fayette, Fulton, Grant Hamilton, Hancock, Henry, Howard, Johnson, Madison, Marion, Miami, Randolph, Rush, Shelby, Tippecanoe, Tipton, Union, Wabash, Wayne, & White Cos.:		
Group I	$16.55	2.20
Group II	15.55	2.20
Group III	12.75	2.20
Group IV	11.25	2.20

DECISION #TN81-1202 -
MOD. #6
(46 FR 24886 - May 1, 1981)
Shelby County, Tennessee

Change:

	Basic Hourly Rates	Fringe Benefits
Cement Masons	$12.75	2.30

DECISION NO. SD81-5150 - Mod. #3
(46 FR 44656 - September 4, 1981)
Minnehaha County, South Dakota

	Basic Hourly Rates	Fringe Benefits
Change:		
Bricklayers; Stonemasons	$13.60	$1.55
Sheet Metal Workers	12.95	1.85+ 3%
Sprinkler Fitters	15.17	2.83

DECISION NO. SD81-5151 -
Mod. #3
(46 FR 44657-September 4, 1981)
Meade and Pennington Counties, South Dakota

	Basic Hourly Rates	Fringe Benefits
Change:		
Electricians:		
Electricians	$12.65	$1.90+ 10%
Cable Splicers	13.20	1.90+ 10%
Sheet Metal Workers	12.80	1.22+ 3%
Sprinkler Fitters	15.17	2.83

STATE: GEORGIA

COUNTIES: CLAYTON, DEKLAB & FULTON

DECISION NUMBER GA82-1033

DATE: DATE OF PUBLICATION

Supersedes Decision Number GA82-1007, dated 2-19-82 in 46 FR 7599.

DESCRIPTION OF WORK: BUILDING CONSTRUCTION PROJECTS (does not include single family homes and apartments up to and including for stories).

	Basic Hourly Rates	Fringe Benefits
ASBESTOS WORKERS	$14.10	1.95
BOILERMAKERS	14.50	3.015
BRICKLAYERS & STONE MASONS	13.22	2.10
CARPENTERS, DRYWALL HANGERS & RESILIENT FLOOR LAYERS	13.50	1.77
CARPET LAYERS	10.05	1.77
CEMENT MASONS	13.20	1.40
ELECTRICIANS:		
Wiremen	14.45	20½%
Cable Splicers	15.35	20½%
ELEVATOR CONST. MECHANICS	12.51	2.465 +a+b
ELEVATOR CONST. HELPERS	8.76	2.465 +a+b
GLAZIERS	13.45	1.84
IRONWORKERS	14.17	1.97
LATHERS	11.80	.66
MARBLE MASONS, TILE SETTERS, & TERRAZZO WORKERS	13.22	2.03
MARBLE, TILE, & TERRAZZO FINISHERS	9.69	.66
MILLWRIGHTS	13.88	1.82
PAINTERS:		
Brush, Roller & Drywall Finishers	13.00	2.45
Paperhangers	13.25	2.45
Drywall taping (where pressurized tools are used), boatswain chair & windowjack work, all steel above 25' (where no scaffold is erected), & any scaffold above 25' (not floored solid)	13.50	2.45
Spray, steamcleaning, waterblasting, sandblasting, steeple-jack work, gold leafing, stencil designing, graining, & marbelizing	14.00	2.45
PILEDRIVERMEN	13.65	1.77
PLASTERERS	13.42	1.65
PLUMBERS & PIPEFITTERS	13.80	2.24
ROOFERS	10.45	.55
SHEET METAL WORKERS	14.09	2.14
SPRINKLER FITTERS	14.57	2.83

WELDERS: Receive rate prescribed for craft performing operation to which welding is incidental.

FOOTNOTES:

a. Seven Paid Holidays: New Year's Day; Memorial Day; Independence Day; Labor Day; Thanksgiving Day; Friday after Thanksgiving Day; Christmas Day.

b. Vacation Pay Credit: Employer contributes 8% of the basic hourly rate for employees with 5 years or more of service, or 6% for employees with 6 months to 5 years of service..

Unlisted classifications needed for work not included within the scope of the classifications listed may be added after award only as provided in the labor standards contract clauses (29 CFR, 5.5 (a)(1)(ii)).

DECISION NO. GA82-1033

POWER EQUIPMENT OPERATORS	Basic Hourly Rates	Fringe Benefits
GROUP A	13.35	1.88
GROUP A-1	13.24	1.88
GROUP B	12.89	1.88
GROUP B-1	12.67	1.88
GROUP C	10.46	1.88
GROUP D-1	11.26	1.88
GROUP D-2	9.65	1.88
GROUP E	9.87	1.88
GROUP F	8.57	1.88

LABORERS		Basic Hourly Rates	Fringe Benefits
GROUP 1		9.51	1.02
GROUP 2		9.73	1.02
GROUP 3		10.01	1.02
GROUP 4		10.26	1.02
GROUP 5		10.58	1.02
GROUP 6	(25¢ above rate for classification under which employed)		

DECISION NO. GA82-1033

CLASSIFICATION DEFINITIONS - LABORERS

GROUP 1 - Batch plant man; buggy rollers (Ga.); cleaners, brick or lumber; clearing of right-of-way & building site (hand tools); concrete curer-sealer and liquid hardner; conveyor operator, used in tending plasterers & bricklayers; electricians laborer; excavator, backfiller, grader, hand; forklift operator, walk-type mech. used in tending plasterers and bricklayers; form oilers; form stripper; metal pan handler; plumber laborer; pipe doper; precast slab layer (floor, roofs, walks, curbs); puddlers, concrete; rail porter; railroad track laborer; reinforcing steel handler; scaffolds and staging for masons & Plasterers, erecting & removing; scarifyer, concrete, mech. or hand; sheeting and shoring laborers; steam jennies, used in cleaning equipment; tenders (all crafts); tool room man; truck spotter dumper; water boy; winch handler (manual); wrecking buildings & miscellaneous structures.

GROUP 2 - All tool operators: air, electric or gas powered, such as jackhammer, paving breaker, tampers, vibrator, spade, chipping hammer, & barco tamp.; bucket dump man, concrete; burner demolition work; chain saw operator; form setter, steel; mixer, mortar, cement, grout, clay, etc. (hand machine oper.); mortar mixer used in connection with hose for gypsum roofs, plastering, asbestos, fiber, soundproofing, etc.; motorized post hole digger; power saw operator, concrete, outside building; steam cleaning machine operator; sewer pipe layer, yarner, wiper & pot pot man; slip form raisers steel or wood, jack or screw type, wheelbarrow operator, motorized.

GROUP 3 - Powderman tender; wagon drill operator, track or wheel type and other equipment used in drilling for blasting.

GROUP 4 - Caisson work, hole man; tunnel laborer.

GROUP 5 - Nozzleman, concrete pneu.; powderman.

GROUP 6 - Chimneys or stacks, isolated.

DECISION NO. GA82-1033

CLASSIFICATION DEFINITIONS - POWER EQUIPMENT OPERATORS:

GROUP A - Crane operator (truck, tower, crawler, or locomotive);

GROUP A-1 - Backhoe operator, clamshell operator, concrete mix operator - mix plant, concrete pump operator - Ridley or similar type, derrick operator, dragline operator, drill operator - caisson foundation type, elevator operator - temporary construction elevator used to haul building material and personnel, elevating grader operator, hoisting engine operator, locomotive operator, mechancis - heavy duty, concrete paving mixer operator, pile driver operator, rock crusher operator, shovel operator, trenching machine operator over 6 feet depth capacity, tugger hoist operator, well drill operator - performing foundation work, winch truck operator - hoisting material, air compressor operator - 365 C.F.M. and over, furnishing air simultaneously for more than one contractor.

GROUP B - Bulldozer operator, dewatering system operator - where multiple pumps are used, dozer shovel operator, drill operator - Quarry Master type, fireman - stationary or portable, forklift operator, generator operator - 75 K.V.A. and over, motor grader operator, motor scraper operator (pans), oilers on cranes with earth boring drill attached with a separate power source, pusher dozer operator, self propelled compactor operator with blade, tractor operator with special equipment, trenching machine operator - up to and including 6 feet depth capacity, well point system operator (including the operation of all pumps on project operated by the contractor.

GROUP B-1 - Elevator operator - inside electric pernament house elevator used to haul building materials and personnel.

GROUP C - Air compressor - 600 cubic feet and over, air compressor operator-battery of two 300 cubic feet and over, hydrohammer operator, concrete batch plant operator.

GROUP D-1 - Oiler-grease truck, truck or locomotive crane,

GROUP D-2 - Oiler - unspecified, pump operator - over 4", up to 4 batteries, welding machine operator - 4 or more batteries, portable, gas, or diesel driven.

GROUP E - Concrete mixer operator - skip types except paving mixers, concrete finishing machine operator, concrete paving machine operator, roller operator - asphalt type, well drill operator - not performing foundation work.

GROUP F - Air compressor operator - over 150 CRM but less than 600 cubic feet, conveyor operator - chain or belt type, sand blasting machine operator, water pump operator 4 inches and over, up to and including three welding machines do not require an operator.

[FR Doc. 82-17664 Filed 7-1-82; 8:45 am]

BILLING CODE 4510-27-C

federal register

Friday
July 2, 1982

Part IV

Department of the Interior

Minerals Management Service

Oil and Gas Leasing; Outer Continental Shelf: Central and Northern California, South Atlantic, Lower Cook Inlet/Shelikof Strait and Mid-Atlantic

4310-84

UNITED STATES
DEPARTMENT OF THE INTERIOR
MINERALS MANAGEMENT SERVICE

Outer Continental Shelf
Central and Northern California, South Atlantic, Lower Cook Inlet/
Shelikof Strait and Mid-Atlantic

Oil and Gas Lease Sale No. RS-2

1. Authority. This notice is published pursuant to the Outer Continental Shelf Lands Act of 1953 (43 U.S.C. 1331-1343), as amended (92 Stat. 629), and the regulations issued thereunder (43 CFR Part 3300). A revision of 43 CFR 3300 appears in the Federal Register of June 16, 1982, at 47 FR 25967 and 26031. The revised regulations will be effective on July 16, 1982, and will therefore apply to this sale.

2. Filing of Bids. Sealed bids may be delivered, in person, to Homer Benton, Room No. 2515, U.S. Department of the Interior, 18th & C Streets, N.W., Washington, D.C., on August 4, 1982, until 4:30 p.m., or to Room 1C100, Auditorium, Geological Survey National Center, 12201 Sunrise Valley Drive, Reston, Virginia, between the hours of 8:30 a.m., e.s.t. and 9:30 a.m., e.s.t., August 5, 1982. Bids received by the authorized officer later than the times and dates specified above will be returned unopened to the bidders. Bids may not be modified or withdrawn unless written modification or withdrawal is received by the authorized officer prior to 9:30 a.m., e.s.t., August 5, 1982. All bids must be submitted and will be considered in accordance with applicable regulations, including 43 CFR Part 3300. The list of restricted joint bidders which applies to this sale was published in 47 FR 14785; April 6, 1982.

3. Method of Bidding. A separate bid in a sealed envelope, labeled, "Sealed Bid for Oil and Gas Lease (insert number of tract), not to be opened until 10 a.m., e.s.t., August 5, 1982," must be submitted for each tract. A suggested form appears in 43 CFR Part 3300, Appendix A. Bidders are advised that tract numbers are assigned solely for administrative purposes and are not the same as block numbers found on official protraction diagrams. All bids received shall be deemed submitted for a numbered tract. Bidders must submit with each bid one-fifth of the cash bonus in cash or by cashier's check, bank draft, or certified check, payable to the order of the Bureau of Land Management. No bid for less than a full tract as described in paragraph 12 will be considered. Bidders submitting joint bids must state on the bid form the proportionate interest of each participating bidder, in percent to no more than five decimal places after the decimal point, e.g., 50.12345 percent. The previous requirement for a joint bidder's statement under 43 CFR 3316.4(g) has been rescinded by the latest revision of regulations at 43 CFR 3300 (see paragraph 1, above). Other documents may be required of bidders under 43 CFR 3316.4. Bidders are warned against violation of 18 U.S.C. 1860, prohibiting unlawful combination or intimidation of bidders.

4. Bidding Systems. All leases awarded for this sale will provide for a yearly rental payment of $8 per hectare or fraction thereof. Leases awarded under 4(a), (b), and (c) will provide for a minimum annual royalty payment of $8 per hectare or fraction thereof. The following systems will be utilized.

a) Bonus Bidding with a 16-2/3 Percent Royalty. Bids on tracts R53-156, R53-157, R53-162, R53-164, R53-169, R53-170, R53-171, R53-176, R53-190, R53-191, R56-189 thru R56-286, R60-1 thru R60-17, R60-19, R60-21, R60-22, R60-23, R60-26 thru R60-72, R60-86 thru R60-110, R60-112, R60-113, R60-115, R60-116, R60-153, R59-1, R59-25, R59-62, and R59-222 must be submitted on a cash bonus basis with a fixed royalty of 16-2/3 percent. All leases

awarded under this system will provide for a minimum royalty payment of $8 per hectare or fraction thereof due at the end of each lease year beginning with the first lease year following a discovery on the lease.

b) Bonus Bidding with a 12-1/2 Percent Royalty. Bids on tracts R56-22, R56-26, R56-27, R56-30, R56-33 thru R56-39, R56-46 thru R56-51, R56-53 thru R56-66, R56-69 thru R56-71, R56-73 thru R56-76, R56-78, R56-79, R56-162 thru R56-173, R59-2, R59-3, R59-5 thru R59-9, R59-11 thru R59-13, R59-16 thru R59-20, R59-24, R59-26 thru R59-28, R59-31 thru R59-35, R59-38 thru R59-42, R59-45 thru R59-50, R59-53 thru R59-56, R59-60, R59-61, R59-63 thru R59-65, R59-69 thru R59-71, R59-76, R59-77, R59-82 thru R59-84, R59-88 thru R59-94, R59-97 thru R59-102, R59-105, R59-114, R59-123, R59-196, R59-197, R59-198, R59-202 thru R59-206, R59-209 thru R59-212, R59-215 thru R59-221, R59-223 thru R59-233, R59-237, R59-238, R59-239, R59-242 thru R59-244, R59-248 thru R59-250, R59-252 and R59-253 must be submitted on a cash bonus basis with a fixed royalty of 12-1/2 percent.

c) Bonus Bidding with a Fixed Sliding Scale Royalty. Bids on tracts R53-197, R53-198, R53-199, R53-204, R53-205, R53-211, R53-212, R53-213, R53-218, R53-219, R53-220, R53-221, R53-225, R53-226, R53-227, R53-231, and R53-233 must be submitted on a cash bonus bid basis with the percent royalty due, in amount or value of production fixed according to the sliding scale formula described below. This formula fixes the percent royalty at a level determined by the value of lease production during each calendar quarter. For purposes of determining the royalty percent due on production during a quarter, the value of production during the quarter will be adjusted for inflation as described below. The determination of the value of the production on which royalty is due will be made pursuant to 30 CFR 250.64.

The fixed sliding scale formula operates in the following way: when the quarterly value of production, adjusted for inflation, is less than or equal to $14.787863 million, a royalty of 16.66667 percent in amount or value of production will be due on the unadjusted value or amount of production. When the adjusted quarterly value of production is equal to or greater than $14.787864 million, but less than or equal to $1197.206141 million, the royalty percent due on the unadjusted value or amount of production is given by

$$Rj = b[\ln (Vj/S)]$$

where

Rj = the percent royalty that is due and payable on the unadjusted amount or value of all production saved, removed or sold in quarter j

b = 11.0

ln = natural logarithm

Vj = the value of production in quarter j, adjusted for inflation, in millions of dollars

S = 3.25

When the adjusted quarterly value of production is equal to or greater than $1197.206142 million, a royalty of 65.00000 percent in amount or value of production will be due on the unadjusted quarterly value of production. Thus, in no instance will the quarterly royalty due exceed 65.00000 percent in amount or value of quarterly production.

In determining the quarterly percent royalty due, Rj, the calculation will be carried to five decimal places (for example, 17.10773 percent). This calculation will incorporate the adjusted quarterly value of production, Vj, in millions of dollars, rounded to the sixth digit, i.e., to the nearest dollar (for example, 15.392847 millions of dollars).

TABLE 1. HYPOTHETICAL QUARTERLY ROYALTY CALCULATIONS

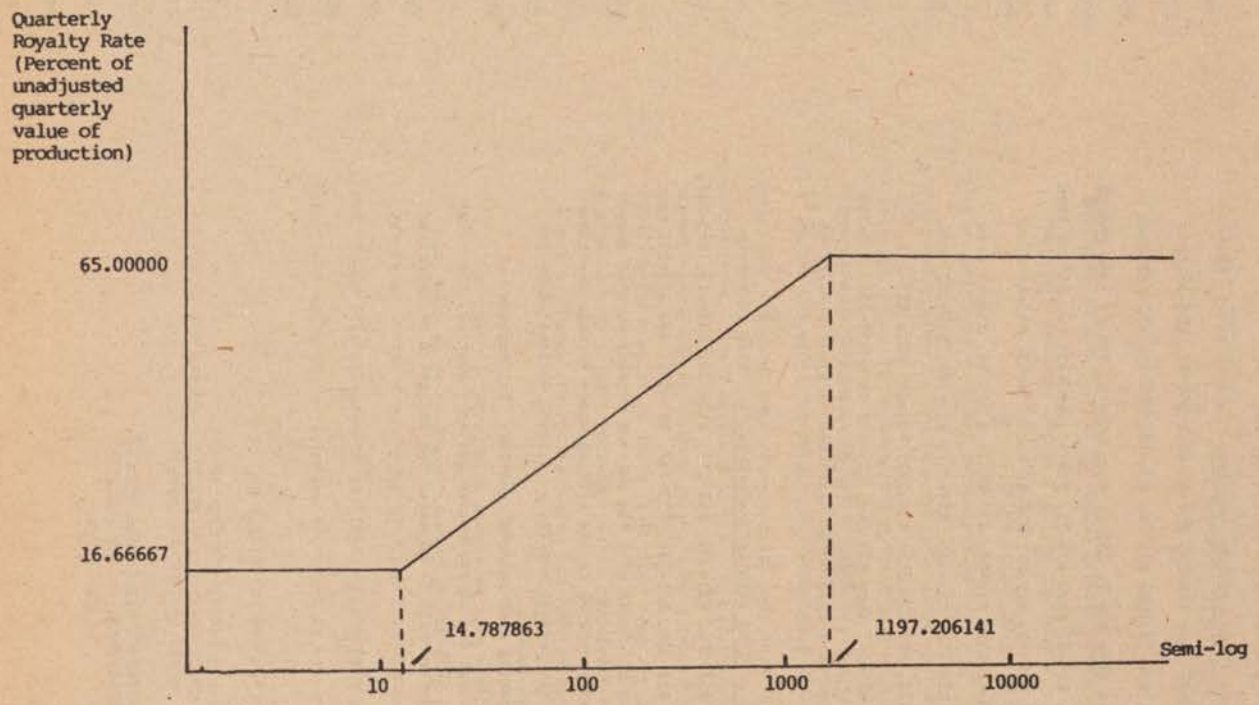
(A) Actual Value of Quarterly Production (Millions of Dollars)	(B) GNP Fixed Weighted Price Index	(C) Inflation Factor[1]	(D) Adjusted Value of Quarterly Production[2] (Vj, Millions of $)	(E) Percent Royalty Rate (Rj)	(F) Royalty Payment[3] (Millions of Dollars)
10.000000	200.0	4/3	7.500000	16.66667	1.666667
30.000000	200.0	4/3	22.500000	21.28346	6.385039
90.000000	200.0	4/3	67.500000	33.36819	30.031378
270.000000	200.0	4/3	202.500000	45.45293	122.722921
810.000000	200.0	4/3	607.500000	57.53767	466.055118
10.000000	250.0	5/3	6.000000	16.66667	1.666667
30.000000	250.0	5/3	18.000000	18.82889	5.648665
90.000000	250.0	5/3	54.000000	30.91362	27.822257
270.000000	250.0	5/3	162.000000	42.99835	116.095557
810.000000	250.0	5/3	486.000000	55.08308	446.173028

1 Column (B) divided by 150.0 (assumed value of GNP fixed weighted price index at time leases are issued).

2 Column (A) divided by Inflation Factor.

3 Column (A) times Column (E) divided by 100. All values are rounded for display purposes only.

Figure 1
Form of the Sliding Royalty Schedule



The form of the sliding scale royalty schedule is illustrated in Figure 1. Note that the effective quarterly royalty rate depends upon the inflation adjusted quarterly value of production. However, this rate is applied to the unadjusted quarterly value of production to determine the royalty payments due.

In adjusting the quarterly value of production for use in calculating the percent royalty due on production during the quarter, the actual value of production will be adjusted to account for the effects of inflation by dividing the actual value of production by the following inflation adjustment factor. The inflation adjustment factor used will be the ratio of the GNP fixed weighted price index for the calendar quarter preceding the quarter of production to the value of that index for the quarter preceding June, 1981. The GNP fixed weighted price index is published monthly in the Survey of Current Business by the Bureau of Economic Analysis, U.S. Department of Commerce. The percent royalty will be due and payable on the actual amount or value of production saved, removed, or sold as determined pursuant to 30 CFR 250.64. The timing of procedures for inflation adjustments and determinations of the royalty due will be specified at a later date. Table 1 provides hypothetical examples of quarterly royalty calculations using the sliding scale formula just described under two different values for the quarterly price index.

d) Bonus Bidding with a Fixed Net Profit Share. Bids on tracts R56-80 thru R56-83, R56-85 thru R56-99, R56-102, R56-103, R56-105, R56-106, R56-109 thru R56-124, R56-127, R56-128, R59-106 thru R59-109, R59-115 thru R59-118, R59-124 thru R59-128, R59-133 thru R59-137, R59-142 thru R59-145, R59-150, R59-151, R59-157, R59-158, R59-163, R59-164, R59-169 thru R59-171, R59-176 thru R59-178, R59-182 thru R59-184, R59-188 thru R59-191, and R59-195 must be submitted on a cash bonus basis with a fixed net profit share rate of 30 percent and a 1.50 capital recovery factor.

Tracts R56-131 thru R56-161, R56-175 thru R56-181, R56-185, R56-186 and R56-188 must be submitted on a cash bonus basis with a fixed net profit share rate of 45 percent and a 0.50 capital recovery factor.

Tracts R60-73 thru R60-85, R60-117, R60-119, R60-121 thru R60-123, R60-125, R60-127 thru R60-131, R60-133 thru R60-138, and R60-141 thru R60-152 must be submitted on a cash bonus basis with a fixed net profit share rate of 40 percent and a 0.75 capital recovery factor. The net profit share payment shall be calculated according to the regulation in 10 CFR 390.

5. Equal Opportunity. Each bidder must have submitted by 9:30 a.m., e.s.t., August 5, 1982, the certification required by 41 CFR 60-1.7(b) and Executive Order No. 11246 of September 24, 1965, as amended by Executive Order No. 11375 of October 13, 1967, on the Compliance Report Certification Form, Form 1140-8 (November 1973), and the Affirmative Action Representation Form, Form 1140-7 (December 1971). See Section 14 "Information to Lessees." These forms should be filed with the Minerals Manager, Atlantic Outer Continental Shelf Region, formerly New York OCS Office, Suite 32-120, 26 Federal Plaza, New York, New York, 10278, along with a statement as to which OCS Office maintains the bidder's company qualification file.

6. Bid Opening. Bids will be opened on August 5, 1982, beginning at 10 a.m., e.s.t., in Room 1C100, Auditorium at the second address stated in paragraph 2. The opening of the bids is for the sole purpose of publicly announcing bids received and no bids will be accepted or rejected at that time. If the Department is prohibited for any reason from opening any bid before midnight, August 5, 1982, that bid will be returned unopened to the bidder as soon thereafter as possible.

7. Deposit of Payment. Any cash, cashier's checks, certified checks, or bank drafts submitted with a bid may be deposited in a suspense account in the U.S. Treasury during the period the bids are being considered. Such a deposit does not constitute and shall not be construed as acceptance of any bid on behalf of the United States.

8. Withdrawal of Tracts. The United States reserves the right to withdraw any tract from this sale prior to issuance of a written acceptance of a bid for that tract.

9. Acceptance or Rejection of Bids. The United States reserves the right to reject any and all bids for any tract. In any case, no bid for any tract will be accepted and no lease for any tract will be awarded to any bidder unless:

(a) The bidder has complied with all requirements of this notice and applicable regulations;

(b) The bid is the highest valid cash bonus bid; and

(c) The amount of the bid has been determined to be adequate by the Secretary of the Interior.

No bid will be considered for acceptance unless it offers a cash bonus in the amount of $62 or more per hectare or fraction thereof.

10. Successful Bidders. Each person who has submitted a bid accepted by the Secretary of the Interior will be required to execute copies of the lease specified below, pay the balance of the cash bonus bid together with the first year's rental and satisfy the bonding requirements of 43 CFR Subpart 3318 within the time provided in 43 CFR 3316.5. A modification of the payments procedure for successful bidders appears in the latest revision of 43 CFR 3300 (see paragraph 1, above). These changes do not apply to the submission of the one-fifth bonus with bids, described in paragraph 3, above.

11. Official Protraction Diagrams. Tracts offered for lease may be located on the following official protraction diagrams which are available at a cost of $2.00 each from:

(a) the Minerals Manager, Pacific Outer Continental Shelf Region, formerly Pacific OCS Office, 1340 W. 6th Street, Room 200, Los Angeles, California 90017,

NI 10-3 San Luis Obispo

NI 10-6 Santa Maria

(b) the Minerals Manager, Atlantic Outer Continental Shelf Region, formerly New York OCS Office, Suite 32-120, 26 Federal Plaza, New York, New York, 10278,

NI 18-2 Manteo

NI 18-5

NI 18-7 Cape Fear

NI 17-12 James Island

NH 17-6

NH 17-2 Brunswick

NH 17-5 Jacksonville

NJ 18-3 Hudson Canyon

NJ 18-6 Wilmington Canyon

NJ 18-8 Chincoteague

NJ 18-9 Baltimore Rise

(c) the Minerals Manager, Alaska Outer Continental Shelf Region, formerly Alaska OCS Office, 620 East 10th Avenue, P.O. Box 1159, Anchorage, Alaska 99510,

NO 5-1, Iliamna

NO 5-2, Seldovia

NO 5-3, Mt. Katmai

NO 5-4, Afognak

12. Tract Descriptions.

Note: There may be gaps in the numbers of the tracts listed. Some of the blocks identified in the final environmental impact statements may not be included in this notice.

The tracts offered for bids are as follows:

OCS OFFICIAL PROTRACTION DIAGRAM, SAN LUIS OBISPO, NI 10-3
(Approved March 26, 1976)

Tract	Block	Description	Hectares
R53-156	897	All	2304.00
R53-157	898	All	2304.00
R53-162	941	All	2304.00
R53-164	943	All	2304.00
R53-169	985	All	2304.00
R53-170	986	All	2304.00
R53-171	987	All	2304.00

OCS OFFICIAL PROTRACTION DIAGRAM, SANTA MARIA, NI 10-6
(Approved March 26, 1976)

Tract	Block	Description	Hectares
R53-176	16	All	2304.00
R53-190	105	All	2304.00
R53-191	106	All	2304.00
R53-197	150	All	2304.00
R53-198	151	All	2304.00
R53-199	152	All	2304.00
R53-204	195	All	2304.00
R53-205	196	All	2304.00
R53-211	239	All	2304.00
R53-212	240	All	2304.00
R53-213	241	All	2304.00
R53-218	283	All	2304.00
R53-219	284	All	2304.00
R53-220	285	All	2304.00
R53-221	286	All	2304.00
R53-225	328	All	2304.00
R53-226	329	All	2304.00
R53-227	330	All	2304.00
R53-231	373	All	2304.00
R53-233	375	All	2304.00

OCS OFFICIAL PROTRACTION DIAGRAM, MANTEO NI 18-2
(Approved October 31, 1974)

Tract	Block	Description	Hectares
R56-22	555	All	2304.00
R56-26	641	All	2304.00
R56-27	642	All	2304.00

OCS OFFICIAL PROTRACTION DIAGRAM, NI 18-5
(Approved August 1, 1975)

Tract	Block	Description	Hectares
R56-30	751	All	2304.00
R56-33	754	All	2304.00
R56-34	794	All	2304.00
R56-35	795	All	2304.00
R56-36	796	All	2304.00
R56-37	837	All	2304.00
R56-38	838	All	2304.00
R56-39	839	All	2304.00

OCS OFFICIAL PROTRACTION DIAGRAM, CAPE FEAR NI 18-7
(Approved June 11, 1975; Revised January 27, 1976; Revised June 3, 1976)

Tract	Block	Description	Hectares
R56-46	175	All	2304.00
R56-47	176	All	2304.00
R56-48	219	All	2304.00
R56-49	220	All	2304.00

CAPE FEAR NI 18-7 (continued)

Tract	Block	Description	Hectares
R56-50	262	All	2304.00
R56-51	263	All	2304.00
R56-53	306	All	2304.00
R56-54	307	All	2304.00
R56-55	308	All	2304.00
R56-56	350	All	2304.00
R56-57	351	All	2304.00
R56-58	352	All	2304.00
R56-59	393	All	2304.00
R56-60	394	All	2304.00
R56-61	395	All	2304.00
R56-62	396	All	2304.00
R56-63	437	All	2304.00
R56-64	438	All	2304.00
R56-65	439	All	2304.00
R56-66	440	All	2304.00
R56-69	483	All	2304.00
R56-70	484	All	2304.00
R56-71	524	All	2304.00
R56-73	526	All	2304.00
R56-74	527	All	2304.00
R56-75	528	All	2304.00
R56-76	568	All	2304.00
R56-78	570	All	2304.00
R56-79	571	All	2304.00
R56-80	611	All	2304.00
R56-81	612	All	2304.00
R56-82	613	All	2304.00
R56-83	614	All	2304.00
R56-85	654	All	2304.00
R56-86	655	All	2304.00
R56-87	656	All	2304.00
R56-88	657	All	2304.00
R56-89	658	All	2304.00
R56-90	698	All	2304.00
R56-91	699	All	2304.00
R56-92	700	All	2304.00
R56-93	701	All	2304.00
R56-94	702	All	2304.00
R56-95	741	All	2304.00
R56-96	742	All	2304.00
R56-97	743	All	2304.00
R56-98	744	All	2304.00
R56-99	745	All	2304.00
R56-102	785	All	2304.00
R56-103	786	All	2304.00
R56-105	788	All	2304.00
R56-106	789	All	2304.00

CAPE FEAR NI 18-7 (continued)

Tract	Block	Description	Hectares
R56-109	828	All	2304.00
R56-110	829	All	2304.00
R56-111	830	All	2304.00
R56-112	831	All	2304.00
R56-113	832	All	2304.00
R56-114	834	All	2304.00
R56-115	872	All	2304.00
R56-116	873	All	2304.00
R56-117	874	All	2304.00
R56-118	875	All	2304.00
R56-119	876	All	2304.00
R56-120	916	All	2304.00
R56-121	917	All	2304.00
R56-122	918	All	2304.00
R56-123	919	All	2304.00
R56-124	960	All	2304.00
R56-127	963	All	2304.00
R56-128	1004	All	2304.00

OCS OFFICIAL PROTRACTION DIAGRAM, JAMES ISLAND NI 17-12
(Approved June 11, 1975)

Tract	Block	Description	Hectares
R56-131	242	All	2304.00
R56-132	243	All	2304.00
R56-133	244	All	2304.00
R56-134	245	All	2304.00
R56-135	246	All	2304.00
R56-136	247	All	2304.00
R56-137	285	All	2304.00
R56-138	286	All	2304.00
R56-139	287	All	2304.00
R56-140	288	All	2304.00
R56-141	289	All	2304.00
R56-142	290	All	2304.00
R56-143	291	All	2304.00
R56-144	329	All	2304.00
R56-145	330	All	2304.00
R56-146	331	All	2304.00
R56-147	334	All	2304.00
R56-148	335	All	2304.00
R56-149	373	All	2304.00
R56-150	374	All	2304.00
R56-151	800	All	2304.00
R56-152	841	All	2304.00
R56-153	842	All	2304.00
R56-154	843	All	2304.00
R56-155	844	All	2304.00
R56-156	885	All	2304.00

JAMES ISLAND NI 17-12 (continued)

Tract	Block	Description	Hectares
R56-157	886	All	2304.00
R56-158	887	All	2304.00
R56-159	888	All	2304.00
R56-160	929	All	2304.00
R56-161	930	All	2304.00

OCS OFFICIAL PROTRACTION DIAGRAM, STETSON MESA NH 17-6
(Approved June 11, 1975)

Tract	Block	Description	Hectares
R56-162	181	All	2304.00
R56-163	182	All	2304.00
R56-164	224	All	2304.00
R56-165	225	All	2304.00
R56-166	226	All	2304.00
R56-167	268	All	2304.00
R56-168	269	All	2304.00
R56-169	312	All	2304.00
R56-170	313	All	2304.00
R56-171	355	All	2304.00
R56-172	356	All	2304.00
R56-173	357	All	2304.00

OCS OFFICIAL PROTRACTION DIAGRAM, BRUNSWICK NH 17-2
(Approved April 29, 1975; Revised September 1, 1978)

Tract	Block	Description	Hectares
R56-175	256	All	2304.00
R56-176	257	All	2304.00
R56-177	298	All	2304.00
R56-178	299	All	2304.00
R56-179	300	All	2304.00
R56-180	301	All	2304.00
R56-181	341	All	2304.00
R56-185	345	All	2304.00
R56-186	386	All	2304.00
R56-188	388	All	2304.00
R56-189	695	All	2304.00
R56-190	696	All	2304.00
R56-191	697	All	2304.00
R56-192	738	All	2304.00
R56-193	739	All	2304.00

BRUNSWICK NH 17-2 (continued)

Tract	Block	Description	Hectares
R56-194	740	All	2304.00
R56-195	741	All	2304.00
R56-196	781	All	2304.00
R56-197	782	All	2304.00
R56-198	783	All	2304.00
R56-199	825	All	2304.00
R56-200	826	All	2304.00
R56-201	827	All	2304.00
R56-202	910	All	2304.00
R56-203	911	All	2304.00
R56-204	914	All	2304.00
R56-205	916	All	2304.00
R56-206	917	All	2304.00
R56-207	952	All	2304.00
R56-208	953	All	2304.00
R56-209	954	All	2304.00
R56-210	955	All	2304.00
R56-211	960	All	2304.00
R56-212	961	All	2304.00
R56-213	962	All	2304.00
R56-214	993	All	2304.00
R56-215	994	All	2304.00
R56-216	995	All	2304.00
R56-217	996	All	2304.00
R56-218	997	All	2304.00
R56-219	998	All	2304.00
R56-220	999	All	2304.00
R56-221	1000	All	2304.00
R56-222	1002	All	2304.00
R56-223	1006	All	2304.00

OCS OFFICIAL PROTRACTION DIAGRAM, JACKSONVILLE NH 17-5
(Approved April 29, 1975)

Tract	Block	Description	Hectares
R56-224	24	All	2304.00
R56-225	27	All	2304.00
R56-226	28	All	2304.00
R56-227	29	All	2304.00
R56-228	30	All	2304.00
R56-229	31	All	2304.00
R56-230	32	All	2304.00
R56-231	33	All	2304.00

JACKSONVILLE NH 17-5 (continued)

Tract	Block	Description	Hectares
R56-232	37	All	2304.00
R56-233	69	All	2304.00
R56-234	70	All	2304.00
R56-235	71	All	2304.00
R56-236	72	All	2304.00
R56-237	73	All	2304.00
R56-238	74	All	2304.00
R56-239	79	All	2304.00
R56-240	80	All	2304.00
R56-241	113	All	2304.00
R56-242	114	All	2304.00
R56-243	115	All	2304.00
R56-244	116	All	2304.00
R56-245	117	All	2304.00
R56-246	124	All	2304.00
R56-247	158	All	2304.00
R56-248	159	All	2304.00
R56-249	160	All	2304.00
R56-250	161	All	2304.00
R56-251	162	All	2304.00
R56-252	203	All	2304.00
R56-253	204	All	2304.00
R56-254	205	All	2304.00
R56-255	206	All	2304.00
R56-256	207	All	2304.00
R56-257	247	All	2304.00
R56-258	248	All	2304.00
R56-259	249	All	2304.00
R56-260	250	All	2304.00
R56-261	251	All	2304.00
R56-262	253	All	2304.00
R56-263	292	All	2304.00
R56-264	293	All	2304.00
R56-265	294	All	2304.00
R56-266	295	All	2304.00
R56-267	296	All	2304.00
R56-268	340	All	2304.00
R56-269	382	All	2304.00
R56-270	426	All	2304.00
R56-271	431	All	2304.00
R56-272	432	All	2304.00
R56-273	465	All	2304.00
R56-274	470	All	2304.00
R56-275	475	All	2304.00
R56-276	476	All	2304.00
R56-277	509	All	2304.00

JACKSONVILLE NH 17-5 (continued)

Tract	Block	Description	Hectares
R56-278	513	All	2304.00
R56-279	514	All	2304.00
R56-280	515	All	2304.00
R56-281	516	All	2304.00
R56-282	561	All	2304.00
R56-283	601	All	2304.00
R56-284	602	All	2304.00
R56-285	645	All	2304.00
R56-286	646	All	2304.00

OCS OFFICIAL PROTRACTION DIAGRAM, ILIAMNA NO 5-1
(Approved March 20, 1975)

Tract	Block	Description	Hectares
R60-1	484	All	2304.00
R60-2	527	All	2304.00
R60-3	615	All	2304.00
R60-4	659	All	2304.00
R60-5	703	All	2304.00
R60-6	748	All	2304.00
R60-7	836	All	2304.00
R60-8	880	All	2304.00
R60-9	923	All	2304.00
R60-10	924	All	2304.00
R60-11	968	All	2304.00
R60-12	1011	All	2304.00
R60-13	1012	All	2304.00
R60-14	1055	All	2304.00
R60-15	1056	All	2304.00

OCS OFFICIAL PROTRACTION DIAGRAM, SELDOVIA NO 5-2
(Approved March 20, 1975)

Tract	Block	Description	Hectares
R60-16	93	1/	588.65
R60-17	94	All	2304.00
R60-19	138	All	2304.00
R60-21	182	All	2304.00
R60-22	186	All	2304.00
R60-23	224	All	2304.00
R60-26	228	All	2304.00
R60-27	229	All	2304.00
R60-28	230	All	2304.00

1/ Seaward of the three geographical mile line.

SELDOVIA NO 5-2 (continued)

Tract	Block	Description	Hectares
R60-29	268	All	2304.00
R60-30	269	All	2304.00
R60-31	270	All	2304.00
R60-32	271	All	2304.00
R60-33	272	All	2304.00
R60-34	273	All	2304.00
R60-35	312	All	2304.00
R60-36	313	All	2304.00
R60-37	314	All	2304.00
R60-38	315	All	2304.00
R60-39	316	All	2304.00
R60-40	317	All	2304.00
R60-41	359	All	2304.00
R60-42	360	All	2304.00
R60-43	361	All	2304.00
R60-44	404	All	2304.00
R60-45	405	All	2304.00
R60-46	487	All	2304.00
R60-47	533	All	2304.00
R60-48	580	All	2304.00
R60-49	621	All	2304.00
R60-50	625	All	2304.00
R60-51	661	All	2304.00
R60-52	662	All	2304.00
R60-53	663	All	2304.00
R60-54	664	All	2304.00
R60-55	665	All	2304.00
R60-56	666	All	2304.00
R60-57	669	All	2304.00
R60-58	705	All	2304.00
R60-59	706	All	2304.00
R60-60	707	All	2304.00
R60-61	713	All	2304.00
R60-62	751	All	2304.00
R60-63	756	All	2304.00
R60-64	757	All	2304.00
R60-65	793	All	2304.00
R60-66	795	All	2304.00
R60-67	800	All	2304.00
R60-68	837	All	2304.00
R60-69	838	All	2304.00
R60-70	881	All	2304.00
R60-71	882	All	2304.00
R60-72	925	All	2304.00

OCS OFFICIAL PROTRACTION DIAGRAM, MT. KATMAI NO 5-3
(Approved July 3, 1975)

Tract	Block	Description	Hectares
R60-73	43	All	2304.00
R60-74	44	All	2304.00
R60-75	88	All	2304.00
R60-76	131	E1/2E1/2	576.00
R60-77	132	All	2304.00
R60-78	176	All	2304.00
R60-79	219	NE1/4,SE1/4NW1/4, E1/2NE1/4NW1/4, S1/2 1/	1752.09
R60-80	220	All	2304.00
R60-81	263	1/	2176.96
R60-82	264	All	2304.00
R60-83	306	1/	2163.71
R60-84	307	All	2304.00
R60-85	308	All	2304.00
R60-86	350	All	2304.00
R60-87	351	All	2304.00
R60-88	352	All	2304.00
R60-89	394	All	2304.00
R60-90	395	All	2304.00
R60-91	396	All	2304.00
R60-92	438	All	2304.00
R60-93	439	All	2304.00
R60-94	479	All	2304.00
R60-95	480	All	2304.00
R60-96	481	All	2304.00
R60-97	482	All	2304.00
R60-98	483	All	2304.00
R60-99	522	All	2304.00
R60-100	523	All	2304.00
R60-101	524	All	2304.00
R60-102	525	All	2304.00
R60-103	526	All	2304.00
R60-104	565	All	2304.00
R60-105	566	All	2304.00
R60-106	567	All	2304.00
R60-107	568	All	2304.00
R60-108	569	All	2304.00
R60-109	570	All	2304.00
R60-110	607	All	2304.00
R60-112	609	All	2304.00
R60-113	610	All	2304.00
R60-115	612	All	2304.00
R60-116	613	All	2304.00
R60-117	651	All	2304.00

1/ Seaward of the three geographical mile line.

MT. KATMAI NO 5-3 (continued)

Tract	Block	Description	Hectares
R60-119	653	All	2304.00
R60-121	655	All	2304.00
R60-122	656	All	2304.00
R60-123	695	All	2304.00
R60-125	697	All	2304.00
R60-127	699	All	2304.00
R60-128	737	E1/2,E1/2W1/2	1728.00
R60-129	738	All	2304.00
R60-130	739	All	2304.00
R60-131	740	All	2304.00
R60-133	742	All	2304.00
R60-134	781	All	2404.00
R60-135	782	All	2304.00
R60-136	783	All	2304.00
R60-137	784	All	2304.00
R60-138	785	All	2304.00
R60-141	827	All	2304.00

OCS OFFICIAL PROTRACTION DIAGRAM, AFOGNAK NO 5-4
(Approved July 3, 1975)

Tract	Block	Description	Hectares
R60-142	48	All	2304.00
R60-143	90	All	2304.00
R60-144	91	All	2304.00
R60-145	92	All	2304.00
R60-146	133	All	2304.00
R60-147	134	All	2304.00
R60-148	135	All	2304.00
R60-149	177	All	2304.00
R60-150	178	All	2304.00
R60-151	221	All	2304.00
R60-152	265	All	2304.00
R60-153	309	All	2304.00

OCS OFFICIAL PROTRACTION DIAGRAM, HUDSON CANYON NJ 18-3
(Approved October 31, 1974)

Tract	Block	Description	Hectares
R59-1	686	All	2304.00
R59-2	689	All	2304.00
R59-3	691	All	2304.00
R59-5	694	All	2304.00
R59-6	733	All	2304.00
R59-7	734	All	2304.00
R59-8	735	All	2304.00
R59-9	736	All	2304.00
R59-11	775	All	2304.00
R59-12	776	All	2304.00
R59-13	777	All	2304.00
R59-16	780	All	2304.00
R59-17	781	All	2304.00
R59-18	818	All	2304.00
R59-19	819	All	2304.00
R59-20	820	All	2304.00
R59-24	824	All	2304.00
R59-25	856	All	2304.00
R59-26	862	All	2304.00
R59-27	863	All	2304.00
R59-28	864	All	2304.00
R59-31	867	All	2304.00
R59-32	904	All	2304.00
R59-33	905	All	2304.00
R59-34	906	All	2304.00
R59-35	907	All	2304.00
R59-38	910	All	2304.00
R59-39	911	All	2304.00
R59-40	948	All	2304.00
R59-41	949	All	2304.00
R59-42	950	All	2304.00
R59-45	953	All	2304.00
R59-46	954	All	2304.00
R59-47	990	All	2304.00
R59-48	991	All	2304.00
R59-49	992	All	2304.00
R59-50	993	All	2304.00
R59-53	996	All	2304.00
R59-54	997	All	2304.00

OCS OFFICIAL PROTRACTION DIAGRAM, WILMINGTON CANYON NJ 18-6
(Approved October 31, 1974)

Tract	Block	Description	Hectares
R59-55	22	All	2304.00
R59-56	23	All	2304.00
R59-60	27	All	2304.00
R59-61	28	All	2304.00
R59-62	63	All	2304.00
R59-63	65	All	2304.00
R59-64	66	All	2304.00
R59-65	67	All	2304.00
R59-69	71	All	2304.00
R59-70	108	All	2304.00
R59-71	109	All	2304.00
R59-76	114	All	2304.00
R59-77	152	All	2304.00
R59-82	157	All	2304.00
R59-83	194	All	2304.00
R59-84	196	All	2304.00
R59-88	200	All	2304.00
R59-89	235	All	2304.00
R59-90	236	All	2304.00
R59-91	237	All	2304.00
R59-92	238	All	2304.00
R59-93	239	All	2304.00
R59-94	240	All	2304.00
R59-97	243	All	2304.00
R59-98	279	All	2304.00
R59-99	280	All	2304.00
R59-100	281	All	2304.00
R59-101	282	All	2304.00
R59-102	283	All	2304.00
R59-105	286	All	2304.00
R59-106	322	All	2304.00
R59-107	323	All	2304.00
R59-108	324	All	2304.00
R59-109	325	All	2304.00
R59-114	330	All	2304.00
R59-115	365	All	2304.00
R59-116	366	All	2304.00
R59-117	367	All	2304.00
R59-118	368	All	2304.00
R59-123	373	All	2304.00
R59-124	408	All	2304.00
R59-125	409	All	2304.00
R59-126	410	All	2304.00

WILMINGTON CANYON NJ 18-6 (continued)

R59-127	411	All	2304.00
R59-128	412	All	2304.00
R59-133	417	All	2304.00
R59-134	452	All	2304.00
R59-135	453	All	2304.00
R59-136	454	All	2304.00
R59-137	455	All	2304.00
R59-142	460	All	2304.00
R59-143	496	All	2304.00
R59-144	497	All	2304.00
R59-145	498	All	2304.00
R59-150	503	All	2304.00
R59-151	540	All	2304.00
R59-157	546	All	2304.00
R59-158	584	All	2304.00
R59-163	589	All	2304.00
R59-164	627	All	2304.00
R59-169	632	All	2304.00
R59-170	669	All	2304.00
R59-171	670	All	2304.00
R59-176	712	All	2304.00
R59-177	713	All	2304.00
R59-178	714	All	2304.00
R59-182	755	All	2304.00
R59-183	756	All	2304.00
R59-184	757	All	2304.00
R59-188	761	All	2304.00
R59-189	798	All	2304.00
R59-190	799	All	2304.00
R59-191	800	All	2304.00
R59-195	804	All	2304.00
R59-196	841	All	2304.00
R59-197	842	All	2304.00
R59-198	843	All	2304.00
R59-202	883	All	2304.00
R59-203	884	All	2304.00
R59-204	885	All	2304.00
R59-205	886	All	2304.00
R59-206	887	All	2304.00
R59-209	927	All	2304.00
R59-210	928	All	2304.00
R59-211	929	All	2304.00
R59-212	930	All	2304.00
R59-215	933	All	2304.00
R59-216	971	All	2304.00
R59-217	972	All	2304.00
R59-218	973	All	2304.00
R59-219	974	All	2304.00
R59-220	975	All	2304.00
R59-221	976	All	2304.00

OCS OFFICIAL PROTRACTION DIAGRAM, CHINCOTEAGUE NJ 18-8
(Approved December 2, 1976)

Tract	Block	Description	Hectares
R59-222	41	All	2304.00
R59-223	129	All	2304.00
R59-224	216	All	2304.00
R59-225	217	All	2304.00
R59-226	260	All	2304.00
R59-227	261	All	2304.00
R59-228	304	All	2304.00
R59-229	305	All	2304.00
R59-230	347	All	2304.00
R59-231	348	All	2304.00

OCS OFFICIAL PROTRACTION DIAGRAM, BALTIMORE RISE NJ 18-9
(Approved December 6, 1976)

Tract	Block	Description	Hectares
R59-232	2	All	2304.00
R59-233	3	All	2304.00
R59-237	45	All	2304.00
R59-238	46	All	2304.00
R59-239	47	All	2304.00
R59-242	50	All	2304.00
R59-243	89	All	2304.00
R59-244	90	All	2304.00
R59-248	133	All	2304.00
R59-249	134	All	2304.00
R59-250	135	All	2304.00
R59-252	177	All	2304.00
R59-253	178	All	2304.00

13. Lease Terms and Stipulations.

(a) Leases resulting from this sale for tracts R56-22, R56-26, R56-27, R56-30, R56-33 thru R56-39, R56-46 thru R56-51, R56-53 thru R56-66, R56-69, R56-70, R56-71, R56-73 thru R56-76, R56-78 thru R56-83, R56-85 thru R56-99, R56-102, R56-103, R56-105, R56-106, R56-109 thru R56-124, R56-127, R56-128, R56-162 thru R56-173, R59-3, R59-5, R59-7 thru R59-9, R59-11 thru R59-13, R59-16 thru R59-20, R59-24, R59-26 thru R59-28, R59-31 thru R59-35, R59-38 thru R59-42, R59-45 thru R59-50, R59-53 thru R59-56, R59-60, R59-61, R59-63 thru R59-65, R59-69 thru R59-71, R59-76, R59-77, R59-82 thru R59-84, R59-88, R59-91 thru R59-94, R59-97, R59-100, R59-101, R59-102, R59-105, R59-108, R59-109, R59-114, R59-117, R59-118, R59-123, R59-126, R59-127, R59-128, R59-133, R59-136, R59-137, R59-142 thru R59-145, R59-150, R59-151, R59-157, R59-158, R59-163, R59-164, R59-169 thru R59-171, R59-176 thru R59-178, R59-182 thru R59-184, R59-188 thru R59-191, R59-195 thru R59-198, R59-202 thru R59-206, R59-209 thru R59-212, R59-215 thru R59-221, R59-224 thru R59-233, R59-237, R59-238, R59-239, R59-242 thru R59-244, R59-248 thru R59-250, R59-252 and R59-253 will be for an initial term of 10 years. All other leases issued as a result of this sale will be for an initial term of five years. Leases issued as a result of this sale will be on Form 3300-1 (September 1978), available from the Outer Continental Shelf Regional Offices listed in paragraph 11, above.

(b) For leases resulting from this sale for tracts offered on a cash bonus basis with fixed sliding scale royalty, listed in paragraph 4(c), Form 3300-1 will be amended as follows:

Sec. 6 Royalty on Production. (a) The lessee agrees to pay the lessor royalty of that percent in amount or value of production from the leased area as determined by the sliding scale royalty formula as follows. When the quarterly value of production, adjusted for inflation, is less than or equal to $14.787863 million, a royalty of 16.66667 percent in amount or value of production will be due on the unadjusted value or amount of production. When the adjusted quarterly value of production is equal to or greater than $14.787864 million, but less than or equal to $1197.206141 million, the royalty percent due on the unadjusted value or amount of production is given by:

$$Rj = b[\ln (Vj/S)]$$

where

Rj = the percent royalty that is due and payable on the unadjusted amount or value of all production saved, removed or sold in quarter j

b = 11.0

ln = natural logarithm

Vj = the value of production in quarter j, adjusted for inflation, in millions of dollars

S = 3.25

When the adjusted quarterly value of production is equal to or greater than $1197.206142 million, a royalty of 65.00000 percent in amount or value of production will be due on the unadjusted quarterly value of production. Thus, in no instance will the quarterly royalty due exceed 65.00000 percent in amount or value of quarterly production.

In determining the quarterly percent royalty due, Rj, the calculation will be carried to five decimal places (for example, 17.10773 percent). This calculation will incorporate the adjusted quarterly value of production, Vj, in millions of dollars, rounded to the sixth digit i.e., to the nearest dollar (for example, 15.392847 millions of dollars). Gas of all kinds (except helium) is subject to royalty. The lessor shall determine whether production royalty shall be paid in amount or value.

(c) For leases resulting from this sale for tracts offered on a cash bonus basis with a fixed net profit share, listed in paragraph 4(d), Form 3300-1 will be amended as follows:

Sec. 4 Rentals. The phrase "which commences prior to a discovery in paying quantities of oil or gas on the leased area" is hereby deleted and replaced by "which commences prior to the date the first net profit share payment becomes due."

Sec. 5. Minimum Royalty. Hereby deleted.

Sec. 6. Royalty on Production. Hereby replaced by Fixed Net Profit Share. The lessee agrees to pay a net profit share rate of __ percent with a ___ capital recovery factor, calculated pursuant to 10 CFR 390.

(d) Except as otherwise noted, the following stipulations will be included in each lease resulting from this sale. It is intended that each tract will be offered with the same stipulations and conditions as previously offered in Sale Nos. 53, 56, 60 and 59. In the following stipulations the term DMMOFO refers to the Regional Deputy Minerals Manager, Offshore Field Operations, Minerals Management Service, formerly Deputy Conservation Manager, Field Operations, U.S. Geological Survey and the term Manager refers to the Minerals Manager of the Outer Continental Shelf (OCS) Region, formerly Manager of the Outer Continental Shelf Office.

Stipulation No. 1

If the DMMOFO has reason to believe that a site, structure, or object of historical or archaeological significance, hereinafter referred to as a "cultural resource," may exist in the lease area and gives the lessee written notice that the lessor is invoking the provisions of this stipulation, the lessee shall upon receipt of such notice comply with the following requirements:

Prior to any drilling activity or the construction or placement of any structure for exploration or development on the lease, including but not limited to, well drilling and pipeline and platform placement, hereinafter in this stipulation referred to as "operation," the lessee shall conduct remote sensing surveys to determine the potential existence of any cultural resource that may be affected by such operations. All data produced by such remote sensing surveys as well as other pertinent natural and cultural environmental data shall be examined by a qualified marine survey archaeologist to determine if indicators are present suggesting the existence of a cultural resource that may be adversely affected by any lease operation. A report of this survey and assessment prepared by the marine survey archaeologist shall be submitted by the lessee to the DMMOFO and the Manager for review.

If such cultural resource indicators are present the lessee shall: (1) locate the site of such operation so as not to adversely affect the identified location; or (2) establish, to the satisfaction of the DMMOFO, on the basis of further archaeological investigation conducted by a qualified marine survey archaeologist or underwater archaeologist using such survey equipment and techniques as deemed necessary by the DMMOFO, either that such operation shall not adversely affect the location identified or that the potential cultural resource suggested by the occurrence of the indicators does not exist.

A report of this investigation prepared by the marine survey archaeologist or underwater archaeologist shall be submitted to the DMMOFO and the Manager for their review. Should the DMMOFO determine that the existence of a cultural resource which may be adversely affected by such operation is sufficiently established to warrant protection, the lessee shall take no action that may result in an adverse effect on such cultural resource until the DMMOFO has given directions as to its preservation.

The lessee agrees that if any site, structure, or object of historical or archaeological significance should be discovered during the conduct of any operations on the leased area, he shall report immediately such findings to the DMMOFO and make every reasonable effort to preserve and protect the cultural resource from damage until the DMMOFO has given directions as to its preservation.

Stipulation No. 2

To be included only in leases resulting from this sale for all tracts with the prefix R53-.

(a) If the DMMOFO has reason to believe that biological populations or habitats exist and require protection, he shall give the lessee notice that the lessor is invoking the provisions of this stipulation and the lessee shall comply with the following requirements. Prior to any drilling activity or the construction or placement of any structure for exploration or development on lease areas including, but not limited to, well drilling and pipeline and platform placement hereinafter referred to as "operation," the lessee shall conduct site specific surveys as approved by the DMMOFO and in accordance with prescribed biological survey requirements to determine the existence of any special biological resource including, but not limited to:

(1) Very unusual, rare, or uncommon ecosystems or ecotones.

(2) A species of limited regional distribution that may be adversely affected by any lease operations.

If the results of such surveys suggest the existence of a special biological resource that may be adversely affected by any lease operation, the lessee shall: (1) relocate the site of such operation so as not to adversely affect the resources identified; or (2) establish to the satisfaction of the DMMOFO, on the basis of the site specific survey, either that such operation will not have a significant adverse effect upon the resource identified or that a special biological resource does not exist. The DMMOFO will review all data submitted and determine, in writing, whether a special biological resource exists and whether it may be significantly affected by the lessee's operations. The lessee may take no action until the DMMOFO has given the lessee written directions on how to proceed.

(b) The lessee agrees that if any area of biological significance should be discovered during the conduct of any operations on the leased area, he shall report immediately such findings to the DMMOFO, and make every reasonable effort to preserve and protect the biololgical resource from damage until the DMMOFO has given the lessee directions with respect to its protection.

Stipulation No. 3

(a) To be included in any lease resulting from this sale for tracts: R53-156, R53-157, R53-162, and R53-164.

Exploratory drilling operations, emplacement of structures (platforms) or seafloor wellheads for production or storage of oil or gas, and the emplacement of pipelines will not be allowed within the potentially unstable portion of this lease block unless or until the lessee has demonstrated to the DMMOFO's satisfaction that mass movement of sediments is unlikely or that exploratory drilling operations, structures (platforms), casing, wellheads and pipelines can be safely designed to protect the environment in case such mass movement occurs at the proposed location. This may necessitate that all exploration for and development of oil or gas be performed from locations outside of the area of unstable sediments, either within or outside of this lease block.

If exploratory drilling operations are allowed, site-specific surveys shall be conducted to determine the potential for unstable bottom conditions. If emplacement of structures (platforms) or seafloor wellheads for production or storage of oil or gas is allowed, all such unstable areas must be mapped. The DMMOFO may also require soil testing before exploration and production operations are allowed.

(b) To be included in any lease resulting from this sale for tracts: R53-226, R53-227, R53-231, and R53-233.

Exploratory drilling operations, emplacement of structures (platforms) or seafloor wellheads for production or storage of oil or gas, and the emplacement of pipelines will not be allowed within the potentially unstable portions of this lease block unless or until the lessee has demonstrated to the DMMOFO's satisfaction that exploratory drilling operations, structures (platforms), casing, wellheads and pipelines can be safely designed to protect the environment at the proposed location. This may necessitate that all exploration for and development of oil or gas be performed from locations outside of the area of submarine canyons or channels, either within or outside of this lease block.

If exploratory drilling operations are allowed, site-specific surveys shall be conducted to determine the potential for unstable bottom conditions. If emplacement of structures (platforms) or seafloor wellheads for production or storage of oil or gas is allowed, all such unstable areas must be mapped. The DMMOFO may also require soil testing before exploration and production operations are allowed.

Stipulation No. 4

To be included only in leases resulting from this sale for: all tracts with the prefix R53-; all tracts with the prefix R56- except R56-26 and R56-27; tracts R59-5, R59-17, R59-32, R59-33, R59-40, R59-41, R59-42, R59-47 thru R59-50, R59-55, R59-56, R59-60 thru R59-65, R59-69 thru R59-71, R59-76, R59-77, R59-82 thru R59-84, R59-88 thru R59-94, R59-97 thru R59-102, R59-105 thru R59-109, R59-114 thru R59-118, R59-23 thru R59-128, R59-133 thru R59-137, R59-142 thru R59-145, R59-150, R59-151, R59-157, R59-158, R59-163, R59-164, R59-169, R59-202, R59-209, R59-210, R59-216, R59-217, R59-218, R59-222 thru R59-233, R59-237 thru R59-239, R59-242 thru R59-244, R59-248 thru R59-250, R59-252, and R59-253.

In this stipulation, the relevant military facilities are as follows for the tracts specified. All tracts with the prefix R53-: the Western Space and Missile Center (WSMC), Vandenberg AFB, Lompoc, California; The Pacific Missile Test Center (PMTC), Pt. Mugu, California; and the Fleet Area Control and Surveillance Facility (FACSFAC), San Diego, California. Tracts R56-22, R56-30, R56-33 thru R56-39, R56-46 thru R56-51, R56-53 thru R56-66, R56-69 thru R56-71, R56-73 thru R56-76, R56-78 thru R56-83, R56-85 thru R56-99, R56-102, R56-103, R56-105, R56-106, R56-109 thru R56-124, R56-127, R56-128, R59-5, R59-17, R59-32, R59-33, R59-40, R59-41, R59-42, R59-47 thru R59-50, R59-55, R59-56, R59-60 thru R59-65, R59-69 thru R59-71, R59-76, R59-77, R59-82 thru R59-84, R59-88 thru R59-94, R59-97 thru R59-102, R59-105 thru R59-128, R59-133 thru R59-137, R59-142 thru R59-145, R59-150, R59-151, R59-157, R59-158, R59-163, R59-164, R59-169, R59-202, R59-209, R59-210, R59-216, R59-217, R59-218, R59-222 thru R59-244, R59-248 thru R59-250, R59-252 and R59-253: Fleet Area Control and Surveillance Facility, Virginia Capes OPAREA, Naval Air Station Oceana, Virginia Beach, Virginia. Tracts R56-131 thru R56-161: Charleston Operating Area Coordinator, Charleston, South Carolina. Tracts R56-162 thru R56-173, R56-175 thru R56-181, R56-185, R56-186, R56-188 thru R56-286: Fleet Area Control and Surveillance Facility, Jacksonville, Florida.

Whether or not compensation for such damage or injury might be due under a theory of strict or absolute liability or otherwise, the lessee assumes all risks of damage or injury to persons or property, which occur in, on, or above the Outer Continental Shelf, to any person or persons or to any property of any person or persons who are agents, employees or invitees of the lessee, its agents, independent contractors or subcontractors doing business with the lessee in connection with any activities being performed by the lessee in, on, or above the Outer Continental Shelf, if such injury or damage to such person or property occurs by reason of the activities of any agency of the U.S. Government, its contractors, or subcontractors, or any of their officers, agents or employees, being conducted as a part of, or in connection with, the programs and activities of the relevant military facility.

Notwithstanding any limitations of the lessee's liability in section 14 of the lease, the lessee assumes the risk whether such injury or damage is caused

in whole or in part by any act or omission, regardless of negligence or fault, of the United States, its contractors or subcontractors, or any of their officers, agents, or employees. The lessee further agrees to indemnify and save harmless the United States against all claims for loss, damage, or injury sustained by the lessee, and to indemnify and save harmless the United States against all claims for loss, damage, or injury sustained by the agents, employees, or invitees of the lessee, its agents or any independent contractors or subcontractors doing business with the lessee in connection with the programs and activities of the aforementioned military installations and agencies, whether the same be caused in whole or in part by the negligence or fault of the United States, its contractors, or subcontractors, or any of their officers, agents, or employees and whether such claims might be sustained under theories of strict or absolute liability or otherwise.

The lessee agrees to control his own electromagnetic emissions and those of his agents, employees, invitees, independent contractors or subcontractors emanating from individual, designated defense warning areas in accordance with requirements specified by the Commander of the relevant military facility to the degree necessary to prevent damage to, or unacceptable interference with Department of Defense flight, testing or operations activities conducted within individual, designated warning areas. Necessary monitoring, control, and coordination with the lessee, his agents, employees, invitees, independent contractors or subcontractors, will be effected by the Commander of the appropriate onshore military installation conducting operations in the particular warning area: provided, however, that control of such electromagnetic emissions shall permit at least one continuous channel of communication between a lessee, its agents, employees, invitees, independent contractors or subcontractors and onshore facilities.

The lessee agrees that prior to operating or causing to be operated on its behalf boat or aircraft traffic into individual, designated warning areas, the lessee shall coordinate and comply with the instructions from the Commander of the relevant military facility, or other appropriate military agency. Such coordination and instruction will provide for positive control of boats and aircraft operating in the warning areas at all times.

Stipulation No. 5

To be included only in leases resulting from this sale for tracts with the prefix R53-.

The lessee, recognizing that mineral exploration and exploitation and recovery operations of the leased areas of submerged lands can impede tactical military operations, hereby recognizes and agrees that the United States reserves and has the right to temporarily suspend operations of the lessee under this lease in the interests of national security requirements. Such temporary suspension of operations, including the evacuation of personnel, and appropriate sheltering of personnel not evacuated (an appropriate shelter shall mean the protection of all lessee personnel for the entire duration of any Department of Defense activity from flying or falling objects or substances), will come into effect upon the order of the DMMOFO, after consultation with the Commander, Western Space and Missile Center (WSMC), Vandenberg AFB, Lompoc, California, the Commander, Pacific Missile Test Center (PMTC), Pt. Mugu, California, and the Commander, Fleet Area Control and Surveillance Facility (FACSFAC), San Diego, California, or other appropriate military agency, or higher authority, when national security interests necessitate such action. It is understood that any temporary suspension of operations for national security may not exceed 72 hours; however, any such suspension may be extended by order of the DMMOFO. During such periods equipment may remain in place.

Stipulation No. 6

To be included only in leases resulting from this sale for all tracts with the prefix R53-.

(a) Pipelines will be required: 1) if pipeline rights-of-way can be determined and obtained; 2) if laying of such pipelines is technologically feasible and environmentally preferable; and 3) if, in the opinion of the lessor, pipelines can be laid without net social loss, taking into account any incremental costs of pipelines over alternative methods of transportation and any incremental benefits in the form of increased environmental protection or reduced multiple use conflicts. The lessor specifically reserves the right to require that any pipeline used for transporting production to shore be placed in certain designated management areas. In selecting the means of transportation, consideration will be given to any recommendation of the intergovernmental planning program for assessment and management of transportation of Outer Continental Shelf oil and gas with the participation of Federal, State and local governments and the industry.

(b) Following the development of sufficient pipeline capacity, no crude oil production will be transported by surface vessel from offshore production sites, except in the case of emergency. Determinations as to emergency conditions and appropriate responses to these conditions will be made by the DMMOFO.

(c) Where the three criteria set forth in the first sentence of this stipulation are not met and surface transportation must be employed, all vessels used for carrying hydrocarbons to shore from the leased area will conform with all standards established for such vessels, pursuant to the Ports and Waterways Safety Act of 1978 (33 U.S.C. 1221 et seq.).

Stipulation No. 7

To be included only in leases resulting from this sale for all tracts with the prefix R53-.

(a) Wells. Subsea well heads and temporary abandonments, or suspended operations that leave protrusions above the sea floor, shall be protected, if feasible and as appropriate, in such a manner as to allow commercial fisheries trawling gear to pass over the structure without snagging or otherwise damaging the structures or the fishing gear. Latitude and longitude coordinates of these structures, along with water depths, shall be submitted to the DMMOFO. The coordinates of such structures will be determined by the lessee utilizing state-of-the-art navigation systems with accuracy of at least ±50 feet (15.25 meters) at 200 miles (322 kilometers).

(b) Pipelines. All pipelines, unless buried, including gathering lines, shall have a smooth surface design. In the event that an irregular pipe

surface is unavoidable due to the need for valves, anodes or other structures, it shall, as appropriate, be protected in such a manner as to allow trawling gear to pass over the object without snagging or otherwise damaging the structure or the fishing gear.

Stipulation No. 8

To be included only in the leases resulting from this sale for all tracts with the prefix R53-.

The lessee shall include in his exploration and development plans, submitted under 30 CFR 250.34, a proposed fisheries training program for review and approval by the DMMOFO. The training program shall be for the personnel involved in vessel operations (related to offshore exploration and development and production operations), and platform and shorebased supervisors. The purpose of the training program shall be to familiarize persons working on the project of the value of the commercial fishing industry, the methods of offshore fishing operations, the potential conflicts between fishing operations and offshore oil and gas activities, the locations of marine mammal and bird rookery sites in the area, the seasonal abundance and sensitivities of these animals to disturbance, and the Federal laws that have been established to protect endangered and threatened species from harassment and injury. The program shall be formulated and implemented by qualified instructors.

Stipulation No. 9

To be included only in the leases resulting from this sale for the fixed sliding scale royalty tracts identified in paragraph 4(c) of this notice.

(a) The royalty rate on production from this lease is subject to consideration for reduction under the same authority that applies to all other oil and gas leases on the Outer Continental Shelf (30 CFR 250.21). The Director, Minerals Management Service may grant a reduction for only one year at a time and reduction of royalty rates will not be approved unless production has been under way for one year or more.

(b) Although the royalty rate specified in section 6(a) of this lease or as subsequently modified in accordance with applicable regulations and stipulations is applicable to all production under this lease, not more than 16-2/3 percent of the production from the lease area may be taken as royalty in amount, except as provided in sec. 15(d); the royalty on any portion of the production from the lease in excess of 16-2/3 percent may only be taken in value of the production from the lease area.

Stipulation No. 10

This stipulation shall be effective for each tract to which it applies only if the Secretary of the Interior and the Governor of the State of California, prior to the approval of a development and production plan for that tract by the Department of the Interior, enter into an agreement pursuant to section 8(g) of the Outer Continental Shelf Lands Act, as amended, 43 U.S.C. section 1337(g). If such agreement has been entered into, this stipulation is to be applied to leases resulting from this sale for tract R53-233.

(1) No producing well may be drilled where the well bore in the producing intervals is closer to the seaward boundary of the State of California than the distance agreed to between the State and the Department based on analysis of pertinent site-specific data, except that in no event shall the agreed distance be further than 750 feet from the seaward boundary of the State. In the absence of an agreed distance, no well shall be drilled closer than 500 feet to the seaward boundary of the State.

(2) The constraint in paragraph (1) shall not apply:

(a) If oil or gas pools or fields underlying both the Outer Continental Shelf and lands subject to the jurisdiction of California are included in a production unit entered into by the relevant lessees and approved by the lessors, or in a production unit entered into by the Federal lessee and the State of California when it is a carried, non-operating owner.

(b) If, in the absence of a production unit as described in (a) above, the State of California permits production from State lands from a point closer than 750 feet from the Federal-State boundary. In the event that such production from State lands does occur, the Federal lessee shall be allowed to produce from offset wells equally close to the boundary in the area of Federal jurisdiction.

Stipulation No. 11

To be included only in leases resulting from this sale for all tracts with the prefix R56-.

Prior to any drilling activity or the construction or placement of any structure for exploration or development on a lease, including but not limited to well drilling and pipeline and platform placement, the lessee will submit to the DMMOFO as part of his exploration and/or development plan a bathymetry map, prepared utilizing remote sensing and/or other survey techniques. This map will include interpretations for the presence of live bottom areas within a minimum of 1,820 m radius of the proposed exploration or production activity site.

For the purpose of this stipulation, live bottom areas are defined as those areas which contain biological assemblages consisting of such sessile invertebrates as sea fans, sea whips, hydroids, anemones, ascidians, sponges, bryozoans, or corals living upon and attached to naturally occurring hard or rocky formations with rough, broken, or smooth topography; or whose lithotope favors the accumulation of turtles, fishes, and other fauna.

If it is determined that the remote sensing data indicate the presence of hard or live bottom areas, the lessee will also submit to the DMMOFO photo-documentation of the sea bottom near proposed exploratory drilling sites or proposed platform locations.

If it is determined that live bottom areas might be adversely impacted by the proposed activities, then the DMMOFO will require the lessee to undertake any measure deemed economically, environmentally, and technically feasible to

protect live bottom areas. These measures may include, but are not limited to, the following:

(a) The relocation of operations to avoid live bottom areas;
(b) The shunting of all drilling fluids and cuttings in such a manner as to avoid live bottom areas;
(c) The transportation of drilling fluids and cuttings to approved disposal sites; and
(d) The monitoring of live bottom areas to assess the adequacy of any mitigation measures taken and the impact of lessee initiated activities.

Stipulation No. 12

To be included only in leases resulting from this sale for tracts R56-27, R56-117 through R56-119, R56-122 and R56-123.

Portions of this lease may be subject to mass movement of sediments related to unstable slopes with associated shallow faulting. Exploratory drilling operations, emplacement of structures (platforms) or seafloor wellheads for production or storage of oil or gas, and the emplacement of pipelines will not be allowed within the potentially unstable portions of this lease block unless or until the lessee has demonstrated to the DMMOFO's satisfaction that mass movement of sediments is unlikely or that exploratory drilling operations, structures (platforms), casing, wellheads, and pipelines can be safely designed to protect the environment in case such mass movement occurs at the proposed location. This may necessitate that all exploration for and development of oil or gas be performed from locations outside of the area of unstable sediments, either within or outside of this lease block.

If exploratory drilling operations are allowed, site-specific surveys shall be conducted to determine the potential for unstable bottom conditions. If emplacement of structures (platforms) or seafloor wellheads for production or storage of oil or gas is allowed, all such unstable areas must be mapped. The DMMOFO may also require soil testing before exploration and production operations are allowed.

Stipulation No. 13

To be included in any lease resulting from this sale for tracts R56-167, R56-169, R56-171, and R56-172.

The lessee shall conduct remote sensing and/or other surveys as specified by the DMMOFO to determine the existence of any unexploded ordnance. The lessee's report to the DMMOFO should document all indications of magnetic or side scan sonar anomalies on the sea floor.

Stipulation No. 14

To be included in leases resulting from this sale for all tracts with the prefix R56-.

Pipelines will be required: (1) if pipeline rights-of-way can be determined and obtained; (2) if laying such pipelines is technically feasible and environmentally preferable; and (3) if, in the opinion of the lessor, pipelines can be laid without net social loss, taking into account any incremental costs of pipelines over alternative methods of transportation and any incremental benefits in the form of increased environmental protection or reduced multiple use conflicts. The lessor specifically reserves the right to require that any pipeline used for transporting production to shore be placed in certain designated management areas. In selecting the means of transportation, consideration will be given to any recommendation of the intergovernmental planning program for assessment and management of transportation of Outer Continental Shelf oil and gas with the participation of Federal, State, and local governments and the industry. Where feasible, all pipelines, including both flow lines and gathering lines for oil and gas, shall be buried to a depth suitable for adequate protection from water currents, sand waves, storm scouring, fisheries trawling gear, and other uses as determined on a case-by-case basis.

Following the development of sufficient pipeline capacity, no crude oil production will be transported by surface vessel from offshore production sites, except in the case of emergency. Determinations as to emergency conditions and appropriate responses to these conditions will be made by the DMMOFO. Where the three criteria set forth in the first sentence of this stipulation are not met and surface transportation must be employed, all vessels used for carrying hydrocarbons to shore from the leased area will conform with all standards established for such vessels, pursuant to the Ports and Waterways Safety Act of 1978 (33 U.S.C. 1221 et seq.).

Stipulation No. 15

To be included only in leases resulting from this sale for tracts with the prefix R60-.

If the DMMOFO has reason to believe that biological populations or habitats exist and require protection, he shall give the lessee notice that the lessor is invoking the provisions of this stipulation and the lessee shall comply with the following requirements:

Prior to the commencement of any drilling activity, or construction or placement of any structure for exploration or development activity, the lessee shall conduct site-specific environmental surveys or studies, including sampling as approved by the DMMOFO, to characterize existing environmental conditions in an identified zone prior to oil and gas operations, and to determine the extent and composition of biological populations or habitats, and the effects of proposed operations on the populations or habitats which might require additional protective measures. The nature and extent of any such surveys or studies will be determined by the DMMOFO on a case-by-case basis.

Based on any surveys or studies which the DMMOFO may require of the lessee, the DMMOFO may require the lessee to: (1) relocate the site of operations so as not to affect adversely the significant biological populations or habitats deserving protection; (2) modify operations in such a way as not to affect adversely the significant biological populations or habitats deserving protection; or (3) establish to the satisfaction of the DMMOFO that such operations will not adversely affect the significant biological populations or habitats deserving protection. Based on any surveys or studies which the

DMMOFO may also require of the lessee, the DMMOFO may require the lessee to provide for periodic sampling of environmental conditions during operations.

The lessee shall submit all data obtained in the course of such surveys or studies to the DMMOFO, with the locational information for drilling or other activity. The lessee may take no action that might result in any effect on the biological populations or habitats surveyed, until the DMMOFO provides written directions to the lessee with regard to permissible actions.

In the event that important biological populations or habitats are identified subsequent to commencement of operations, the lessee shall make every reasonable effort to preserve and protect all biological populations and habitats within the lease area, until the DMMOFO provides written instructions to the lessee with regard to the biological populations or habitats identified.

Stipulation No. 16

To be included only in leases resulting from this sale for all tracts with the prefix R60-.

The lessee shall include in any exploration and development plans, submitted under 30 CFR 250.34, a proposed environmental training program for all personnel involved in exploration or development activities (including personnel of the lessee's contractors and subcontractors) for review and approval by the DMMOFO. The program shall be designed to inform each person working on the project of specific types of environmental, social, and cultural concerns which relate to the individual's job. The program shall be formulated by qualified instructors experienced in each pertinent field of study, and shall employ effective methods to insure that personnel are informed of archaeological, geological, and biological resources, including bird colonies and sea mammal concentration areas, to insure the importance of avoidance and non-harassment of wildlife resources is understood.

The program shall be designed to increase the sensitivity and understanding of personnel to the community values, customs, and lifestyles in areas in which such personnel will be operating and shall include information concerning avoidance of conflicts with commercial fishing operations and with commercial fishing gear.

The lessee shall also submit for review and approval a continuing technical environmental briefing program for supervisory and managerial personnel of the lessee and its agents, contractors, and subcontractors.

Stipulation No. 17

To be included only in leases resulting from this sale for tracts with the prefix R60-.

Pipelines will be required: (a) if pipeline rights-of-way can be determined and obtained; (b) if laying such pipelines is technologically feasible and environmentally preferable; and (c) if, in the opinion of the lessor, pipelines can be laid without net social loss, taking into account any incremental costs of pipelines over alternative methods of transportation and any incremental benefits in the form of increased environmental protection or reduced multiple use conflicts. The lessor specifically reserves the right to require that any pipeline used for transporting production to shore be placed in certain designated management areas. In selecting the means of transportation, consideration will be given to any recommendation of the intergovernmental planning program for assessment and management of transportation of Outer Continental Shelf oil and gas with participation of Federal, State, and local governments and industry.

All pipelines, including both flow lines and gathering lines for oil and gas, shall be designed and constructed to provide for adequate protection from water currents, storms, geohazards, fisheries trawling gear, and other hazards as determined on a case-by-case basis.

Following the development of sufficient pipeline capacity, no crude oil production will be transported by surface vessel from offshore production sites, except in the case of emergency. Determinations as to emergency conditions and appropriate responses to these conditions will be made by the DMMOFO.

Where the three criteria set forth in the first sentence of this stipulation are not met and surface transportation must be employed, all vessels used for carrying hydrocarbons to shore from the leased area will conform with all standards established for such vessels, pursuant to the Ports and Waterways Safety Act of 1978 (33 U.S.C. 1221 et seq.).

Stipulation No. 18

To be included only in leases resulting from this sale for all tracts with the prefix R60-.

(a) Wells. Subsea wellheads and temporary abandonments, or suspended operations that leave protrusions above the sea floor, shall be protected, if feasible and as appropriate, in such a manner as to allow commercial fisheries trawling gear to pass over the structure without snagging or otherwise damaging the structures or the fishing gear. Latitude and longitude coordinates of these structures, along with water depths, shall be submitted to the DMMOFO. The coordinates of such structures will be determined by the lessee utilizing state-of-the-art navigation systems with accuracy of at least ±50 feet (15.25 meters) at 200 miles (322 kilometers).

(b) Pipelines. All pipelines, unless buried, including gathering lines, shall have a smooth surface design. In the event that an irregular pipe surface is unavoidable due to the need for valves, anodes or other structures, it shall, as appropriate, be protected in such a manner as to allow trawling gear to pass over the object without snagging or otherwise damaging the structure or the fishing gear.

Stipulation No. 19

To be included only in the leases resulting from this sale for all tracts with the prefix R59-.

If biological populations or habitats which may require additional protection are identified by the DMMOFO on any tracts in the leasing area, the DMMOFO will require the lessee to conduct environmental surveys or studies, including sampling, as

approved by the DMMOFO, to determine existing environmental conditions, the extent and composition of biological populations or habitats, and the effects of proposed or existing operations on the populations or habitats which might require additional protective measures. The DMMOFO will give written notification to the lessee of his decision to require such surveys. The nature and extent of any surveys or studies will be determined by the DMMOFO on a case-by-case basis.

Based on any surveys or studies which the DMMOFO may require of the lessee, the DMMOFO may require the lessee to: (1) relocate the site of operations so as not to adversely affect the biological populations or habitats deserving protection; or (2) modify operations in such a way as not to adversely affect the biological populations or habitats deserving protection; or (3) establish to the satisfaction of the DMMOFO that such operations will not adversely affect the biological populations or habitats deserving protection.

Operations, including siting, must be conducted to insure the protection and continued viability of the biological populations or habitats deserving protection in a manner consistent with the other purposes of the Outer Continental Shelf Lands Act, as amended.

The lessee will submit all data obtained in the course of such surveys to the DMMOFO, with the locational information for drilling or other activity. The lessee may take no action that might affect the biological populations or habitats surveyed, until the DMMOFO provides written directions to the lessee, with regard to permissible actions.

In the event that biological populations or habitats deserving protection are identified subsequent to commencement of operations, the lessee shall make every reasonable effort to preserve and protect all biological populations and habitats within the lease area, until the DMMOFO provides written instructions to the lessee with regard to the biological populations or habitats identified.

Stipulation No. 20

To be included only in leases resulting from this sale for tracts with the prefix R59-.

Pipelines will be required, (1) if pipeline rights-of-way can be determined and obtained, (2) if laying such pipelines is technologically feasible and environmentally preferable, and (3) if, in the opinion of the lessor, pipelines can be laid without net social loss, taking into account any incremental costs of pipelines over alternative methods of transportation and any incremental benefits in the form of increased environmental protection or reduced multiple use conflicts. The lessor specifically reserves the right to require that any pipeline used for transporting production to shore be placed in certain designated management areas. In selecting the means of transportation, consideration will be given to any recommendation of the Intergovernmental Planning Program for Outer Continental Shelf Oil and Gas Leasing, Transportation and Related Facilities, with the participation of Federal and State governments, industry, and private interests. Where feasible and environmentally preferable, all pipelines, including both flow lines and gathering lines for oil and gas, shall be buried to a depth suitable for adequate protection from water currents, sand waves, storm scouring, fisheries trawling gear, and other factors as determined on a case-by-case basis.

Following the completion of pipeline installation, no crude oil production will be transported by surface vessel from offshore production sites, except in the case of emergency. Determinations as to emergency conditions and appropriate responses to these conditions will be made by the DMMOFO. Where the three criteria set forth in the first sentence of this stipulation are not met and surface transportation must be employed, all vessels used for carrying hydrocarbons to shore from the leased area will conform with all applicable sections of Titles 33 and 46 of the U.S. Code and the regulations issued thereunder by the U.S. Coast Guard.

Stipulation No. 21

To be included only in the leases resulting from this sale for all tracts with the prefix R59-.

The DMMOFO may require the lessee to dispose of drill cuttings and drilling muds by shunting the material to a depth and location below the ocean surface as specified by the DMMOFO, or by transporting the material to disposal sites approved and permitted by appropriate regulatory agencies. After consultation with the appropriate regulatory agencies, the DMMOFO shall determine the method of disposal based upon review of relevant sources of information.

Based upon the composition of produced formation waters the site-specific environmental conditions in a leasing area, and data from relevant sources, the DMMOFO may require the lessee to reinject formation waters. The DMMOFO shall provide written notice to the lessee of a decision to require reinjection of such formation waters.

Stipulation No. 22

To be included only in leases resulting from this sale for tracts R59-47 through R59-253.

(a) Whether or not compensation for such damage or injury might be due under a theory of strict or absolute liability or otherwise, the lessee assumes all risks of damage or injury to persons or property, which occurs in, on, or above the Outer Continental Shelf, to any person or persons or to any property of any person or persons who are agents, employees or invitees of the lessee, its agents, independent contractors or subcontractors doing business with the lessee in connection with any activities being performed by the lessee in, on, or above the Outer Continental Shelf, if such injury or damage to such person or property occurs by reason of the activities of any agency of the U.S. Government, its contractors, or subcontractors, or any of their officers, agents or employees, being conducted as a part of, or in connection with, the programs and activities of the National Aeronautics and Space Administration (NASA), Wallops Flight Center. The lessee assumes this risk whether such injury or damage is caused in whole or in part by any act or omission, regardless of negligence or fault, of the United States, its contractors or subcontractors, or any of their officers, agents, or employees.

Notwithstanding any limitations of the lessee's liability in section 14 of the lease, the lessee assumes this risk whether such injury or damage is caused in whole or in part by any act or omission, regardless of negligence or fault, of the United States, its contractors or subcontractors, or any of their officers, agents, or employees. The lessee further agrees to indemnify and save harmless the United States against all claims for loss, damage, or injury sustained by the lessee, the agents, employees, or invitees of the lessee, its agents, or any independent contractors or subcontractors doing business with the lessee in connection with the programs and activities of the NASA, Wallops Flight Center, whether the same be caused in whole or in part by the negligence or fault of the United States, its contractors, or subcontractors or any of their officers, agents, or employees, and whether such claims might be sustained under a theory of strict or absolute liability or otherwise.

(b) The lessee, when operating or causing to be operated on its behalf, boat, ship, or aircraft traffic into the leased area or surrounding area of the lease, including any part of the Outer Continental Shelf between the 35th and 39th parallels, shall enter into an agreement with the Director, Wallops Flight Center, prior to commencing such traffic. Such agreement shall provide for positive control of boats, ships, and aircraft operating in the above designated areas and will provide for the avoidance of interference with the programs and activities of the NASA Wallops Flight Center.

(c) Upon recommendation by the Director, Wallops Flight Center, when the activities of the NASA Wallops Flight Center may endanger personnel or property, the lessee agrees, upon receipt of notice from the DMMOFO, to evacuate all personnel from all structures on the lease and to shut-in and secure all wells and other equipment, including pipelines on the lease, within 48 hours or within such longer period as may be specified by the DMMOFO. The DMMOFO shall not require evacuation of personnel and shutting-in and securing of equipment for a period of time greater than 72 hours; however, such period of time may be extended by subsequent notice from the DMMOFO. Equipment and structures may remain in place on the lease during such time as the evacuation remains in effect.

(d) The lessee agrees to control his own electromagnetic emissions and those of his agents, employees, invitees, independent contractors or subcontractors emanating from the leased area or surrounding area of the lease, including any part of the Outer Continental Shelf between the 35th and 39th parallels, in accordance with the requirements specified by the Director, Wallops Flight Center, to the degree necessary to prevent damage to, or unacceptable interference with, the programs and activities of the NASA, Wallops Flight Center.

Stipulation No. 23

Leases for the following tracts will include this stipulation, which will apply only to operations within the designated portions of such tracts:

Tracts Showing Evidence of Mass Movement

Tracts	NJ 18-3 (Hudson Canyon)	
R59-6	- 733	NW1/4SW1/4, S1/2SE1/4, NE1/4SE1/4
R59-7	- 734	W1/2SW1/4
R59-8	- 735	SW1/4
R59-13	- 777	N1/2NE1/4
R59-16	- 780	S1/2NW1/4, W1/2SW1/4
R59-17	- 781	SE1/4, E1/2SW1/4, SW1/4SW1/4, S1/2NE1/4, SE1/4NW1/4
R59-24	- 824	S1/2, S1/2N1/2
R59-31	- 867	SE1/4NW1/4, NE1/4SW1/4, S1/2NE1/4, N1/2SE1/4
R59-38	- 910	W1/2NW1/4, NE1/4NW1/4, NE1/4, SE1/4, SE1/4SW1/4
R59-39	- 911	S1/2, S1/2NW1/4, NW1/4NW1/4, S1/2NE1/4, NE1/4NE 1/4
R59-45	- 953	S1/2NE1/4, N1/2SE1/4
R59-46	- 954	NW1/4SW1/4, NE1/4NW1/4, N1/2NE1/4, SE1/4NE1/4
R59-49	- 990	SW1/4NW1/4, N1/2SW1/4
R59-50	- 993	NE1/4SE 1/4
	NJ 18-6 (Wilmington Canyon)	
R59-55	- 22	E1/2NE1/4
R59-56	- 23	S1/2NW1/4, NW1/4NW1/4, N1/2SW1/4, W1/2SE1/4
R59-61	- 28	SE1/4SE1/4
R59-62	- 63	NE1/4SE1/4
R59-70	- 108	SW1/4NE1/4, NW1/4SE1/4
R59-76	- 114	SW1/4SW1/4
R59-82	- 157	NE1/4NE1/4
R59-135	- 453	SE1/4
R59-136	- 454	S1/2NW1/4
R59-143	- 496	NE1/4SE1/4
R59-144	- 497	NW1/4, NW1/4NE1/4, NW1/4SW1/4
R59-157	- 546	S1/2SW1/4, NE1/4SW1/4
R59-164	- 627	N1/2NW1/4
R59-191	- 800	SW1/4SE1/4
R59-198	- 843	E1/2NW1/4
R59-220	- 975	SW1/4SW1/4
	NJ 18-8 (Chincoteague)	
R59-228	- 304	SE1/4SE1/4
R59-229	- 305	SW1/4SW1/4
R59-231	- 348	E1/2E1/2
	NJ 18-9 (Baltimore Rise)	
R59-242	- 50	N1/2NE1/4
R59-244	- 90	SE1/4SW1/4
R59-248	- 133	E1/2NE1/4, NE1/4SE1/4
R59-249	- 134	N1/2, N1/2SW1/4, NW1/4SE1/4

Tracts Showing Evidence of Shallow Faults

	NJ 18-3 (Hudson Canyon)	
R59-28	- 864	SE1/4NE1/4
R59-38	- 910	S1/2NE1/4, W1/2NW1/4, NW1/4SE1/4
R59-39	- 911	NE1/4NE1/4, S1/2NE1/4, SW1/4SW1/4, E1/2SW1/4, NW1/4SE1/4
R59-45	- 953	NW1/4SW1/4, SW1/4NW1/4, NW1/4NE1/4
R59-46	- 954	NE1/4NE1/4

Tracts NJ 18-6 (Wilmington Canyon)

R59-114 - 330 N1/2SW1/4, SW1/4SW1/4
R59-123 - 373 NE1/4NE1/4

Portions of this tract may be subject to unstable slopes or shallow faults, (mass movement of sediments). Exploratory drilling operations, emplacement of structures (platforms) or seafloor wellheads for production or storage of oil or gas, and the emplacement of pipelines will not be allowed within the potentially unstable portions of this lease block unless or until the lessee has demonstrated to the DMMOFO's satisfaction that mass movement of sediment is unlikely or that exploratory drilling operations, structures (platforms), casing, wellheads and pipelines can be safely designed to protect the environment in case such mass movement occurs at the proposed location. This may necessitate that all exploration for and development of oil or gas be performed from locations outside of the area of instability, either within or outside of this lease block.

If exploratory drilling operations are allowed, site-specific surveys shall be conducted to determine the potential for unstable bottom conditions. The extension of these surveys may be required outside of the leased block. If emplacement of structures (platforms) or seafloor wellheads for production or storage of oil or gas are allowed, all such unstable areas must be mapped. The DMMOFO may also require soil testing before exploration and production operations are allowed.

Stipulation No. 24

To be included only in leases resulting from this sale for tracts R59-60, R59-61, R59-69, and R59-215.

If the DMMOFO believes any undetonated explosives may exist in a leased tract, the lessee shall conduct surveys as specified by the DMMOFO to determine the location of any undetonated explosives. Upon completion of any such surveys, the lessee shall forward a report and all pertinent data to the DMMOFO for review. Should the DMMOFO determine that the existence of such devices may adversely affect any activity or operation, such as the construction or placement of any structure for exploration or development on the lease, the lessee shall take no action until the DMMOFO has given directions as to the conduct of that operation.

Stipulation No. 25

To be included only in the leases resulting from this sale for the net profit share tracts listed in paragraph 4(d) of this notice.

The net profit share payment specified in sec. 6 of this lease may be satisfied in whole or in part by the lessor taking production in amount rather than in value. However, no more than 16-2/3 percent of the production from the lease area may be taken in amount, except as provided in sec. 15(d). The net profit share obligations of the lessee shall be calculated to include as a credit, the value of production taken in amount by the lessor.

14. Information to Lessees. With respect to tracts with the prefix R53-, the Department of the Interior will seek the advice of the State of California and other Federal agencies to identify areas of special biological or cultural resources.

Operations on some of the tracts offered for lease may be restricted by designation of fairways, precautionary zones, or traffic separation schemes established by the Coast Guard pursuant to the Ports and Waterways Safety Act (33 U.S.C. 1221 et seq.). Such areas might be established, among other reasons, for the purpose of protecting commercial fisheries. Corps of Engineers permits are required for construction of any artificial islands, installations and other devices permanently or temporarily attached to the seabed located on the Outer Continental Shelf in accordance with section 4(e) of the Outer Continental Shelf Lands Act of 1953, as amended.

Bidders are advised that the Departments of the Interior and Transportation have entered into a Memorandum of Understanding dated May 6, 1976, concerning the design, installation, operation and maintenance of offshore pipelines. Bidders should consult both Departments for regulations applicable to offshore pipelines.

Bidders are also advised that in accordance with sec. 16 of each lease offered at this sale, the lessor may require a lessee to operate under a unit, pooling, or drilling agreement, and that the lessor will give particular consideration to requiring unitization in instances where one or more reservoirs underlie two or more leases with a different royalty rate, or a royalty rate based on a sliding scale, or a fixed net profit share.

With respect to leases resulting from this sale for all tracts with the prefix R53-, to reduce the impacts of aircraft disturbances at seabird colonies

and marine mammal rookeries along the coast, a distance of at least one mile from the coastline and an altitude of 1,000 feet should be maintained, consistent with aircraft safety, from specific areas to be identified by the DMMOFO. The lessee is advised that all violations may be reported to the U.S. Fish and Wildlife Service, National Marine Fisheries Service, or the California Department of Fish and Game, as appropriate, for disposition.

Revisions of Department of Labor regulations on Affirmative Action requirements for Government Contractors (including lessees) have been deferred, pending review of those regulations (see Federal Register of August 25, 1981, at 46 F.R. 42865 and 42968). Should those changes become effective at any time before the issuance of leases resulting from this sale, Section 18 of the lease form, Form 3300-1 (September 1978), would be deleted from leases resulting from this sale. In addition, existing stocks of the Affirmative Action Forms described in section 5 of this notice contain language that would be superseded by the revised regulations at 41 CFR 60-1.5(a)(1) and 60-1.7(a)(1).

Pending the issuance of revised versions of Forms 1140-7 and 1140-8 by the Bureau of Land Management, submission of Form 1140-7 (December 1971) and Form 1140-8 (November 1973) will not invalidate an otherwise acceptable bid, and the revised regulations' requirements will be deemed to be part of the existing Affirmative Action Forms.

Notice is hereby given that portions of tracts R53-199, R53-205, R53-212, R53-213, R53-219, R53-221, R53-227, and R53-233 may contain a shallow "bright spot" seismic amplitude anomaly which may be indicative of a shallow gas deposit. Surface occupancy above this anomaly and drilling through the anomaly will not be allowed unless or until the lessee has demonstrated to the DMMOFO's satisfaction that a potentially hazardous accumulation of shallow gas does not exist or that exploratory drilling operations, structures (platforms), casing, and wellheads can be placed or drilling plans designed to assure safe operations in the area above the anomaly. This may necessitate that all exploration for and development of oil and gas be performed from locations outside the area of concern, either within or outside this lease block.

In implementing stipulation 8, the DMMOFO will require that training programs include the locations of marine mammal and bird rookery sites in the area, the seasonal abundance and sensitivities of these animals to disturbance, and the Federal laws that have been established to protect endangered and threatened species from harassment and injury.

With respect to tracts with the prefix R56-, the Department of the Interior will seek the advice of the States of North Carolina, South Carolina, Georgia, and Florida, and other Federal agencies, to identify areas of special concern which might require appropriate protective measures for live bottom areas and areas which might contain cultural resources. If it is determined that live bottom areas might be adversely affected by the proposed activities, then the DMMOFO, in consultation with the Regional Director, Fish and Wildlife Service (FWS), the States, EPA, and other Federal agencies with jurisdiction and expertise to protect the environment, will require the lessee, pursuant to Section 5(a) of the OCS Lands Act, as amended, to undertake any measures to protect live bottom areas.

With respect to leases resulting from this sale for all tracts with the prefix R56-, bidders are advised that the West Indian manatee is a marine mammal which is officially listed as an Endangered Species by the Department of the Interior. It is protected by the Endangered Species Act of 1973, as amended (87 Stat. 884, 16 U.S.C. 1531-1543), and the Marine Mammal Protection

Act of 1972, as amended (86 Stat. 1027, 16 U.S.C. 1361-1407), and various other State and Federal laws and regulations. On October 22, 1979, (44 FR 60963) Interior promulgated regulations (50 CFR 17.100-17.108) providing a means for establishing manatee protection areas. Also, the Florida Manatee Sanctuary Act of 1978 declares the entire State of Florida a "refuge and sanctuary for the manatees." A cooperative agreement between Interior and Florida on endangered species became effective on June 23, 1976. A similar cooperative agreement with the State of Georgia became effective on October 6, 1977.

For those tracts listed in paragraph 13(a) above providing for leases with an initial period of more than five years, bidders are advised that pursuant to 30 CFR 250.34-1(a)(3), the lessee shall submit to the DMMOFO either an exploration plan or a general statement of exploration intentions prior to the end of the ninth lease year.

With respect to leases resulting from this sale for all tracts with the prefix R60-, bidders are advised that the conduct of all activities related to leases issued as a result of this lease sale, the lessee and its agents, contractors, and subcontractors will be subject to the provisions of the Marine Mammal Protection Act of 1972, the Endangered Species Act of 1973, as amended, and International Treaties. Violations of these Acts and Treaties may be reported to the National Marine Fisheries Service or U.S. Fish and Wildlife Service, as appropriate. The lessee or his contractors should be aware that disturbance of wildlife could be determined to constitute harassment, and thereby be in violation of existing laws. Behavioral disturbance of most birds and mammals found in or near the sale 60 area would be unlikely if ocean vessels and aircraft maintained at least a 1-mile distance from observed wildlife or known wildlife concentration areas such as bird colonies or marine mammal rookeries. Therefore, in concurrence with the National Marine Fisheries Service and the U.S. Fish and Wildlife Service, it is recommended that aircraft or vessels operated by lessees maintain at least a 1-mile distance from observed wildlife or known wildlife concentration areas. Human safety will take precedence at all times over distances recommended herein for avoidance or disturbance of wildlife. Maps locating major wildlife concentration areas are available through the DMMOFO and appropriate resource agencies.

With respect to leases resulting from this sale for all tracts with the prefix R60-, bidders are advised that the State of Alaska will be consulted by the DMMOFO throughout the stages of OCS development. In addition to State involvement in the Intergovernmental Planning Program (IPP), the Scientific Committee of the OCS Advisory Board, and the review of exploration and development plans, the DMMOFO may involve the State in the implementation of Stipulation 15.

With respect to leases resulting from this sale for all tracts with the prefix R59-, bidders are advised that: In the enforcement of Stipulation No. 19, the DMMOFO will receive recommendations from the Biological Task Force (BTF) composed of designated representatives of the Minerals Management Service, Fish and Wildlife Service, the National Marine Fisheries Service, and the Environmental Protection Agency. The task force may consult with representatives of the affected States before making recommendations to the DMMOFO. It is intended that this BTF will remain in existence throughout the operating life of the field. The DMMOFO will consult with the BTF in identifying areas or resources of biological importance, on the conduct of the biological surveys by lessees, and on the appropriate course of action after the surveys have been conducted. In a memorandum to the DMMOFO (April 9, 1980), the Biological Task Force identifed

submarine canyons as areas of biological concern for which it may recommend biological surveys or other monitoring programs. Lack of available "site-specific" information precludes the identification at this time of specific lease tracts for which such studies will or will not be recommended. Based on information generated from on-going canyon studies and on the level of drilling activity at a given time, the Task Force will determine on a case-by-case basis whether or not to recommend biological studies or monitoring programs prior to or during exploration and/or production-related OCS operations in or adjacent to submarine canyons.

With respect to leases resulting from this sale on tracts R59-33, R59-34, R59-35, R59-38, R59-39, R59-41, R59-42, R59-45, R59-46, R59-50, R59-53, R59-54, R59-60, R59-61, R59-69, R59-75, R59-76, and R59-82, the following requirement will apply: At least 20 days prior to moving a rig on-site, the lessee must notify the Chief, Marine and Wetlands Protection Branch, U.S. Environmental Protection Agency, Region II, 26 Federal Plaza, Suite 1642, New York, New York 10278, in writing, stating on what date a rig is to be moved on-site.

With respect to leases resulting from the sale for all tracts with the prefix R59-, lessees are encouraged to include a fisheries training program in their exploration and development plans. This training program should be designed to familiarize platform and shore based supervisors and persons involved in vessel operations with the value of the commercial fishing industry, the methods of offshore fishing operations, and the potential hazards, conflicts, and impacts resulting from offshore oil and gas activites. This program should be formulated and implemented by qualified and experienced instructors in fishing activities, methods of communication, and navigational safety.

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15. OCS Orders. Operations on all leases resulting from this sale will be conducted in accordance with the provisions of all relevant OCS Orders, as of their effective date, and any other applicable OCS Order as it becomes effective.

Director, Minerals Management Service
Harold E. Doley, Jr.

Approved: JUN 28 1982

Donald Paul Hodel

Under Secretary of the Interior
Donald P. Hodel

UNITED STATES
DEPARTMENT OF THE INTERIOR
MINERALS MANAGEMENT SERVICE

Outer Continental Shelf
Central and Northern California, South Atlantic,
Lower Cook Inlet/Shelikof Strait and Mid-Atlantic

Notice of Leasing Systems, Sale No. RS-2

Sec. 8(a)(8) (43 U.S.C. 1337 (a)(8)) of the Outer Continental Shelf (OCS) Lands Act, as amended, requires that, at least 30 days before any lease sale, a notice be submitted to the Congress and published in the Federal Register:

(A) identifying the bidding systems to be used and the reasons for such use; and

(B) designating the tracts to be offered under each bidding system and the reasons for such designation.

This notice is published pursuant to these requirements.

A. Bidding systems to be used. In OCS Sale No. RS-2, tracts will be offered under the following four bidding systems as authorized by Sec. 8(a)(1) (43 U.S.C. 1337 (a)(1)): (1) bonus bidding with a fixed 16-2/3 percent royalty on 210 tracts, (2) bonus bidding with a fixed 12-1/2 percent royalty on 161 tracts, (3) bonus bidding with a sliding scale royalty on 17 tracts, and (4) bonus bidding with a fixed net profit share on 166 tracts.

(1) Bonus Bidding with a 16-2/3 Percent Royalty. This system is authorized by Sec. (8)(a)(1)(A) of the OCS Lands Act, as amended. This system has been used extensively since the passage of the OCS Lands Act in 1953 and imposes greater risks on the lessee than systems with higher contingency payments, but may yield more rewards if a commercial field is discovered. The relatively high front-end payments required may encourage rapid exploration.

(2) Bonus Bidding with a 12-1/2 Percent Royalty. This system is authorized by Sec. (8)(a)(1)(A) of the OCS Lands Act, as amended. This system has been chosen for certain deep water tracts proposed for Sale RS-2 because these tracts are expected to require substantially higher exploration, development, and production costs, as well as longer times before initial production, in comparison to shallow water tracts. DOI analyses indicate that the minimum economically developable discovery on a tract in such deepwater areas under a fixed 12-1/2 percent royalty system would be less than for the same tracts under a 16-2/3 percent royalty system. As a result, more tracts may be explored and developed. In addition, the lower royalty rate system is expected to yield more rapid production rates and higher economic profits. It is not anticipated, however, that the larger cash bonus bid associated with a lower royalty rate will significantly reduce competition, since the higher costs for exploration and development are the primary restraints to competition.

(3) Bonus Bidding with a Sliding Scale Royalty. This system is authorized by Sec. (8)(a)(1)(C) of the OCS Lands Act, as amended. The sliding scale is designed to establish higher royalty rates for larger reservoirs with higher production rates. As such, the expected bonus is reduced compared to a fixed one-sixth royalty system. This may improve competition for leases, and also tends to reduce the likelihood of production losses that could result if higher royalty rates are set by other means, such as royalty bidding, prior to reservoir delineation and production. The sliding scale formula provided for Sale RS-2 is based on the current assumed range of costs and wellhead prices for this area.

The fixed sliding scale formula operates in the following way: when the quarterly value of production, adjusted for inflation, is less than or equal to $14.787863 million, a royalty of 16.66667 percent in amount or value of production saved, removed or sold will be due on the unadjusted value or amount of production. When the adjusted quarterly value of production is equal to or greater than $14.787864 million, but less than or equal to $1197.206141 million, the royalty percent due on the unadjusted value or amount of production is given by

$$Rj = b\ [\ln (Vj/S)]$$

where

Rj = the percent royalty that is due and payable on the unadjusted amount or value of all production saved, removed or sold in quarter j

b = 11.0

ln = natural logarithm

Vj = the value production in quarter j, adjusted for inflation, in millions of dollars

S = 3.25

When the adjusted quarterly value of production is equal to or greater than $1197.206142 million, a royalty of 65.00000 percent in amount or value of production saved, removed or sold will be due on the unadjusted quarterly value of production. Thus, in no instance will the quarterly royalty due exceed 65.00000 percent in amount or value of quarterly production saved, removed or sold.

In adjusting the quarterly value of production for use in calculating the percent royalty due on production during the quarter, the actual value of production will be adjusted to account for the effects of inflation by dividing the actual value of production by the following inflation adjustment factor. The inflation adjustment factor used will be the ratio of the GNP fixed weighted price index for the calendar quarter preceding the quarter of production to the value of that index for the quarter preceding June, 1981. The GNP fixed weighted price index is published monthly in the Survey of Current Business by the Bureau of Economic Analysis, U.S. Department of Commerce. The percent royalty will be due and payable on the actual amount or value of production saved, removed, or sold as determined pursuant to 30 CFR 250.64.

(4) Bonus Bidding with a Fixed Net Profit Share. This system is authorized by Sec. (8)(a)(1)(D) of the OCS Lands Act, as amended. This system was established by Department of Energy (DOE) regulations effective May 14, 1980 (45 Fed. Reg. 36784 May 30, 1980). This system has been used in ten previous OCS sales. The profit share system designed for this sale may increase competition by generating greater contingency payments to the Government and thereby reducing the initial cash bonus. It may also increase the volume of production because certain allowable capital costs can be deducted prior to any liability for profit share payments. In addition, the profit share system may foster the development of marginal fields when compared to a royalty system since the Government shares more of the risk and the lessees' incremental costs are lower in the presence of a capital recovery.

A profit share system which uses cash bonus as the bid variable avoids percentage bids at high levels which would make future development either economically inefficient or simply uneconomic. In addition, it is easier to administer and unitize adjacent tracts with similar profit share rates. Furthermore, a fixed profit share better assures that firms who can produce at lower costs are more likely to obtain leases than would be the case if it were possible for less efficient firms to simply bid away higher percentages of lower profits.

For 83 tracts, firms will be permitted a capital recovery factor of 1.50 over their actual allowable costs before any profit share payments are due. The profit share rate for these tracts is 30 percent. Forty-one tracts will have a capital recovery factor of 0.50 and a profit share rate of 45 percent. Forty-two tracts will have a capital recovery factor of 0.75 and a profit share rate of 40 percent. These parameters were selected on the basis of DOE and DOI studies regarding the effect on bonuses, profit-share payments, Government receipts, gross production, minimal economic tract sizes and particularly on the incentive to alter the production profile.

(B) Designation of Tracts. The selection of tracts to be offered under the four systems was based on the following factors:

(1) As a rule, tracts are to be offered using the same bidding system as was designated for these tracts at the preceding sale during calendar year 1981.

(2) Lease terms on adjacent tracts were considered in order to reduce administrative costs and barriers to unitization, and to enhance orderly development of each field.

(3) Generally, tracts in deep water were selected for 1/8 royalty based on the favorable performance of this system in these high cost areas.

The specific tracts to be offered under each system are as follows:

(a) Bonus Bidding with a 16-2/3 Percent Royalty--Tracts R53-156, R53-157 R53-162, R53-164, R53-169 thru R53-171, R53-176, R53-190, R53-191, R56-189 thru R56-286, R60-1 thru R60-17, R60-19, R60-21 thru R60-23, R60-26 thru R60-72, R60-86 thru R60-110, R60-112, R60-113, R60-115, R60-116, R60-153, R59-1, R59-25, R59-62, and R59-222.

(b) Bonus Bidding with a 12-1/2 Percent Royalty--Tracts R56-22, R56-26, R56-27, R56-30, R56-33 thru R56-39, R56-46 thru R56-51, R56-53 thru R56-66, R56-69 thru R56-71, R56-73 thru R56-76, R56-78, R56-79, R56-162 thru R56-173, R59-2, R59-3, R59-5 thru R59-9, R59-11 thru R59-13, R59-16 thru R59-20, R59-24, R59-26 thru R59-28, R59-31 thru R59-35, R59-38 thru R59-42, R59-45 thru R59-50, R59-53 thru R59-56, R59-60, R59-61, R59-63 thru R59-65, R59-69 thru R59-71, R59-76, R59-77, R59-82 thru R59-84, RS-88 thru R59-94, R59-97 thru R59-102, R59-105, R59-114, R59-123, R59-196 thru R59-198, R59-202 thru R50-206, R59-209 thru R59-212, R59-215 thru R59-221, R59-223 thru R59-233, R59-237 thru R59-239, R59-242 thru R59-244, R59-248 thru R59-250, R59-252 and R59-253.

(c) Bonus Bidding with a Sliding Scale Royalty--Tracts R53-197 thru R53-199, R53-204, R53-205, R53-211 thru R53-213, R53-218 thru R53-221, R53-225 thru R53-227, R53-231, and R53-233.

(d) Bonus Bidding with a Fixed Net Profit Share--All remaining tracts.

Director, Minerals Management Service
Harold E. Doley, Jr.

Approved: JUN 25 1982

Under Secretary of the Interior
Donald Paul Hodel

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Friday
July 2, 1982

Part V

Federal Trade Commission

Premerger Notification Program; Paperwork Burden

FEDERAL TRADE COMMISSION

16 CFR Parts 801, 802 and 803

Premerger Notification Program; Paperwork Burden

AGENCY: Federal Trade Commission.

ACTION: Notice of request for comments.

SUMMARY: The purpose of this notice of request for comments by the Federal Trade Commission is to incorporate public views on the operation of the Hart-Scott-Rodino premerger notification program prior to formulating specific proposals. The Federal Trade Commission, with the concurrence of the Assistant Attorney General for Antitrust, has several times amended the rules in order to improve the program's effectiveness and lessen the burden of complying with the rules. This review of the program is principally directed toward reducing the cost to the public of complying with the rules.

DATES: Comments must be received on or before August 2, 1982.

ADDRESSES: Written comments should be submitted to both (1) the Secretary, Federal Trade Commission, Room 172, Washington, D.C. 20580 and (2) the Assistant Attorney General, Antitrust Division, Department of Justice, Room 3214, Washington, D.C. 20530.

FOR FURTHER INFORMATION CONTACT: Roberta S. Baruch, Attorney or Kenneth M. Davidson, Attorney, Premerger Notification Office, Bureau of Competition, Room 303, Federal Trade Commission, Washington, D.C. 20580. Telephone: (202) 523–3404.

SUPPLEMENTARY INFORMATION: In furtherance of the effort to reduce the overall paperwork burden imposed by the Hart-Scott-Rodino premerger notification rules, the staff of the Federal Trade Commission has developed information relevant to the operation of the rules and has considered preliminarily four approaches to lessening the burden.

This notice is divided into three parts. Part One describes the development of the notification rules. Part Two provides tables summarizing enforcement activities of the Federal Trade Commission and the Department of Justice and premerger notification filings received during 1981. Part Three presents the four approaches to reducing the paperwork burden—raising the dollar reporting thresholds, establishing higher dollar reporting thresholds for specific industries, eliminating subsequent notification requirements for certain transactions and permitting incorporation by reference in relating transactions—and a preliminary discussion of the merits of these approaches.

Part One

Background. In 1976, the Congress enacted section 7A of the Clayton Act (the Hart-Scott-Rodino Antitrust Improvement Act of 1976, 15 U.S.C. 18a) to improve the effectiveness of antitrust enforcement. Previously the antitrust agencies often lacked the necessary information and sufficient time to obtain an adequate remedy for an illegal acquisition. The Federal Trade Commission has summarized congressional objectives of the Act:

> [T]he Act requires that the agencies receive prior notification of significant acquisitions between sizeable parties, provides certain tools to facilitate a prompt but thorough investigation, assures an opportunity to seek a preliminary injunction before the parties are legally free to complete the transaction and eliminates the problem of unscrambling the assets when one of the agencies obtains an order injoining consummation of the acquisition. (Third Annual Report to Congress by the Federal Trade Commission pursuant to section 201 of the Hart-Scott-Rodino Antitrust Improvements Act of 1976, dated December 31, 1979, at p. 2).

The premerger notification rules (16 CFR Parts 801, 802, and 803) closely track the specific provisions of the Act. The statutory limits on the size of persons and transactions subject to the reporting requirements were incorporated into the original rules, along with the categorical exemptions listed in the Act. Since then, pursuant to their authority under section 7A of the Clayton Act (15 U.S.C. 18a(d)(2)(B)), the antitrust enforcement agencies have adopted additional exemptions to reduced the compliance burden.

The Act exempts two categories of transactions that are unlikely to result in antitrust violations. One kind is defined in terms of the size——*i.e.*, the dollar value of the parties and of the transaction. The second kind is based on the nature of the transaction. For example, acquisitions of goods or reality in the ordinary course of business, limited acquisitions of or by foreign persons, and certain acquisitions in regulated industries are exempt under the Act.

During the three years that the premerger program has been in operation, the Commission has taken several steps to reduce the reporting burden.

- On November 19, 1979 (44 FR 66782), the Commission amended the premerger rules to exempt many acquisitions valued at less than $15 million, so that smaller transactions covered by the Act—but generally unlikely to raise antitrust concerns—no longer have to be reported. 16 CFR 802.20.
- On April 7, 1981, the Bureau of Competition issued a formal interpretation permitting reporting parties to incorporate by reference certain documents they may have submitted with a previous filing. CCH Trade Regulation Reporter ¶ 42,475. (This change is also included in the recently proposed amendments to the premerger rules.)
- In response to suggestions from the public, the Bureau of Competition has changed the format of the report form to make it more convenient to use. In addition, this new form further reduces the number of documents that must be submitted with the filing, reflecting the staff's experience that certain documents are not likely to contain information important to antitrust enforcement decisions.

In addition to the steps already taken to reduce the reporting burden, the Commission also has proposed additional ways to reduce the burden. On July 29, 1981, the Commission published for comment a notice of proposed rulemaking (46 FR 38710) that would exempt certain transactions that are reviewed by federal regualtory agencies from the premerger reporting requirements.

Under the proposal, the following transactions would be exempted from the reporting requirement:

- Certain transactions that require approval by the Civil Aeronautics Board.
- Certain transactions that require the consent or approval of the appropriate regulatory agency under the Change in Bank Control Act or the Change in Savings and Loan Control Act.

The quantity of informtion that must be submitted by filing persons would be reduced as follows:

- Copies of documents that were prepared for the Securities and Exchange Commission and were submitted with a previous filing could be incorporated by reference in a subsequent filing by the same person.
- Registration statements filed with the Securities and Exchange Commission that do not directly relate to the transaction being reported would not have to be submitted.

The final form of these rules is currently being reviewed. That form will reflect both the comments received on the proposed rules and the results of an independent study of the premerger rules conducted by Professor Samuel C. Thompson of the University of Virginia.

Professor Thompson's study, *Evaluation of the Premerger Notification Program*, is available from the Federal Trade Commission which funded the study.

The Federal Trade Commission's premerger notification office has begun a project to lessen the burden of complying with the notification rules for persons who are unfamiliar with the rules. The premerger notification office is preparing two sets of introductory materials. One set will explain in simplified terms what transactions are subject to the prior notification requirements of the rules, and will provide references to key sections of the rules. The other will explain in basic terms how to fill out the notification form and provide examples of common entries. The Commission welcomes suggestions from the public on topics to be included in these introductory materials.

The Federal Trade Commission also welcomes comments on the information contained in Part Two and the questions raised in Part Three of this notice.

Part Two

A. A Profile of Premerger Notification Transactions and Preliminary Enforcement Activities During 1981

The tables in this section provide a statistical profile of merger and acquisition transactions that were subject to filing requirements during 1981. The transactions have been grouped according to various criteria (e.g., size of transaction, size of acquiring firm, percentage of voting securities acquired and industry grouping). The various criteria are compared in the tables with the level of enforcement interest as indicated by a "clearance" or a "second request."

The measures of enforcement interest chosen reflect the division of enforcement authority between the Federal trade Commission and the Department of Justice and the investigatory authority conferred by the Hart-Scott-Rodino amendments. All premerger notification filings are sent to both agencies because both have authority under the Clayton Antitrust Act to prevent unlawful transactions and each agency briefly reviews all filings. If either or both agencies decide the transaction should be scrutinized more closely then a "clearance" process is undertaken to insure that only one agency will proceed with an investigation. If further analysis suggests the possibility of an antitrust violation, the investigating agency will typically utilize the premerger act's authority to issue a request for additional information ("second request") to the parties to the transaction.

"Clearance" and "second requests" have been chosen as measures of enforcement interest rather than lawsuits brought or won or settlements agreed upon for two reasons. First, the number of instances in which lawsuits are instituted or settlements are reached are too few to draw conclusions about the relevance of the various criteria. Second, and more importantly, the purpose of the Hart-Scott-Rodino amendments was to provide premerger scrutiny of those transactions that are likely to violate the antitrust laws. The universe of transactions that ought to receive close review corresponds most closely to those where clearance has been granted or a second request has issued.

The current universe of transactions for specific industries is too small to suggest any pattern of enforcement activity by size of transaction. Accordingly the tables only detail enforcement activity by industry group.

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TABLE I

ACQUISITIONS BY SIZE OF TRANSACTION, 1/ 1981
(By Size Range)

Transaction Range ($ Millions)	H-S-R Transactions		Clearance Granted to FTC or DOJ					Second Requests Issued				
			Number		Percent 4/			Number		Percent 4/		
	Number 2/	Percent 3/	FTC	DOJ	FTC	DOJ	Total	FTC	DOJ	FTC	DOJ	Total
Less than 15	87	11.4	7	3	8.0	3.4	11.5	2	1	2.3	1.1	3.4
15 up to 25	173	22.7	13	12	7.5	6.9	14.5	9	6	5.2	3.5	8.7
25 up to 50	207	27.2	23	18	11.1	8.7	19.8	6	7	2.9	3.4	6.3
50 up to 100	125	16.4	18	9	14.4	7.2	21.6	12	5	9.6	4.0	13.6
100 up to 150	53	7.0	6	3	11.3	5.7	17.0	4	-	7.5	-	7.5
150 up to 200	24	3.1	6	2	25.0	8.3	33.3	2	-	8.3	-	8.3
200 up to 300	34	4.5	9	4	26.5	11.8	38.2	6	1	17.6	2.9	20.6
300 up to 500	23	3.0	10	3	43.4	13.0	56.5	4	3	17.4	13.0	30.4
500 up to 1000	18	2.4	6	3	33.3	16.7	50.0	3	2	16.7	11.1	27.8
1000 and up	18	2.4	6	5	33.3	27.8	61.1	3	2	16.7	11.1	27.8
All Transactions	762	100.0	104	62	13.6	8.1	21.8	51	27	6.7	3.5	10.2

1/ The size of transaction is based on the aggregate total amount of voting securities and assets to be held by the acquiring person as a result of the transaction and is taken from the response to item 3(c) of the premerger notification and report form.

2/ During calendar year 1981, 1083 transactions were reported under the Hart-Scott-Rodino premerger notification program. The smaller number, 762, reflects adjustments to eliminate the following types of transactions: (1) 211 transactions reported under Sections 7A(c)(6) and 7A(c)(8) (transactions involving certain financial businesses and regulated industries); (2) 27 transactions which were followed by separate notifications for one or more additional transactions between the same parties during 1981 (such transactions are listed here as a single consolidated transaction); (3) 31 transactions found to be non-reportable; (4) 4 incomplete transactions (only one party to the transaction filed notification) and; (5) 48 secondary acquisitions (filed pursuant to Section 801.30(a)(4)) reported as a result of reportable primary transactions. The table does not however, exclude 23 competing offers or 74 multiple-party transactions (transactions involving two or more acquiring or acquired persons).

3/ Percentage of total transactions.

4/ Percentage of transaction range group.

Note: Detail may not add to total due to rounding.

TABLE II

ACQUISITIONS BY SIZE OF TRANSACTION 1/, 1981
(Cumulative)

Transaction Amount ($ Million)	H-S-R Transactions		Clearance Granted to FTC or DOJ					Second Requests Issued				
			Number		Percentage of Total Number of Clearances Granted			Number		Percentage of Total Number of Second Requests		
	Number 2/	Percent	FTC	DOJ	FTC	DOJ	Total	FTC	DOJ	FTC	DOJ	Total
Less than 15	87	11.4	7	3	4.2	1.8	6.0	2	1	2.6	1.3	3.8
Less than 25	260	34.1	20	15	12.0	9.0	21.1	11	7	14.1	9.0	23.1
Less than 50	467	61.3	43	33	25.9	19.9	45.8	17	14	21.8	17.9	39.7
Less than 100	592	77.7	61	42	36.7	25.3	62.0	29	19	37.2	24.4	61.5
Less than 150	645	84.6	67	45	40.4	27.1	67.5	33	19	42.3	24.4	66.7
Less than 200	669	87.8	73	47	44.0	28.3	72.3	35	19	44.9	24.4	69.2
Less than 300	703	92.3	82	51	49.4	30.7	80.1	41	20	52.6	25.6	78.2
Less than 500	726	95.3	92	54	55.4	32.5	88.0	45	23	57.7	29.5	87.2
Less than 1000	744	97.6	98	57	59.0	34.3	93.4	48	25	61.5	32.1	93.6
All transactions	762	100.0	104	62	62.7	37.3	100.0	51	27	65.4	34.6	100.0

1/ The size of transaction is based on the aggregate total amount of voting securities and assets to be held by the acquiring person as a result of the transaction and is taken from the response to item 3(c) of the premerger notification and report form.

2/ During calendar year 1981, 1083 transactions were reported under the Hart-Scott-Rodino premerger notification program. The smaller number, 762, reflects adjustments to eliminate the following types of transactions: (1) 211 transactions reported under Sections 7A(c)(6) and 7A(c)(8) (transactions involving certain financial businesses and regulated industries); (2) 27 transactions which were followed by separate notifications for one or more additional transactions between the same parties during 1981 (such transactions are listed here as a single consolidated transaction); (3) 31 transactions found to be non-reportable; (4) 4 incomplete transactions (only one party to the transaction filed notification) and; (5) 48 secondary acquisitions (filed pursuant to Section 801.30(a)(4)) reported as a result of reportable primary transactions. The table does not however, exclude 23 competing offers or 74 multiple-party transactions (transactions involving two or more acquiring or acquired persons).

Note: Detail may not add to total due to rounding.

TABLE III

TRANSACTIONS INVOLVING THE GRANTING OF CLEARANCE BY AGENCY, 1981

Transaction Range ($ Millions)	Clearance Granted By Agency			Clearance Granted as a Percentage of:								
				Total Number of Transactions 1/			Transactions in Each Transaction Range Group 2/			Total Number of Clearances Granted		
	FTC	DOJ	Total	FTC	DOJ	Total	FTC	DOJ	Total	FTC	DOJ	Total
Less than 15	7	3	10	0.9	0.4	1.3	8.0	3.4	11.5	4.2	1.8	6.0
15 up to 25	13	12	25	1.7	1.6	3.3	7.5	6.9	14.5	7.8	7.2	15.1
25 up to 50	23	18	41	3.0	2.4	5.4	11.1	8.7	19.8	13.9	10.8	24.7
50 up to 100	18	9	27	2.4	1.2	3.5	14.4	7.2	21.6	10.8	5.4	16.3
100 up to 150	6	3	9	0.8	0.4	1.2	11.3	5.7	17.0	3.6	1.8	5.4
150 up to 200	6	2	8	0.8	0.3	1.0	25.0	8.3	33.3	3.6	1.2	4.8
200 up to 300	9	4	13	1.2	0.5	1.7	26.5	11.8	38.2	5.4	2.4	7.8
300 up to 500	10	3	13	1.3	0.4	1.7	43.4	13.0	56.5	6.0	1.8	7.8
500 up to 1000	6	3	9	0.8	0.4	1.2	33.3	16.7	50.0	3.6	1.8	5.4
1000 and up	6	5	11	0.8	0.7	1.4	33.3	27.8	61.1	3.6	3.0	6.6
All Clearances	104	62	166	13.6	8.1	21.8	13.6	8.1	21.8	62.7	37.3	100.0

1/ During calendar year 1981, 1083 transactions were reported under the Hart-Scott-Rodino premerger notification program. The smaller number, 762, reflects adjustments to eliminate the following types of transactions: (1) 211 transactions reported under Sections 7A(c)(6) and 7A(c)(8) (transactions involving certain financial businesses and regulated industries); (2) 27 transactions which were followed by separate notifications for one or more additional transactions between the same parties during 1981 (such transactions are listed here as a single consolidated transaction); (3) 31 transactions found to be non-reportable; (4) 4 incomplete transactions (only one party to the transaction filed notification) and; (5) 48 secondary acquisitions (filed pursuant to Section 801.30(a)(4)) reported as a result of reportable primary transactions. The table does not however, exclude 23 competing offers or 74 multiple-party transactions (transactions involving two or more acquiring or acquired persons).

2/ Percentages also appear in TABLE I.

Note: Detail may not add to total due to rounding.

TABLE IV

TRANSACTIONS INVOLVING THE ISSUANCE OF SECOND REQUESTS, 1981

Transaction Range ($ Millions)	Transactions Involving the Issuance of Second Requests			Second Requests Issued as a Percentage of:								
				Total Number of Transactions 1/			Transactions in Each Transaction Range Group 2/			Total Number of Second Requests		
	FTC	DOJ	Total	FTC	DOJ	Total	FTC	DOJ	Total	FTC	DOJ	Total
Less than 15	2	1	3	0.3	0.1	0.4	2.3	1.1	3.4	2.6	1.3	3.8
15 up to 25	9	6	15	1.2	0.8	2.0	5.2	3.5	8.7	11.5	7.7	19.2
25 up to 50	6	7	13	0.8	0.9	1.7	2.9	3.4	6.3	7.7	9.0	16.7
50 up to 100	12	5	17	1.6	0.7	2.2	9.6	4.0	13.6	15.4	6.4	21.8
100 up to 150	4	-	4	0.5	-	0.5	7.5	-	7.5	5.1	-	5.1
150 up to 200	2	-	2	0.3	-	0.3	8.3	-	8.3	2.6	-	2.6
200 up to 300	6	1	7	0.8	0.1	0.9	17.6	2.9	20.6	7.7	1.3	9.0
300 up to 500	4	3	7	0.5	0.4	0.9	17.4	13.0	30.4	5.1	3.8	9.0
500 up to 1000	3	2	5	0.4	0.3	0.7	16.7	11.1	27.8	3.8	2.6	6.4
1000 and up	3	2	5	0.4	0.3	0.7	16.7	11.1	27.8	3.8	2.6	6.4
All Transactions	51	27	78	6.7	3.5	10.2	6.7	3.5	10.2	65.4	34.6	100.0

1/ During calendar year 1981, 1083 transactions were reported under the Hart-Scott-Rodino premerger notification program. The smaller number, 762, reflects adjustments to eliminate the following types of transactions: (1) 211 transactions reported under Sections 7A(c)(6) and 7A(c)(8) (transactions involving certain financial businesses and regulated industries); (2) 27 transactions which were followed by separate notifications for one or more additional transactions between the same parties during 1981 (such transactions are listed here as a single consolidated transaction); (3) 31 transactions found to be non-reportable; (4) 4 incomplete transactions (only one party to the transaction filed notification) and; (5) 48 secondary acquisitions (filed pursuant to Section 801.30(a)(4)) reported as a result of reportable primary transactions. The table does not however, exclude 23 competing offers or 74 multiple-party transactions (transactions involving two or more acquiring or acquired persons).

2/ Percentages also appear in TABLE I.

Note: Detail may not add to total due to rounding.

TABLE V

ACQUISITIONS BY REPORTING THRESHOLD, 1981

Threshold	H-S-R Transactions		Clearance Granted to FTC or DOJ					Second Requests Issued				
			Number		Percentage of Threshold Group			Number		Percentage of Threshold Group		
	Number 1/	Percent	FTC	DOJ	FTC	DOJ	Total	FTC	DOJ	FTC	DOJ	Total
$15 Million	20	2.6	1	-	5.0	-	5.0	-	-	-	-	-
15%	48	6.3	9	4	18.8	8.3	27.1	5	1	10.4	2.1	12.5
25%	41	5.4	5	2	12.2	4.9	17.1	2	-	4.9	-	4.9
50%	470	61.7	63	34	13.4	7.2	20.4	24	14	5.1	3.0	8.1
Assets Only	183	24.0	26	22	14.2	12.0	26.2	20	12	10.9	6.6	17.5
All Transactions	762	100.0	104	62	13.6	8.1	21.8	51	27	6.7	3.5	10.2

1/ During calendar year 1981, 1083 transactions were reported under the Hart-Scott-Rodino premerger notification program. The smaller number, 762, reflects adjustments to eliminate the following types of transactions: (1) 211 transactions reported under Sections 7A(c)(6) and 7A(c)(8) (transactions involving certain financial businesses and regulated industries); (2) 27 transactions which were followed by separate notifications for one or more additional transactions between the same parties during 1981 (such transactions are listed here as a single consolidated transaction); (3) 31 transactions found to be non-reportable; (4) 4 incomplete transactions (only one party to the transaction filed notification) and; (5) 48 secondary acquisitions (filed pursuant to Section 801.30(a)(4)) reported as a result of reportable primary transactions. The table does not however, exclude 23 competing offers or 74 multiple-party transactions (transactions involving two or more acquiring or acquired persons).

Note: Detail may not add to total due to rounding.

TABLE VI

TRANSACTIONS BY ASSETS OF ACQUIRING PERSONS, 1981

Asset Range ($ Millions)	H-S-R Transactions		Clearance Granted to FTC or DOJ					Second Requests Issued				
	Number 1/	Percent	Number		Percentage of Asset Range Group			Number		Percentage of Asset Range Group		
			FTC	DOJ	FTC	DOJ	Total	FTC	DOJ	FTC	DOJ	Total
Less than 15	13	1.7	-	-	-	-	-	-	-	-	-	-
15 up to 25	10	1.3	1	-	10.0	-	10.0	1	-	10.0	-	10.0
25 up to 50	28	3.7	1	4	3.6	14.3	17.9	1	3	3.6	10.7	14.3
50 up to 100	43	5.6	4	5	9.3	11.6	20.9	-	2	-	4.7	4.7
100 up to 150	49	6.4	5	5	10.2	10.2	20.4	3	-	6.1	-	6.1
150 up to 200	39	5.1	5	2	12.8	5.1	17.9	2	-	5.1	-	5.1
200 up to 300	52	6.8	8	4	15.4	7.7	23.1	2	1	3.8	1.9	5.8
300 up to 500	86	11.3	4	6	4.7	7.0	11.6	2	5	2.3	5.8	8.1
500 up to 1000	112	14.7	11	8	9.8	7.1	17.0	5	3	4.5	2.7	7.1
1000 and up	320	42.0	64	27	20.0	8.4	28.4	35	12	10.9	3.8	14.7
Assets not available	10 2/	1.3	1	1	10.0	10.0	20.0	-	1	-	10.0	10.0
All Transactions	762	100.0	104	62	13.6	8.1	21.8	51	27	6.7	3.5	10.2

1/ During calendar year 1981, 1083 transactions were reported under the Hart-Scott-Rodino premerger notification program. The smaller number, 762, reflects adjustments to eliminate the following types of transactions: (1) 211 transactions reported under Sections 7A(c)(6) and 7A(c)(8) (transactions involving certain financial businesses and regulated industries); (2) 27 transactions which were followed by separate notifications for one or more additional transactions between the same parties during 1981 (such transactions are listed here as a single consolidated transaction); (3) 31 transactions found to be non-reportable; (4) 4 incomplete transactions (only one party to the transaction filed notification) and; (5) 48 secondary acquisitions (filed pursuant to Section 801.30(a)(4)) reported as a result of reportable primary transactions. The table does not however, exclude 23 competing offers or 74 multiple-party transactions (transactions involving two or more acquiring or acquired persons).

2/ This category is made up 9 acquiring individuals whose assets could not be accurately determined based on the submitted documents and a foreign acquiring person wholly-owned by a foreign government.

Note: Detail may not add to total due to rounding.

TABLE VII

TRANSACTIONS BY SALES OF ACQUIRING PERSONS, 1981

Sales Range ($ Millions)	H-S-R Transactions		Clearance Granted to FTC or DOJ					Second Requests Issued				
			Number		Percentage of Sales Range Group			Number		Percentage of Sales Range Group		
	Number 1/	Percent	FTC	DOJ	FTC	DOJ	Total	FTC	DOJ	FTC	DOJ	Total
Less than 15	22	2.9	1	-	4.5	-	4.5	1	-	4.5	-	4.5
15 up to 25	17	2.2	-	1	-	5.9	5.9	-	1	-	5.9	5.9
25 up to 50	22	2.9	-	1	-	4.5	4.5	-	-	-	-	-
50 up to 100	36	4.7	-	2	-	5.6	5.6	-	2	-	5.6	5.6
100 up to 150	50	6.6	6	6	12.0	12.0	24.0	1	2	2.0	4.0	6.0
150 up to 200	28	3.7	-	5	-	17.9	17.9	-	-	-	-	-
200 up to 300	60	7.9	7	3	11.7	5.0	16.7	5	1	8.3	1.7	10.0
300 up to 500	69	9.1	8	5	11.6	7.2	18.8	2	3	2.9	4.3	7.2
500 up to 1000	96	12.6	14	5	14.6	5.2	19.8	7	3	7.3	3.1	10.4
1000 and up	338	44.4	68	33	20.1	9.8	29.9	35	14	10.4	4.1	14.5
Sales not available	24 2/	3.1	-	1	-	4.2	4.2	-	1	-	4.2	4.2
All Transactions	762	100.0	104	62	13.6	8.1	21.8	51	27	6.7	3.5	10.2

1/ During calendar year 1981, 1083 transactions were reported under the Hart-Scott-Rodino premerger notification program. The smaller number, 762, reflects adjustments to eliminate the following types of transactions: (1) 211 transactions reported under Sections 7A(c)(6) and 7A(c)(8) (transactions involving certain financial businesses and regulated industries); (2) 27 transactions which were followed by separate notifications for one or more additional transactions between the same parties during 1981 (such transactions are listed here as a single consolidated transaction); (3) 31 transactions found to be non-reportable; (4) 4 incomplete transactions (only one party to the transaction filed notification) and; (5) 48 secondary acquisitions (filed pursuant to Section 801.30(a)(4)) reported as a result of reportable primary transactions. The table does not however, exclude 23 competing offers or 74 multiple-party transactions (transactions involving two or more acquiring or acquired persons).

2/ Transactions in this category include acquiring individuals whose sales could not be accurately determined, newly formed acquiring companies and foreign companies with no U.S. operations.

Note: Detail may not add to total due to rounding.

TABLE VIII

TRANSACTIONS BY ASSETS OF ACQUIRED ENTITY 1/, 1981

Asset Range ($ Millions)	H-S-R Transactions		Clearance Granted to FTC or DOJ					Second Requests Issued				
			Number		Percentage of Asset Range Group			Number		Percentage of Asset Range Group		
	Number 2/	Percent	FTC	DOJ	FTC	DOJ	Total	FTC	DOJ	FTC	DOJ	Total
Less than 15	83	10.9	4	3	4.8	3.6	8.4	2	2	2.4	2.4	4.8
15 up to 25	108	14.2	10	10	9.3	9.3	18.5	6	4	5.6	3.7	9.3
25 up to 50	145	19.0	16	15	11.0	10.3	21.4	7	6	4.8	4.1	9.0
50 up to 100	117	15.4	18	8	15.4	6.8	22.2	10	3	8.5	2.6	11.1
100 up to 150	58	7.6	10	1	17.2	1.7	19.0	6	-	10.3	-	10.3
150 up to 200	28	3.7	3	4	10.7	14.3	25.0	1	2	3.5	7.1	10.7
200 up to 300	46	6.0	8	3	17.4	6.5	23.9	5	1	10.9	2.2	13.0
300 up to 500	39	5.1	6	3	15.4	7.7	23.1	2	1	5.1	2.6	7.7
500 up to 1000	43	5.6	7	4	16.3	9.3	25.6	3	4	7.0	9.3	16.3
1000 and up	56	7.3	14	6	25.0	10.7	35.7	7	2	12.5	3.6	16.1
Assets not available	39 3/	5.1	8	5	20.5	12.8	33.3	2	2	5.1	5.1	10.3
All Transactions	762	100.0	104	62	13.6	8.1	21.8	51	27	6.7	3.5	10.2

1/ The assets of the acquired entity were taken from responses to item 2(d)(i) (Assets to be Acquired) or from items 4(a) or 4(b) (SEC documents and annual reports) of the premerger notification and report form.

2/ During calendar year 1981, 1083 transactions were reported under the Hart-Scott-Rodino premerger notification program. The smaller number, 762, reflects adjustments to eliminate the following types of transactions: (1) 211 transactions reported under Sections 7A(c)(6) and 7A(c)(8) (transactions involving certain financial businesses and regulated industries); (2) 27 transactions which were followed by separate notifications for one or more additional transactions between the same parties during 1981 (such transactions are listed here as a single consolidated transaction); (3) 31 transactions found to be non-reportable; (4) 4 incomplete transactions (only one party to the transaction filed notification) and; (5) 48 secondary acquisitions (filed pursuant to Section 801.30(a)(4)) reported as a result of reportable primary transactions. The table does not however, exclude 23 competing offers or 74 multiple-party transactions (transactions involving two or more acquiring or acquired persons).

3/ For thirty-three of these transactions the value of the assets up the entity being acquired is not available. The other six transactions involve the formation of joint ventures, none of which had any assets.

Note: Detail may not add to total due to rounding.

TABLE IX

TRANSACTIONS BY SALES OF ACQUIRED ENTITY 1/, 1981

Sales Range ($ Millions)	H-S-R Transactions		Clearance Granted to FTC or DOJ						Second Request Issued					
			Number		Percentage of Sales Range Group				Number		Percentage of Sales Range Group			
	Number 2/	Percent	FTC	DOJ	FTC	DOJ	Total		FTC	DOJ	FTC	DOJ	Total	
Less than 15	90	11.8	6	2	6.7	2.2	8.9	2	1	2.2	1.1	3.3		
15 up to 25	73	9.6	8	3	11.0	4.1	15.1	6	1	8.2	1.4	9.6		
25 up to 50	140	18.4	8	13	5.7	9.3	15.0	2	5	1.4	3.6	5.0		
50 up to 100	141	18.5	20	12	14.2	8.5	22.7	10	6	7.1	4.3	11.3		
100 up to 150	48	6.3	7	6	14.6	12.5	27.1	4	3	8.3	6.2	14.6		
150 up to 200	31	4.1	4	3	12.9	9.7	22.6	3	-	9.7	-	9.7		
200 up to 300	30	3.9	8	1	26.7	3.3	30.0	2	-	6.7	-	6.7		
300 up to 500	47	6.2	12	7	25.5	14.9	40.4	8	2	17.0	4.3	21.3		
500 up to 1000	46	6.0	12	3	26.1	6.5	32.6	4	3	8.7	6.5	15.2		
1000 and up	64	8.4	14	8	21.9	12.5	34.4	7	4	10.9	6.2	17.2		
Sales not available	52 3/	6.8	5	4	9.6	7.7	17.3	3	2	5.8	3.8	9.6		
All Transactions	762	100.0	104	62	13.6	8.1	21.8	51	27	6.7	3.5	10.2		

1/ The sales of the acquired entity were taken from respnses to items 5 (dollar revenues) and items 4(a) and 4(b) (SEC documents and annual reports) of the premerger notification and report form.

2/ During calendar year 1981, 1083 transactions were reported under the Hart-Scott-Rodino premerger notification program. The smaller number, 762, reflects adjustments to eliminate the following types of transactions: (1) 211 transactions reported under Sections 7A(c)(6) and 7A(c)(8) (transactions involving certain financial businesses and regulated industries); (2) 27 transactions which were followed by separate notifications for one or more additional transactions between the same parties during 1981 (such transactions are listed here as a single consolidated transaction); (3) 31 transactions found to be non-reportable; (4) 4 incomplete transactions (only one party to the transaction filed notification) and; (5) 48 secondary acquisitions (filed pursuant to Section 801.30(a)(4)) reported as a result of reportable primary transactions. The table does not however, exclude 23 competing offers or 74 multiple-party transactions (transactions involving two or more acquiring or acquired persons).

3/ Transactions in this category are represented by the acquisition of newly formed corporations or corporate joint ventures from which no sales have been generated and the acquisition of assets which had produced no sales or revenues.

Note: Detail may not add to total due to rounding.

TABLE X

INDUSTRY GROUP OF ACQUIRING PERSON AND ACQUIRED ENTITY, 1981

2-Digit SIC Code 1/	Industry Description	Acquiring Person						Acquired Entity							
		Number 2/	Clearance Granted to FTC or DOJ			Second Requests Issued			Number 2/	Clearance Granted to FTC or DOJ			Second Requests Issued			Number of 2-Digit Intra-Industry Transactions
			FTC	DOJ	Total	FTC	DOJ	Total		FTC	DOJ	Total	FTC	DOJ	Total	
01	Agricultural Production-Crops	2	-	-	-	-	-	-	2	-	1	1	-	-	-	1
02	Agricultural Production-Livestock	1	-	-	-	-	-	-	1	-	-	-	-	-	-	-
10	Metal Mining	4	-	-	-	-	-	-	4	1	-	1	1	-	1	-
11	Anthracite Mining	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-
12	Bituminous Coal and Lignite Mining	3	-	-	-	-	-	-	16	3	1	4	-	-	-	3
13	Oil and Gas Extraction	27	1	3	4	1	3	4	36	2	2	4	-	1	1	11
14	Mining and Quarrying of Nonmetallic Minerals, Except Fuels	3	1	-	1	-	-	-	3	1	-	1	-	-	-	-
15	Building Construction-General Contractors and Operative Builders	10	-	-	-	-	-	-	5	-	-	-	-	-	-	5
16	Construction other than Building Construction-General Contractors	4	-	-	-	-	-	-	6	-	1	1	-	1	1	-
17	Construction-Special Grade Contractors	1	-	-	-	-	-	-	2	-	1	1	-	-	-	-
20	Food and Kindred Products	42	8	6	14	4	2	6	44	9	6	15	5	4	9	27
21	Tobacco Manufacturers	3	1	-	1	-	-	-	-	-	-	-	-	-	-	-
22	Textile Mill Products	1	-	-	-	-	-	-	2	-	1	1	-	1	1	-
23	Apparel and other Finished Products made from Fabrics and Similar Materials	1	-	-	-	-	-	-	4	-	-	-	-	-	-	1
24	Lumber and Wood Products, Except Furniture	5	-	-	-	-	-	-	6	-	-	-	-	-	-	1
25	Furniture and Fixtures	2	-	-	-	-	-	-	2	-	2	2	-	1	1	-
26	Paper and Allied Products	9	2	-	2	1	-	1	7	2	-	2	-	-	-	2
27	Printing, Publishing and Allied Industries	18	-	-	-	-	-	-	12	-	-	-	-	-	-	5
28	Chemicals and Allied Products	30	7	4	11	2	3	5	28	6	4	10	3	3	6	16
29	Petroleum Refining and Related Industries	20	7	1	8	5	1	6	18	4	3	7	3	1	4	4
30	Rubber and Misc. Plastics Products	7	3	1	4	1	-	1	12	1	-	1	-	-	-	1
31	Leather and Leather Products	2	1	-	1	-	-	-	-	-	-	-	-	-	-	-
32	Stone, Clay, Glass, and Concrete Products	9	3	1	4	3	-	3	18	7	1	8	6	-	6	5
33	Primary Metal Industries	26	8	2	10	3	-	3	20	4	2	6	4	1	5	3
34	Fabricated Metal Products, Except Machinery and Transportation Equipment	20	5	4	9	1	1	2	20	3	4	7	2	1	3	8
35	Machinery, Except Electrical	47	12	3	15	10	3	13	51	11	4	15	7	3	10	23
36	Electrical and Electronic Machinery, Equipment and Supplies	17	6	2	8	3	1	4	32	10	3	13	5	2	7	9
37	Transportation Equipment	11	2	1	3	-	-	-	15	4	3	7	1	1	2	3
38	Measuring, Analyzing and Controlling Instruments; Photographic, Medical and Optical Goods; Watches and Clocks	4	-	1	1	-	-	-	13	4	-	4	3	-	3	1
39	Miscellaneous Manufacturing Industries	1	1	-	1	1	-	1	6	1	-	1	1	-	1	1

TABLE X (continued)

INDUSTRY GROUP OF ACQUIRING PERSON AND ACQUIRED ENTITY, 1981

2-Digit SIC Code 1/	Industry Description	Acquiring Person							Acquired Entity							Number of 2-Digit Intra-Industry Transactions
			Clearance Granted to FTC or DOJ			Second Requests Issued				Clearance Granted to FTC or DOJ			Second Requests Issued			
		Number 2/	FTC	DOJ	Total	FTC	DOJ	Total	Number 2/	FTC	DOJ	Total	FTC	DOJ	Total	
40	Railroad Transportation	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-
42	Motor Freight Transportation and Warehousing	6	-	-	-	-	-	-	4	-	-	-	-	-	-	-
44	Water Transportation	6	-	-	-	-	-	-	7	-	-	-	-	-	-	2
45	Transportation by Air	1	-	-	-	-	-	-	4	1	-	1	1	-	1	-
47	Transportation Services	2	-	-	-	-	-	-	-	-	-	-	-	-	-	-
48	Communication	16	2	1	3	1	-	1	28	-	-	-	-	-	-	7
49	Electric, Gas, and Sanitary Services	12	-	-	-	-	-	-	5	-	-	-	-	-	-	1
50	Wholesale Trade-Durable Goods	32	3	4	7	3	1	4	32	4	2	6	3	-	3	12
51	Wholesale Trade-Nondurable Goods	32	-	6	6	-	3	3	34	4	3	7	1	1	2	11
52	Building Materials, Hardware, Garden Supply and Mobile Home Dealers	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-
53	General Merchandise Stores	13	5	2	7	-	-	-	8	3	1	4	-	-	-	5
54	Food Stores	9	2	-	2	-	-	-	4	1	-	1	-	-	-	3
55	Automotive Dealers and Gasoline Service Stations	-	-	-	-	-	-	-	2	-	-	-	-	-	-	-
56	Apparel and Accessory Stores	2	-	-	-	-	-	-	6	-	-	-	-	-	-	-
57	Furniture, Home Furnishings, and Equipment Stores	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-
58	Eating and Drinking Places	4	-	-	-	-	-	-	6	-	2	2	-	-	-	2
59	Miscellaneous Retail	11	-	1	1	-	-	-	14	1	1	2	-	-	-	8
60	Banking	6	-	-	-	-	-	-	7	-	-	-	-	-	-	5
61	Credit Agencies other than Banks	15	1	-	1	-	-	-	23	-	-	-	-	-	-	10
62	Security and Commodity Brokers, Dealers, Exchanges, and Services	14	-	-	-	-	-	-	12	2	-	2	-	-	-	5
63	Insurance	43	3	1	4	1	1	2	48	2	1	3	1	-	1	30
64	Insurance Agents, Brokers, and Service	5	-	-	-	-	-	-	6	1	-	1	1	-	1	3
65	Real Estate	13	-	-	-	-	-	-	11	-	-	-	-	-	-	3
67	Holding and other Investment Offices	16	-	-	-	-	-	-	11	1	-	1	-	-	-	5
70	Hotels, Rooming Houses, Camps, and other Lodging Places	5	-	1	1	-	-	-	8	-	-	-	-	-	-	2
72	Personal Services	2	1	-	1	-	-	-	3	1	-	1	-	-	-	2
73	Business Services	9	-	3	3	-	1	1	18	1	3	4	-	2	2	5
75	Automotive Repair, Services, and Garages	1	1	-	1	1	-	1	7	-	-	-	-	-	-	-
76	Miscellaneous Repair Services	1	-	-	-	-	-	-	1	-	-	-	-	-	-	-
78	Motion Pictures	8	-	2	2	-	1	1	4	-	1	1	-	1	1	1
79	Amusement and Recreation Services, Except Motion Pictures	2	-	-	-	-	-	-	5	-	-	-	-	-	-	-
80	Health Services	20	3	7	10	2	3	3	23	4	7	11	2	3	5	19

TABLE X (continued)

INDUSTRY GROUP OF ACQUIRING PERSON AND ACQUIRED ENTITY, 1981

2-Digit SIC Code 1/	Industry Description	Acquiring Person							Acquired Entity							Number of 2-Digit Intra-Industry Transactions
			Clearance Granted to FTC or DOJ			Second Requests Issued				Clearance Granted to FTC or DOJ			Second Requests Issued			
		Number 2/	FTC	DOJ	Total	FTC	DOJ	Total	Number 2/	FTC	DOJ	Total	FTC	DOJ	Total	
89	Miscellaneous Services	4	-	-	-	-	-	-	3	-	-	-	-	-	-	-
99	Nonclassifiable Establishments	-	-	-	-	-	-	-	2	-	-	-	-	-	-	-
DV	Diversified Companies	87	14	4	18	7	3	10	24	4	-	4	-	-	-	7
00	Not Available	34 3/	1	1	2	1	-	1	4 4/	1	2	3	1	-	1	1
	All Transactions	762	104	62	166	51	27	78	762	104	62	166	51	27	78	279

1/ 2-Digit SIC codes are part of the system of Standard Industrial Classification established by the U.S. Government, Standard Industrial Classification Manual, 1972 Executive Office of the President - Office of Management and Budget. The SIC groupings used in this table were determined from responses submitted by filing parties to item 5 of the premerger notification and report form.

2/ During calendar year 1981, 1083 transactions were reported under the Hart-Scott-Rodino premerger notification program. The smaller number, 762, reflects adjustments to eliminate the following types of transactions: (1) 211 transactions reported under Sections 7A(c)(6) and 7A(c)(8) (transactions involving certain financial businesses and regulated industries); (2) 27 transactions which were followed by separate notifications for one or more additional transactions between the same parties during 1981 (such transactions are listed here as a single consolidated transaction); (3) 31 transactions found to be non-reportable; (4) 4 incomplete transactions (only one party to the transaction filed notification) and; (5) 48 secondary acquisitions (filed pursuant to Section 801.30(a)(4)) reported as a result of reportable primary transactions. The table does not however, exclude 23 competing offers or 74 multiple-party transactions (transactions involving two or more acquiring or acquired persons).

3/ Transactions included in this category represent newly formed companies, companies with no U.S. operations and notification filed by individuals.

4/ Transactions included in this category represent the acquisition of newly formed companies and the acquisition of assets located outside the U.S.

Note: Detail may not add to total due to rounding.

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B. Summary of Transaction Notifications Received and Formal Enforcement Activity Taken Since the Inception of the Premerger Notification Program

The table in this section presents the number of filings received annually under the Hart-Scott-Rodino premerger notification program and the number of formal enforcement actions taken by the Federal Trade Commission and the Department of Justice with respect to mergers since the program went into effect. The number of filings listed in this table for 1981 is greater than the number of transactions included in tables in the previous section because it includes banking mergers, secondary acquisitions and two-step mergers. The formal enforcement actions listed here are not necessarily based on premerger notification filings.

These formal actions do not represent the full enforcement impact of the program. For example, these categories do not reflect transactions that were abandoned after the parties learned that an enforcement agency intended to oppose consummation of the transaction. Nor do they reflect transactions that were deterred because of the assurance that enforcement agencies would review all transactions subject to premerger notification program.

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TABLE XI

PREMERGER TRANSACTIONS FILED AND MERGER ENFORCEMENT ACTIVITY SINCE THE HART-SCOTT-RODINO ANTITRUST IMPROVEMENTS ACT BECAME EFFECTIVE

Calendar Year	Number of FTC Enforcement Actions Authorized 3/				Number of DOJ Enforcement Actions 3/		
	Number of Transactions	Preliminary Injunctions	Consent Orders	Complaints 4/ Issued	Preliminary Injunctions	Consent Agreements	Actions Initiated
1978 1/ 2/	355	0	2	4	2	2	8
1979 2/	868	3	6	4	6	3	10
1980	824	2	13	5	3	4	5
1981	1083	4	6	4	0	2	2

1/ The premerger notification rules went into effect on September 5, 1978.

2/ Revised rule 16 CFR § 802.20 went into effect on November 21, 1979. This rule expanded considerably the number of transactions valued at $15 million or less that are exempt from reporting requirements.

3/ These legal actions taken by the Federal Trade Commission and the Department of Justice may or may not be based on premerger filings.

4/ Does not include complaints where consent order was obtained in the same year.

Source: Second, Third, Fourth and Fifth Annual Reports to Congress pursuant to Section 201 of the Hart-Scott-Rodino Antitrust Improvements Act of 1976 and supplemented by enforcement agency data.

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Part Three

A. Should the size of Person or Size of Transaction Dollar Reporting Levels Be Raised Based On

- *Enforcement Patterns?*
- *Inflation?*

Background. Section 7A of the Clayton Act, 18 U.S.C. 18a (The Hart-Scott-Rodino Antitrust Improvements Act of 1976) requires, in part, that any merger or acquisition between a business entity with annual sales or assets exceeding $100 million and a business entity with annual sales or assets exceeding $10 million which involve the purchase of more than $15 million in voting securities and assets be reported in the prescribed manner prior to consummating the transaction. The Federal Trade Commission, with the concurrence of the Assistant Attorney General for Antitrust was granted authority to exempt transactions "which are not likely to violate the antitrust laws." Section 7A(d)(2) of the Clayton Act, 15 U.S.C. 18a(d)(2). The issue considered here is whether the materials presented in Part Two concerning enforcement patterns and the inflation since 1976 provide an adequate basis for increasing the dollar size for reportability.

One index for accommodating the effect of inflation is the implicit price deflator for the Gross National Product. This index is a broad indicator of price trends that includes personal consumption expenditures for durable goods, nondurable goods, and services; gross private domestic investment in farm and nonfarm structures, residential and nonresidential structures, and producers' durable equipment; imports and exports; and government purchases of goods and services.

The GNP implicit price deflator has increased about 47 percent since 1976, as shown in the following table:

GNP Implicit Price Deflator

1976=100

1976	100.00
1977	105.84
1978	113.58
1979	123.21
1980	134.25
1981	146.61

Source: Department of Commerce, *Survey of Current Business.* (Index converted to a 1976 basis.)

Preliminary Conclusion: The preliminary conclusion of the staff is that if any changes are warranted in dollar levels such changes should be limited to the size of transaction. There appears to be some basis for raising the size of transaction test to $25 million.

Discussion

Inflation. The staff does not believe that, by itself, inflation provides an adequate basis for creating exemptions under section 7A(d)(2) of the Clayton Act, 15 U.S.C. 18a(d)(2). Congress did not index dollar amounts to accommodate inflation; rather it conditioned the exemption authority on a finding concerning the likelihood of antitrust violations. In addition the staff believes that automatically indexing stated dollar amounts would unnecessarily complicate an already intricate statutory structure.

Nevertheless, the staff does believe that inflation may have some legitimate role in establishing reporting exemptions if used in conjunction with other factors. This role is based on the apparent Congressional decision that only larger transactions be subject to notification requirements, an intention that is eroded by inflation. The greater Congressional concern about larger transactions is generally related to antitrust analysis where market share (for which size is an imperfect surrogate) is often used as an indicator of market power. Therefore inflation in conjunction with other indications that smaller transactions are of lesser antitrust significance might justify an increase in the size of person or size of transaction test.

Enforcement Patterns. Table I suggests that there is some correlation between the size of transactions and enforcement interest by the Federal Trade Commission and Department of Justice. This pattern is also evident in Tables VIII and IX which reflect the size of acquired entities. No comparable pattern is evident from the tables based on the size of acquiring firm or the percentages of voting securities being acquired.

While Table I suggests a pattern that enforcement interest increases with size of transaction, it does not indicate either a complete lack of enforcement interest below a certain size or a dramatic break (i.e. increase) in enforcement interest above a particular size level. Thus, the tables by themselves do not provide a natural or obvious choice for a new size of transaction test. Nevertheless it might be justifiable to raise the size of transaction threshold to $25 million on the grounds that both: the enforcement interest in transactions below $25 million has been relatively low—approximately one of each seven transactions receive "clearance" for investigation; and, the increase in nominal dollar amount from $15 million to $25 million does not greatly raise in constant dollars the size of transaction test chosen by the Congress in 1976 for § 7A(a)(3)(B). (This approach would also eliminate all transactions currently reportable under 16 CFR 802.20(b)). On the other hand, raising the transaction size to $25 million would eliminate eighteen of the seventy-eight second requests issued by the Federal Trade Commission and the Department of Justice during 1981. In other words, the increase in size of transaction test would eliminate almost one quarter of the transactions which received the highest level of preliminary antitrust scrutiny.

B. Should Separate Size of Person or Size of Transaction Tests Be Established for Specific Industries Based On

- *Enforcement Patterns?*
- *Industry Size Characteristics?*

Background. The 1976 Hart-Scott-Rodino Antitrust amendments to the Clayton Act exempt or modify reporting requirements for transactions involving firms in particular industries and for transactions involving particular kinds of goods. For example, section 7A(c) of the Act, 15 U.S.C. 18a(c), exempts transactions in specified regulated industries and sales of goods and realty in the ordinary course of business. But the Act does not provide for different dollar size tests for different industries. On the other hand, prior to section 7A of the Act the Federal Trade Commission initiated premerger notification requirements which established size criteria for transactions in the cement, dairy and food distribution industries that were lower than the subsequent criteria established under section 7A. *Commission Enforcement Policy with Respect to Vertical Mergers in the Cement Industry,* January 17, 1967, CCH Trade Regulation Reporter ¶ 4520; *Commission Enforcement Policy with Respect to Mergers in the Food Distribution Industries,* January 17, 1967, CCH Trade Regulation Reporter ¶ 4525; *Enforcement Policy with Respect to Mergers in the Dairy Industry,* 43 FR 1992, January 13, 1978, amended 43 FR 28046, June 28, 1978. These programs arose out of a history of antitrust litigation and the programs relied on industry definitions based on that litigation experience.

Preliminary Conclusion. The staff does not believe it is likely that an administrable premerger notification system can be established which sets separate size requirements for different industries.

Discussion. While the staff recognizes the significance of a $15 or $25 million transaction varies in different industries, it has not developed a generally satisfactory method to establish appropriate levels for different industries or to identify which transactions should be included within an industry. Establishing separate industry reporting criteria raises a host of difficult and related issues.

As noted earlier the number of premerger filings for specific industries was not large enough to discern patterns of enforcement activity even using the grossly overbroad industry categories that are defined by two digit Standard Industrial Classifications (SIC). While two digit SIC definitions almost surely comprehend too many different business activities to provide a useful definition of an industry, are there better uniform definitions? How many separate industry categories with separate reporting criteria should be established? Will the establishment of a multitude of separate standards unduly complicate an already complex statutory program? If separate reporting criteria are established for a few industries, will the absence of separate criteria be unfair to some of the remaining industries that are lumped together under general reporting criteria? In the absence of clear benchmarks reflecting size-based enforcement patterns for specific industries, how should the size criteria be established for different industries? If separate size criteria are to be set with reference to the minimum efficient scale of firms within an industry, how is this always controversial question of scale economies to be determined? And how would the industry be monitored to determine technological or organizational changes in scale economies?

Assuming industries could be defined and relevant size criteria could be determined for individual industries it is not obvious how reporting parties would identify whether transactions would meet specific industry criteria. For example, if reportability of a transaction depended on the acquiring firm and the acquired entity having a specified combined amount of annual sales or revenues from particular goods or services, or assets engaged in certain specified activities, how would an acquiring firm be able to predict the relevant sales or assets level of the prospective acquired entity to determine reportability prior to consummating the transaction?

The objections to establishing separate size requirements for different industries are practical, not theoretical. It may be possible at some point to overcome these practical problems and establish separate reporting thresholds for certain industries under the Hart-Scott-Rodino premerger notification system. Acceptable separate industry size tests must satisfy three requirements: the criteria which define the industry must be objective; the size threshold must be based on antitrust considerations; and, acquiring parties must be able to determine which industry size thresholds apply prior to consummating a transaction. The appropriateness of higher separate size thresholds ought to be established by data showing that a significant number of transactions in that industry are being reported which generate very little antitrust enforcement interest.

C. Should the Requirement That a Party File Separate Notifications for Additional Purchases of Voting Securities of One Business Entity Be

- *Eliminated?*
- *Simplified?*

Background. Under existing rules 16 CFR 801.1(h) a person who purchases the voting securities of a business entity in several transactions may be required to file several premerger notifications. The requirement for additional filings is triggered by the person increasing its holdings of voting securities beyond several threshold levels which are stated in terms of percentages of the total number of voting securities of the business entity. For example, a party is required to file once for acquisitions of 15 percent or more of a business entity's voting securities. Before the same party can acquire 25 percent or more of the voting securities of the same entity it must file again, and finally, prior to acquiring 50 percent of the entity's securities it must file again. Where a party knows how many securities it ultimately wishes to purchase it may avoid multiple filings by filing for the highest applicable threshold initially.

Under proposed rule 16 CFR 803.2(e) a party who files for the acquisition of voting securities at one threshold may for a period of 90 days incorporate by reference any documents or information contained in the notification in any subsequent filing to cross another threshold. Under 16 CFR 804.7 a party may acquire voting securities pursuant to the notification for a period of one year. If the minimum percentage of securities filed for are acquired within one year the party may, pursuant to 16 CFR 802.21(b), buy additional securities (but not more than the maximum permitted at that threshold) for an additional four years.

Preliminary Conclusion. The staff does not believe that the subsequent notification requirements should be eliminated; however the staff does believe that the incorporation by reference standard of proposed § 803.2(e) could be expanded to a period of up to one year for subsequent filings for higher thresholds of voting securities.

Discussion. The staff continues to believe that it is useful to require multiple notifications for acquisitions of voting securities for reasons already stated by the Federal Trade Commission. In its Statement of Basis and Purpose for § 801.1(h) the Commission said, "working control or significant influence may arise at different points with respect to different companies. The * * * [lower] thresholds give the enforcement agencies adequate opportunities to assess the ability of a significant minority shareholder to influence or direct management, "43 FR 33465, July 31, 1978.

Although it is important that the enforcement agencies receive notice prior to a person increasing its securities holdings significantly, the information sent to the agencies in successive filings is often identical, apart from the statement of holdings. For this reason proposed § 803.2(e) permits parties to incorporate by reference any documents or information contained in their previous filing for a period of 90 days. Limiting the right to incorporate by reference to 90 days reflected practical considerations about the period of time the enforcement agencies can reasonably maintain access to filed information and the extent to which a filing for a higher threshold is likely to differ from a previous filing.

Upon further consideration, the staff believes that the time period during which incorporation by reference is permitted might appropriately be extended to one year. The one year period for incorporation by reference would then match the period established by § 803.7, during which a party may purchase voting securities pursuant to a filed notification.

D. Should a Party Filing for an Acquisition Be Permitted to Incorporate by Reference Information or Documents Contained Therein in Related Secondary Acquisitions?

Background. Under existing rules, 16 CFR 801.4, whenever a party obtains control of a business entity it is also deemed to be separately acquiring any voting shares held by that business entity. The acquisition of these voting shares (i.e. the "secondary acquisitions") will trigger separate

reporting obligations if the direct acquisition of such shares would have been reportable. So, for example, an acquiring person is required to file six separate notifications if it acquired one large firm which held more than fifteen percent of the voting securities of five firms each valued at more than $15 million.

Preliminary Conclusion. The staff believes that a party should be permitted to incorporate by reference any information or documents in related "secondary acquisitions."

Discussion. Experience has shown that multiple filing of identical information in related secondary acquisitions is unnecessary.

List of Subjects in 16 CFR Parts 801, 802 and 803

Antitrust.

By direction of the Commission.

Carol M. Thomas,

Secretary.

[FR Doc. 82-18035 Filed 7-1-82; 8:45 am]

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federal register

Friday
July 2, 1982

Part VI

Department of Commerce

National Oceanic and Atmospheric Administration

Spiny Lobster Fishery of the Gulf of Mexico and South Atlantic

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 640

[Docket No. 2614-107]

Spiny Lobster Fishery of the Gulf of Mexico and South Atlantic

AGENCY: National Oceanic and Atmospheric Administration, (NOAA), Commerce.

ACTION: Final rule.

SUMMARY: NOAA issues final regulations to implement the Fishery Management Plan for the Spiny Lobster Fishery of the Gulf of Mexico and South Atlantic. The intended effect of these regulations is to prevent overfishing, increase the yield from the fishery, reduce user—group conflicts, and obtain the basic information required for improved management of the fishery.

EFFECTIVE DATES: June 30, 1982; except for §§ 640.6, 640.20(c), 640.21, 640.22, 640.23, 640.24, and those prohibitions in § 640.7 that cross-reference these sections, which are effective on July 26, 1982.

ADDRESSES: A copy of the Regulatory Impact Review may be obtained from Jack T. Brawner, Regional Director, Southeast Region, National Marine Fisheries Service, 9450 Koger Boulevard, St. Petersburg, FL 33702.

FOR FURTHER INFORMATION CONTACT: Jack T. Brawner, 813-893-3141.

SUPPLEMENTARY INFORMATION: These regulations implement the Fishery Management Plan for Spiny Lobster in the Gulf of Mexico and South Atlantic (FMP). This FMP was prepared jointly by the Gulf of Mexico and South Atlantic Fishery Management Councils (Councils). The Assistant Administrator for Fisheries, NOAA, approved the FMP on February 2, 1982, under the authority of the Magnuson Fishery Conservation and Management Act (Magnuson Act). A notice of proposed rulemaking was published on March 12, 1982 (47 FR 10878), initiating a 45-day comment period which ended April 26, 1982.

An emergency interim rule implementing the closed season portion of the FMP was published on March 30, 1982 (47 FR 13353), under section 305(e) of the Magnuson Act. The interim rule was effective for 45 days (April 1 through May 15) and was extended for an additional 45 days on May 16, 1982 (47 FR 21256).

The preamble to the notice of proposed rulemaking contains information on the spiny lobster fishery, its economic value, and its relative importance to the recreational and commercial sectors. The problems in the fishery (i.e., harvest of undersized lobsters and harvest during the spawning season) and the management measures to resolve them are also discussed in detail.

Section 640.5, Recordkeeping and reporting, was reserved in the proposed regulations. This section is also being reserved in this final rule, because the reporting system has not been completely developed and forms have not yet been prepared. It is anticipated that the mandatory reporting system will be implemented by regulatory amendment shortly after sampling procedures and reporting forms are developed and approved. The forms will be submitted to the Office of Management and Budget for approval under section 3507 of the Paperwork Reduction Act, Pub. L. 96-511.

Response to Comments

No comments were received on the FMP during the public comment period; however, the Coast Guard recommended several changes in the proposed regulations. One other comment was received which opposed implementing by emergency regulations the closed season in the FCZ.

That commenter, representing spiny lobster fishermen who fish beyond the fishery conservation zone (FCZ) during Florida's closed season, strongly objected to the emergency interim rule to close the fishing season. The following specific objections were raised: (1) No emergency exists; (2) the rule prevents all feasible fishing for spiny lobster beyond Florida's territorial limits; (3) the 200-mile limit is inappropriate because lobsters do not migrate across the Gulf Stream into Florida's waters; and (4) the rule was introduced in a manner designed to avoid public protest.

In the judgment of the Councils, the National Marine Fisheries Service (NMFS), and numerous fishermen who testified at public hearings, the increasing harvest of lobsters from the FCZ during the time the State has a closed fishing season to protect the major reproductive period constituted a resource emergency. The spiny lobster fishery is a high-value fishery subjected to intensive fishing effort. Extensive harvest during the spawning season would seriously reduce reproductive potential and result in recruitment overfishing.

The emergency rule governs fishing for spiny lobster in portions of the Atlantic Ocean and Gulf of Mexico over which the United States exercises exclusive management authority. Lobster fishing outside of U.S. waters during the closed season is not governed by these regulations. However, lobster fishermen transporting their catch from outside U.S. waters through the FCZ must document, with proper bills of lading, that the lobsters were taken from waters outside the FCZ and, therefore, were not taken in violation of the regulations.

Although the issue of larval recruitment has not been resolved conclusively, the Councils and NMFS believe there is sufficient scientific evidence to indicate that lobsters spawning in the FCZ may contribute significantly to the stock within U.S. waters. The protection of the spawning stock during the closed season is considered to be a sound conservation measure. The question of whether lobsters spawning beyond U.S. waters contribute to the U.S. stock is irrelevant, because the regulations do not pertain to fishing activities beyond the FCZ.

The Councils and NMFS ensured that the public would have an adequate opportunity to comment on all aspects of the FMP, including the closed season. Eight public hearings, including three in the Florida Keys, were held (February 10 through February 19, 1981) to receive public comment on the FMP. A 45-day comment period (January 23, 1981, through March 9, 1981) was also provided to allow the public to send written comments on the draft environmental impact statement. There was strong support for the measure from both commercial and recreational fishermen, and no comments objecting to the closed season were received. An additional 45-day public comment period on the FMP and proposed regulations was initiated by publication of the proposed rule in the Federal Register on March 12, 1982.

Changes From the Proposed Rule

This final rule differs from the proposed rule in that a provision has been added, § 640.20(d), to prohibit possession of spiny lobsters in the FCZ during the closed season. A new paragraph (e) was added to § 640.7, Prohibitions, to reference this provision. These modifications are consistent with the FMP and the intended effect of the proposed rule and will facilitate enforcement of the closed season. This prohibition eliminates the burden of requiring enforcement personnel to observe the actual takings of lobsters from the FCZ during the closed season, and the allowance for possession of lobsters accompanied by a proper bill of lading will avoid any adverse impacts

on fishermen who have legally harvested lobsters.

To further protect undersized lobsters and in keeping with the intent of the FMP, a sentence was added to § 640.22(b) specifying that undersized lobsters may not be retained aboard vessels that are docked. Other changes, discussed in the following paragraphs, have been made in the final rule in response to comments received during the public comment period. In addition, minor changes have been made to clarify the definitions of "commercial fisherman," "degradable panel," "fishery conservation zone," "Regional Director," and the texts of §§ 640.1, 640.4, 640.7(j), 640.20 (a)(1) and (d), and 640.22(a). Also, a new paragraph (d) was added to § 640.6 to clarify that each trap or string of traps is to be marked with a buoy.

The Coast Guard provided the only comments received on the proposed regulations. It recommended that § 640.3(b) be revised to include Monitor Marine Sanctuary, Key Largo Coral Reef Marine Sanctuary and Gray's Reef National Marine Sanctuary. Section 640.3(b) was rewritten to clarify that these regulations apply within the boundaries of any national park, monument, or marine sanctuary within the FCZ.

The Coast Guard also noted that the vessel identification requirements as written in § 640.6 apply to all vessels fishing recreationally or commercially, with or without traps. The Councils intended that the identification system would apply only to vessels engaged in the spiny lobster trap fishery. Section 640.6 of the final rule has been revised to clarify that requirement.

The Coast Guard also recommended that the language in § 640.8 be revised to reflect more accurately current boarding practices and to accommodate fishermen. Section 640.8 has been rewritten to comply with the Coast Guard's suggestions.

Classification

The Assistant Administrator, after considering all comments received on the FMP, emergency regulations, and proposed regulations, has determined that the FMP and the final regulations comply with the national standards, other provisions of the Magnuson Act, and other applicable law.

The adoption and implementation of the FMP is a major Federal action that will have a significant impact on the quality of the human environment. Under the National Environmental Policy Act and NOAA Directive 02–10, a draft environmental impact statement was filed with the Environmental Protection Agency. The notice of availability was published on January 23, 1981 (46 FR 7433). The final environmental impact statement was filed and a notice of availability was published on March 19, 1982 (47 FR 11960).

The NOAA Administrator has determined that these rules are not major under Executive Order 12291. A Regulatory Impact Review (RIR) has been prepared which analyzes the expected benefits and costs of the regulatory action. The review provides the basis for the Administrator's determination. The RIR indicates that the final regulations will result in benefits to fishermen and the economy which substantially exceed the total costs incurred by government and the private sector. Benefits expected to accrue during the first year of implementation include a $3.3 million increase in industry revenue, increased recreational participation, and a substantial reduction of user-group conflicts. The regulations are designed to prevent overfishing and increase the landings of spiny lobsters without unduly burdening any user groups.

These regulations will be enforced via a State/Federal cooperative agreement that will maximize cost effectiveness. Enforcement will be accomplished with existing resources. Compliance with the regulation requiring vessel and gear markings will impose a minimal burden on new participants; virtually all current participants have complied with this requirement by adopting the markings required by the State of Florida.

The implementing regulations do not contain any information collection requirements, as defined by the Paperwork Reduction Act, for individuals, small businesses, or other persons, since the data collection system will not be implemented at this time. Prior to implementation of the data collection system, forms will be approved by the Office of Management and Budget.

These regulations will have a significant impact on a substantial number of small entities under the Regulatory Flexibility Act. A final regulatory flexibility analysis has been prepared in compliance with the Regulatory Flexbility Act, and has been combined with the RIR which is summarized above and is available (see "addresses").

The Assistant Administrator has determined that there is good cause to waive all or part of the 30-day period of delayed effectiveness required under the Administrative Procedure Act (APA). The closed season in the FCZ is intended to occur concurrently with the closure of State waters by the State of Florida. The State waters are closed to spiny lobster fishing from April 1 through July 25. This year, the season was closed in the FCZ by an emergency interim rule. The interim rule expires on June 29, but the closed season does not end until July 25. To maintain the continuity of the closed season and protect the spawning stock in the FCZ, it is essential that certain portions of these final regulations governing the closure be implemented on June 30 (see "effective dates"). All remaining sections of the regulations will be effective on July 26 to coincide with the beginning of the fishing season.

List of Subjects in 50 CFR Part 640

Fish; Fisheries; Fishing.

Dated: June 30, 1982.

William G. Gordon,

Assistant Administrator for Fisheries, National Marine Fisheries Service.

50 CFR is amended by adding a new Part 640 to read as follows:

PART 640—SPINY LOBSTER FISHERY OF THE GULF OF MEXICO AND SOUTH ATLANTIC

Subpart A—General Provisions

Sec.

640.1 Purpose and scope.
640.2 Definitions.
640.3 Relation to other laws.
640.4 Vessels, permits, and fees.
640.5 Recordkeeping and reporting.
[Reserved]
640.6 Gear and vessel identification.
640.7 General prohibitions.
640.8 Enforcement.
640.9 Penalties.

Subpart B—Management Measures

640.20 Seasons.
640.21 Harvest limitations.
640.22 Size limitations.
640.23 Gear limitations.
640.24 Authorized activities.

Authority: 16 U.S.C. 1801 *et seq.*

Subpart A—General Provisions

§ 640.1 Purpose and scope.

The purpose of this part is to implement the Fishery Management Plan for the Spiny Lobster Fishery of the Gulf of Mexico and South Alantic developed by the South Atlantic and Gulf of Mexico Fishery Management Councils under the Magnuson Act. The regulations in this Part govern fishing for spiny lobster by vessels of the United States within the FCZ in the Atlantic Ocean and Gulf of Mexico along the coast of the South Atlantic States from the Virginia/North Carolina border south and through the Gulf of Mexico.

§ 640.2 Definitions.

In addition to the definitions in the Magnuson Act, and unless the context requires otherwise, the terms used in this part have the following meanings:

Authorized Officer means:

(a) Any commissioned, warrant, or petty officer of the United States Coast Guard;

(b) Any certified enforcement officer or special agent of the National Marine Fisheries Service;

(c) Any officer designated by the head of any Federal or State agency which has entered into an agreement with the Secretary and the Commandant of the Coast Guard to enforce the provisions of the Magnuson Act; or

(d) Any Coast Guard personnel accompanying and acting under the direction of any person described in paragraph (a) of this definition.

Carapace length means a head-length measurement taken from the orbital notch inside the orbital spine, in a line parallel to the lateral rostral sulcus, to the posterior margin of the cephalothorax (Figure 1).

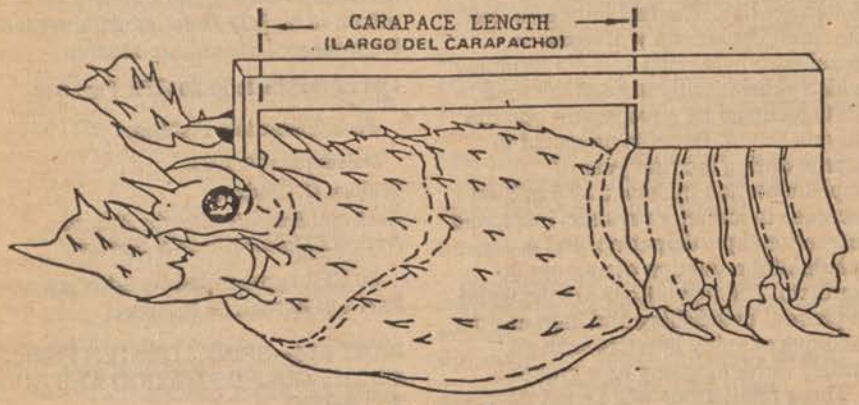


Figure 1

Center Director means the Center Director, Southeast Fisheries Center, National Marine Fisheries Service, 75 Virginia Beach Drive, Miami, Florida 33149; telephone 305–361–5761.

Commercial fisherman means a fisherman who sells all or any part of his catch.

Degradable panel means a panel constructed of wood, cotton, or other material that will degrade at the same rate as a wooden trap.

Fish includes the spiny lobster, *Panulirus argus*.

Fishery conservation zone (FCZ) means that area adjacent to the United States which, except where modified to accommodate international boundaries, encompasses all waters from the seaward boundary of each of the coastal States to a line on which each point is 200 nautical miles from the baseline from which the territorial sea of the United States is measured.

Fishing means any activity, other than scientific research conducted by a scientific research vessel, which involves:

(a) The catching, taking, or harvesting of fish;

(b) The attempted catching, taking, or harvesting of fish;

(c) Any other activity which can reasonably be expected to result in the catching, taking, or harvesting of fish; or

(d) Any operations at sea in support of, or in preparation for, any activity described in paragraph (a), (b), or (c) of this definition.

Fishing vessel means any vessel, boat, ship, or other craft which is used for, equipped to be used for, or of a type which is normally used for:

(a) Fishing; or

(b) Aiding or assisting one or more vessels at sea in the performance of any activity relating to fishing, including, but not limited to, preparation, supply, storage, refrigeration, transportation, or processing.

Live box means a container used for holding live lobsters aboard a vessel.

Magnuson Act means the Magnuson Fishery Conservation and Management Act (16 U.S.C. 1801 *et seq.*).

Management area means that area of the FCZ adjacent to the territorial sea off the coasts of the States adjacent to the Gulf of Mexico and off the Atlantic Coast south of the Virginia-North Carolina border.

Operator, with respect to any vessel, means the master or other individual on board and in charge of that vessel.

Owner, with respect to any vessel means:

(a) Any person who owns that vessel in whole or in part;

(b) Any charterer of the vessel, whether bareboat, time, or voyage;

(c) Any person who acts in the capacity of a charterer, including, but not limited to, parties to a management agreement, operating agreement, or other similar arrangement that bestows control over the destination, function, or operation of the vessel; or

(d) Any agent designated as such by any person described in paragraph (a), (b), or (c) of this definition.

Person means any individual (whether or not a citizen of the United States), corporation, partnership, association, or other entity (whether or not organized or existing under the laws of any State), and any Federal, State, local, or foreign government or any entity of any such government.

Recreational fisherman means a fisherman who does not sell any part of his catch.

Regional Director means the Regional Director, National Marine Fisheries Service, Southeast Region, Duval Building, 9450 Koger Boulevard, St. Petersburg, Florida 33702; telephone 813–893–3141, or his designee.

Secretary means the Secretary of Commerce or a designee.

Spiny lobster means the species *Panulirus argus*.

Tail length means the measurement, with the tail in a straight, flat position, from the anterior end of the exoskeleton ("shell") of the first abdominal (tail) segment to the tip of the closed tail.

U.S.-harvested fish means fish caught, taken, or harvested by vessels of the United States within any fishery regulated under the Magnuson Act.

Vessel of the United States means:

(a) A vessel documented or numbered by the U.S. Coast Guard under U.S. law; or

(b) A vessel under five net tons which is registered under the laws of any State.

§ 640.3 Relation to other laws.

(a) The regulations in this Part apply within the boundaries of any national park, monument, or marine sanctuary in the Gulf of Mexico and South Atlantic FCZ.

(b) Persons affected by these regulations should be aware that other Federal and State statutes and regulations may apply to their activities.

(c) Certain responsibilities relating to data collection and enforcement may be performed by authorized State personnel under a cooperative agreement entered into by the State, the U.S. Coast Guard, and the Secretary.

§ 640.4 Vessel permits and fees.

No permits are required for fishing vessels engaged in commercial fishing for spiny lobsters within the FCZ (but

see vessel identification requirements in § 640.6(a)).

§ 640.5 Recordkeeping and reporting. [Reserved]

§ 640.6 Gear and vessel identification.

(a) Traps, buoys, and all vessels and boats engaged in the spiny lobster trap fishery must be identified by the number and color code issued by the Regional Director, or through Florida's identification system.

(b) An application for a Federal number and color code must be submitted and signed by the owner or operator of the vessel on an appropriate form obtained from the Regional Director. The application must be sumbitted to the Regional Director 45 days prior to the date on which the applicant desires receipt of the number and color code.

(c) Vessels and boats engaged in the spiny lobster trap fishery must permanently and conspicuously display such color code and number in a manner as to be readily identifiable from the air and water; such color representation must be in the form of a circle at least 20 inches in diameter and the identification number must be at least 10 inches high.

(d) Each trap, unless part of a string of traps, must be marked by a floating buoy or a buoy designed to be submerged and automatically released at a certain time. Each string of traps must be marked with a buoy at each end of the string.

(e) Buoys must be of such color as to be easily distinguished, seen, and located; the identification number must be legible and at least 3 inches high on each buoy.

(f) Each trap, can, drum, or similar device must have a legible identification number at least 3 inches high permanently attached as in the case of buoys.

(g) All spiny lobster traps fished in the FCZ will be presumed to be the property of the most recently documented owner.

(h) Upon the sale or transfer of all or part of an owner's interest in spiny lobster traps which are fished in the FCZ, that owner must report the sale or transfer within 15 days to the Regional Director if the identification number and color code for those traps were issued by the Regional Director.

(i) Unmarked spiny lobster traps fished in the FCZ at any time are illegal gear, which may be disposed of in any appropriate manner by the Secretary or the Secretary's designee (including an Authorized Officer). Lines and buoys are considered part of the trap. If owners of these unmarked traps can be ascertained, those owners remain subject to appropriate civil penalties.

§ 640.7 General prohibitions.

It is unlawful for any person to:

(a) Fish for spiny lobster without a vessel number, or falsify or fail to affix and maintain vessel and gear markings, as required by § 640.6;

(b) Fail to comply immediately with enforcement and boarding procedures specified in § 640.8;

(c) Place traps in the water or harvest spiny lobsters from traps before or after the dates specified in § 640.20(a);

(d) Harvest spiny lobster by methods other than traps during the closed season specified in § 640.20 (b) and (c);

(e) Possess spiny lobster or any parts thereof in the FCZ, except as specified in § 640.20;

(f) Retain on board or possess on land any berried lobster taken in the FCZ;

(g) Strip eggs from or otherwise molest any berried lobster;

(h) Pull or tend traps except during the hours specified in § 640.21(b);

(i) Willfully tend, open, pull, or otherwise molest another person's traps, except as provided in § 640.21(b);

(j) Catch or retain more lobsters during the special nontrap recreational fishery than are specified in § 640.21(c);

(k) Retain lobsters smaller than the minimum size, except as specified in § 640.22;

(l) Use traps without degradable panels, or prohibited gear or methods, as specified in § 640.23;

(m) Possess, have custody or control of, ship, transport, offer for sale, sell, purchase, import without a proper bill of lading, land or export any spiny lobster or parts thereof taken or retained in violation of the Magnuson Act, this part, or any other regulation promulgated under the Magnuson Act;

(n) Refuse to permit an Authorized Officer to board a fishing vessel subject to such person's control for purposes of conducting any search or inspection in connection with the enforcement of the Magnuson Act, this part, or any other regulation or permit issued under the Magnuson Act;

(o) Forcibly assault, resist, oppose, impede, intimidate or interfere with any Authorized Officer in the conduct of any search or inspection described in paragraph (n) of this section;

(p) Resist a lawful arrest for any act prohibited by this part;

(q) Interfere with, delay, or prevent, by any means, the apprehension or arrest of another person, knowing that such other person has committed any act prohibited by this part;

(r) Transfer directly or indirectly, or attempt to so transfer, any U.S.-harvested fish to any foreign fishing vessel while such foreign vessel is within the FCZ, unless the foreign fishing vessel has been issued a permit under Section 204 of the Magnuson Act which authorizes the receipt by such vessel of the U.S.-harvested fish of the species concerned; or

(s) Violate any other provision of this part, the Magnuson Act, or any regulation or permit issued under the Magnuson Act.

§ 640.8 Enforcement.

(a) *General.* The operator of any fishing vessel subject to this part shall immediately comply with instructions issued by an Authorized Officer to facilitate safe boarding and inspection of the vessel, its gear, equipment, documents, and catch for purposes of enforcing the Magnuson Act and this part.

(b) *Signals.* Upon being approached by a Coast Guard cutter or aircraft, or any other vessel or aircraft authorized to enforce the Magnuson Act, the operator of a fishing vessel shall be alert for signals conveying enforcement instructions. The VHF–FM radiotelephone is the normal method of communicating between vessels. However, visual methods or loudhailer may be used if the radio does not work. The following signals, extracted from U.S. Hydrographic Office publication H.O. 102 International Code of Signals, may be communicated by flashing light or signal flags:

(1) "L" means "You should stop your vessel instantly."

(2) "SQ3" means "You should stop or heave to; I am going to board you."

(3) "AA AA AA etc." is the call to an unknown station or general call. The operator should respond by identifying his vessel by radio, visual signals, or illuminating his vessel identification required by § 640.6(a) and (b).

(4) "RY–CY" means "You should proceed at low speed. A boat is coming to you."

(c) *Boarding.* A vessel signaled to stop or heave to for boarding must;

(1) Stop immediately and lay to or maneuver in such a way as to permit the Authorized Officer and his party aboard;

(2) Provide a safe ladder for the Authorized Officer and his party, if necessary;

(3) When necessary to facilitate the boarding, provide a man rope, safety line, and illunmination for the ladder; and

(4) Take such other actions as necessary to ensure the safety of the

Authorized Officer and his party and to facilitate the bording.

§ 640.9 Penalties.

Any person or fishing vessel found to be in violation of this part is subject to the civil and criminal penalty provisions and forfeiture provisions of the Magnuson Act, and to 50 CFR Parts 620 (Citations) and 621 (Civil Procedures) and other applicable law.

Subpart B—Management Measures

§ 640.20 Seasons.

(a) *Trap fishery.* (1) The trap fishing season for spiny lobster begins on July 26, one hour before official sunrise, and ends March 31, one hour after official sunset. Traps may be placed in the water on or after July 21, but spiny lobsters may not be harvested until the beginning of the season. Traps must be removed prior to April 6; any spiny lobsters taken between April 1 and April 6 must be returned to the water unharmed.

(2) Traps in the management area during the period between 0001 hours April 6 and 2400 hours July 20 will be considered unclaimed or abandoned property and may be disposed of according to § 640.6(i).

(b) *Non-trap fishery.* The fishing season for other harvesting methods begins 0001 hours July 26 and ends 2400 hours March 31.

(c) *Non-trap recreational fishery.* There is a special non-trap recreational fishing season the first full weekend preceding July 21 from 0001 hours Saturday until 2400 hours Sunday.

(d) *Possession.* Spiny lobsters or any parts thereof may be possessed in the FCZ only during the seasons specified in paragraphs (a), (b), and (c) of this section, unless accompanied by a proper bill of lading or other proof indicating lawful harvest outside the FCZ.

§ 640.21 Harvest limitations.

(a) *Berried lobsters.* All berried (egg-bearing) lobsters must be returned to the water unharmed. Berried lobsters may not be stripped of their eggs or otherwise molested. If found in a trap, a berried lobster may be retained in the trap if it is immediately returned to the water.

(b) *Pulling traps.* (1) Traps may be pulled or tended only during the period beginning one hour before official sunrise and ending one hour after official sunset.

(2) Traps may be pulled or tended only by the owner's vessel, unless the boat tending another person's trap has on board written consent of the trap owner.

(c) *Recreational catch.* During the two-day season described in § 640.20(c), the catch is limited to six lobsters per person per day, up to a maximum of 24 lobsters per boat per day.

§ 640.22 Size limitations.

(a) *Carapace length.* Except as provided in paragraph (b) of this section, spiny lobsters with a carapace length of 3.0 inches or less, or with a tail length of less than 5.5 inches, must be returned immediately to the water unharmed.

(b) *Attractants.* Live lobsters under the minimum size may be held in a shaded live box aboard a vessel for use as attractants in traps. No more than three undersized lobsters for each trap carried on board, or 200 undersized lobsters, whichever is greater, may be retained. Undersized lobsters to be used as attractants in traps may not be retained aboard vessels or boats that are docked.

§ 640.23 Gear limitations.

(a) *Degradable panel.* Traps constructed of material other than wood must have a panel constructed of wood, cotton, or other degradable material located in the upper half of the sides or on top of the trap, that, when removed, will leave an opening in the trap no smaller than the diameter found at the throat or entrance of the trap.

(b) *Prohibited gear and methods.* (1) Spiny lobster may not be taken with spears, hooks, or similar devices, or grear containing such devices. In the FCZ, the possession of speared, pierced, or punctured lobsters is prima-facie evidence that prohibited gear was used to take such lobsters.

(2) Spiny lobsters may not be taken with poisons or explosives.

§ 640.24 Authorized activities.

The Secretary may authorize, for the acquisition of information and data, activities otherwise prohibited by these regulations.

[FR Doc. 82-18224 Filed 6-30-82; 5:06 pm]

BILLING CODE 3510-22-M

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AGENCY PUBLICATION ON ASSIGNED DAYS OF THE WEEK

The following agencies have agreed to publish all documents on two assigned days of the week (Monday/Thursday or Tuesday/Friday). This is a voluntary program. (See OFR NOTICE 41 FR 32914, August 6, 1976.)

Monday	Tuesday	Wednesday	Thursday	Friday
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DOT/FAA	USDA/REA		DOT/FAA	USDA/REA
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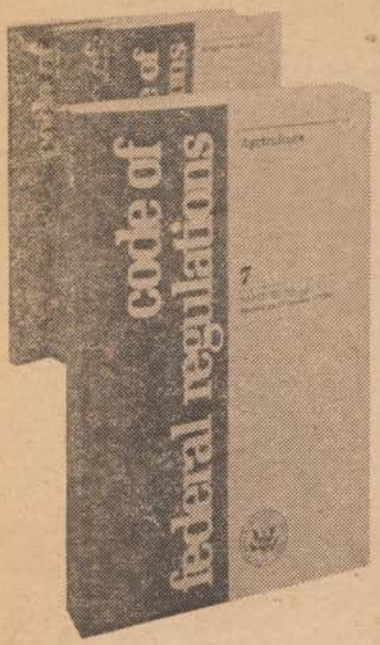
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List of Public Laws

Last Listing June 30, 1982

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