and low distortion magnifications at 140–60,000x with 140 to 1000x in the normal microscopic range which permits an overlap of light and electron microscopy. The article is also designed for confident use [through ease of operation] by beginning students with a minimum of detailed programming.

Domestic instruments available at the time the article was ordered were the Model EMU–4C, a relatively complex instrument designed for the use of an expert which provides low distortion magnification at 500x and higher, available from the Adam David Company and the Elektros Incorporated Model ETEM–101, a relatively simple low resolution instrument. The Department of Health, Education, and Welfare (HEW) advised in its memorandum dated October 24, 1974, that for the applicant's intended uses (1) 60 KV accelerating voltage for adequate contrast, (2) low magnifications overlapping the optical microscope and (3) simplicity and ease of operation are pertinent. HEW also advised that the article provides better low magnification range capabilities (140x–1000x range) and a higher accelerating voltage (60KV) than the ETEM–101. In addition HEW advised that the Model EMU–4C is too complex for the applicant's educational purposes.

We, therefore, find that neither the Model EMU–4C nor the Model ETEM–101 was of equivalent scientific value to the foreign article for such purposes as the article is intended to be used at the time the article was ordered.

The Department of Commerce knows of no other instrument or apparatus of equivalent scientific value to the foreign article, for such purposes as this article is intended to be used, which was being manufactured in the United States at the time the article was ordered.

(Catalog of Federal Domestic Assistance Program No. 11.105, Importation of Duty-Free Educational and Scientific Materials)

A. H. STUART,
Director,
Special Import Programs Division.

[FR Doc.74–27865 Filed 11–27–74;8:45 am]

YALE UNIVERSITY

Decision on Application for Duty-Free Entry of Scientific Article

The following is a decision on an application for duty-free entry of a scientific article pursuant to section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89–651, 80 Stat. 897) and the regulations issued thereunder as amended (37 FR 3892 et seq.).

A copy of the record pertaining to this decision is available for public review during ordinary business hours of the Department of Commerce, at the Office of Import Programs, Department of Commerce, Washington, D.C. 20230.

Docket numer: 75–00030–90–90000. Applicant: Yale University, Purchasing Department, 260 Whitney Avenue, New Haven, Connecticut 06520. Article: Rotating Anode X-Ray Diffraction System, Model RU–200 PL. Manufacturer: Rigaku Denki Co., Japan. Intended use of article: The article is intended to be used for studies of purified enzymes, including hexokinase and alkaline phosphatase, and membranes to determine the detailed three dimensional structure of the molecule and its complexes in order to understand the specificity, mechanism chemistry, and stability of the enzyme. The article will also be used in the courses: Molecular Biophysics and Biochemistry for teaching purposes.

Comments: No comments have been received with respect to this application.

Decision: Application approved. No instrument or apparatus of equivalent scientific value to the foreign article, for such purposes as this article is intended to be used, is being manufactured in the United States.

Reasons: The foreign article provides a focused spot of minimal size (point foci 0.1 x 0.1 millimeters squared) and a rotating anode target for maximum X-ray brilliance. The Department of Health, Education, and Welfare (HEW) advised in its memorandum dated November 4, 1974 that the capabilities described above are pertinent to the applicant's purposes. HEW also advised that it knows of no domestic instrument of equivalent scientific value to the foreign article for such purposes as the article is intended to be used.

The Department of Commerce knows of no other instrument or apparatus of equivalent scientific value to the foreign article, for such purposes as this article is intended to be used, which is being manufactured in the United States.

(Catalog of Federal Domestic Assistance Program No. 11.105, Importation of Duty-Free Educational and Scientific Materials)

A. H. STUART,
Director,
Special Import Programs Division.

[FR Doc.74–27868 Filed 11–27–74;8:45 am]

Office of the Secretary

SEMINAR ON INSTITUTIONAL AND LEGAL CONSTRAINTS TO COOPERATIVE ENERGY R&D

Notice of Meeting

The U.S. Department of Commerce and the Industrial Research Institute will co-sponsor a seminar on institutional and legal constraints to cooperative energy research and development. The seminar is scheduled for December 16, 1974, at the Main International Conference Room, Department of State, 2201 C Street, NW., Washington, D.C.

Advanced registration is required. The registration fee of $20.00 includes luncheon at the Department of State.

To register, send your name, title, affiliation, address and check for $20.00 to Commerce Technical Advisory Board, U.S. Department of Commerce, Room 3877, 14th Street and Constitution Avenue, NW., Washington, D.C. 20230. Make checks payable to "Seminar on Cooperative R&D." Please respond as quickly as possible. Space is limited and reservations will be accepted on a first-come first-served basis. Cancellations may be made if received by December 10, 1974.

Background. Our Nation is now involved in a thorough examination of the deployment of our national resources to meet our long term energy requirements. Because of the high risk and large investments involved, many experts feel that a number of industry-Government and multicompany cooperative research and development programs should be considered.

At the recommendation of the Commerce Technical Advisory Board, the Department of Commerce and the Industrial Research Institute are sponsoring a seminar to provide an opportunity for open dialogue between industry and Government on this important subject. Industry spokesmen will have an opportunity to indicate their potential interest in joint ventures and to express their percepion of the major barriers to such ventures. Government spokesmen can spell out the acceptable approaches to joint ventures. Both sides can explore the importance of joint ventures to our future development of energy resources.

AGENDA

Monday Morning, December 16, 9:30 a.m.

CALL TO ORDER

Betsy Ancker-Johnson, Assistant Secretary for Science and Technology, U.S. Department of Commerce.

Keynote Speaker: Honorable Frederick B. Dent, Secretary, U.S. Department of Commerce.

Session Chairman: S. William Gouse, Jr., Director, Office of R&D, and Acting Director, Office of Coal Research, U.S. Department of the Interior.

OVERVIEW STATEMENTS ON THE CONSTRAINTS TO FORMATION OF R&D CONSORTIA

William D. Carey, Member of CTAB, Vice President, Arthur D. Little, Inc.; F. L. Cuthbert, Principal Investigator, Industrial Research Institute.

FEAR OF ANTITRUST VIOLATIONS AS DETERRENTS

Cases Presented by: Dayton H. Clewell, Senior Vice President, Mobil Oil Corporation; David Swan, Vice President-Technology, Kennecott Copper Corporation.

COFFEE BREAK

Government Speakers:

Thomas E. Kauper, Assistant Attorney General for the Antitrust Division, U.S. Department of Justice; Karl E. Bakke, General Counsel, U.S. Department of Commerce.

OPPORTUNITY FOR QUESTIONS ON THE CASES

12:30 P.M., LUNCH, DEPARTMENT OF STATE

Monday Afternoon, December 16, 2 p.m.

Session Chairman: Donald W. Collier, IRI Vice President—Research, Borg-Warner Corporation (Past President, IRI).

GOVERNMENT PATENT POLICY AS A DETERRENT IN THE FORMATION OF R&D CONSORTIA

Case Presented by: Jason M. Salsbury, Director, Chemical Research, American Cyanamide Company.

Government Speaker: Betsy Ancker-Johnson, Chairman, Government Patent Policy Committee.

GOVERNMENT DELAYS AS A DETERRENT

Case Presented by: Philip C. White, General Manager, Research, Standard Oil Company (Indiana) (Past President, IRI).

GENERAL DISCUSSION

Panel to include all speakers

Anticipated Adjournment Time: 4:30 p.m.

Further information may be obtained by writing Dr. Bruce Robinson or Mrs. Florence Feinberg, Room 3877, Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, D.C. 20230, or by calling either at (202) 967–5065.

BETSY ANCKER-JOHNSON,
Assistant Secretary of Commerce for Science and Technology.

NOVEMBER 20, 1974.

[FR Doc.74-27870 Filed 11-27-74;8:45 am]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[FAP 5B3051]

BORG-WARNER CORP.

Filing of Petition for Food Additive

Pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 409(b(5), 72 Stat. 1786; 21 U.S.C. 348 (b)(5)), notice is given that a petition (FAP 5B3051) has been filed by Carr, Bonner, O'Connell, Kaplan and Thompson, 900 Seventeenth St., NW., Washington, DC 20006, on behalf of Borg-Warner Corp. proposing that the food additive regulations (21 CFR Part 121) be amended to provide for the safe use of an acrylonitrile/butadiene/styrene copolymer in contact with food other than carbonated beverages. The environmental impact analysis report and other relevant material have been reviewed, and it has been determined that the proposed use of the additive will not have a significant environmental impact. Copies of the environmental impact analysis report may be seen in the office of the Assistant Commissioner for Public Affairs, Rm. 15B–42 or the office of the Hearing Clerk, Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20852, during working hours, Monday through Friday.

Dated: November 21, 1974.

HOWARD R. ROBERTS,
Acting Director, Bureau of Foods.

[FR Doc.74-27871 Filed 11-27-74;8:45 am]

INSPECTION AND RELATED SERVICES OF DRUGS MANUFACTURED IN FOREIGN COUNTRIES

Agreement Between the Defense Supply Agency and the Food and Drug Administration

Pursuant to the notice published in the FEDERAL REGISTER of October 3, 1974 (39 FR 35697) that future agreements or memoranda of understanding between the Food and Drug Administration and others would be published in the FEDERAL REGISTER, the Commissioner of Food and Drugs issues the following notice:

An interagency agreement was approved and accepted by the Food and Drug Administration and the Defense Supply Agency on October 15, 1974 and October 22, 1974, respectively. This agreement, which provides for reimbursement by the Defense Supply Agency to the Food and Drug Administration for performing certain inspection and related services relating to drugs manufactured in foreign countries, reads as follows:

INTERAGENCY AGREEMENT BETWEEN THE DEFENSE SUPPLY AGENCY AND THE FOOD AND DRUG ADMINISTRATION

The Defense Supply Agency (hereinafter called DSA) agrees to reimburse the Food and Drug Administration (hereinafter called FDA) for services as provided and described herein.

Purpose: To provide for DSA certain inspection and related services of drugs manufactured in foreign countries.

I. STATUTORY RIGHTS AND OBLIGATIONS

Any and all statutory rights and obligations of FDA with respect to licensed biologics, certifiable antibiotics and drugs and with respect to the evaluation and issuance, by FDA, of New Drug Applications, are in no way affected by this agreement.

II. SERVICES TO BE PERFORMED

A. *FDA agrees:*

To inspect, at DSA's request, drug manufacturing plants and facilities of foreign manufacturers being considered by DSA as possible suppliers of drugs.

1. Such inspection by FDA will be performed by qualified FDA personnel.

2. Such inspections will be made for the purpose of appraising and evaluating the quality assurance capability and performance in relation to compliance with the Current Good Manufacturing Practice Regulations (21 CFR 133), where applicable, and requirements of solicitations for bids and resulting contracts. Such inspections will also identify the existence of foreign patents or licenses, if materials to be used are from Communist controlled areas, whether clients are in compliance with applicable approved new drug applications and whether the specification requirements of DSA can be met.

3. FDA will furnish DSA with a written report of its findings. The report will make a recommendation as to whether the firm surveyed is qualified to produce the pertinent supplies as required by solicitation for bid and contracts. These reports will be furnished within 30 days or an earlier mutually agreed upon time. If written reports cannot be furnished within the agreed upon time, FDA will telephone results of inspection to DSA and follow with written confirmation.

B. *DSA agrees:*

1. To furnish written requests for inspection services.

2. To furnish FDA with an annual estimate of the number of inspections to be required, the estimate not to be binding on either party.

3. To notify FDA of any specific changes in DSA contracting and purchasing arrangements which might affect this agreement.

4. To furnish FDA concurrent with requests for foreign inspection any background or inspectional data, as available in-house, for any foreign inspection conducted by FDA under this agreement.

5. To furnish FDA copies of all current drug and pharmaceutical specifications used in procurement. This will include, but not be limited to, Federal specification, military purchase descriptions, etc.

C. *Revisions:*

1. Additional procedures and revisions as may be necessary for the implementation of this agreement and to effectuate the intention of the parties may be developed jointly by FDA and DSA. Such revisions shall become effective on such date as is mutually agreed upon by the parties.

2. In the event that the time requirements expressed herein cannot be met by FDA, the DSA will be advised promptly.

D. *Other Provisions:*

1. In the event FDA has inspected the facilities of the foreign manufacturer within one (1) calendar year of the date of the inspection request from DSA, a written report of that inspection will be furnished DSA. DSA will review the report and if additional information is required, FDA will furnish the required information or perform the supplementary inspection necessary.

2. Nothing in this agreement will preclude DSA representatives from making visits to foreign suppliers with FDA or separately.

3. FDA personnel carrying out inspection services will be made available as witnesses or be permitted to supply information and data to DSA for GAO protest, Armed Services Board of Contract Appeal cases and such other cases where expertise is required.

III. LIAISON OFFICERS

A. Mr. Gordon J. Keefe, Special Project Officer for Medical Materiel Management, DSAH–PV, Headquarters Defense Supply Agency, Cameron Station, Alexandria, Virginia 22314. Telephone: (202) 274–6441.

B. Mr. Richard McDermaid, Foreign Inspection Program, HFO–120, Food and Drug Administration, 5600 Fishers Lane, Rockville, Maryland 20852. Telephone: (301) 443–1855.

IV. PERIOD OF AGREEMENT

This agreement, when accepted by both parties, will have an effective date beginning July 1, 1974, and continue for an indefinite period of time, and may be modified by mutual consent of both parties or may be terminated by either party upon a thirty (30) day advance written notice to the other.

V. COST

DSA shall reimburse FDA an amount not to exceed $20,000 for FY 75 services as outlined in this agreement.

VI. FUNDING

A. Billing will be based on the rates effective under the Food and Drug Administration's user charges policy at the time service is rendered and shall be based on actual time records covering each inspection analysis performed by FDA. Such billings shall designate the service performed (i.e., inspection of facilities, testing of samples, etc.), name of manufacturer or bidder involved, and shall itemize the charges by designating the type of cost (i.e., salaries, per diem, transportation, etc.), and the computation of the sum billed.

B. FDA shall submit vouchers quarterly, on Standard Form 1080, and mail to:

Defense Personnel Support Center, 2800 South 20th Street, Philadelphia, Pennsylvania 19101, Attn: Medical Materiel Directorate DPSC–A.

C. Administrative billing requirements shall be in accordance with GAO Policy and Procedure, Title 7, section 8.4.

VII. AUTHORITY

This agreement is entered into under the authority of the Economy Act approved June 30, 1932, as amended 31 U.S.C. 686.

Approved and accepted for the Food and Drug Administration.

EDWARD A. STEFFEE,
Associate Commissioner for Administration.

Date: October 15, 1974.

Approved and accepted for the Defense Supply Agency.

P. F. COSGROVE, Jr.,
Deputy Director.

Date: October 22, 1974.

Effective date. This agreement became effective July 1, 1974.

Dated: November 22, 1974.

SAM D. FINE,
Associate Commissioner for Compliance.

[FR Doc.74-27873 Filed 11-27-74;8:45 am]

INVESTIGATIONAL USE OF DRUGS BY THE DEPARTMENT OF DEFENSE

Memorandum of Understanding Between the Food and Drug Administration and the Department of Defense

Pursuant to the notice published in the FEDERAL REGISTER of October 3, 1974 (39 FR 35697) that future agreements or memoranda of understanding between the Food and Drug Administration and others would be published in the FEDERAL REGISTER, the Commissioner of Food and Drugs issues the following notice:

A Memorandum of Understanding was approved and accepted by the Food and Drug Administration and the Department of Defense on August 19, 1974 and October 24, 1974, respectively, replacing one that was signed in 1964. This memorandum, which establishes procedures to be followed by the Department of Defense and the Food and Drug Administration regarding the investigational use of drugs by the Department of Defense, reads as follows:

MEMORANDUM OF UNDERSTANDING BETWEEN THE FOOD AND DRUG ADMINISTRATION AND THE DEPARTMENT OF DEFENSE CONCERNING INVESTIGATIONAL USE OF DRUGS BY THE DEPARTMENT OF DEFENSE

The Department of Defense (hereinafter called DOD) and the Food and Drug Administration of the Department of Health, Education, and Welfare (hereinafter called FDA) hereby jointly agree to the terms and conditions as described herein.

Purpose. To establish the procedures to be followed by the Department of Defense and the Food and Drug Administration regarding the investigational use of drugs by the Department of Defense. This Memorandum of Understanding, when signed by representatives of the agencies, replaces the current Memorandum of Understanding signed in 1964.

Background. Section 505(a) of the Federal Food, Drug, and Cosmetic Act, as amended by section 104 of Pub. L. 87-781, 76 Stat. 784; 21 U.S.C. 355(a) (1970) established procedures for the approval required before a new drug can be introduced into interstate commerce. Section 505(i) of the act (21 U.S.C. 355(i)) establishes exemptions from the approval procedures for drugs which will be used only for manufacture of other drugs or for investigational purposes. That section provides the authority for the regulations to give effect to the general guidance of the statute, promulgated in 21 CFR 312.1 (formerly 130.3) by Secretary of Health, Education, and Welfare. These regulations establish the procedure and prescribe the necessary forms to be filed in order to exempt drugs to be used only for investigational purposes from the approval procedures of the Federal Food, Drug, and Cosmetic Act.

A Memorandum of Understanding was executed by the Departments of Defense and Health, Education, and Welfare in 1964 to state the procedures that will be followed to ensure that the requirements of the Federal Food, Drug, and Cosmetic Act and the investigational drug regulations issued under that act are fully met without jeopardizing or impeding the requirements of national security or the requirements of Federal laws and regulations relating to such use of drugs.

The Surgeon General of each Military Department has established within his office a formal "Review Board" which carefully considers each research proposal from its own agency or from outside contractors or grantees which involve the use of human subjects in the clinical investigation of new drugs. Each "Review Board" is staffed with highly qualified professionals capable of performing competent review of such research proposals to ensure adequate protection of human subjects. The DOD assumes full responsibility for the protection of all human subjects involved in research under its sponsorship whether this involves investigational drugs or other hazards. Before a clinical test may be performed with an investigational drug, the plan of the test and other pertinent details must be submitted to the appropriate "Review Board," the Board must indicate its approval, and the approval must be confirmed by the appropriate Surgeon General.

Experience in operating under this Memorandum of Understanding from 1964 to 1974 indicates that the DOD adheres to the standards of the FDA; that human subjects have been adequately protected in the DOD-sponsored studies; that the DOD has been able to effectively carry out its responsibilities for national security without compromise of the intent of the above-cited statutes and regulations; and that certain exemptions provided the DOD from meeting the ordinary requirements of the investigational new drug regulations are no longer necessary. Accordingly, the DOD and the FDA agree to the following new procedures to meet the requirements of the Federal Food, Drug, and Cosmetic Act concerning investigational use of drugs:

I. SUBSTANCE OF AGREEMENT

The Food and Drug Administration and the Department of Defense agree that:

1. Clinical investigations that are classified for reasons of national security will not require the filing of a formal "Claim for Exemption" to the FDA. The DOD shall be solely responsible for determining the security classification of such research projects. Approval by the appropriate "Review Board" and Surgeon General of a test classified for reasons of national security will automatically exempt the drug being employed from the application of the new drug section of the Food, Drug, and Cosmetic Act during such investigational study. The DOD will report to the FDA unclassified findings associated with such studies which the FDA should be aware of in order to make a sound evaluation of non-classified studies proposed on the same or similar drugs. Additionally, the DOD will discuss its classified investigations of drugs on a frequent basis with personnel from the FDA who have proper security clearance.

2. When the unique requirements of the military dictate the extensive use in military personnel of drugs which, though not yet approved, have been tested under the investigational new drug regulations sufficiently to establish with reasonable certainty their safety and efficacy, special ad hoc review and approval for such use will be effected expeditiously through joint action by representatives of the Department of Defense and the Food and Drug Administration to ensure timely response to the military need. The DOD will report to the FDA findings associated with such use which the FDA should be aware of in order to make a sound evaluation of other studies proposed on the same or similar drug.

3. In all other cases involving the clinical testing of investigational drugs under programs sponsored by the DOD and conducted either by the DOD within its own research facilities, or for the DOD by a contractor or grantee, the ordinary provisions of 21 CFR 312.1 (formerly 130.3) of the Code of Federal Regulations governing the investigational use of new drugs in human beings shall be followed.

II. NAME AND ADDRESS OF PARTICIPATING AGENCIES

A. Department of Defense
Washington, DC 20314

B. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20852

III. LIAISON OFFICERS

A. Col. Edward J. Huycke
Director, Professional Services
Office of the Assistant Secretary of Defense (Health and Environment)
Washington, DC 20301
Telephone: (202) 697-9658

B. John Jennings, M.D.
Associate Commissioner for Medical Affairs, HFM-1
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20852
Telephone: (301) 443-4124

IV. PERIOD OF AGREEMENT

This agreement, when accepted by both parties, covers an indefinite period of time and is subject to modification by mutual consent by both parties.

V. AUTHORITY

This agreement is entered into under the authority of the Economy Act, approved June 30, 1932, as amended, 31 U.S.C. 686.

Approved and accepted for the Department of Defense.

V. MCKENZIE,
Acting Assistant Secretary, Health and Environment.

Date 10/24/74

Approved and accepted for the Food and Drug Administration.

A. M. SCHMIDT,
Commissioner, Food and Drug Administration.

Date 8/19/74

Effective date. This Memorandum of Understanding became effective on October 24, 1974.

Dated: November 21, 1974.

SAM D. FINE,
Associate Commissioner for Compliance.

[FR Doc.74-27872 Filed 11-27-74;8:45 am]