System Devices Panel, an FDA advisory committee, which recommended approval of the application. On July 28, 1980, FDA approved the application by a letter to the sponsor from the Acting Director of the Bureau of Medical Devices.

A summary of the safety and effectiveness data on which FDA's approval is based is on file in the office of the Hearing Clerk (address above) and is available upon request from that office. Requests should be identified with the name of the device and the Hearing Clerk docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition under section 515(g) of the act (21 U.S.C. 360e(g)) for administrative review of FDA's decision to approve this application. A petitioner may request either a formal hearing under Part 12 (21 CFR Part 12) of FDA's administrative practices and procedures regulations or a review of the application and of FDA's action by an independent advisory committee of experts. A petition must be in the form of a petition for reconsideration of FDA action under § 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish the notice of its decision in the Federal Register. If FDA grants the petition, the notice will state the issue to be reviewed, the form of review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before October 14, 1980, file with the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, four copies of each petition and supporting data and information, identified with the name of the device and the Hearing Clerk docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 3, 1980.

Joseph P. Hile,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-27936 Filed 9-11-80; 8:45 am]

BILLING CODE 4110-03-M

[Docket No. 80N-0329]

PCB Contaminants; Cooperative Agreement

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration announces its intent to award a Cooperative Agreement to the Health and Welfare, Canada. The purpose of the agreement is to provide financial assistance to continue its study of PCB toxicity in monkeys. The cost of this Cooperative Agreement will be $65,700 for the first year. It is estimated that this agreement will extend for a total of 2 years.

FOR FURTHER INFORMATION CONTACT: Sandra Case, State Contracts and Assistance Agreements Section (HFA-513), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-6604.

SUPPLEMENTARY INFORMATION: This Cooperative Agreement is awarded under section 301 of the Public Health Service Act (42 U.S.C. 241).

This study will provide information for evaluation of an international problem, i.e., the significance of the entry of environmental PCB's into the food supply, and the occurrence of PCB's in mother's milk. Since one of the major areas of contamination is the Great Lakes, the cooperative nature of the study represents a significant move to the pooling of scientific effort to investigate a serious problem that is of concern to both the United States and Canada.

The work to be carried out by the FDA contribution will directly support the maintenance of test animals and analytical work on tissues derived from the test animals. The animals will be housed in the laboratories of the Toxicology Research Division, Health Protection Branch (HPB), in a section that has been specifically designed for the maintenance of subhuman primates, in the recently completed New Research Center. The HPB has had previous experience in the maintenance of primates as a result of these extensive studies with other environmental contaminants such as lead and methylmercury. Thus the funds will be used for an integral part of the HPB study, and can only be successfully utilized if the whole project is controlled by the HBP.

Dated: September 3, 1980.

Joseph P. Hile,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-27937 Filed 9-11-80; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CA 7061 WR]

California; Proposed Continuation of Withdrawal and Opportunity for Public Hearing

September 5, 1980.

As a result of the review made pursuant to Section 204(l) of the Federal Land Policy and Management Act of 1976 (90 Stat. 2754; 43 U.S.C. 1714), the Bureau of Land Management, U.S. Department of the Interior, proposes to continue the following Public Water Reserve withdrawal:

San Bernardino Meridian, California

T. 18 S., R. 7 E.,
Sec. 9, NW¼NE¼;
Sec. 18, Lot 7.

The area described aggregates approximately 85.19 acres in San Diego County, California.

This withdrawal was created by Executive Order of December 31, 1912, which segregated the land from settlement, nonmetalliferous location, sale, or entry in order to preserve the public lands and the water thereon for general public use and benefit.

No change in the segregative effect of the withdrawal or the use of the lands is proposed.

For a period of 30 days from the date of publication of this notice, all persons who wish to submit comments, suggestions, or objections in connection with the proposed withdrawal continuation may present their views in writing to the undersigned authorized officer of the Bureau of Land Management.

Notice is hereby given that an opportunity for a public hearing is afforded in connection with the proposed withdrawal continuation. All interested persons who desire to be heard on the proposed continuation must submit a written request for a hearing to the undersigned officer. If the State Director, in his discretion, determines that a public hearing is justified, a notice will be published in the Federal Register giving the time and place of such hearing. The public hearing will be scheduled and conducted in accordance with BLM Manual, Section 2351.16B.