ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Kelco Division of Merck & Co., Inc., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of gellan gum as a stabilizer and thickener in foods, generally.

FOR FURTHER INFORMATION CONTACT: Blondell Anderson, Center for Food Safety and Applied Nutrition (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: Under 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 7A4022) has been filed by Kelco Division of Merck & Co., 8355 Aero Dr., San Diego, CA 92123, proposing that 21 CFR Part 172—Food Additives Permitted for Direct Addition to Food for Human Consumption be amended to provide for the safe use of gellan gum as a stabilizer and thickener in foods, generally.

The potential environmental impact of this action is being reviewed. If the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c).

Dated: November 19, 1987.

Richard J. Ronk,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 87-27609 Filed 12-1-87; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 87N-0229]

Opportunity for Hearing on Proposal to Withdraw Approval of a New Drug Application for an Anthelmintic Drug Product

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing an opportunity for hearing on a proposal to withdraw approval of a new drug application (NDA) for an anthelmintic drug product that has been established as generally recognized as safe and effective in a final over-the-counter (OTC) drug monograph under 21 CFR Part 330 and is no longer considered to be a "new drug" as defined in section 201(p) of the Federal Food, Drug, and Cosmetic Act (the act). Products that are not considered "new drugs" do not require an approved NDA for marketing.

DATES: Hearing requests are due on January 4, 1988; data or information in support of hearing requests are due on February 1, 1988.

ADDRESS: Requests for hearing, supporting data, and other comments should be identified with Docket No. 87N-0229, and submitted to: Dockets Management Branch (HFA-305), Rm. 4-62, Food and Drug Administeration, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFN-210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8000.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 1, 1986 (51 FR 27756), FDA published a final monograph for OTC anthelmintic drug products. That monograph became effective on February 2, 1987, and establishes the conditions under which OTC anthelmintic drug products are generally recognized as safe and effective and are not misbranded, and which therefore may be marketed without an approved NDA. After February 2, 1987, and OTC anthelmintic drug product must either comply with such conditions or, if it does not, be considered a new drug and be shown to be safe and effective and not misbranded for its claimed uses pursuant to an approved NDA.

Section 201(p) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(p)) defines a "new drug as "any drug" * * * the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof, * * *; or * * * has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions." Under section 505(a) of the act (21 U.S.C. 355(a)), a new drug may not be introduced or delivered for introduction into interstate commerce unless an approved application is effective with respect to such drug.

It is unnecessary for any manufacturer or distributor of a drug product that complies with the requirements of the final OTC drug monograph to submit a supplemental, abbreviated, or full NDA covering such a product. In accordance with 21 CFR 330.10, any such product may lawfully be marketed without an approved NDA. Accordingly, reformulation and/or relabeling, without prior agency approval, to meet the requirements of the final OTC drug monograph is sufficient for the lawful marketing of any OTC anthelmintic drug product subject to the monograph.

The agency has classified gentian violet and hexylresorcinol as nonmonograph ingredients for anthelmintic use. All NDA's for the use of these ingredients as an anthelmintic have been withdrawn prior to the publication of this notice.

One prescription drug product subject to an NDA was submitted by its manufacturer for consideration under the OTC drug review. The ingredient and all the indications for use that were subject to that NDA are now included in the final monograph for OTC anthelmintic drug products. This drug product when marketed pursuant to the conditions of the final monograph for OTC anthelmintic drug products is no longer a new drug and, therefore, is not eligible for an NDA under section 505 of the act (21 U.S.C. 355). Accordingly, the agency is proposing to withdraw approval for the following NDA for this product.

NDA	Drug	Firm
16-883	Antiminth (Pyrantel Pamoate).	Roerig Division Pfizer, Inc., New York, NY 10017

Therefore, notice is hereby given to the holder of the NDA identified above and all other interested persons that the Director of the Center for Drug Evaluation and Research, proposes to issue an order under section 505(e) of the act (21 U.S.C. 355(e)), withdrawing approval of the NDA and all amendments and supplements thereto. The Director is proposing to withdraw this NDA on the grounds that FDA's publication of the final monograph for OTC anthelmintic drug products determined the conditions of safety and effectiveness within the meaning of 21 CFR Part 330 and thereby established that the drug ingredient is considered generally recognized by qualified experts as safe and effective for use as an anthelmintic by the public and is not misbranded. Accordingly, the agency has determined that pyrantel pamoate for anthelmintic use is not a "new drug" as defined in section 201(p) of the act. This notice of opportunity for hearing encompasses all issues relating to the legal status of the drug products subject to it.

In accordance with the provisions of section 505 of the act (21 U.S.C. 355) and the regulations promulgated thereunder (21 CFR Parts 310 and 314), the applicant is hereby given an opportunity for a hearing to show why approval of the new drug application should not be withdrawn and an opportunity to raise, for administrative determination, all issues relating to the legal status of the drug product named above.

An applicant who decides to seek a hearing shall file: (1) On or before January 4, 1988 a written notice of appearance and request for hearing, and (2) on or before February 1, 1988 the data, information, and analyses relied on to justify a hearing, as specified in 21 CFR 314.200. Any other interested person may also submit comments on this notice. The procedures and requirements governing this notice of opportunity for hearing; a notice of appearance and request for hearing; a submission of data, information, and analyses to justify a hearing; other comments; and a grant or denial of hearing are contained in 21 CFR 314.200.

The failure of an applicant to file timely written notice of appearance and request for hearing, as required by 21 CFR 314.200, constitutes an election by that person not to use the opportunity for a hearing concerning the action proposed, and a waiver of any contentions concerning the legal status of that person's drug product. Any such drug product may not lawfully be marketed except in compliance with Subpart B of 21 CFR Part 357. The Food and Drug Administration will initiate appropriate regulatory action to remove such noncomplying drug products from the market promptly after the applicable effective date of the final monograph or after a final decision is reached on this proposal to withdraw any affected NDA, as the situation may be.

A request for a hearing may not rest upon mere allegations or denials, but must set forth specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. If it conclusively appears from the face of the data, information, and factual analyses in the request for the hearing that there is no genuine and substantial issue of fact which precludes the withdrawal of approval of the application, or when a request for hearing is not made in the required format or with the required analyses, summary judgment will be entered against the person(s) who requests the hearing, making findings and conclusions, and denying a hearing.

All submissions pursuant to this notice shall be filed in triplicate, with the Docket Management Branch, Food and Drug Administration (HFA-305), Room 4-62, 5600 Fishers Lane, Rockville, MD 20857.

All submissions pursuant to this notice, except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. Any scheduled oral hearing will be announced in the Federal Register.

This notice is issued pursuant to provisions of the Federal, Food, Drug, and Cosmetic Act (sec. 505, 52 Stat. 1052-53, as amended (21 U.S.C. 355)), and under the authority delegated to the Director of the Center for Drug Evaluation and Research (21 CFR 5.82).

Dated: November 22, 1987.

Carl Peck,

Director, Center for Drug Evaluation and Research.

[FR Doc. 87-27610 Filed 12-1-87; 8:45 am]

BILLING CODE 4160-01-M

National Institutes of Health

National Heart, Lung, and Blood Institute; Meeting of the National High Blood Pressure Education Program Coordinating Committee

Notice is hereby given of the meeting of the National High Blood Pressure Education Program Coordinating Committee, sponsored by the National Heart, Lung, and Blood Institute, on January 22, 1988, from 8:30 a.m. to 1 p.m., at the Bethesda Hyatt Regency Hotel, One Bethesda Metro Center, Bethesda, Maryland 20814, (301) 657-1234.

The entire meeting is open to the public. The Coordinating Committee is meeting to define the priorities, activities, and needs of the participating groups in the National High Blood Pressure Education Program. Attendance by the public will be limited to space available.

For the detailed program information, agenda, list of participants, and meeting summary, contact: Dr. Edward J. Roccella, Coordinator, National High Blood Pressure Education Program, Office of Prevention, Education, and Control, National Heart, Lung, and Blood Institute, National Institutes of Health, Building 31, Room 4A05, Bethesda, Maryland 20892, (301) 496-0554.

Dated: November 24, 1987.

James B. Wyngaarden,

Director, NIH.

[FR Doc. 87-27665 Filed 12-1-87; 8:45 am]

BILLING CODE 4140-01-M

National Institute of Arthritis and Musculoskeletal and Skin Diseases; Amended Meeting Notice

Notice is hereby given that the November 12, 1987, meeting of the Arthritis and Musculoskeletal and Skin Diseases Special Grants Review Committee (AMS) of the National Institute of Arthritis and Musculoskeletal and Skin Diseases was cancelled due to inclement weather.

Due to prior commitments of several members, the meeting has been rescheduled as a closed telephone conference for December 15, 1987. The conference will be closed in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5, U.S.C. and sec. 10(d) of Pub. L. 92-463, for the review, discussion and evaluation of individual research grant applications. These applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Program No. 13.846, project grants in arthritis, musculoskeletal and skin diseases research, National Institutes of Health)

Dated: November 24, 1987.

Betty J. Beveridge,

Committee Management Officer, NIH.

[FR Doc. 87-27666 Filed 12-1-87; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of Administration

[Docket No. N-87-1758]

Submission of Proposed Information Collections to OMB

AGENCY: Office of Administration, HUD.

ACTION: Notices.

SUMMARY: The proposed information collection requirements described below have been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposals.

ADDRESS: Interested persons are invited to submit comments regarding these proposals. Comments should refer to the proposal by name and should be sent to: John Allison, OMB Desk Officer, Office of Management and Budget, New