Board of Governors of the Federal Reserve System, October 31, 1980.

Jefferson A. Walker,

Assistant Secretary of the Board.

[FR Doc. 80-34736 Filed 11-6-80; 8:45 am]

BILLING CODE 6210-01-M

GENERAL ACCOUNTING OFFICE

Regulatory Reports Review; Receipt of Report Proposal

The following request for clearance of a report intended for use in collecting information from the public was received by the Regulatory Reports Review Staff, GAO, on October 31, 1980. See 44 U.S.C. 3512 (c) and (d). The purpose of publishing this notice in the Federal Register is to inform the public of such receipt.

The notice includes the title of the request received; the name of the agency sponsoring the proposed collection of information; the agency form number, if applicable; and the frequency with which the information is proposed to be collected.

Written comments on the proposed NRC request are invited from all interested persons, organizations, public interest groups, and affected businesses. Because of the limited amount of time GAO has to review the proposed request, comments (in triplicate) must be received on or before November 25, 1980, and should be addressed to Mr. John M. Lovelady, Senior Group Director, Regulatory Reports Review, United States General Accounting Office, Room 5106, 441 G Street, NW., Washington, DC 20548.

Further information may be obtained from Patsy J. Stuart of the Regulatory Reports Review Staff, 202-275-3532.

Nuclear Regulatory Commission

The NRC requests clearance of a revision of 10 CFR Part 20, Standards for Protection Against Radiation, Burial of Small Quantities of Radionuclides. The revision to Part 20 is the deletion of § 20.304 which allows licensees to bury small quantities of radionuclides without prior approval by NRC. Deletion of 10 CFR 20.304 will increase the number of licensees who must submit applications for burial of radionuclides as required by section 20.302. The NRC estimates that an additional 26 licensees will be required to submit applications and that 24 hours will be required to prepare each application.

John M. Lovelady,

Senior Group Director, Regulatory Reports Review.

[FR Doc. 80-34774 Filed 11-6-80; 8:45 am]

BILLING CODE 1610-01-M

GENERAL SERVICES ADMINISTRATION

Privacy Act of 1974; Amended System of Records

AGENCY: General Services Administration.

ACTION: Notification of amended system of records.

SUMMARY: The purpose of this document is to give notice, pursuant to the provisions of the Privacy Act of 1974, 5 U.S.C. 552a, of intent to amend a system of records that is maintained by GSA. The system of records, Investigation Case Files GSA/ADM-24, will be amended to change the records storage medium from only paper records to a combination of paper records and computer records. An amended system report was filed with the Speaker of the House, the President of the Senate, and the Office of Management and Budget on September 30, 1980.

DATES: Any interested party may submit written comments regarding the proposal. To be considered, comments must be received on or before December 8, 1980. The amendment shall become effective as proposed without further notice on December 8, 1980, unless comments are received that would result in a contrary determination.

ADDRESS: Address comments to General Services Administration (HRAR), Washington, DC 20405.

FOR FURTHER INFORMATION: Mr. William Hiebert, Records Management Branch, Information Management Division, (202) 566-0673.

Background: The Office of Inspector General (OIG) system of records, Investigation Case Files, is being amended by changing the record storage medium from only paper records to a combination of paper records and computer records. A computer system is necessary due to the increased number of investigation case files that will be covered by the system of records. The use of computers will reduce the staff time required to maintain the records and also provide instant access to investigation information. The system of records notice GSA/ADM-24, Investigation Case Files, was last published in the Federal Register on August 29, 1980, 45 FR 57878.

The amended system of records notice GSA/ADM-24 will read as follows:

GSA/ADM-24 (23-00-0024)

SYSTEM NAME:

Investigation Case Files.

SECURITY CLASSIFICATION:

Some of the material contained in the system has been classified in the interests of the national security pursuant to Executive Order 11652.

SYSTEM LOCATION:

The system is located in the Office of Inspector General, 18th and F Streets NW., Washington, DC 20405. The data base for this system is on computers operated by the Neshaminy Valley Information Processing Company, 4850 Street Road, Trevose, PA 19049.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals covered by the system are employees, applicants for employment, and former employees of GSA and commissions, committees, and small agencies serviced by GSA. Also included are historical researchers, employees of contractors performing custodial or guard services in buildings under GSA jurisdiction, individuals who were the source of an individual complaint or an allegation that a crime had taken place, witnesses having information or evidence on any side of an investigation, and identification of possible and actual suspects in the criminal, administrative, or civil actions.

CATEGORIES OF RECORDS IN THE SYSTEM:

Investigative files contain information such as name, date and place of birth, experience, and investigatory material. These records are used as a basis for issuance of subpoenas; security clearances; suitability determinations; and civil, criminal, and administrative actions.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. App. Section 2 et seq.; Executive Order 10405, April 27, 1953; Executive Order 11478, August 8, 1969; Executive Order 11652, March 8, 1972; Executive Order 11246, September 24, 1965; and 40 U.S.C. 276a through a-7, 276c, 318 (a) through (d), and 327 through 331.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Records are used by GSA officials and representatives of other Government agencies on a need-to-know basis in the performance of their official duties under the authorities set

forth above and also for the following routine uses:

1. *Law enforcement:* Records maintained by the Office of Inspector General may be disseminated in any of the following manners:

a. A record of any case in which there is an indication of a violation of law, whether civil, criminal, or regulatory in nature, may be disseminated to the appropriate Federal, State, local, or foreign agency charged with the responsibility for investigating or prosecuting such violation or charged with enforcing or implementing such law;

b. A record may be disseminated to a Federal, State, local, or foreign agency or to an individual organization in the course of investigating a potential or actual violation of any law, whether civil, criminal, or regulatory in nature, or during the course of a trial or hearing or the preparation for a trial or hearing for such violation, if there is reason to believe that such agency, individual, or organization possesses information relating to the investigation, trial, or hearing and the dissemination is reasonably necessary to elicit such information or to obtain the cooperation of a witness or an informant;

c. A record relating to a case or matter may be disseminated in an appropriate Federal, State, local, or foreign court or grand jury proceeding in accordance with established constitutional, substantive, or procedural law or practice;

d. A record relating to a case or matter may be disseminated to an actual or potential party or his or her attorney for the purpose of negotiation or discussion on such matters as settlement of the case or matter, plea bargaining, or informal discovery proceedings;

e. A record relating to a case or matter that has been referred by an agency for investigation, prosecution, or enforcement or that involves a case or matter within the jurisdiction of any agency may be disseminated to such agency to notify the agency of the status of the case or matter or of any decision or determination that has been made or to make such other inquiries and reports as are necessary during the processing of the case or matters;

f. A record relating to a case or matter may be disseminated to a foreign country pursuant to an international treaty or convention entered into and ratified by the United States or to an executive agreement;

g. A record may be disseminated to a Federal, State, local, foreign, or international law enforcement agency to assist in the general crime prevention and detection efforts of the recipient agency or to provide investigative leads to such agency;

h. A record may be disseminated to a Federal agency, in response to its request, in connection with the hiring or retention of an employee, the issuance of a security clearance, the reporting of an investigation of an employee, the letting of a contract, or the issuance of a license, grant, or other benefit by the requesting agency, to the extent that the information relates to the requesting agency's decision on the matter; or

i. A record may be disseminated to the public, news media, trade associations, or organized groups when the purpose of the dissemination is educational or informational, such as descriptions of crime trends or distinctive or unique modus operandi, provided that the record does not contain any information identifiable to a specific individual other than such modus operandi.

2. *Grievance, complaint, appeal:* A record from this system or records may be disclosed to an authorized appeal or grievance examiner, formal complaints examiner, equal employment opportunity investigator, arbitrator, or other duly authorized official engaged in investigation or settlement of a grievance, complaint, or appeal filed by an employee. A record from this system of records may be disclosed to the United States Office of Personnel Management in accordance with the agency's responsibility for evaluation of Federal personnel management.

3. *Congressional inquiries:* A record from this system of records may be disclosed as a routine use to a Member of Congress or to a congressional staff member in response to an inquiry of the congressional office made at the request of the individual about whom the record is maintained.

4. *Private relief legislation:* The information contained in this system of records may be disclosed to the Office of Management and Budget in connection with the review of private relief legislation as set forth in OMB Circular No. A–19 at any stage or the legislative coordination and clearance process as set forth in the circular.

5. *GSA agents:* A record from this system of records may be disclosed as a routine use (a) to an expert, a consultant, or a contractor, of GSA to the extent necessary to further the performance of a Federal duty and (b) to a physician to conduct a fitness-for-duty examination of a GSA officer or employee.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records in files and file folders and magnetically encoded records on electronic media; e.g., disk drives and tapes.

RETRIEVABILITY:

Paper records are retrieved manually by name from files that are indexed alphabetically and filed numerically by location and incident. Magnetically encoded records are retrieved from computer files organized by investigation case file number.

SAFEGUARDS:

Paper records are stored in locked alarmed vault type rooms and/or three-way combination dial safes with access limited to authorized personnel. Computer based records are protected by system, file, and date element level passwords and by user right-of-access codes with all access restricted to authorized personnel. Information is released only to authorized officials on a need-to-know basis.

SYSTEM MANAGER(S) AND ADDRESS:

The official responsible for the system is the Executive Director, Office of Inspector General, 18th and F Sts. NW., Washington, DC 20405. Mailing address: General Services Administration (JM), Washington, DC 20405.

NOTIFICATION PROCEDURE:

Inquiries by individuals as to whether the system contains a record pertaining to themselves should be addressed to the system manager or the Director of Information (XI), 18th and F Sts. NW., Washington, DC 20405.

RECORD ACCESS PROCEDURES:

Requests from individuals for access to records should be addressed to the Executive Director, Office of Inspector General, and should include full name (maiden name where appropriate), address, and date and place of birth. Only general inquiries may be made by phone.

CONTESTING RECORD PROCEDURES:

GSA rules for access to records and for contesting the contents and appealing initial determinations are promulgated in 41 CFR Part 105–64, published in the **Federal Register.**

RECORD SOURCE CATEGORIES:

Individuals, employees, informants, law enforcement agencies, other government agencies, employers, references, co-workers, neighbors,

educational institutions, and intelligence sources.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

In accordance with 5 U.S.C. 552a(j), this system of records is exempt from all provisions of the Privacy Act of 1974 with the exception of subsections (b); (c)(1) and (2); (e)(4)(A) through (F); (e)(6), (7), (9), (10), and (11); and (i) of the act, to the extent that information in the system pertains to the enforcement of criminal laws, including police efforts to prevent, control, or reduce crime or to apprehend criminals; to the activities of prosecutors, courts, and correctional, probation, pardon, or parole authorities; and to (1) information compiled for the purpose of identifying individual criminal offenders and alleged offenders and consisting only of identifying data and notations of arrests, the nature and disposition of criminal charges, sentencing, confinement, release, and parole and probation status; (2) information compiled for the purpose of a criminal investigation, including reports of informants and investigators, that is associated with an identifiable individual; or (3) reports of enforcement of the criminal laws, from arrest or indictment through release from supervision. This system is exempted to maintain the efficacy and integrity of the Office of Inspector General's law enforcement function.

In accordance with 5 U.S.C. 552a(k), this system of records is exempt from subsections (c)(3); (d); (e)(1); (e)(4) (G), (H), and (I); and (f) of the Privacy Act of 1974. The system is exempt:

a. To the extent that the system consists of investigatory material compiled for law enforcement purposes; however, if any individual is denied any right, privilege, or benefit to which the individual would otherwise be eligible as a result of the maintenance of such material, such material shall be provided to such individual, except to the extent that the disclosure of such material would reveal the identify of a source who furnished information to the Government under an express promise that the identity of the source would be held in confidence, or, prior to the effective date of the act, under an implied promise that the identity of the source would be held in confidence; and

b. To the extent the system consists of investigatory material compiled solely for the purpose of determining suitability, eligibility, or qualifications for Federal civilian employment, military service, Federal contracts, or access to classified information, but only to the extent that the disclosure of such material would reveal the identity of a source who furnished information to the Government under an express promise that the identity of the source would be held in confidence, or, prior to the effective date of the act, under an implied promise that the identity of the source would be held in confidence.

This system has been exempted to maintain the efficacy and integrity of lawful investigations conducted pursuant to the Office of Inspector General's law enforcement responsibilities and responsibilities in the areas of Federal employment, Government contracts, and access to security classified information.

Dated: October 31, 1980.

Ben Schiffman,

Director of Administrative Services.

[FR Doc. 80-34728 Filed 11-6-80; 8:45 am]

BILLING CODE 6820-34-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Mountaire Feeds, Inc.; Premix AB-5-3N; Withdrawal of Approval of NADA

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration withdraws approval of a new animal drug application (NADA) providing for use of Premix AB-5-3N (buquinolate and roxarsone). Finished feeds containing the premix are fed to poultry as an aid in preventing coccidiosis and enhancing growth and pigmentation. The sponsor, Mountaire Feeds, Inc., requested the withdrawal of approval.

EFFECTIVE DATE: November 17, 1980.

FOR FURTHER INFORMATION CONTACT: David N. Scarr, Bureau of Veterinary Medicine (HFV-214), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1846.

SUPPLEMENTARY INFORMATION: Mountaire Feeds, Inc., 124 East Fifth, P.O. Box 5391, North Little Rock, AR 72119, is the sponsor of NADA 37-983 which provided for use of Premix AB-5-3N (3.30 percent buquinolate and 2.0 percent roxarsone) in making finished poultry feeds. The feeds are indicated as aids in prevention of coccidiosis caused by *E. tenella, E. necatrix,* and *E. acervulina* and for stimulating growth and improving feed efficiency and pigmentation in broiler chickens. The application was originally approved December 14, 1967. By letter of August 27, 1980, the sponsor requested withdrawal of approval of the NADA because, since the approval date, the product has not been manufactured.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(e), 82 Stat. 345-347 (21 U.S.C. 360b(e))), under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1) and redelegated to the Bureau of Veterinary Medicine (21 CFR 5.84), and in accordance with § 514.115 *Withdrawal of approval of applications* (21 CFR 514.115), notice is given that approval of NADA 37-983 and all supplements for Mountaire Feeds, Inc., Premix AB-5-3N is hereby withdrawn, effective November 17, 1980.

Dated: October 30, 1980.

Gerald B. Guest,

Acting Director, Bureau of Veterinary Medicine.

[FR Doc. 80-34567 Filed 11-6-80; 8:45 am]

BILLING CODE 4110-03-M

[Docket No. 80N-0189; DESI 6566]

Orphenadrine Citrate Tablets; Drugs for Human Use; Drug Efficacy Study Implementation; Amendment

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: This notice (1) announces that Norflex Tablets (orphenadrine citrate) are a controlled-release dosage form and not a conventional dosage form as implied in previous notices, and (2) announces the conditions for marketing the product. The drug is effective for the relief of discomfort associated with acute, painful musculoskeletal conditions.

DATES: Bioavailability supplements to approved new drug applications due on or before May 6, 1981; other supplements due on or before January 6, 1981.

ADDRESSES: Communications in response to this notice should be identified with the reference number DESI 6566, directed to the attention of the appropriate office named below, and addressed to the Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

Supplements to full new drug applications (identify with NDA number): Division of Neuropharmacological Drug Products (HFD-120), Rm. 10B-34, Bureau of Drugs.

Original abbreviated new drug applications and supplements thereto (identify as such): Division of Generic Drug Monographs (HFD-530), Bureau of Drugs.

Requests for the report of the National Academy of Sciences-National Research

Council: Public Records and Documents Center (HFI–35), Rm. 12A.12.

Requests for guidelines or information on conducting bioavailability tests: Division of Biopharmaceutics (HFD–520), Bureau of Drugs.

Requests for opinion of the applicability of this notice to specific product: Division of Drug Labeling Compliance (HFD–310), Bureau of Drugs.

Other communications regarding this notice: Drug Efficacy Study Implementation Project Manager (HFD–501), Bureau of Drugs.

FOR FURTHER INFORMATION CONTACT: Mary E. Catchings, Bureau of Drugs (HFD–32), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–3650.

SUPPLEMENTARY INFORMATION: In a notice (DESI 6566) published in the **Federal Register** of June 25, 1970 (35 FR 10394) as amended on March 11, 1974 (39 FR 9487) (Docket No. FDC–D–686 (now Docket No. 80N–0189)), the Food and Drug Administration (FDA) announced its conclusions that the following drug product is regarded as a new drug, that it is effective for the indication described below, and that abbreviated new drug applications and abbreviated supplements to previously approved new drug applications will be accepted.

NDA 12–157; Norflex Tablets containing 100 milligrams orphenadrine citrate; Riker Laboratories, 19901 Nordhoff St., Northridge, CA 91324.

Other drugs included in the notice of March 11, 1974, are not affected by this notice.

Abbreviated new drug applications were submitted in response to the March 11, 1974 notice. Upon further review, however, FDA has determined that Norflex Tablets are a controlled-release dosage form and not a conventional dosage form as implied in the March 11, 1974 notice. The abbreviated new drug applications submitted were for orphenadrine citrate in conventional dosage form that releases all the drug within 15 minutes, while Norflex controlled-release tablets release the drug over an 8- to 12-hour period. FDA believes that this significant increase in the rate of release of orphenadrine citrate may lead to a higher incidence of adverse effects than has occured with the controlled-released dosage form. Therefore the notice of March 11, 1974, is amended to reflect that Norflex Tablets are a controlled-released dosage form and that the finding that an ANDA is acceptable applies only to controlled-release products. It is further amended to require, in accord with 21 CFR 320.21 (a) and (f), supplements to approved applications and new or pending abbreviated new drug applications to furnish data adequate to assure the biologic availability of the drug and a rate of release that will be safe and effective.

Such drugs are regarded as new drugs (21 U.S.C. 321(p)). Supplemental new drug applications are required to revise the labeling in and to update previously approved applications providing for such drugs. Such a drug may not be marketed if it is not the subject of an approved new drug application.

A. *Effectiveness classification.* The Food and Drug Administration has reviewed all available evidence and concludes that orphenadrine citrate in a controlled-release dosage form is effective for the indication in the labeling conditions below.

B. *Conditions for approval and marketing.* The Food and Drug Administration is prepared to approve abbreviated new drug applications and supplements to previously approved new drug applications under conditions described herein.

1. *Form of drug.* Orphenadrine citrate preparations are in controlled-release tablet from suitable for oral administration.

2. *Labeling conditions.* a. The label bears the statement, "Caution: Federal law prohibits dispensing without prescription."

b. The drug is labeled to comply with all requirements of the act and regulations, the labeling bears adequate information for safe and effective use of the drug, and the label and other labeling include appropriate statements about its slow release. The indication is as follows:

Orphenadrine citrate is indicated as an adjunct to rest, physical therapy, and other measures for the relief of discomfort associated with acute, painful musculo-skeletal conditions. The mode of action of this drug has not been clearly identified, but may be related to its sedative or analgesic properties. Orphenadrine citrate does not directly relax tense skeletal muscles in humans.

3. *Marketing Status.* a. Maketing of such drug products that are now the subject of an approved or effective new drug aplication may be continued provided that, on or before January 6, 1981, the holder of the application has submitted (i) a supplement for revised labeling, including the label and other container labeling, that is in accord with the labeling conditions described in this notice, and (ii) a supplement to provide updating information with respect to items 6 (components), 7 (composition), and 8 (methods, facilities, and controls) of new drug application form FD–356H (21 CFR 314.1(c)).

In addition, on or before May 6, 1981, the holders of such applications are required to supplement their applications to provide (1) evidence from in vivo bioavailability studies comparing the single-dose 100-milligram oral formulation to two doses of an oral solution of 50 milligrams of orhpenadrine citrate administered every 6 hours (total dose in 12 hours equals 100 milligrams), and (2) data from dissolution testing on three consecutive lots of the product. Guidelines on conducting dissolution tests and bioavailability studies are available from the Division of Biopharmaceutics at the address given above.

b. Approval of an abbreviated new drug application (21 CFR 314.1(f)) containing full information with respect to items 6 (components), 7 (composition), and 8 (methods, facilities, and controls) of new drug application form FD–356H (21 CFR 314.1(c)) must be obtained before marketing such products. An abbreviated new drug application is required to contain evidence from in vivo bioavailability studies comparing a single dose of 100 milligrams of the oral formulation to two doses of an oral solution of 50 milligrams of orphenadrine citrate administered every 6 hours (total dose in 12 hours equals 100 milligrams), and (2) data from dissolution testing on three consecutive lots of the product. Guidelines on conducting dissolution tests and bioavailability studies are available from the Division of Biopharmaceutics. Marketing before approval of a new drug application will subject such products, and those persons who caused the products to be marketed, to regulatory action.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 502, 505, 52 Stat. 1050–1053, as amended (21 U.S.C. 352, 355)) and under the authority delegated to the Director of the Bureau of Drugs (21 CFR 5.70).

Dated: October 26, 1980.

J. Richard Crout,

Director, Bureau of Drugs.

[FR Doc. 80-34414 Filed 11-6-80; 8:45 am]

BILLING CODE 4110-03-M

[Docket No. 77N–0283; DESI 5378 and 11673]

Phentermine Tablets and Capsules; Drugs for Human Use; Drug Efficacy Study Implementation

AGENCY: Food and Drug Administration (FDA).

ACTION: Notice.

SUMMARY: This notice amends previous **Federal Register** notices on drug products containing phentermine resin complex or phentermine hydrochloride to include additional strengths and state the marketing conditions fot these drug products. Also, this notice rescinds the notice of opportunity for hearing on the proposal to refuse to approve the new drug application (ANDA 85–128) for Adipex-P Tablets (containing 37.5 milligrams phentermine hydrochloride).

ADDRESS: Communications in response to this notice should be directed to the attention of the appropriate office named below, and addressed to the Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

Supplements to full new drug applications (identify with NDA number): Division of Neuropharmacological Drug Products (HFD–120), Rm. 10B–34, Bureau of Drugs.

Original abbreviated new drug applications and supplements thereto (identify as such): Division of Generic Drug Monographs (HFD–530), Bureau of Drugs.

Requests for labeling guidelines: Division of Neuropharmacological Drug Products (HFD–120), Rm. 10B–45, Bureau of Drugs.

Requests for guidelines or information on conducting dissolution tests: Division of Biopharmaceutics (HFD–520), Bureau of Drugs.

Requests for the report of the National Academy of Sciences-National Research Council: Public Records and Document Center (HFI–35), Rm. 12A–12.

Requests for opinion of the applicability of this notice to specific products: Division of Drug Labeling Compliance (HFD–310), Bureau of Drugs.

Other communications regarding this notice: Drug Efficacy Study Implementation Project Manager (HFD–501), Bureau of Drugs.

FOR FURTHER INFORMATION CONTACT: Douglas I. Ellsworth, Bureau of Drugs (HFD–32), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–3650.

SUPPLEMENTARY INFORMATION: In a notice (DESI 5378) published in the **Federal Register** of August 8, 1970 (35 FR 12678), FDA classified Ionamin '15' Capsules and Ionamin '30' Capsules (containing 15 milligrams and 30 milligrams of phentermine as resin complexes) as possibly effective drug products. In a followup notice published in the **Federal Register** of July 19, 1974 (39 FR 26459, formerly Docket No. FDC–D–687, now Docket No. 77N–0283), FDA reclassified the products to be effective in the management of exogenous obesity as a short-term (a few weeks) adjunct in a regimen of weight reduction based on caloric restriction. Abbreviated new drug applications (ANDAs) were allowed. The notice also reclassified all remaining possibly effective claims to lacking substantial evidence of effectiveness and offered an opportunity for hearing on them. No person requested a hearing and the claims are no longer allowable in labeling.

In another notice (DESI 11673) published in the **Federal Register** of February 12, 1973 (38 FR 4280), the agency announced its conclusion that Wilpo Tablets containing 8 milligrams phentermine hydrochloride are effective for the exogenous obesity indication stated above.

Since publication of the above notices several firms submitted ANDA's for phentermine hydrochloride tablets or capsules in 30-milligram and 37.5-milligram strengths. To determine whether such strengths are appropriate for abbreviated new drug applications the Director of the Bureau of Drugs has considered the reports of the National Academy of Sciences-National Research Council, Drug Efficacy Study Group on phentermine, the pharmacokinetic characteristics of the drug, and other available information. In view of the long biologic half-life inherent to phentermine, equivalent therapeutic responses and safety can be expected from either a slow-release form (e.g., resin complex) or from an immediate-release formulation of the drug (e.g., hydrochloride salt). The half-life of phentermine is reported to be approximately 20 hours. Therefore, phentermine products whose extent of absorption are identical will provide similar mean steady-state plasma concentrations even if their rates of absorption differ provided the phentermine is fully available for absorption (evidence of dissolution can be used as a measure of availability for absorption). In addition, dosage strength is not critical to the therapeutic effect. Based on the above information, the Director has concluded that the safety and effectiveness conclusions reached concerning the DESI products Wilpo and Ionamin apply to strengths of 30 milligrams and 37.5 milligrams of phentermine hydrochloride. The Director has also concluded that the pharmacokinetic characteristics of phentermine render a claim of controlled-release for a specific formulation of the drug clinically meaningless and misleading.

This notice pertains to all of the products described below.

1. NDA 11–613; Ionamin '15' Capsules and Ionamin '30' Capsules containing respectively 15 and 30 milligrams phentermine as a resin complex; Pennwalt Prescription Products, 755 Jefferson Rd., Rochester, NY 14603.

2. NDA 12–737; Wilpo Tablets containing 8 milligrams phentermine hydrochloride; Dorsey Laboratories, Division of Sandoz, Inc., P.O. Box 83288, Lincoln, NE 68501. Approval of this NDA was withdrawn in the **Federal Register** of March 9, 1979 (44 FR 13079) for failure of the holder to submit required reports. Marketing of the product had been discontinued.

3. ANDA 86–329; Phentermine Hydrochloride Capsules containing 30 milligrams phentermine hydrochloride; Zenith Laboratories, Inc., 140 LeGrand Ave., Northvale, NJ 07647.

4. ANDA 85–933; Adipex-P Tablets containing 30 milligrams phentermine hydrochloride; Lemmon Pharmacal Co., P.O. Box 30, Sellersville, PA 18960.

5. ANDA 86–911; Adipex-P Capsules containing 30 milligrams Phentermine hydrochloride; Lemmon Pharmacal Co.

Othr drugs included in the previous notices are not affected by this notice.

In a notice published in the **Federal Register** of September 16, 1977 (42 FR 46592, Docket No. 77N–0283), the Director offered an opportunity for a hearing on a proposal to refuse approval of an abbreviated new drug application (ANDA 85–128) for Adipex-P Tablets containing 37.5 milligrams phentermine hydrochloride submitted by Lemmon Pharmacal Co. Based upon the reevaluation of phentermine drug products, the Director has concluded that abbreviated new drug applications are suitable for conventional drug products containing 37.5 milligrams phentermine hydrochloride (equivalent to 30 milligrams of phentermine base). Therefore, the notice of opportunity for hearing of September 16, 1977 is hereby rescinded.

Accordingly, the July 19, 1974 and February 12, 1973 notices are amended as follows:

Such drugs are regarded as new drugs (21 U.S.C. 321(p)). Supplemental new drug applications are required to revise the labeling in and to update previously approved applications providing for such drugs. An approved new drug application is a requirement for marketing such drug products.

In addition to the products specifically named above, this notice applies to any drug product that is not the subject of an approved new drug application and is identical to a product named above. It may also be applicable, under 21 CFR 310.6, to a similar or related drug product that is not the subject of an approved new drug application. It is the responsibility of every drug manufacturer or distributor to review

this notice to determine whether it covers any drug product that the person manufactures or distributes. Such person may request an opinion of the applicability of this notice to a specific drug product by writing to the Division of Drug Labeling Compliance (address given above).

A. *Effectiveness classification.* The Food and Drug Administration has reviewed all available evidence and concludes that phentermine, as a resin complex or as the hydrochloride, is effective for the indication in the labeling conditions below.

B. *Conditions for approval and marketing.* The Food and Drug Administration is prepared to approve abbreviated new drug applications and supplements to previously approved new drug applications under conditions described herein.

1. *Form of drug.* The drug product is in tablet or capsule form suitable for oral administration.

2. *Labeling conditions.* a. The label bears the statement, "Caution: Federal law prohibits dispensing without prescription."

b. The drug is labeled to comply with all requirements of the act and regulations, and the labeling bears adequate information for safe and effective use of the drug. A labeling guideline for the drug is available from the Food and Drug Administration (address given above). The indication is as follows:

For use in the management of exogenous obesity as a short-term adjunct (a few weeks) in a regimen of weight reduction based on caloric restriction.

3. *Marketing Status.* a. Marketing of such drug products that are now the subject of an approved or effective new drug application or abbreviated new drug application may be continued provided that, on or before January 6, 1981, the holder of the application has submitted (i) a supplement for revised labeling as needed to be in accord with the labeling conditions described in this notice, and complete container labeling if current container labeling has not been submitted, and (ii) a supplement to provide full updating information with respect to items 6 (components), 7 (composition), and 8 (methods, facilities, and controls) of new drug application form FD–356H (21 CFR 314.1(c)).

b. Approval of an abbreviated new drug application (21 CFR 314(f)) must be obtained before marketing such product. The application must contain full manufacturing information with respect to items 6 (components), 7 (composition), and 8 (methods, facilities, and controls) of new drug application form FD–356H. In addition, the application must contain dissolution rate data. Depending on the formulation, the dissolution rate data must demonstrate that the product meets one of the following requirements. For a product that is formulated to be fast dissolving (not formulated as a cationic resin complex or utilizing any other slow release mechanism), the data must show that at least 80 percent of the labeled amount of the drug dissolves in 60 minutes. For a product formulated to be slow release, such as a cationic resin complex, the data must show that at least 80 percent of the labeled amount of the drug dissolves in 6 hours. In vitro dissolution studies are to be conducted in accordance with the methods provided in the guidelines on conducting dissolution tests, which are available from the Division of Biopharmaceutics at the address given above.

Marketing before approval of a new drug application will subject such products, and those persons who caused the products to be marketed, to regulatory action.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 502, 505, 52 Stat. 1050–1053, as amended (21 U.S.C. 352, 355)) and under the authority delegated to the Director of the Bureau of Drugs (21 CFR 5.70).

Dated: October 26, 1980.

J. Richard Crout,

Director, Bureau of Drugs.

[FR Doc. 80-34415 Filed 11-6-80; 8:45 am]

BILLING CODE 4110-03-M

[Docket No. 80N-0413]

Safety of Certain Food Ingredients; Opportunity for Public Hearing

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces an opportunity for public hearing on the safety of candelilla wax, collagen, methylpolysilicones, and oiticica oil to determine whether they are generally recognized as safe (GRAS) or subject to a prior sanction. This action accords with procedures of a comprehensive safety review that the agency is conducting. Interested persons are invited to give their views on the safety of these substances.

DATE: Requests to make oral presentations at the public hearing must be postmarked on or before December 8, 1980.

ADDRESSES: Written requests to the Select Committee on GRAS Substances, Life Sciences Research Office, Federation of American Societies for Experimental Biology, 9650 Rockville Pike, Bethesda, MD 20014, or to the Dockets Management Branch (formerly the Hearing Clerk's office) (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Corbin I. Miles, Bureau of Foods (HFF–335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–472–4750.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 26, 1973 (38 FR 20053), FDA issued a notice advising the public that an opportunity would be provided for oral presentation of data, information, and views at public hearings to be conducted by the Select Committee on GRAS Substances of the Life Sciences Research Office, Federation of American Societies for Experimental Biology (the Select Committee), about the safety of ingredients used in food to determine whether they are GRAS or subject to a prior sanction.

The agency now announces that the Select Committee is prepared to conduct a public hearing on the following categories of food ingredients: Candelilla wax, collagen, methylpolysilicones, and oiticica oil. The public hearing will provide an opportunity, before the Select Committee reaches its final conclusions, for any interested person(s) to present scientific data, information, and views on the safety of this substance, in addition to those previously submitted in writing under notices published in the **Federal Register** of July 26, 1973 (38 FR 20051, 20053), April 17, 1974 (39 FR 13798), and March 28, 1978 (43 FR 12941).

The Select Committee has reviewed all the available data and information on the food ingredients listed above and has reached one of the following five tentative conclusions on the status of each:

1. There is no evidence in the available information that demonstrates or suggests reasonable grounds to suspect a hazard to the public when it is used at levels that are now current or that might reasonably be expected in the future.

2. There is no evidence in the available information that demonstrates or suggests reasonable grounds to suspect a hazard to the public when it is used at levels that are now current and in the manner now practiced. However, it is not possible to determine, without additional data, whether a significant increase in consumption would constitute a dietary hazard. (This finding

does not apply to the substances covered by this notice.)

3. Although no evidence in the available information demonstrates a hazard to the public when it is used at levels that are now current and in the manner now practiced, uncertainties exist requiring that additional studies be conducted. (This finding does not apply to the substances covered by this notice.)

4. The evidence is insufficient to determine that the adverse effects reported are not deleterious to the public health when it is used at levels that are now current and in the manner now practiced. (This finding does not apply to the substances covered by this notice.)

5. The information available is not sufficient to make a tentative conclusion.

The following table lists the ingredient, the Select Committee's tentative conclusion (keyed to five types of conclusion listed above), and the available information on which the Select Committee reached its conclusions:

Substances	Select committee tentative conclusion	Scientific literature review (order No.; price code; price)[1]	Other information (order No.; price code; price)[1]
Candelilla Wax	1	PB 287-762/AS; A02; $5.00	1. Letter, Oct. 18, 1966, L. E. Buckley, FDA, Washington, DC, to J. H. Heckman, Keller and Heckman, Washington, DC. 2. Letter, Feb. 1, 1967, L. E. Buckley, FDA, Washington, DC, to E. I. Lambert, National Association of Chewing Gum Manufacturers, Washington, DC. 3. Letter, Oct. 11, 1961, F. A. Cassidy, FDA, Washington, DC, to H. W. Conner, Wm. Wrigley, Jr. Co., Chicago, IL. 4. Letter, Aug. 7, 1959, A. A. Checchi, FDA, Washington, DC, to B. E. Sievert, Frank B. Hess Co. Inc., Jersey City, NJ. 5. Committee on GRAS List Survey (Phase III, 1978). 1975 Resurvey of the annual poundage of food chemicals generally recognized as safe (GRAS). (PB 228-081/AS; A03; $6.00). 6. Safety data relating to the use of candelilla wax in chewing gum, 1980. Submitted to FASEB, Bethesda, MD, by National Association of Chewing Gum Manufacturers, New York. Sect. 1. Hodge, H. C. 1973. University of California, San Francisco, CA. A critical review of the (1) Feeding studies of candelilla wax incorporated in gum base. (2) Together with studies of the possible carcinogenic potential by other routes of administration. Sect. 2. Toxicity test upon laboratory sample 36731 #12, Type 11 G. R. S. rubber and candelilla wax. Sect. 3a. Letter, Feb. 27, 1948, I. Davidson Mount Sinai Hospital, New York, to H. W. Conner, Wm. Wrigley, Jr. Co., Chicago, IL; summary of pathological findings on rats receiving various gum base mixtures. b. Letter, Jan. 3, 1949, I. Davidson, Mount Sinai Hospital, New York, to H. W. Conner, Wm. Wrigley, Jr. Co., Chicago, IL; summary of pathological findings on rats receiving various gum base mixtures. c. Letter, July 12, 1950, I. Davidson, Mount Sinai Hospital, New York, to H. W. Conner, Wm. Wrigley, Jr. Co., Chicago, IL; summary of pathological findings on rats receiving various gum base mixtures. d. Letter, Dec. 23, 1952, I. Davidson, Mount Sinai Hospital, New York, to H. W. Conner, Wm. Wrigley, Jr. Co., Chicago, IL; summary of pathological findings on rats receiving various gum base mixtures. Sect. 4. Harrisson, J. W. E. 1948. Toxicity test upon laboratory sample 36222, #16, 50/50 mixture candelilla wax and Heveatex (styrene and butadiene) polymer N-1017 Sect. 5. Harrisson, J. W. E. 1949. Toxicity test upon laboratory sample 39348, #17, Heveatex 50%, candelilla wax, hydrogenated fat. Sect. 6. Harrisson, J. W. E. 1953. (Condensed reort on long-term safety studies on gum base (including 25 percent candelilla wax employing rats and dogs.) Sect. 7. Harrisson, J. W. E. 1952. Summary, carcinogenicity studies on gum base (including 25 percent candelilla wax). 7. Letter, Dec. 20, 1968, W. G. Orr, FDA, Washington, DC, to D. D. Abbott, LaWall and Harrisson Research Laboratories, Inc., Philadelphia, PA. 8. Letter, Dec. 13, 1963, W. F. Randolph, FDA, Washington, DC, to P. E. Smith Jr., E. I. duPont de Nemours and Co., Inc., Wilmington, DE. 9. Memorandum, Sept. 20, 1979, H. I. Chinn, FASEB, Bethesda, MD. 10. Subcommittee on Review of the GRAS List (Phase II, 1972) A comprehensive survey of industry on the use of food chemicals generally recognized as safe (GRAS). (PB 221-921 through PB 221-949 or PB 221-920 for set; E99; $173.00. 11. Lipstick use studies, 1959. Submitted to FASEB, Bethesda, MD, by the Toilet Goods Association, Inc., New York.
Collagen	1	PB 289-599/AS; A05; $6.00	1. Brusick, D. J. 1977. Mutagenicity evaluation of Code 21 coria with poly dust. Submitted to Teepak, Danville, IL, by Litton Bionetics, Inc., Kensington, MD. 2. Letter, Sept. 20, 1960, F. A. Cassidy, FDA, Washington, DC, to J. G. Finch, Ithicon, Inc., Somerville, NJ. 3. Committee on GRAS List Survey (Phase III, 1978). 1975 resurvey of the annual poundage of food chemicals generally recognized as safe (GRAS). (PB 286-081/AS, A03, $6.00). 4. Collagen, Aug. 5, 1977. Submitted to FDA, Washington, DC, by Devro, Inc., Somerville, NJ, Corrected June 2, 1978. 5. Letter Dec. 6, 1979, L. H. Froehlich, Teepak, Inc., Chicago, IL, to F. R. Senti, FASEB, Bethesda, MD. 6. Letter, Jan. 21, 1980, L. H. Froehlich, Teepak, Inc., Chicago, IL, to F. R. Senti, FASEB, Bethesda, MD. 7. Letter, Jan. 18, 1980, E. R. Lieberman, Technical Consultant, Bridgewater, NJ, to L. Froehlich, Teepak, Inc., Chicago, IL. 8. Letter, June 1, 1979, C. I. Miles, FDA, Washington, DC, to F. R. Senti, FASEB, Bethesda, MD. 9. Morgareidge, K. 1967. Subacute feeding studies with a cross-linked coacervate in rats and dogs. Submitted to FASEB, Bethesda, MD, by L. H. Froehlich, Teepak, Inc., Chicago, IL.

Substances	Select committee tentative conclusion	Scientific literature review (order No., price code; price)[1]	Other information (order No., price code; price)[1]
			10. Nehring, P. 1978. "Coria-casings" der Firma Teepak. Submitted to Thomasen & Drijver Verblifa N. V., Deventer, Holland, from Institut fur Konserventechnologie, Braunschweig, W. Germany.
			11. Evaluation of the health aspects of gelatin as a food ingredient (SCOGS-58). Submitted to FDA by FASEB. (PB 254-527, A02, $5.00.)
			12. Evaluation of the health aspects of soy protein isolates as food ingredients (SCOGS-101). Submitted to FDA by FASEB. (BP 300-717, A05, $8.00.)
			13. Letter, May 1, 1979, G.A. Sellers Devro, Inc., Somerville, NJ, to F. R. Senti, FASEB, Bethesda, MD.
Methylpolysilicones	1	PB 289-396/AS; A04; $5.25	1. Letter, Oct. 18, 1960, F. A. Cassidy, FDA, Washington, DC, to T. W. Nale, Union Carbide Corp., New York.
			2. Letter, Aug. 21, 1961, F. A. Cassidy, FDA, Washington, DC, to L. Jennings, National Dairy Products Corp., New York.
			3. Memorandum, Jan. 7, 1980, H. I. Chinn, FASEB, Bethesda, MD.
			4. Letter, Feb. 25, 1963, D. R. Kleber, Jr., Dow Corning Corp., Chicago, IL, to B. M. Crippin, Jr., Hormel and Co., Austin, MN.
			5. Pollard, H. M. 1960. Oral toxicity of DC 15 Unpublished report to Dow Corning Corp., Midland, MI.
			6. Subcommittee on Review of the GRAS List (Phase II, 1972). A comprehensive survey of industry on the use of food chemicals generally recognized as safe (GRAS). (PB 221-921 through PB 221-949 or PB 221-920 for the set; E99; $173.00.)
			7. University of Birmingham, 1967-1970. Studies on silicone antifoam compound MS Antifoam M (compound F 9816).
			I. 90-day feeding test on rats, 1967a.
			II. Acute feeding study, 1967b.
			III. 120-day feeding test in dogs, 1968.
			IV. 80-week feeding study on mice, 1970.
Oiticica Oil	5	PB 287-764/AS; A02; $4.00	1. Letter, Mar. 30, 1960, F. A. Cassidy, FDA, Washington, DC, to F. G. Buerk, Murray Oil Products, Co., New York.
			2. Letter, Mar. 31, 1960, F. A. Cassidy, FDA, Washington, DC, to M. Hassol, Brazilian Industrial Oils, Inc., New York.

[1] Price subject to change.

Reports in the table with "PB" prefixes may be obtained from the National Technical Information Service, U.S. Department Commerce, 5285 Port Royal Rd., Springfield, VA 22161.

In addition to the information contained in the table above, the Select Committee supplemented, where appropriate, its review with specific information from specialized sources as announced in a previous hearing opportunity notice published in the **Federal Register** of September 23, 1974 (39 FR 34218).

The Select Committee's tentative reports on candelilla wax, collagen, and methylpolysilicones for direct food use and oiticica oil for use in food-contact surfaces are available for review at the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, and also at the Public Information Office, Food and Drug Administration, Rm. 3807, 200 C St. SW., Washington, DC 20204. In addition, all reports and documents used by the Select Committee to review the ingredient are available for review at the Docket Management Branch. To schedule the public hearing, the Select Committee must be informed of the number of persons who wish to attend and the amount of time requested to give their views. Accordingly, any interested person who wishes to appear at the public hearing to make an oral presentation shall so inform the Select Committee in writing addressed to the Select Committee on GRAS Substances, Life Sciences Research Office, Federation of American Societies for Experimental Biology, 9650 Rockville Pike, Bethesda, MD 20014. A copy of each such request shall be sent to the Dockets Management Branch address noted above, and all requests shall be placed on public display in that office. Any such request must be postmarked on or before December 8, 1980, shall state the substance(s) on which an opportunity to present oral views is requested, and shall state how much time is required for the presentation. Requests should specify the docket number found in brackets in the heading of this notice. As soon as possible after the requested deadline, a notice announcing the date, time, place, and scheduled presentations for any public hearing that may be requested will be published in the **Federal Register.**

The purpose of the public hearing is to receive data, information, and views not previously available to the Select Committee about the substances listed above. Information already contained in the scientific literature reviews and in the tentative Select Committee reports shall not be duplicated, although views on the interpretation of this material may be presented.

Depending on the number of requests for opportunity to make oral presentations, the Select Committee may reduce the time requested for any presentation. Because of time limitations, individuals and organizations with common interests are urged to consolidate their presentations. Any interested person may, in lieu of an oral presentation, submit written views, which shall be considered by the Select Committee. Three copies of such written views, identified with the docket number found in brackets in the heading of this notice, shall be addressed to the Select Committee at the address noted above, and must be postmarked not later than 10 days before the scheduled date of the hearing. A copy of any written views shall be sent to the Dockets Management Branch, Food and Drug Administration, and shall be placed on public display in that office.

A public hearing will be presided over by a member of the Select Committee. Hearings will be transcribed by a reporting service, and a transcript of each hearing may be purchased directly from the reporting service and will be placed on public display in the Dockets Management Branch, Food and Drug Administration.

Dated: October 29, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-34565 Filed 11-6-80; 8:45 am]

BILLING CODE 4110-03-M

[Docket No. 80N-0438]

Safety of Certain Food Ingredients; Opportunity for Public Hearing

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces an opportunity for public hearing on the safety of ethoxylated soya fatty acid amines to determine whether they are generally recognized as safe (GRAS) or subject to a prior sanction. This action accords with procedures of a comprehensive safety review the agency is conducting. Interested persons are invited to give their views on the safety of these substances.

DATE: Requests to make oral presentations to the public hearing must be postmarked on or before December 8, 1980.

ADDRESSES: Written requests to the Select Committee on GRAS Substances, Life Sciences Research Office, Federation of American Societies for Experimental Biology, 9650 Rockville Pike, Bethesda, MD 20014, and to the Dockets Management Branch (formerly the Hearing Clerk's office) (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Leo F. Mansor, Bureau of Foods (HFF-335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-4750.

SUPPLEMENTARY INFORMATION: In the Federal Register of July 26, 1973 (38 FR 20053), FDA issued a notice advising the public that an opportunity would be provided for oral presentation of data, information, and views at public hearings to be conducted by the Select Committee on GRAS Substances of the Life Sciences Research Office, Federation of American Societies for Experimental Biology (the Select Committee) about the safety of ingredients used in food to determine whether they are GRAS or subject to a prior sanction. The agency now announces that the Select Committee is prepared to conduct a public hearing on ethoxylated soya fatty acid amines for use as components of lubricants in forming metal cans used as food and beverage containers. The public hearing will provide an opportunity for interested persons to present to the Select Committee scientific data, information, and views on the safety of these substances, in addition to those previously submitted in writing under notices published in the Federal Register of July 26, 1973 (38 FR 20051, 20053), April 17, 1974 (39 FR 13798), and March 26, 1978 (43 FR 12941).

The Select Committee has reviewed all the available data and information on the food ingredients listed above and has reached one of the following five tentative conclusions on the status of each:

1. There is no evidence in the available information that demonstrates or suggests reasonable grounds to suspect a hazard to the public when it is used at levels that are now current or that might reasonably be expected in the future.

2. There is no evidence in the available information that demonstrates or suggests reasonable grounds to suspect a hazard to the public when it is used at levels that are now current and in the manner now practiced. However, it is not possible to determine, without additional data, whether a significant increase in consumption would constitute a dietary hazard. (This finding does not apply to the substances covered by this notice.)

3. Although no evidence in the available information demonstrates a hazard to the public when it is used at levels that are now current and in the manner now practiced, uncertainties exist requiring that additional studies be conducted. (This finding does not apply to the substances covered by this notice.)

4. The evidence is insufficient to determine that the adverse effects reported are not deleterious to the public health when it is used at levels that are now current and in the manner now practiced. (This finding does not apply to the substances covered by this notice.)

5. The information available is not sufficient to make a tentative conclusion.

The Select Committee will evaluate the information received at the public hearing and use it in reaching its conclusion.

The following table lists the ingredient, the Select Committee's tentative conclusions (keyed to the five types of conclusions listed above), and the available information on which the Select Committee reached its conclusions:

Substance	Select committee tentative conclusion	Scientific literature review (order No.; price code; price[1])	Animal study report (order No.; price code; price)	Other information
Ethoxylated soya fatty acid amines.	1	PB-289-414A02; $5.00		1. Letter, May 18, 1961, F. A. Cassidy, FDA, Washington, DC, to J. W. Bausch, Armour & Co., Washington, DC. 2. Doyle, R. L.; Majors, P. A. 1973. Acute toxicity and irritation studies of samples RD 4409 and Ethomeen® T/12. Submitted to FASEB, Bethesda, MD, by Armak Co., McCook, IL. 3. Evans, R. A.; McDougal, J. E.; Glass, M. G. 1950. Oral toxicity and irritation studies on products of the chemical division. Submitted to FASEB, Bethesda, MD, by Armak Co., McCook, IL. 4. Goater, T. O.; Griffiths, D.; McElligott, T. F. 1965a. Ninety-day oral toxicity of Ethomeen® T/12—albino rats. Imperial Chemical Industries Ltd., Cheshire, England. Submitted to FASEB, Bethesda, MD, by Armak Co., McCook, IL. 5. Goater, T. O.; Griffiths, D.; McElligott, T. F. 1965b. Ninety-day oral toxicity of Ethomeen® T/12—beagle dogs. Imperial Chemical Industries Ltd., Cheshire, England. Submitted to FASEB, Bethesda, MD, by Armak Co., McCook, IL. 6. Memorandum of telcon, Nov. 16, 1979, L. L. Jacobs, S. H. Mack Co., St. Charles, IL, and F. R. Senti, FASEB, Bethesda, MD. 7. Memorandum of telcon, Oct. 29, 1979, W. E. Link, Sherex Chemical Co., Inc., Dublin, OH, and F. R. Senti, FASEB, Bethesda, MD. 8. Memorandum of telcon, Nov. 15, 1979, R. A. Neal, The Ironsides Co., Columbus, OH, and F. R. Senti, FASEB, Bethesda, MD.

Substance	Select committee tentative conclusion	Scientific literature review (order No.; price code; price [1])	Animal study report (order No.; price code; price)	Other information
				9. Evaluation of the health aspects of hydrogenated soybean oil as a food ingredient (SCOGS-70). PB-266-280/AS. 10. Memorandum, Dec. 14, 1979, F. R. Senti, FASEB, Bethesda, MD.

[1] Price subject to change.

Reports in the table with "PB" prefixes may be obtained from the National Technical Information Service, U.S. Department of Commerce, 5285 Port Royal Rd., Springfield, VA 22161.

In addition to the information contained in the documents listed in the table above, the Select Committee supplemented, where appropriate, its reviews with specific information from specialized sources as announced in a previous hearing opportunity notice published in the **Federal Register** of September 23, 1974 (39 FR 334218).

The Select Committee's tentative report on ethoxylated soya fatty acid amines is available for review at the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, and also at the Public Information Office, Food and Drug Administration, Rm. 3807, 200 C St. SW., Washington, DC 20204. In addition, all reports and documents used by the Select Committee to review the ingredients are available for review at the office of the Dockets Management Branch.

To schedule the public hearing, the Select Committee must be informed of the number of persons who wish to attend and the time required to give their views. Accordingly, any interested person who wishes to appear at the public hearing to make an oral presentation shall inform the Select Committee in writing addressed to the Select Committee on GRAS Substances, Life Sciences Research Office, Federation of American Societies for Experimental Biology, 9650 Rockville Pike, Bethesda, MD 20014. A copy of each request shall be sent to the Dockets Management Branch (address above). All requests will be placed on public display in that office. Any such request must be received by or postmarked on or before December 8, 1980, state the substance(s) on which an opportunity to present oral views is requested and must state how much time is being requested for the presentation. Requests shall specify the docket number found in brackets in the heading of this notice. As soon as possible after the request deadline, a notice announcing the date, time, place, and scheduled presentations for any public hearing that may be requested will be published in the **Federal Register**.

The purpose of the public hearing is to receive data, information, and views not previously available to the Select Committee about the substances listed above. Information already contained in the scientific literature reviews and in the tentative Select Committee report shall not be duplicated, although views on the interpretation of this material may be presented.

Depending on the number of requests for opportunity to make oral presentations, the Select Committee may reduce the time requested for any presentation. Because of time limitations, individuals and organizations with common interests are urged to consolidate their presentations. Any interested person may, in lieu of an oral presentation, submit written views, which shall be considered by the Select Committee. Three copies of such written views, identified with the docket number found in brackets in the heading of this notice, shall be addressed to the Select Committee at the address noted above and must be postmarked no later than 10 days before the scheduled date of the hearing. A copy of any written views shall be sent to the Dockets Management Branch, Food and Drug Administration, and will be placed on public display in that office.

A public hearing will be presided over by a member of the Select Committee. Hearings will be transcribed by a reporting service, and a transcript of each hearing may be purchased directly from the reporting service and will be placed on public display in the Dockets Management Branch (formerly the Hearing Clerk's office) (HFA-305), Food and Drug Administration.

Dated: October 29, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-34566 Filed 11-6-80; 8:45 am]

BILLING CODE 4110-03-M

[Docket No. 80D-0358]

Effectiveness Evaluation of Anthelmintics; Availability of Guideline

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The agency announces the availability of a guideline for use in developing data to establish the effectiveness of swine anthelmintic drugs. The agency invites interested persons to submit written comments on the guideline.

ADDRESSES: The guideline is available for public examination at, and comments may be submitted to, the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857. Single copies are available from the Information Services Staff (HFV-5), Bureau of Veterinary Medicine, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Charles E. Haines, Bureau of Veterinary Medicine (HFV-138), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3410.

SUPPLEMENTARY INFORMATION: The Federal Food, Drug, and Cosmetic Act requires that a new animal drug be the subject of an approved new animal drug application (NADA) before it may be marketed. Section 512(b)(1) of the act (21 U.S.C. 360b(b)(1)) requires that each NADA include full reports of investigations which show that the drug is safe and effective for use. Section 512(d) of the act (21 U.S.C. 360b(d)) describes the criteria that must be met before a new animal drug may be approved, including a requirement that a drug's effectiveness be shown by "substantial evidence" as defined in section 512(d)(3) (21 U.S.C. 360b(d)(3)).

The Bureau of Veterinary Medicine has prepared a guideline that addresses the type of data to be included in an NADA for swine anthelmintic drugs to establish "substantial evidence" of effectiveness for the drug.

Requests for single copies of the guideline should be addressed to the Information Services Staff (HFV-5) (address above). A copy of the guideline is on file in the office of the Hearing Clerk (HFA-305) (address above).

Interested persons may submit written comments on the guideline to the Hearing Clerk (HFA–305). Such comments will be considered in determining whether amendments to or revisions of the guideline are warranted. Comments should be in four copies (except that individuals may submit single copies of comments), identified with the Hearing Clerk docket number found in brackets in the heading of this document. The guideline and received comments may be seen in the Hearing Clerk's office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 3, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-34714 Filed 11-6-80; 8:45 am]

BILLING CODE 4110-03-M

[Docket No. 80G-0412]

Hoffmann-La Roche, Inc.; Filing of Petition for Affirmation of GRAS Status

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: Hoffmann-LaRoche, Inc., has filed a petition (GRASP 0G0265) proposing affirmation that dl-alpha-tocopherol is generally recognized as safe (GRAS) for use to aid in blocking nitrosamine formation in bacon.

DATE: Comments by January 6, 1981.

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Donna A. Dennis, Bureau of Foods (HFF–335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–472–4750.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (secs. 201(s), 409, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348)) and the regulations for affirmation of GRAS status in § 170.35 (21 CFR 170.35), notice is given that a petition (GRASP 0G0265) has been filed by Hoffmann-LaRoche, Inc., Nutley, NJ 07110, proposing affirmation that dl-alpha-tocopherol used at a level of 0.05 percent in bacon to block nitrosamine formation is GRAS. The petition has been placed on display at the office of the Hearing Clerk (HFA–305), Food and Drug Administration.

Any petition that meets the formal requirements outlined in § 170.35 is filed by the agency. There is no prefiling review of the adequacy of data to support a GRAS conclusion. Thus, the filing of petition for GRAS affirmation should not be interpreted as preliminary indication of suitability for affirmation.

Interested persons, may, on or before January 6, 1981 review the petition and/or file comments (four copies, identified with the Hearing Clerk docket number found in brackets in the heading of this document) with the Hearing Clerk (HFA–305), Food and Drug Administration, RM 4–62, 5600 Fishers Lane, Rockville, MD 20857. Comments should include any available information that would be helpful in determining whether the substance is, or is not, GRAS. A copy of the petition and received comments may be seen in the Hearing Clerk's office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 23, 1980.

Sanford A. Miller,

Director, Bureau of Foods.

[FR Doc. 80-34719 Filed 11-6-80; 8:45 am]

BILLING CODE 4110-03-M

[Docket No. 80N-0370]

Prescription Drugs; Draft Guideline Patient Package Inserts

AGENCY: Food and Drug Administration.

ACTION: Notice; clarification of comment period.

SUMMARY: The Food and Drug Administration (FDA) is clarifying its policy on comments on draft guideline patient package inserts (PPI's). The agency is taking this action because of requests it has received for an extension beyond October 27, 1980, of the comment period on the agency's guideline PPI's published September 12, 1980. FDA is not granting an extension of the comment period, but will consider late-filed comments to the extent possible.

ADDRESS: Written comments to the Dockets Management Branch (formerly the Hearing Clerk's office) (HFA–305), Food and Drug Administration, Rm. 44–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Stephen C. Groft, Bureau of Drugs (HFD–107), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4893.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 12, 1980 (45 FR 60785), FDA published 10 draft guidelines PPI's for the following drugs and drug classes: ampicilins, benzodiazepines, cimetidine, clofibrate, digoxin, methoxsalen, propoxyphene, phenytoin, thiazides, and warfarin. The agency provided until October 27, 1980, (or 45 days) for comments on the draft guideline. The agency also stated its intention to publish final guideline PPI's in November 1980, for cimetidine, clofibrate, and propoxyphene, in December 1980, for ampicillins, phenytoin, and warfarin, and in January 1981, for benzodiazepines, digoxin, methoxsalen, and thiazides.

On October 21, 1980, Endo Laboratories, Inc., Garden City, NY asked FDA for a 30-day extension of the comment period on the draft guidelines. On October 22, 1980, the American College of Physicians, Philadelphia, PA, asked for a 30-day extension of the comment period because the college had not received an FDA mailing of copies of the draft guideline PPI's until October 16. While FDA specifically solicits the submission of late-filed comments (comments received after October 27, 1980) and will consider them to the extent possible, for the following reasons the agency declines to formally extend the official comment period.

FDA guidelines are issued under section 10.90 (21 CFR 10.90) of the agency's administrative practices and procedures regulations. FDA guidelines do not establish legal requirements, and while a person may rely upon the guidelines with assurance that they are acceptable to FDA, their use in not required. A drug manufacturer, distributor, or dispenser is therefore free to adopt labeling that differs from the FDA guideline PPI as long as its PPI complies with the agency's regulations.

In publishing draft guideline PPI's for the 10 drugs or drug classes to which the agency intends initially to apply the requirements, FDA provided 45 days for comment. The agency also published the guidelines in a format that permits commenters to make written comments directly on their **Federal Register** copy of the guidelines. Given the length of the guidelines, the issues they raise, and their format, FDA believes that 45 days is adequate time to comment on the guidelines. An extension of the type requested will prevent the agency from meeting its scheduled publication of final PPI guidelines as announced in the notice of draft guidelines, that is, in November 1980, December 1980, and January 1981. With respect to the request of the American College of Physicians, while FDA's mailing of individual copies of the proposed guidelines to organizations of health professionals was intended to facilitate the filing of comments by them, it was not intended to substitute for the notice provided by the publication of the draft guidelines in the **Federal Register** of September 12. FDA will, nonetheless, consider all comments received before the agency concludes the preparation of

final guidelines, even if the comments are received after October 27.

Dated: November 3, 1980.

Joseph P. Hile,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-34718 Filed 11-4-80; 10:05 am]

BILLING CODE 4110-03-M

Small Business Participation; Notice of Open Meeting

AGENCY: Food and Drug Administration.

ACTION: Notice of meeting.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming Small Business Exchange Meeting to be chaired by Lloyd R. Claiborne, Regional Food and Drug Director, Region V, Chicago Field Office.

DATE: This meeting will be held at 9 a.m., Wednesday, December 10, 1980.

ADDRESS: The meeting will be held at the Conrad Hilton Hotel, 720, S. Michigan Ave., Chicago, IL 60605.

FOR FURTHER INFORMATION CONTACT: Danny D. Horner, Small Business Representative, Food and Drug Administration, 175 W. Jackson Blvd., Chicago, IL 60604, 312–353–9406.

SUPPLEMENTARY INFORMATION: The purpose of this meeting is to encourage dialogue between small businesses and FDA officials. The meeting will provide a forum for the owners and managers of small businesses to express their concerns about FDA, encourage discussion about the effects of regulation and regulatory alternatives, convey knowledge about the agency's operations and procedures, and increase participation by small businesspersons in FDA's decisionmaking process.

Dated: November 3, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-34715 Filed 11-6-80; 8:45 am]

BILLING CODE 4110-03-M

Small Business Participation; Notice of Open Meeting

AGENCY: Food and Drug Administration.

ACTION: Notice of meeting.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming Small Business Exchange Meeting to be chaired by Caesar A. Roy, Regional Food and Drug Director, Region II, New York Field Office.

DATE: This meeting will be held at 1 p.m., Tuesday, December 9, 1980.

ADDRESS: The meeting will be held at the East Orange Library, 21 S. Arlington Ave., East Orange, NJ 07018.

FOR FURTHER INFORMATION CONTACT: George R. Walden, Small Business Representative, Food and Drug Administration, 20 Evergreen Place, East Orange, NJ 07018, 201–645–6365.

SUPPLEMENTARY INFORMATION: The purpose of this meeting is to encourage dialogue between small businesses and FDA officials. The meeting will provide a forum for the owners and managers of small businesses to express their concerns about FDA, encourage discussion about the effects of regulation and regulatory alternatives, convey knowledge about the agency's operations and procedures, and increase participation by small businesspersons in FDA's decisionmaking process.

Dated: November 3, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-34716 Filed 11-6-80; 8:45 am]

BILLING CODE 4110-03-M

Small Business Participation; Notice of Open Meeting

AGENCY: Food and Drug Administration.

ACTION: Notice of meeting.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming Small Business Exchange Meeting to be chaired by James W. Swanson, Regional Food and Drug Director, Regions X and IX, Seattle Field Office and San Francisco Field Office.

DATE: This meeting will be held at 1:30 p.m., Wednesday 17, 1980.

ADDRESS: The meeting will be held at the Santa Ana Public Library, Spurgeon Room, 26 Civic Center Plaza, Santa Ana, CA 92702.

FOR FURTHER INFORMATION CONTACT: J. Lawrence Stevens, Small Business Representative, Food and Drug Administration, 1600 N. Broadway, Santa Ana, CA 92706, 714–836–2380.

SUPPLEMENTARY INFORMATION: The purpose of this meeting is to encourage dialogue between small businesses and FDA officials. The meeting will provide a forum for the owners and managers of small businesses to express their concerns about FDA, encourage discussion about the effects of regulation and regulatory alternatives, convey knowledge about the agency's operations and procedures, and increase participation by small businesspersons in FDA's decisionmaking process.

Dated: November 3, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-34717 Filed 11-6-80; 8:45 am]

BILLING CODE 4110-03-M

National Institutes of Health

Aging Review Committee; Meeting

Pursuant to Public Law 92–463, notice is hereby given of the meeting of the Aging Review Committee, National Institute on Aging, on December 3–4, 1980, in Building 31, Conference Room 8, National Institutes of Health, Bethesda, Maryland.

The meeting will be open to the public from 9:00 a.m. to 10:00 a.m. on December 3, for introductory remarks. Attendance by the public will be limited to space available.

In accordance with the provisions set forth in Sections 552b(c)(4) and 552b(c)(6), Title 5, U.S. Code and Section 10(d) of Public Law 92–463, the meeting will be closed to the public on December 3, from 10:00 a.m. to adjournment on December 4, for the review, discussion and evaluation of individual 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, disclosure of which would constitute a clearly unwarranted invasion of personal privacy. Ms. June C. McCann, Committee Management Officer, NIA, Building 31, Room 2C08, National Institutes of Health, Bethesda, maryland, Area Code 301, 496–4120, will provide summaries of meetings and rosters of Committee members as well as substantive program information.

Dated: October 28, 1980.

Suzanne L. Fremeau,

Committee Management Officer, NIH

(Catalog of Federal Domestic Assistance Program No. 13.866, Aging Research, National Institutes of Health.)

Note.—NIH programs are not covered by OMB Circular A-95 because the fit the description of "programs not considered appropriate" in section 8(b)(4) and (5) of that Circular.

[FR Doc. 80-34770 Filed 11-6-80; 8:45 am]

BILLING CODE 4110-08-M

Breast Cancer Task Force Committee; Meeting

Pursuant to Public Law 92–463, notice is hereby given of the meeting of the Breast Cancer Task Force Committee, National Cancer Institute, December 9–10, 1980, Building 1, Wilson Hall,