for the separate portions of each committee meeting are listed above.

The open public hearing portion of each meeting shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairman determines will facilitate the committee's work.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this Federal Register notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairman's discretion.

Persons interested in specific agenda items to be discussed in open session may ascertain from the contact person the approximate time of discussion.

A list of committee members and summary minutes of meetings may be requested from the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday. The FDA regulations relating to public advisory committees may be found in 21 CFR Part 14.

The Commissioner, with the concurrence of the Chief Counsel, has determined for the reasons stated that those portions of the advisory committee meetings so designated in this notice shall be closed. The Federal Advisory Committee Act (FACA), as amended by the Government in the Sunshine Act (Pub. L. 94-409), permits such closed advisory committee meetings in certain circumstances. Those portions of a meeting designated as closed, however, shall be closed for the shortest possible time, consistent with the intent of the cited statutes.

The FACA, as amended, provides that a portion of a meeting may be closed where the matter for discussion involves a trade secret; commercial or financial information that is privileged or confidential; information of a personal nature, disclosure of which would be a clearly unwarranted invasion of personal privacy; investigatory files compiled for law enforcement purposes; information the premature disclosure of which would be likely to significantly frustrate implementation of a proposed agency action; and information in certain other instances not generally relevant to FDA matters.

Examples of portions of FDA advisory committee meetings that ordinarily may be closed, where necessary and in accordance with FACA criteria, include the review, discussion, and evaluation of drafts of regulations or guidelines or similar preexisting internal agency documents, but only if their premature disclosure is likely to significantly frustrate implementation of proposed agency action; review of trade secrets and confidential commercial or financial information submitted to the agency; consideration of matters involving investigatory files compiled for law enforcement purposes; and review of matters, such as personnel records or individual patient records, where disclosure would constitute a clearly unwarranted invasion of personal privacy.

Examples of portions of FDA advisory committee meetings that ordinarily shall not be closed include the review, discussion, and evaluation of general preclinical and clinical test protocols and procedures for a class of drugs or devices; consideration of labeling requirements for a class of marketed drugs or devices; review of date and information on specific investigational or marketed drugs and devices that have previously been made public; presentation of any other data of information that is not exempt from public disclosure pursuant to the FACA, as amended; and, notably deliberative sessions to formulate advice and recommendations to the agency on matters that do not independently justify closing.

Dated: August 6, 1982.

Arthur Hull Haynes, Jr.,

Commissioner of Food and Drugs.

[FR Doc. 21963 Filed 8-12-82; 8:45 am]

BILLING CODE 4160-01-M

International Multifoods; Napiana Broiler Concentrate Containing Roxarsone; Withdrawal of Approval of NADA

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of a new animal drug application (NADA) sponsored by International Multifoods Corp. providing for use of Napiana Broiler Concentrate 3-nitro-4-hydroxyphenylarsonic acid (roxarsone) for growth stimulation in chickens and turkeys. The firm requested withdrawal of approval.

EFFECTIVE DATE: August 23, 1982.

FOR FURTHER INFORMATION CONTACT: Howard Meyers, Bureau of Veterinary Medicine (HFV-218), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4093.

SUPPLEMENTARY INFORMATION: International Multifoods Corp., 1200 Multifoods Bldg., Eighth and Marquette Sts., Minneapolis, MN 55402, is the sponsor of NADA 9-028 which provides for use of Napiana Broiler Concentrate 3-nitro-4-hydroxyphenylarsonic acid (roxarsone), an intermediate premix containing 0.10 percent roxarsone which provides for growth stimulation in chickens and turkeys. The product, originally sponsored by Nappanee Milling Co., Nappanee, IN, became effective April 15, 1953. In their submission of March 11, 1982, to the Bureau of Veterinary Medicine, International Multifoods requested withdrawal of approval of the NADA because the product was no longer being marketed. Approval of this NADA had not been codified in the Code of Federal Regulations.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(e), 82 Stat. 345-347 (21 U.S.C. 360b(e))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Bureau of Veterinary Medicine (21 CFR 5.84) and in accordance with § 514.115 Withdrawal of approval of applications (21 CFR 514.115), notice is given that approval of NADA 9-028 and all supplements for Napiana Broiler Concentrate 3-nitro-4-hydroxyphenylarsonic acid (roxarsone) is hereby withdrawn, effective August 23, 1982.

Dated: August 6, 1982.

Lester M. Crawford,

Director, Bureau of Veterinary Medicine.

[FR Doc. 82-21964 Filed 8-12-82; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 82N-0266]

New Drug Status of OTC Combination Drug Products Containing Caffeine, Phenylpropanolamine, and Ephedrine

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces that it

has determined that combination drug products consisting of caffein, phenylpropanolamine, and ephedrine are new drugs and as such are required to be the subject of an approved new drug application (NDA). FDA has concluded that this combination, available over-the-counter (OTC) and typically labeled for use as a nasal decongestant, bronchodilator, and stimulant, is not included in the OTC Drug Review. FDA further states its conclusion that these products present a potential hazard to health. The agency revokes any prior advisory opinion that would preclude enforcement against these products.

EFFECTIVE DATE: August 13, 1982.

FOR FURTHER INFORMATION CONTACT: Eileen R. Hodkinson, National Center for Drugs and Biologics (HFD-30), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; 301-443-6490.

SUPPLEMENTARY INFORMATION:

Combination drug products consisting of the triple combination of caffeine, phenylpropanolamine, and ephedrine and/or their salts are currently available over-the-counter (OTC) and are labeled for uses as a nasal decongestant, bronchodilator, and stimulant and for use as a diet aid/stimulant. The agency has determined that these drug products are new drugs as defined under section 201(p) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 321(p)) in that they are 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 their labeling, and they have not been used for a material time or to a material extent.

As a general rule, FDA has deferred new drug enforcement actions with respect to products included in the ongoing OTC Drug Review. In the agency's view, however, this triple-combination product is not the kind of product that is, or was ever intended to be, included in the OTC Drug Review. No evidence on the safety or effectiveness of the triple combination was submitted to the review. In addition to having no known medical rationale, the triple combination has a highly suspect marketing history, suggesting that it is frequently used to mimic, and capitalize on the market for, controlled substances.

Although individual active ingredients of this triple combination, at certain levels and for certain indications, alone and in some combinations are being reviewed in the OTC Drug Review, the agency has concluded that the triple combination is not included in the Review. Any prior statements by FDA employees suggesting that the triple combination is included in the OTC Drug Review are incorrect and are hereby revoked.

The agency also believes that this triple combination presents a potential health hazard. The combination of caffeine, phenylpropanolamine, and ephedrine has been marketed and promoted as a product capable of producing effects similar to those produced by controlled substances, and has been widely misused and abused. Even when taken as indicated in its labeling, however, this combination drug product is known to cause excess central nervous system stimulation that could have adverse physiological consequences. Further, the combination of these three ingredients is irrational and without medical justification; the concomitant symptoms of nasal congestion, asthma, and the need for stimulation at the same time does not occur in any significant patient population. Nor has ephedrine been shown effective as a diet aid. Thus, because of this potential health hazard, even if the combination were under review as part of the OTC Drug Review, enforcement action against the triple combination as a new drug would be appropriate.

Therefore, because products containing the triple combination of ingredients, i.e., caffeine, phenylpropanolamine, and ephedrine and/or their salts, are new drugs and no approval of an application filed pursuant to section 505(b) of the act is effective for such drugs, nor is a notice of claimed investigational exemption pursuant to section 505(i) of the act and 21 CFR 312.1 on file, shipment of these products in interstate commerce violates section 301(d) of the act (21 U.S.C. 331(d)). Further, under section 502(f)(1) of the act (21 U.S.C. 352(f)(1)), these drugs are misbranded in that their labeling fails to bear adequate directions for use and they are not exempt from such requirements under 21 CFR 201.115 because they are unapproved new drugs. Shipment of these drugs in interstate commerce and their manufacture from components received in interstate commerce violate section 301 (a) and (k) of the act, respectively. Persons engaging or participating in or causing the manufacture or shipment of these drugs are subject to regulatory action, and the drugs themselves are subject to seizure under section 304 of the act (21 U.S.C. 334).

As explained above, FDA has concluded that these products were never intended to be included in the OTC Drug Review and that, even if they were included, enforcement actions could be taken against these products consistent with FDA's Compliance Policy Guide because the drugs present a potential health hazard. In any case, this document, as an official advisory opinion by FDA, removes any potential restraint on enforcement actions brought with respect to these drugs. Such a restraint could be argued to exist because the agency's Compliance Policy Guide is, in some circumstances, an advisory opinion of the agency that must be followed until amended or revoked (21 CFR 10.85 (d)(3) and (e)). An advisory opinion may, however, be amended or revoked at any time after it is issued, and notice of amendment of revocation may be given in the Federal Register. This is such a notice. Any statement by FDA, in the Compliance Policy Guide or otherwise, that suggests in any way that enforcement will not be taken against the products referred to in this notice is hereby revoked to the extent that that statement applies to such products. In addition, the Commissioner of Food and Drugs has determined that substantial public interest considerations preclude continued acceptance by FDA of any action undertaken or completed in alleged conformity with what anyone may believe to have been a prior advisory opinion that these products could be legally marketed, *see* 21 CFR 10.85(h). Because there is no legitimate use for these products, no transition period for use of the products is applicable, *id.*

The agency has considered whether there is any need to undertake notice and comment rulemaking in order to state in the Federal Register its position on these drugs. It has concluded that no such requirement exists. This statement, even if taken as a revocation of valid prior advisory opinions, is in accordance with FDA's regulations which do not require notice and comment rulemaking for publication of such revocation. In addition, this statement of the agency policy with respect to these drugs is not a substantive rule because it does not have, in it and of itself, the force and effect of law. *Cf. Burroughs Wellcome Co.* v. *Schweiker*, 649 F. 2d 221, 225 (4th Cir. 1981). This announcement is not a "declaration" that the drug is a new drug made after appropriate administrative proceedings. Rather, it is a statement of FDA's position. The government is prepared to present proof to support the agency's conclusion that

these products are new drugs in the course of any action that may be brought to enforce the law with respect to these products. *Cf. United States v. An Article of Drug * * * X-Otag Plus Tablets*, 602 F. 2d 1387, 1390–91 (10th Cir. 1979).

Dated: August 10, 1982.

Arthur Hull Hayes, Jr.,

Commissioner of Food and Drugs.

[FR Doc. 82-22195 Filed 8-12-82; 12:47 pm]

BILLING CODE 4160-01-M

National Institutes of Health

Meeting of the Arteriosclerosis, Hypertension and Lipid Metabolism Advisory Committee

Pursuant to Pub. L. 92-463, notice is hereby given of the meeting of the Arteriosclerosis, Hypertension, and Lipid Metabolism Advisory Committee, National Heart, Lung, and Blood Institute, October 8, 1982, Confercene Room 7, 6th Floor, C-Wing, Building 31, National Institutes of Health, Bethesda, Maryland 20205. The entire meeting will be open to the public from 8:30 a.m. to approximately 5:00 p.m. on Friday, October 8, to evaluate program support in Arteriosclerosis, Hypertension, and Lipid Metabolism. Attendance by the public will be limited on a space available basis.

Ms. Terry Bellicha, Chief, Public Inquiry and Reports Branch, National Heart, Lung, and Blood Institute, Building 31, Room 4A21, National Institutes of Health, Bethesda, Maryland 20205, (301) 496–4236, will provide summaries of the meeting and rosters of the committee members.

Dr. G. C. McMillan, Associate Director, Arteriosclerosis, Hypertension, and Lipid Metabolism Program, NHLBI, Room 4C–12, Federal Building, National Institutes of Health, Bethesda, Maryland 20205, (301) 496–1613, will furnish substantive program information.

(Catalog of Federal Domestic Assistance Program No. 13.837, Heart and Vascular Diseases Research, National Institutes of Health)

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

Dated: July 19, 1982.

Betty J. Beveridge,

NIH Committee Management Officer.

[FR Doc. 82-22042 Filed 8-12-82; 8:45 am]

BILLING CODE 4140-01-M

Office of the Secretary

Agency Forms Submitted to the Office of Management and Budget for Clearance

Each Friday the Department of Health and Human Services (HHS) publishes a list of information collection packages it has submitted to the Office of Management and Budget (OMB) for clearance in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). The following are those packages submitted to OMB since the last list was published on August 6.

Public Health Service

Health Resources Administration

Subject: Uncompensated Services Assurances Report (0935–0021)—Extension.
Respondents: Federally aided (Hill-Burton) health care facilities
OMB Desk Officer: Richard Eisinger.

National Institutes of Health

Subject: Case-Control Study of Brain Tumors and Occupational Factors—New
Respondents: Individuals
OMB Desk Officer: Richard Eisinger

Office of Human Development Services

Subject: Child Welfare Services State Plan—New
Respondents: State agencies responsible for administering programs under title IV–B of the Social Security Act
Subject: State Plan for Foster Care and Adoption Assistance—New
Respondents: State agencies responsible for administering programs under title IV–E of the Social Security Act
OMB Desk Officer: Milo Sunderhauf

Office of the Secretary

Subject: Community Service Assurance Report (Hill-Burton) (Formerly part of OMB No. 0935–0021)—Extension.
Respondents: Recipients of Hill-Burton funds/hospitals and other health facilities
Subject: Request for Funds (TFS–5805)—New
Respondents: Grantees of Department paid by TFCS Letters of Credit
Subject: Payment Voucher on Letter of Credits (TFS–5401)—New
Respondents: Grantees of Department paid by FRB Letter of Credit
OMB Desk Officer: Richard Eisinger

Copies of the above information collection clearance packages can be obtained by calling the HHS Reports Clearance Officer on 202–245–6511.

Written comments and recommendations for the proposed information collections should be sent directly to both the HHS Reports Clearance Officer and the appropriate OMB Desk Officer designated above at the following addresses:

J. J. Strnad, HHS Reports Clearance Officer, Hubert H. Humphrey Building, Room 524–F, Washington, D.C. 20201
OMB Reports Management Branch, New Executive Office Building, Room 3208, Washington, D.C. 20503, ATTN: (name of OMB Desk Officer)

Dated: August 6, 1982.

Dale W. Sopper,

Assistant Secretary for Management and Budget.

[FR Doc. 82-21924 Filed 8-12-82; 8:45 am]

BILLING CODE 4150-04-M

Public Health Service

National Toxicology Program; Availability of Cancer Bioassay Reports on 11-Aminoundecanoic Acid, C.I. Disperse Yellow 3, D & C Red No. 9, Gum Arabic, and Stannous Chloride

The HHS' National Toxicology Program today announces the availability of technical reports on carcinogenesis bioassays of 11-aminoundecanoic acid, a chemical used to make Nylon-11; C.I. Disperse Yellow 3, a monazo dye; D & C Red No. 9, a pigment used in externally applied drugs and cosmetics; gum arabic, a food additive; and stannous chloride, an inorganic tin compound.

In this 103–104 week feeding study, 11-aminoundecanoic acid was carcinogenic for male rats, inducing neoplastic nodules in the liver and transitional-cell carcinomas in the urinary bladder. The test chemical was not carcinogenic for female rats. No clear evidence was found for the carcinogenicity of 11-aminoundecanoic acid in mice of either sex, although the increase in malignant lymphoma in male mice may have been associated with administration of 11-aminoundecanoic acid.

In a 103 week feeding study, C.I. Disperse Yellow 3 was considered carcinogenic for male rats, causing an increased incidence of neoplastic nodules of the liver; this dye was not carcinogenic for female rats. In addition, the stomach tumors found in the male rats may have been induced by the administration of the test chemical. C.I. Disperse Yellow 3 was carcinogenic for female mice, as evidenced by the