engaged in scientific misconduct in this clinical research supported by NCI, National Institutes of Health (NIH), cooperative agreements.

Specifically, Ms. Diaz intentionally fabricated and/or falsified research data and information collected at RPMC for the Breast Cancer Prevention Trial (BCPT) under the National Surgical Adjuvant Breast and Bowel Project (NSABP) and a secondary prevention trial for lung cancer sponsored by the M.D. Anderson Cancer Center and Eastern Cooperative Oncology Group (ECOG). Ms. Diaz falsified data related to entry criteria and treatment compliance on the secondary lung cancer prevention trial. She fabricated reports of follow-up examinations for subjects entered on the BCPT, falsified laboratory test results, and forged signatures of physicians on informed consent documents.

ORI has implemented the following administrative actions for the three (3) year period beginning March 13, 1999:

(1) Ms. Diaz is prohibited from serving in any advisory capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant; and

(2) Any institution that submits an application for PHS support for a research project on which Ms. Diaz's participation is proposed or which uses her in any capacity on PHS supported research, or that submits a report of PHS-funded research in which she is involved, must concurrently submit a plan for supervision of her duties to the funding agency for approval. The supervisory plan must be designed to ensure the scientific integrity of Ms. Diaz's research contribution. The institution also must submit a copy of the supervisory plan to ORI.

FOR FURTHER INFORMATION CONTACT: Acting Director, Division of Research Investigations Office of Research Integrity 5515 Security Lane, Suite 700 Rockville, MD 20852 (301) 443–5330.

Chris B. Pascal,

Acting Director, Office of Research Integrity.

[FR Doc. 99–7234 Filed 3–24–99 8:45 am]

BILLING CODE 4160–17–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98P–0043]

Agency Information Collection Activities; Announcement of OMB Approval; Food Labeling: Nutrition Labeling of Dietary Supplements on a ''Per Day'' Basis

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Food Labeling: Nutrition Labeling of Dietary Supplements on a ''Per Day'' Basis'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 12, 1999 (64 FR 1765), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–395. The approval expires on March 31, 2002. A copy of the supporting statement for this information collection is available on the Internet at ''http://www.fda.gov/ohrms/dockets''.

Dated: March 17, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99–7233 Filed 3–24–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99F–0487]

Exxon Chemical Co.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Exxon Chemical Co. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of fatty acids, C10-13-branched, vinyl esters as a comonomer in polymers used as components of adhesive formulations intended for use in contact with food.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3081.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 9B4650) has been filed by Exxon Chemical Co., P.O. Box 3272, Houston, TX 77253–3272. The petition proposes to amend the food additive regulations in § 175.105 Adhesives (21 CFR 175.105) to provide for the safe use of fatty acids, C 10-13-branched, vinylesters as a comonomer in polymers used as components of adhesive formulations intended for use in contact with food.

The agency has determined under 21 CFR 25.32(i) that this action is of the type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: March 5, 1999.

Laura M. Tarantino,

Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 99–7231 Filed 3–24–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 77N–0240; DESI 1786]

Nitroglycerin Transdermal System; Opportunity for a Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is proposing to withdraw approval of one new drug application (NDA) and five abbreviated new drug applications (ANDA's) for certain single-entity coronary vasodilator drug products containing nitroglycerin in a transdermal system.

FDA is offering the holders of the applications an opportunity for a hearing on the proposal. The basis for the proposal is that the sponsors of these products have failed to submit acceptable data on bioavailability and bioequivalence.

DATES: Hearing requests are due by April 26, 1999; data and information in support of hearing requests are due by May 24, 1999.

ADDRESSES: Communications in response to this notice should be identified with the reference number DESI 1786 and directed to the attention of the appropriate office named below.

A request for a hearing, supporting data, and other comments are to be identified with Docket No. 77N–0240 and submitted to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

A request for applicability of this notice to a specific product should be directed to the Division of Prescription Drug Compliance and Surveillance (HFD–330), Center for Drug Evaluation and Research, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855.

FOR FURTHER INFORMATION CONTACT: Mary E. Catchings, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION:

I. Background

In a notice (DESI 1786) published in the **Federal Register** of February 25, 1972 (37 FR 4001), FDA announced its evaluation of reports received from the National Academy of Sciences/National Research Council, Drug Efficacy Study Group, on certain coronary vasodilator drugs. FDA classified controlled-release tablets of nitroglycerin as possibly effective for indications relating to the management, prophylaxis, or treatment of anginal attacks.

Notices published in the **Federal Register** of August 26, 1977 (42 FR 43127), October 21, 1977 (42 FR 56156), and September 15, 1978 (43 FR 41282), amended earlier notices (37 FR 26623, December 14, 1972; and 38 FR 18477, July 11, 1973) by temporarily exempting nitroglycerin in controlled-release forms from the time limits established for the Drug Efficacy Study Implementation (DESI) program (paragraph XIV, category I exemption). FDA granted this exemption to allow manufacturers additional time to study the effectiveness and bioavailability of their products. FDA also added additional dosage forms of nitroglycerin to the Drug Efficacy Study and the paragraph XIV, category I exemption.

The exemption notices established conditions for marketing the single-entity coronary vasodilators and identical, similar, or related products (§ 310.6 (21 CFR 310.6)), whether or not they had been marketed and whether or not they were subjects of approved NDA's. FDA required distributors and manufacturers to have ANDA's (conditionally approved, pending the results of ongoing studies) to market products not the subject of NDA's. If at least one drug sponsor was conducting clinical studies on a chemical entity, FDA permitted the marketing of all firms' products containing the same chemical entity in a similar dosage form, provided each product met the other conditions. Not all sponsors, therefore, were required to conduct clinical studies. Because bioavailability is specific for an individual product, however, FDA required each firm to conduct a bioavailability study on its own product.

In a notice published in the **Federal Register** of July 15, 1993 (58 FR 38129), after completing its review of the clinical studies submitted for the transdermal delivery system of nitroglycerin, FDA announced its conclusions that this dosage form of nitroglycerin is effective. The notice set forth the conditions for marketing and approval of such products. To receive full approval of an application based on effectiveness, as well as safety, the notice required that sponsors submit bioavailability/bioequivalence studies within 1 year.

The sponsors of the drug products listed in section II of this document are not in compliance with the July 15, 1993, notice in that they either have not submitted any bioavailability/bioequivalence data or have not submitted additional data on incomplete or inadequate studies.

Accordingly, this notice reclassifies the products to lacking substantial evidence of effectiveness, proposes to withdraw approval of the applications, and offers an opportunity for a hearing on the proposal.

II. NDA's and ANDA's Known by FDA to Be Subject to This Notice

1. NDA 20–146; Nitrodisc, release rate 0.2 milligrams (mg) of nitroglycerin per hour (h); G.D. Searle & Co., P.O. Box 5100, Chicago, IL 60680 (Searle).

Nitrodisc, release rate 0.3 mg of nitroglycerin per h; Searle.

Nitrodisc, release rate 0.4 mg of nitroglycerin per h; Searle.

2. ANDA 88–727; Deponit, release rate 0.2 mg of nitroglycerin per h; Schwarz Pharma, Inc., 5600 West County Line Rd., Mequon, WI 53092 (Schwarz) (formerly held by Wyeth Laboratories, Inc., P.O. Box 8297 Philadelphia, PA 19101).

3. ANDA 88–782; Nitroglycerin Transdermal System (NTS), release rate 0.2 mg of nitroglycerin per h; Hercon Pharmaceutical Co., Inc., P.O. Box 786, York, PA 17405 (Hercon).

4. ANDA 88–783; NTS, release rate of 0.6 mg of nitroglycerin per h; Hercon.

5. ANDA 89–022; Deponit, release rate 0.4 mg of nitroglycerin per h; Schwarz.

6. ANDA 89–516; NTS, release rate of 0.4 mg of nitroglycerin per h; Hercon.

III. Notice of Opportunity for a Hearing

On the basis of all the data and information available to her, the Director of the Center for Drug Evaluation and Research is unaware of any adequate and well-controlled clinical investigation conducted by experts who are qualified by scientific training and experience meeting the requirements of section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355), 21 CFR 314.126, and 21 CFR part 320 that demonstrates effectiveness (i.e., bioavailability/bioequivalence) of the drugs that have been found to be in compliance with the conditions established for continued marketing.

Therefore, notice is given to the holders of the NDA and ANDA's listed in section II of this document and to all other interested persons that the Director of the Center for Drug Evaluation and Research proposes to issue an order under section 505(e) of the act withdrawing approval of the applications and all amendments and supplements thereto on the ground that new information before her with respect to the drug products, evaluated with the evidence available to her when the applications were approved, shows there is a lack of substantial evidence that the drug products will have the effect they purport or are represented to have under the conditions of use prescribed, recommended, or suggested in the labeling.

In addition to the holders of the applications specifically named in section II of this document, this notice of opportunity for a hearing applies to all persons who manufacture or distribute a drug product, not the subject of an approved application, that is identical, related, or similar to a drug product named in section II of this document, as defined in § 310.6. It is the responsibility of every drug

manufacturer or distributor to review this notice of opportunity for a hearing to determine whether it covers any drug product that they manufacture or distribute. Such persons may request an opinion on the applicability of this notice to a specific drug product by writing to the Division of Prescription Drug Compliance and Surveillance (address above).

This notice of opportunity for a hearing encompasses all issues relating to the legal status of the drug products subject to it (including identical, related, or similar drug products as defined in § 310.6), e.g., any contention that any such product is not a new drug because it is generally recognized as safe and effective within the meaning of section 201(p) of the act (21 U.S.C. 321(p)) or because it is exempt from part or all of the new drug provisions of the act under the exemption for products marketed before June 25, 1938, in section 201(p) of the act, or under section 107(c) of the Drug Amendments of 1962 (Pub. L. 87–781), or for any other reason.

In accordance with section 505 of the act and parts 310 and 314 (21 CFR parts 310 and 314), an applicant and all other persons subject to this notice are hereby given an opportunity for a hearing to show why approval of the applications should not be withdrawn.

An applicant or any other person subject to this notice who decides to seek a hearing shall file: (1) On or before April 26, 1999, a written notice of appearance and request for hearing; and (2) on or before May 24, 1999, the data, information, and analyses relied on to demonstrate that there is a genuine issue of material fact to justify a hearing, as specified in § 314.200. Any other interested person may also submit comments on this notice. The procedures and requirements governing this notice of opportunity for a hearing, a notice of appearance, and request for a hearing, information and analyses to justify a hearing, other comments, and a grant or denial of a hearing are contained in §§ 314.151 and 314.200 and in 21 CFR part 12.

The failure of an applicant or any other person subject to this notice to file a timely written notice of appearance and request for a hearing, as required by § 314.200, constitutes an election by that person not to use the opportunity for a hearing concerning the action proposed and a waiver of any contentions concerning the legal status of that person's drug products.Any new drug product marketed without an approved new drug application is subject to regulatory action at any time.

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

All submissions under this notice of opportunity for a hearing are to be filed in four copies. Except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, the submissions may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday. This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 505 (21 U.S.C. 355)) and under authority delegated to the Director of the Center for Drug Evaluation and Research (21 CFR 5.82).

Dated: March 3, 1999.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 99–7232 Filed 3–24–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Workshop on International Outreach and Training on Good Agricultural and Good Manufacturing Practices for Fresh Produce

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

The Food and Drug Administration (FDA) is announcing the following meeting: Workshop on International Outreach and Training on Good Agricultural and Good Manufacturing Practices for Fresh Produce. The topics to be discussed are developing a collaborative process for identifying training needs for foreign growers and producers who export fresh produce to the United States and identifying effective strategies to best meet those needs.

Date and Time: The meeting will be held on April 26 and 27, 1999, from 8:30 a.m. to 5:30 p.m., and on April 28, 1999, from 8:30 a.m. to 12 noon.

Location: The workshop will be held at the Inn and Conference Center, University of Maryland University College, University Blvd. at Adelphi Rd., College Park, MD, 301–985–7300.

Contact: Camille E. Brewer, Center for Food Safety and Applied Nutrition (HFS–32), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–260–2314, FAX 202–260–9653, e-mail ''cbrewer@oc.fda.gov''.

Registration: The meeting is open to the public. However, space is limited and preregistration is required. Send preregistration information (including name, title, firm name, address, telephone, and fax number), to Wendy Buckler, JIFSAN (HFS–6), Center for Food Safety and Applied Nutrition, FDA, 200 C St. SW., Washington, DC 20204, 202–205–4153, FAX 202–260–1654, e-mail ''wbuckler@bangate.fda.gov''. Translation into Spanish will be available. Limited space will be available at no cost to groups interested in exhibiting outreach, education, and training materials on produce safety. However, all exhibitors must preregister with Ms. Buckler.

If you need special accommodations due to a disability, please contact Ms. Buckler at least 7 days in advance.

SUPPLEMENTARY INFORMATION: On October 2, 1997, the President announced the ''Initiative to Ensure the Safety of Imported and Domestic Fruits and Vegetables'' (fresh produce safety initiative). As part of the fresh produce safety initiative, the President directed the Secretary of the Department of Health and Human Services (DHHS) and the Secretary of the U.S. Department of Agriculture (USDA), in cooperation with the agricultural community, to issue within 1 year guidance on good agricultural practices and good manufacturing practices for fresh fruits and vegetables. FDA coordinated the effort for DHHS.

FDA announced the availability of the final good agricultural practices and good manufacturing practices guidance on October 29, 1998 (63 FR 58055), after receiving and considering comments on the draft guidance from producers, foreign governments, and trade associations both in writing and during two separate rounds of public meetings on successively more developed drafts of the guide. The final guide (the guide) details a broad approach on how to minimize microbial contamination of produce through the control of: Water, manure, worker health and hygiene,