EVALUATION OF THE HEALTH ASPECTS OF COCONUT OIL, PEANUT OIL, AND OLEIC ACID AS THEY MAY MIGRATE TO FOOD FROM PACKAGING MATERIALS, AND LINOLEIC ACID AS A FOOD INGREDIENT

1977

Prepared for

Bureau of Foods
Food and Drug Administration
Department of Health, Education, and Welfare
Washington, D. C.

Contract No. FDA 223-75-2004
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Life Sciences Research Office
Federation of American Societies for Experimental Biology
9650 Rockville Pike
Bethesda, Maryland 20014
NOTICE

This report is one of a series concerning the health aspects of using the Generally Recognized as Safe (GRAS) or prior sanctioned food substances as food ingredients, being made by the Federation of American Societies for Experimental Biology (FASEB) under contract no. 223-75-2004 with the Food and Drug Administration (FDA), U.S. Department of Health, Education, and Welfare. The Federation recognizes that the safety of GRAS substances is of national significance, and that its resources are particularly suited to marshalling the opinions of knowledgeable scientists to assist in these evaluations. The Life Sciences Research Office (LSRO), established by FASEB in 1962 to make scientific assessments in the biomedical sciences, is conducting these studies.

Qualified scientists were selected as consultants to review and evaluate the available information on each of the GRAS substances. These scientists, designated the Select Committee on GRAS Substances, were chosen for their experience and judgment with due consideration for balance and breadth in the appropriate professional disciplines. The Select Committee's evaluations are being made independently of FDA or any other group, governmental or nongovernmental. The Select Committee accepts responsibility for the content of each report. Members of the Select Committee who have contributed to this report are named in Section VII.

Tentative reports are made available to the public for review in the Office of the Hearing Clerk, Food and Drug Administration, after announcement in the Federal Register, and opportunity is provided for any interested person to appear before the Select Committee at a public hearing to make oral presentation of data, information, and views on the substances covered by the report. The data, information, and views presented at the hearing are considered by the Select Committee in reaching its final conclusions. Reports are approved by the Select Committee and the Director of LSRO, and subsequently reviewed and approved by the LSRO Advisory Committee (which consists of representatives of each constituent society of FASEB) under authority delegated by the Executive Committee of the Federation Board. Upon completion of these review procedures the reports are approved and transmitted to FDA by the Executive Director of FASEB.

While this is a report of the Federation of American Societies for Experimental Biology, it does not necessarily reflect the opinion of all of the individual members of its constituent societies.

Kenneth D. Fisher, Ph.D., Director
Life Sciences Research Office
FASEB
## CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>I. Introduction</td>
<td>1</td>
</tr>
<tr>
<td>II. Background information</td>
<td>2</td>
</tr>
<tr>
<td>III. Consumer exposure data</td>
<td>5</td>
</tr>
<tr>
<td>IV. Biological studies</td>
<td>6</td>
</tr>
<tr>
<td>V. Opinion</td>
<td>9</td>
</tr>
<tr>
<td>VI. References cited</td>
<td>11</td>
</tr>
<tr>
<td>VII. Scientists contributing to this report</td>
<td>17</td>
</tr>
</tbody>
</table>
I. INTRODUCTION

This report concerns the health aspects of using coconut oil, peanut oil, and oleic acid as they may migrate to food from packaging materials, and linoleic acid as a food ingredient. It has been based partly on the information contained in a scientific literature review (monograph) furnished by FDA (1), which summarizes the world's scientific literature from 1920 through 1973. To assure completeness and currency as of the date of this report this information has been supplemented by searches of over 30 scientific and statistical reference sources and compendia that are generally available; use of new, relevant books and reviews and the literature citations contained in them; consideration of current literature citations obtained through computer retrieval systems of the National Library of Medicine; searches for relevant data in the files of FDA; and by the combined knowledge and experience of members of the Select Committee and the LSRO staff. In addition, an announcement was made in the Federal Register of June 7, 1977 (42 FR 29105-29107) that opportunity would be provided for any interested person to appear before the Select Committee at a public hearing to make oral presentation of data, information and views on the health aspects of using coconut oil, peanut oil, and oleic acid as they may migrate to food from packaging materials and linoleic acid as a food ingredient. The Select Committee received no requests for such a hearing on coconut oil, peanut oil, oleic acid and linoleic acid.

As indicated in the Food, Drug, and Cosmetic Act [21 USC 321(s)], GRAS substances are exempt from the premarking clearance that is required for food additives. It is stated in the Act and in the Code of Federal Regulations (2) [21 CFR 170.3 and 170.30] that GRAS means general recognition of safety by experts qualified by scientific training and experience to evaluate the safety of substances on the basis of scientific data derived from published literature. These sections of the Code also indicate that expert judgment is to be based on the evaluation of results of credible toxicological testing or, for those substances used in food prior to January 1, 1958, on a reasoned judgment founded in experience with common food use, and is to take into account reasonably anticipated patterns of consumption, cumulative effects in the diet, and safety factors appropriate for the utilization of animal experimentation data. FDA (2) recognizes further that it is impossible to provide assurance that any substance is absolutely safe for human consumption.

*The document (PB-228 546/8) is available from the National Technical Information Service, U.S. Department of Commerce, P.O. Box 1553, Springfield, Virginia 22161.
The Select Committee on GRAS Substances of LSRO is making its evaluations of these substances in full recognition of the foregoing provisions. In reaching its conclusions on safety, the Select Committee, in accordance with FDA's guidelines, is relying primarily on the absence of substantive evidence of, or reasonable grounds to suspect, a significant risk to the public health. While the Select Committee realizes that a conclusion based on such reasoned judgment is expected even in instances where the available information is qualitatively or quantitatively limited, it recognizes that there can be instances where, in the judgment of the Select Committee, there are insufficient data upon which to base a conclusion. The Select Committee, aware that biological testing is dynamic, bases its conclusions on information now available; it cannot anticipate the results of experiments not yet conducted or those of tests that may be reconduded, using new technologies. These conclusions will need to be reviewed as new or better information becomes available.

In this context, the LSRO Select Committee on GRAS Substances has reviewed the available information on coconut oil, peanut oil, oleic acid and linoleic acid and submits its interpretation and assessment in this report, which is intended for the use of FDA in determining the future status of these substances under the Federal Food, Drug, and Cosmetic Act.

II. BACKGROUND INFORMATION

Coconut oil and peanut oil are vegetable oils, the term generally used to describe substances from plant sources, principally oil-bearing seeds, that are greasy or oily fluids at ordinary temperatures. Vegetable oils consist primarily of triglycerides, which are esters formed by the combination of three molecules of fatty acids with one molecule of glycerol. Simple triglycerides occur rarely in nature, i.e., the three fatty acids in a single molecule usually differ. Further, vegetable oils used as or in foods are composed of mixtures of triglycerides in varying amounts. They also contain small percentages of non-glyceridic substances commonly removed, or largely so, in refining; these include phosphatides, carbohydrates and carbohydrate derivatives, protein fragments, and various resinous and mucilaginous materials of uncertain identity (3). In the early 1960's attention was directed to the presence of a toxic substance, aflatoxin, in moldy oilseeds, produced as a metabolite of the fungus, Aspergillus flavus (4). In 1966, Parker and Melnick (5) studied the effect of alkali refining, washing and bleaching of peanut and corn oils, and concluded that conventional processing practices effectively remove any aflatoxin found in the oils investigated, as measured by the aflatoxin analytical methods then available.

Most of the vegetable oils are comprised of glycerides containing combinations of saturated and unsaturated fatty acids including oleic acid (C₁₇H₃₅COOH).
which is cis-9-octadecanoic acid, linoleic acid (C_{17}H_{31}COOH), which is cis-9,
cis-12-octadecadienoic acid, caprylyc acid (C_{7}H_{15}COOH), capric acid
(C_{9}H_{19}COOH), lauric acid (C_{11}H_{23}COOH), myristic acid (C_{13}H_{27}COOH),
palmitic acid (C_{15}H_{31}COOH), palmitoleic acid (C_{15}H_{29}COOH), stearic acid
(C_{17}H_{35}COOH), linolenic acid (C_{17}H_{29}COOH), arachidic acid (C_{18}H_{39}COOH),
erucic acid (C_{21}H_{41}COOH), and lignoceric acid (C_{23}H_{47}COOH). Varying
amounts of free fatty acids may be dissolved in the glyceridic oils depending
on such factors as the condition of the oilseed prior to processing, conditions
of processing, and conditions of storage of the oil (6).

Quantitative composition of a specific vegetable oil, peanut oil for
example, varies depending upon the peanut variety from which it is derived,
and upon the climatic conditions and agronomic practices under which it is
grown. Typical fatty acid composition of coconut oil and peanut oil is given
in Table I.

**TABLE I**

Typical Fatty Acid Composition of Coconut Oil and Peanut Oil

<table>
<thead>
<tr>
<th>Substance</th>
<th>Fatty acid</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coconut oil</td>
<td>Caproic and caprylic</td>
<td>7.0 (7)</td>
</tr>
<tr>
<td></td>
<td>Capric</td>
<td>6.0 (7)</td>
</tr>
<tr>
<td></td>
<td>Lauric</td>
<td>49.5 (7)</td>
</tr>
<tr>
<td></td>
<td>Myristic</td>
<td>19.5 (7)</td>
</tr>
<tr>
<td></td>
<td>Palmitic</td>
<td>8.5 (7)</td>
</tr>
<tr>
<td></td>
<td>Stearic</td>
<td>2.0 (7)</td>
</tr>
<tr>
<td></td>
<td>Oleic</td>
<td>6.0 (7)</td>
</tr>
<tr>
<td></td>
<td>Linoleic</td>
<td>1.5 (7)</td>
</tr>
<tr>
<td>Peanut oil</td>
<td>Palmitic</td>
<td>11.5 (7)</td>
</tr>
<tr>
<td></td>
<td>Stearic</td>
<td>6.0 (8)</td>
</tr>
<tr>
<td></td>
<td>Arachidic</td>
<td>3.0 (7)</td>
</tr>
<tr>
<td></td>
<td>Oleic</td>
<td>5.0 (8)</td>
</tr>
<tr>
<td></td>
<td>Linoleic</td>
<td>1.5 (7)</td>
</tr>
<tr>
<td></td>
<td>Oleic</td>
<td>2.0 (8)</td>
</tr>
<tr>
<td></td>
<td>Linoleic</td>
<td>26.0 (7)</td>
</tr>
<tr>
<td></td>
<td>Linoleic</td>
<td>22.0 (8)</td>
</tr>
</tbody>
</table>
This report concerns the evaluation of coconut oil, peanut oil, oleic acid, and linoleic acid as GRAS substances used as authorized by the following sections of the Code of Federal Regulations (2):

Coconut oil, refined 21 CFR 182.70: Substances migrating to food from cotton and cotton fabrics used in dry food packaging.

Peanut oil 21 CFR 182.70: Substances migrating to food from cotton and cotton fabrics used in dry food packaging.

Oleic acid 21 CFR 182.90: Substances migrating to food from paper and paperboard products used in food packaging.

21 CFR 182.70: Substances migrating to food from cotton and cotton fabrics used in dry food packaging.

Linoleic acid 21 CFR 182.5065: Nutrients and/or dietary supplements.

Oleic acid is also authorized by sections 172.860 and 172.862 of the Code for use in food and in the manufacture of food components or food-grade additives; peanut stearine is authorized by section 182.40 as a natural extractive used in conjunction with spices, seasonings, and flavorings. The Select Committee has no information concerning the extent of such uses and is not evaluating oleic acid and peanut stearine for these purposes. The Flavor and Extract Manufacturers' Association (FEMA) regards oleic acid as GRAS for flavoring purposes (9), but it is not among the substances included in the Code as natural or synthetic flavoring substances or adjuvants that "may be safely used in food" (172.510 and 172.515). It is not being evaluated for this purpose in this report.

The Food Chemicals Codex (10) specifies that food-grade oleic acid should contain no more than 3 ppm of arsenic, 10 ppm of heavy metals (as lead), 2 percent unsaponifiable matter, 0.01 percent ash, and 0.4 percent water; acid value 196 to 204, iodine value 83 to 103, and saponification value 196 to 206; its solidification point should not be above 10°C. The Codex provides no specifications for coconut oil, peanut oil, or linoleic acid. However, the U.S. Pharmacopeia (11) provides the following specifications for peanut oil: specific gravity, 0.912 to 0.920; heavy metals, 0.001 percent; the free fatty acids in 10 g must require not more than 2 ml of 0.02 N sodium hydroxide for neutralization; iodine value, 84 to 100; saponification value, 185 to 195; unsaponifiable matter, not more than 1.5 percent.

Other vegetable oils, hydrogenated soybean oil (12) and tall oil (13), and other fatty acids, caprylic acid (14) and stearic acid (15), have been evaluated in other reports of the Select Committee.
III. CONSUMER EXPOSURE DATA

No estimates are available of the amounts of coconut oil, peanut oil, or oleic acid that may migrate to food packaged in paper or cotton fabrics containing these substances. Moreover, no information is available concerning the amounts of these substances used in such packaging materials, the kinds of foods packaged, or the storage and handling conditions to which the packaged foods are subjected. Obviously, the amounts of chemicals used in the preparation of packaging materials that may migrate or be abraded from them, and thus enter the contained food, will be influenced by these factors. It is reasonable to assume, however, that the amounts will be small.

No estimates are available of the amounts of linoleic acid consumed when it is used as a nutrient or dietary supplement. Request was made of the food industry for this information by a subcommittee of the National Research Council as part of its survey on the use of GRAS substances (16), but none of the respondents indicated that linoleic acid was being used for this purpose.

Despite the uncertainty concerning the possible consumer exposure to coconut oil, peanut oil, and oleic acid as a result of migration to food from packaging materials, and the lack of consumption data on linoleic acid as it may be used as a nutrient or dietary supplement, it should be recognized that these substances are among the several vegetable oils and fatty acids that constitute major sources of fat in the diet. The fat component of such food products as margarine, shortenings, salad and cooking oils, mayonnaise, and imitation dairy products, consist entirely or largely of vegetable oils such as those from soybean, cottonseed, corn, coconut and peanut; all contain oleic acid and linoleic acid in substantial amounts. The magnitude of possible per capita consumption of coconut and peanut oils, for example, is seen in the data in Table II. The 1970 figures in Table II are reasonably typical of annual consumption over the past decade although a slight downward trend is apparent.

TABLE II

<table>
<thead>
<tr>
<th>Oil</th>
<th>Total 1970 usage as or in foods</th>
<th>Per capita daily intake$^a$</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Million pounds</td>
<td>Million kg</td>
</tr>
<tr>
<td>Coconut</td>
<td>348</td>
<td>158</td>
</tr>
<tr>
<td>Peanut</td>
<td>176</td>
<td>80</td>
</tr>
</tbody>
</table>

$^a$Based on a population of 205 million.
IV. BIOLOGICAL STUDIES

Absorption and metabolism

Fats and fatty acids are involved in normal human metabolism and serve an important role as energy sources. Fatty acid oxidation provides approximately one-half of the oxidative energy in liver, kidney, heart, and skeletal muscle (18).

The coefficients of fat digestibility (absorbed/ingested) of oleic and linoleic acids fed to rats for 16 days were found to be 73 and 84 percent, respectively (19). The fatty acids were fed at a level of about 15 g per kg initial body weight per day. When [1-14C] oleic acid was fed to 250 g rats (single intubated dose of about 0.5 g having a specific radioactivity of 2300 counts per min. per mg), 66 to 92 percent of the fed radioactivity was absorbed in 24 hours. Of the absorbed radioactivity, 38 to 96 percent was found as fatty acids in lymph fat, about 2 percent of which was in phospholipids and the remainder in neutral fat; about 16 percent of the absorbed radioactivity was excreted as carbon dioxide (20). Cenedella and Allen (21) found that male rats intubated with [1-14C] linoleate (12 μc of radioactivity) excreted radioactive carbon dioxide at the rate of about 21 percent of the administered labeled linoleate per hour.

Basu and Nath (22) found that 50 and 60 percent, respectively, of intubated doses of coconut oil or peanut oil (about 6 g per kg) was absorbed by rats within six hours. More than 90 percent of most vegetable oils (50 to 140 g per person) was digested by human volunteers without adverse physiological effects except some tendency to laxative effects with some fats at high doses. Digestibility of coconut oil and peanut oil was 98 percent. Measurements were made on subjects receiving 50 to 140 g of the fat daily over a period of three days (23).

It is to be noted in this respect that the heating of vegetable oils, as would occur during such cooking procedures as deep frying, has been found to alter their absorbability and/or digestibility. Roy (24) found that the heating (300°C for 45 minutes) of most vegetable oils decreases their absorbability. The study involved mixing the unheated or heated fats (about 1.6 g per 16 g of diet) in rat diets, feeding for three-day periods and measuring the fecal fat. The absorption of peanut oil was essentially unchanged by heating. The absorption of coconut oil was reduced from 98.4 percent to 94.9 percent by heating. Crampton et al. (25) noted markedly depressed growth of rats and depressed feed utilization, when the animals were fed peanut oil heated for 30 minutes at 275°C, at a 10 percent dietary level (about 10 g per kg). No depression of growth rate or feed utilization occurred when peanut oil heated for only 15 minutes was fed. Further studies by Crampton et al. (26-28) suggest that these effects are probably not due to the development of a toxic factor or to a lack of vitamin E, but may be due to the presence of monomeric or dimeric acyl radicals that are "inimical to the well-being of the animals." Raju and Rajagopalan (29)
found that heated coconut oil (270°C for 8 hours) incorporated into the diet of rats at the 15 percent level (about 15 g per kg) adversely affected weight gain and feed efficiency and led to enlarged, fatty livers. When fed at a 30 percent level (about 30 g per kg) all animals died within one week.

Several possible biological effects of oleic and/or linoleic acids have been reported including the uncoupling of oxidative phosphorylation (30), the swelling of rat liver mitochondria (31-34), and increasing plasma cholesterol level in rats fed a diet containing 15 percent linoleic acid for eight weeks (35). Some of these findings are not supported by the work of other investigators (36).

The addition of 5 percent (about 5 g per kg) of coconut oil or peanut oil as the sole fat source to the diet of 60 g rats for four weeks resulted in an increased fecal excretion of calcium and a decreased retention of calcium and phosphorus (37). Rao and De (38) noted that the inclusion of 10 percent (about 10 g per kg) coconut oil in a normal diet resulted in increased fecal excretion of calcium and an increased utilization of calcium in growing rats. A positive calcium balance was observed when three adult rats were fed a diet containing 7.44 percent (about 4 g per kg) coconut oil (39). Basu and Nath (40) found that the addition of coconut oil to the diet of humans increased the total (urinary and fecal) elimination of calcium whereas the addition of peanut oil increased the absorption of calcium and phosphorus. According to Goodhart and Shils (41), the absorption of calcium requires the presence of fat in the diet, but when the level of fat is high (especially those fats with higher melting points), the absorption of calcium is impaired.

**Short-term studies**

Sunde (42) found that day-old chicks receiving 5 percent (about 7 g per kg initial body weight) oleic acid or linoleic acid in their diets for four weeks showed improved feed utilization as measured by grams gained per gram of feed. No adverse effects were observed.

Flesch (43) observed that the administration by stomach tube of 10 ml (about 2 g per kg) of oleic acid every other day for four days to four albino rabbits resulted in scaling lesions on their ears. The effect was reversible. Lower doses of oleic acid or ethyl oleate failed to have this effect.

Thomasson (44) fed 21-day-old male Wistar rats seven different doses, ranging from 10 to 73 calories percent, of 20 different oils, including peanut oil and coconut fat, for six weeks. Generally, the various oils and fats used showed some differences in growth-promoting effect, but the food-efficiency seemed to have a constant value and to be independent of the type of fat used. No adverse effects were reported.
Harris and Mosher (45) fed refined coconut oil to 120-day-old male and female Wistar rats at a dietary level of 25 percent (about 25 g per kg of body weight) for 90 days. Growth rate was slightly less than that of the control animals. The only other adverse effect observed was a slight fatty infiltration of the liver.

The Select Committee has found no reports indicating that coconut oil, peanut oil, oleic acid, or linoleic acid are allergenic.

Carcinogenicity

Gothoskar and Ranade (46) found that the daily administration of 0.1 ml of peanut oil (about 1 g per kg per day) by stomach tube to Wistar rats for six months did not induce grossly observable abnormalities that warranted histological examination. No effect was observed on liver weight. Adult hybrid mice of XVII X C57 black strain, fed 0.05 ml of peanut oil (about 80 mg per kg of body weight) daily for life, developed no malignant lesions of the digestive tract. Gammal et al. (47) reported that feeding a diet containing 20 percent coconut oil to weanling Sprague-Dawley rats for four months did not enhance the carcinogenicity of orally administered 7,12-dimethylbenz(α)anthracene. A number of studies, not considered relevant to this report, have been published on the effects of topical application of various fatty acids, including oleic and linoleic acids, on the enhancement of the activity of carcinogens.

It is noteworthy that Fabian (48) found some commercial coconut oils in Germany to contain carcinogenic polycyclic aromatic hydrocarbons (PAH). One lot, for example, contained 18.6 ppb of 3,4-benzo(α)pyrene, an oral carcinogen. It was pointed out, however, that refining the oil by steam deodorization and activated carbon treatment would be expected to eliminate harmful concentrations of PAH. Fabian's report is supported by Biernoth and Rost (49) who found up to 62 ppb of benzo(α)pyrene in commercial samples of coconut oils prepared from smoke-dried copras. Processing history has a bearing on PAH content as demonstrated by Grimmer and Hildebrant (50, 51) who found no benzo(α)pyrene in fresh coconut meat, 0.5 ppb in sun dried, and 13.7 ppb in smoke dried copra. Likewise, refining procedures affect the PAH content of vegetable oils, qualitatively and quantitatively (49, 52); a combination of bleaching with activated carbon and deodorization reduces PAH to very low levels. Standards for the levels of PAH in vegetable oils have not been established nor are there standard procedures for the refining of vegetable oils. However, according to Jamieson (6) and Weiss (53) processors of oils and and users in the food industry in the United States customarily deodorize and bleach vegetable oils employing Fuller's earth and activated carbon.
Teratogenesis and mutagenesis

Clegg (54) studied the teratogenicity of BHA and BHT in four strains of mice and four strains of rats using peanut oil as the vehicle for oral administration. In all experiments, animals receiving peanut oil alone showed no indication of teratogenic effects as compared to untreated controls. Dosage was not indicated.

The Select Committee has found no reports of teratologic studies of oleic acid, linoleic acid, or coconut oil.

Bhatnagar, et al. (55) and Swaminathan and Natarajan (56, 57) evaluated the mutagenic effects on barley and triticum seeds of coconut oil, peanut oil and oleic acid. Chromosomal aberrations were observed in all treatments but viable mutants were absent.

The Select Committee has found no reports of mutagenic studies of oleic acid, linoleic acid, coconut oil, or peanut oil in animals.

Atherosclerosis

It is recognized (58) that some investigators consider dietary fat as one of the risk factors in the etiology of atherosclerosis, a position taken, in part, because serum levels of cholesterol are influenced by the nature of dietary fat. Ahrens et al. (59), for example, has shown in human subjects on formula diets, that consumption of coconut oil results in higher serum cholesterol concentrations than does consumption of corn oil.

However, considering the limited uses for coconut oil, peanut oil, oleic acid, and linoleic acid covered in this report, it is improbable that the very small intakes that would be expected therefrom could be significant factors in influencing serum cholesterol levels. This question will be dealt with in other reports of the Select Committee, such as that on hydrogenated soybean oil (12), where intakes are more significant and consideration of their possible atherosclerotic impact more appropriate.

V. OPINION

Coconut oil, peanut oil, oleic acid, and linoleic acid have been used as foods or as food components by man for many years. These two oils and the two fatty acids are rapidly absorbed after oral administration, metabolized, and the metabolic products are utilized and excreted. None of the available biological information indicates that these substances are hazardous to man or animals even when consumed at levels that are orders of magnitude greater than could result from their use for the purposes covered in this report.
The evidence now available indicates that linoleic acid is not being used by the food industry as a nutrient or dietary supplement.

Based on these considerations, the Select Committee concludes that:

There is no evidence in the available information on coconut oil, peanut oil, and oleic acid that demonstrates, or suggests reasonable grounds to suspect, a hazard to the public as they are now used in paper and cotton packaging material for food at levels now current or as they might reasonably be expected to be used for such purposes in the future.

There is no evidence in the available information on linoleic acid that demonstrates, or suggests reasonable grounds to suspect, a hazard to the public when it is used as a nutrient or dietary supplement at levels now current or that might reasonably be expected in the future.
VI. REFERENCES CITED


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October 28, 1977
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