

the indications for which the drug has been reclassified from possibly effective to lacking substantial evidence of effectiveness may on or before April 9, 1973, petition for the issuance of a regulation providing for other certification of the drug for such indications. The petition must be supported by a full factual and well documented medical analysis which shows reasonable grounds for the issuance of such regulation.

The petition for issuance of said regulation should be filed (preferably in triplicate) with the Hearing Clerk, Department of Health, Education, and Welfare, Room 6-38, 5600 Fishers Lane, Rockville, Md. 20852.

This notice is issued pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 502, 507, 52 Stat. 1051-51, as amended, 59 Stat. 463, as amended; 21 U.S.C. 352, 357) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 2.120).

Dated: March 3, 1973.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner
for Compliance.

[FR Doc. 73-4544 Filed 3-3-73; 3:45 am]

ACUPUNCTURE DEVICES LABELING Notice to Manufacturers, Packers and Distributors

The Commissioner of Food and Drugs is aware of the current interest in the United States surrounding the use of acupuncture needles, stimulators, and other accessories for medical purposes. Acupuncture paraphernalia are being imported into this country and are also being manufactured domestically for various medical uses, including the treatment and diagnosis of serious diseases, anesthesia, and pain relief. These products are devices and must comply with all applicable provisions of the Federal Food, Drug, and Cosmetic Act.

It is the position of the Food and Drug Administration that the safety and effectiveness of acupuncture devices have not yet been established by adequate scientific studies to support the many and varied uses for which such devices are being promoted, including uses for analgesia and anesthesia. Although various theories have been advanced as to how medical results can be obtained through the use of acupuncture, none has been proved or generally accepted, and there is a body of scientific opinion which questions the safety and effectiveness of acupuncture in many of the uses for which it is now being applied.

Under the Federal Food, Drug, and Cosmetic Act, all devices must be properly labeled to be in compliance with the law. Devices which are not safe for use by the laity, or for which adequate directions cannot be written for safe use by the laity, must be labeled as prescription devices and must be accompanied by labeling which provides the prescribing practitioner with adequate directions for their safe and effective use. Because the

safety and effectiveness of acupuncture devices have not yet been adequately demonstrated, and labeling therefore cannot be devised, which would provide adequate directions for safe and effective use, they may not be labeled in accordance with the requirements for prescription devices as stated in 21 CFR 1.106(d). Until evidence is obtained demonstrating that acupuncture is a safe and effective medical technique, acupuncture devices must be limited to investigational or research use.

Current Food and Drug Administration regulations do not contain specific provisions governing the shipment of investigational devices in interstate commerce for clinical research or experimental use. The Commissioner of Food and Drugs is aware of the need for such regulations to provide adequate guidance as to the labeling for experimental devices to be used on human beings. Therefore, the Commissioner intends to publish at a later date proposed regulations which would govern all investigational devices. In the interim, this notice will apply to all acupuncture devices.

In order to establish guidelines under which manufacturers, packers, and distributors can properly label acupuncture devices for investigational use, the Food and Drug Administration met on September 22, 1972, with individuals concerned with the use of acupuncture in the United States. These included representatives of the States of California and New York, the city of New York, the American Society of Anesthesiologists, the National Institutes of Health, the Federation of State Medical Boards, the American Medical Association, medical practitioners, and the Food and Drug Administration Medical Device Advisory Committee. It was the consensus of this group that acupuncture devices should be restricted to investigational use by licensed practitioners and that the labeling for these devices should include this restriction in addition to other information.

Accordingly, the Commissioner of Food and Drugs concludes that until substantial scientific evidence is obtained by valid research studies supporting the safety and therapeutic usefulness of acupuncture devices, the Food and Drug Administration will regard as misbranded any acupuncture device shipped in interstate commerce if the following information does not appear in the labeling:

- (a) The name of the device.
- (b) The name and place of business of the manufacturer, packer, or distributor.
- (c) An accurate statement of the quantity of the contents.
- (d) The composition of the device and whether it is sterile, nonsterile, reusable, or disposable.
- (e) The dimension or other pertinent physical characteristics of the device.
- (f) The following statement: "Caution: Experimental device limited to investigational use by or under the direct supervision of a licensed medical or den-

tal practitioner. This device is to be used only with informed consent under conditions designed to protect the patient as a research subject, where the scientific protocol for investigation has been reviewed and approved by an appropriate institutional review committee, and where conditions for such use are in accordance with State law."

Instructions for the use of the device for the purpose for which it is being investigated and, to the extent such information is known, any human hazards, contraindications, precautions, or side effects associated with its use, should be provided to researchers and investigators. The Food and Drug Administration, however, will regard as misbranded any acupuncture device shipped in interstate commerce if accompanied by claims of diagnostic or therapeutic effectiveness.

Pending promulgation of separate regulations for conducting clinical investigations of investigational devices, researchers and investigators shall assure adequate informed consent and institutional committee review for such investigations, utilizing as a guideline the standards established for investigational drugs in 21 CFR 130.37 and in Division 10 unit C of form FD-1571, in 21 CFR 130. (a) (2).

Dated: February 21, 1973.

SHERWYN GARDNER,
Deputy Commissioner
of Food and Drugs.

[FR Doc. 73-4540 Filed 3-3-73; 3:45 am]

[Docket No. FDC-D-255; NDA 11-370 etc. DESI 10732]

LAVEMA COMPOUND SOLUTION AND LAVEMA ENEMA POWDER

Final Order on Objections and Request for a Hearing Regarding Withdrawal of Approval of New-Drug Application

In the FEDERAL REGISTER of September 30, 1971 (36 FR 19184), the Food and Drug Administration announced the evaluation of a report received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group on several preparations containing oxyphenisatin, including Lavema Compound Solution and Lavema Enema Powder, Winthrop Laboratories, Division of Sterling Drug, Inc., 90 Park Avenue, New York, NY 10016 (NDA's 12-58 and 11-370; DESI 10732).

The announcement stated that new evidence of clinical experience, not contained in the new drug applications, evaluated together with the evidence available to the Commissioner until after the applications were approved, evaluated together with the evidence available to the Commissioner when the applications were approved, reveals the oxyphenisatin base and acetate are not shown to be safe for use under the conditions of use contained in the approved applications. The announcement further stated the conclusion of the Food and Drug Administration that in view of the hazards associated with the use of oxy-

phenisatin, including hepatitis and jaundice, and the availability of alternative drugs having a wider margin of safety, the ratio of benefit-to-risk with either orally or rectally administered drugs containing oxyphenisatin base or acetate, does not justify their continued marketing.

II. RECOMMENDED USES

Lavema Compound Solution is recommended: For use as a cleansing enema for fecal impaction; for removal of barium following barium enema; for constipation on isolated occasions; prior to proctosigmoidoscopic examination; for preoperative preparation of the lower bowel; and postoperatively. Lavema Enema Powder is recommended: For use as a cleansing enema before roentgenography; before proctosigmoidoscopic and fluoroscopic examination of the colon; for preoperative preparation of the large intestine; and for administration on isolated occasions to patients with severe constipation not relieved by aqueous enemas. Lavema Enema Powder is also recommended for use as a barium enema adjuvant.

III. GENERAL OBJECTIONS

In its request for an opportunity for a hearing, Winthrop Laboratories contends that FEDERAL REGISTER notice of October 29, 1971, is defective and/or incorrect in several important respects: Lavema contains oxyphenisatin base compared to oxyphenisatin acetate which is present in the oral laxative preparations which were also subject to the October 29, 1971, order; the Lavema drugs are administered by the rectal rather than the oral route; Lavema drugs are prescription drugs rather than over-the-counter drugs, as is the case with the laxatives; the laxatives contain the wetting agent, dioctyl sodium sulfosuccinate, which is not present in the enemas; the laxative is intended for repeated administration while the enemas are intended for single dose administration; the orally administered preparation is present in the bowel for at least 8 hours; the enema is administered in the hospital while the laxative may be taken outside of the hospital; there have been no reports associating the use of Lavema with liver toxicity; and the alternative enemas, mainly saline, have been associated with toxic reactions. Winthrop has submitted the affidavit of Monroe Trout, M.D., Medical Director of Sterling Drug, Inc., in support of these contentions. Each of these points will be discussed in order.

The announcement provided an opportunity for a hearing on withdrawal of the new drug applications for Lavema Compound Solution and Lavema Enema Powder (NDA's 12-587 and 11-370). Thirty days were allowed for filing a written appearance requesting a hearing by any interested persons giving the reasons why approval of the new drug applications should not be withdrawn, together with a well-organized and full-factual analysis of the clinical and other investigational data they were prepared

to prove in support thereof. A request for a hearing was submitted by Winthrop Laboratories, Division of Sterling Drug, Inc., on October 29, 1971.

The medical presentation of Winthrop Laboratories has been considered, and the Commissioner of Food and Drugs concludes that there is no genuine and substantial issue of fact requiring a hearing and that the legal arguments offered are insubstantial, all as explained in more detail below.

I. THE DRUGS

Lavema Compound Solution is a disposable enema kit, supplied in 180 ml. bottles, containing a liquid solution which has oxyphenisatin base as its active ingredient. Lavema Enema Powder is a powder preparation, supplied in 3 gm. packets, which has oxyphenisatin base as its active ingredient.

1. *Lavema contains oxyphenisatin in the unacetylated compound while the orally administered laxatives contained oxyphenisatin acetate.* The sponsor states that the acetate is more soluble while the unacetylated base form is less soluble, and implies that the base is less absorbed than the acetate from the gastrointestinal tract. However, Winthrop does not present adequate scientific evidence to support this suggestion or to show that, in fact, it results in greater safety. While the acetate form of various compounds is frequently more soluble, in the case of oxyphenisatin both the acetate and the base are quite insoluble and are not readily absorbed. The "U.S. Dispensatory and Physicians' Pharmacology," J. B. Lippincott Co., 1967, pages 796-797. It has been found that the unacetylated form of oxyphenisatin is more readily absorbed than the acetate form and evidence indicates that the oxyphenisatin acetate has to be deacetylated and converted to the unacetylated form in order for detectable absorption to occur. G. Ferlmann and W. Vogt, "Deacetylation and Absorption of Phenolic Laxatives," Arch. Exptl. Pathol. Pharmacol. 250(4), 479-487 (1965). Since Winthrop has failed to present adequate scientific data to refute this evidence or to support its own contention, the Commissioner finds a lack of evidence of safety on this point.

2. *Lavema is administered rectally while the laxatives are administered orally.* The sponsor attaches two points of significance to this fact, both of which are discussed under points 5 and 6 below.

3. *The Lavema drugs are prescription items administered in the hospital under the supervision of a physician which will severely decrease the likelihood of toxic liver reaction.* Winthrop presented no evidence to support this contention, and fails to show that the administration of the drug under a doctor's supervision may severely decrease the likelihood of toxic liver reaction if the toxic liver reaction is based on hypersensitivity (see point 5 below). The close observation by a physician may facilitate the early diagnosis of toxic liver reaction, but would not prevent the occurrence of such re-

action. The Commissioner therefore finds inadequate evidence of safety with respect to this point.

4. *The oral preparation contains a wetting agent (dioctyl sodium sulfosuccinate).* Winthrop asserts that the presence of this wetting agent is likely to enhance the absorption of the drug. This is a theoretical possibility. However, Winthrop presents no scientific evidence to document this theory. The wetting agent is irrelevant with respect to absorption since oxyphenisatin acetate largely remains in the unabsorbable acetate form in the bowel. The Commissioner therefore finds a lack of adequate evidence of safety to support the theoretical contention made in this point.

5. *Frequency of administration.* Winthrop states, that, based on the literature reports, the liver toxicity apparently is dependent on number of doses and that if the liver toxicity is due to hypersensitivity reaction, one would not expect it to occur with Lavema which is usually given as a single treatment. This point is based on Winthrop's speculation of a decreased likelihood of Lavema being associated with toxic liver reaction whether this reaction is on a dose-related basis or on a hypersensitivity basis. However, as Winthrop readily admits, the exact mechanism of the toxic action of oxyphenisatin has not been determined at the present time. The law requires the sponsor to determine by scientific evidence that a drug is safe, rather than relying upon speculation and hypothesis. It is therefore incumbent upon Winthrop to show the mechanism for this toxicity. In the absence of well-documented evidence of the mechanism of the toxic reaction, cannot be assumed that the drug administered as a single rectal dose will cause hepatic toxicity. The Commissioner therefore finds a lack of adequate safety data to support this point.

6. *The rectally administered preparation is expelled within 15 to 30 minutes while the oral preparation is subject to absorption for at least 3 hours.* Two important facts must be taken into consideration here. First, the orally administered drug, as pointed out above, apparently must undergo deacetylation prior to any significant amount of absorption as the base. On the other hand, the rectally administered drug is already in the base and it is more suitable for absorption immediately after insertion in the body. Second, the dose administered is quite different. The oral product contains 3 milligrams of oxyphenisatin and recommended dose is one capsule twice a day. In contrast, the rectally administered product contains 20 milligrams oxyphenisatin base. In spite of these facts, Winthrop has submitted no scientific data to support its theory that a shorter period of exposure associated with the rectal product results in absorption or greater safety. The Commissioner therefore finds a lack of evidence of safety on this point.

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7. *The enema is administered in the hospital.* This contention is discussed under point 3 above.

8. *There are no reports of association of liver toxicity with the use of Lavema.* The lack of adverse reaction reports, which are available on an ad hoc basis, does not constitute or substitute for adequate scientific evidence of safety. Toxic reactions may go unnoticed or unreported, or may not properly be associated with the causative drug. Only scientific studies can adequately show safety. Potential toxicity exists with Lavema as well as with the orally administered agents, and the law requires the sponsor of the drug to prove safety.

9. *The alternative methods which may be used instead of Lavema are not without toxicity.* Winthrop states that the saline type of enemas may be associated with aberrations of electrolyte balance in anuric patients. But this potential danger exists primarily in patients who already have extremely severe renal disease, and a physician using enemas in the hospital will be able to identify and exclude that type of patient very easily.

Furthermore, there are enemas safer than the Lavema drugs that are available for use for the conditions for which the Lavema drugs are recommended. First, for use before proctosigmoidoscopy and before roentgenography examination of the colon, an ordinary saline enema, a warm water and soap suds enema, a tap water enema if renal problems are expected, a glycerine suppository or any safe cathartic that does not contain oxyphenisatin are safer for use than the Lavema drugs. Second, for preoperative preparation of the large intestine, a warm saline enema or a warm water and soap suds enema is safer than the Lavema drugs. Third, for isolated cases of severe constipation not relieved by aqueous enemas, a stimulant cathartic (other than oxyphenisatin) with or without a saline or soap suds and water enema is safer for use than the Lavema drugs. Fourth, for fecal impaction, an oil retention enema, containing mineral, cottonseed or olive oil, or manual dilatation are safer for use than the Lavema drugs. Fifth, as a barium enema adjuvant, air insufflation is safer than use of the Lavema drugs. Sixth, for removal of barium following a barium enema, an oral cathartic laxative not containing oxyphenisatin is safer for use than the Lavema drugs. Finally, use of enemas postoperatively is uncommon. When an enema is needed for this indication, the saline enema and soap suds and water enema are safer for this use than the Lavema drugs.

IV. THE DATA TO SUPPORT THE CLAIMS OF SAFETY

Winthrop has submitted the reports of three unpublished studies conducted for it, which it contends constitute substantial evidence of safety of the Lavema products, and a lengthy list of medical endorsements.

A. THE STUDIES

1. The first report submitted consists of a study conducted by J. O. Hoppe con-

taining the following information from animal studies concerning dihydroxyphenylisatin: toxicity, irritation, information on mode of action, and how it differs from tannic acid. The Commissioner notes that tannic acid is a highly toxic drug. It is assumed that the researcher had hoped to show dihydroxyphenylisatin less toxic than tannic acid.

The acute toxicity studies were conducted with dihydroxyphenylisatin both intravenously and orally on mice. The oral dosage was a suspension form of the drug, while the clinical form of the drug is a solution.

The dihydroxyphenylisatin irritation tests were conducted on rabbits. The study shows a degree of irritation which may be clinically significant.

The investigator himself concluded that he lacked sufficient data to permit a free discussion of the mode of action of dihydroxyphenylisatin and stated that he had not conducted a comparative study of the drug with tannic acid.

2. The second report was submitted by F. Coulston, H. P. Drobeck, and M. Rennie, who conducted a study for Winthrop to determine the irritant effect of 0.02 percent of dihydroxyphenylisatin on the rectal mucosa of monkeys. The results of this study showed that a single rectal installation of 0.02 percent solution (only two times the maximum clinical concentration) had the potential for causing slight to moderate visible hyperemia of the rectal mucosa while an equal volume of saline solution administered in a similar manner had no effect.

3. The third study, conducted for Winthrop by J. O. Hoppe and Mr. Brosseau, was conducted to duplicate experimentally a collapse syndrome detected in elderly patients following a barium enema containing Lavema. The authors state that five experiments were conducted on dogs, although the report indicates that one experiment was carried out on five dogs by administration of varying amounts of Lavema.

Although the results failed to confirm the clinical reports of adverse cardiovascular effects, an adequate evaluation of the potential cardiovascular activity of oxyphenisatin would require parenteral studies as well.

4. *Summary.* The animal data are not sufficient to give a proper characterization of the potential toxicity of Lavema. They do indicate that oxyphenisatin base is irritating enough for one to be legitimately concerned about potential clinical irritancy. No data were submitted to show that Lavema is not toxic to the liver. Based on these studies, the Commissioner finds that Winthrop Laboratories has not submitted adequate evidence of safety of Lavema.

B. THE MEDICAL ENDORSEMENTS

Winthrop has submitted comments from approximately 66 physicians who have administered the Lavema drugs to their patients at Winthrop's request. These comments are testimonials at best and do not comprise in any manner adequate proof of safety. Moreover, none of these physicians makes any reference to

any adequate scientific studies having been conducted on the Lavema drugs establish their safety in use. No pre-post-clinical data for the evaluation of the safety of the Lavema drugs is presented in any of these statements. The large numbers of clinical cases referred to in the comments are not documented with actual patient data.

V. LEGAL OBJECTIONS

For the reasons discussed below, Winthrop's objections are insubstantial and inapplicable to this withdrawal.

Winthrop cites "Bell v. Goddard," 3 F. 2d 177, 181 (C.A. 7, 1966) for the proposition that the Commissioner must show that one or more of the grounds for withdrawal under section 305(e) have been met. Winthrop contends that this condition has not been met since there is new evidence of clinical experience relating to Winthrop's product which reveals that it is unsafe in use. However, discussed in detail in the introduction to this order and under Part III above, jaundice, hepatitis, and liver hypersensitivity have been demonstrated to occur the acetate form. The acetate when orally ingested is converted to the base form in which the drug is absorbed and which is responsible for its laxative action. The base form is the sole active ingredient in the Lavema drugs. Winthrop has presented no scientific evidence whatever to show how this evidence is inapplicable to the Lavema products.

Winthrop also objects to the Commissioner's conclusion that the ratio benefit-to-risk with either orally or rectally administered drugs containing oxyphenisatin, base or acetate, does not justify their continued marketing, on the ground that this is an opinion. Winthrop has filed the affidavit of Dr. Monte Trout, in support of this contention. Dr. Trout's affidavit has already been discussed (Part III, above). Moreover, the law requires that Winthrop submit evidence consisting of adequate tests by methods reasonably applicable to demonstrate that the Lavema drugs are safe for use for their labeled conditions. Since new evidence of clinical experience reveals that the Lavema drugs are not shown to be safe and Winthrop has failed to submit any adequate scientific study to demonstrate the Lavema drugs to be safe, the Act mandates that the new drug applications be withdrawn. The Commissioner has reached a legal conclusion, and merely issued an advisory opinion.

The Winthrop position appears to be bottomed on the contention that, once a drug is marketed, the Commissioner may not permit it to remain on the market absent clear proof of harm. The statute, however, provides that the burden of proving safety remains forever on the drug sponsor. The Commissioner need find, as he did in this case, only that new evidence shows that the sponsor has failed to satisfy its burden of proving safety. In order to withdraw the new drug application, 21 U.S.C. 355(e) (2).

In this instance, Winthrop relies solely upon theory and hypothesis unsupported by scientific tests; upon animal stud-

not even related to the toxicity question involved; and upon testimonials from physicians that do not purport to be based on scientific tests. Winthrop has failed to identify even one scientific study to support its contentions. Accordingly, there is no possible basis for a finding that the drug has been proved safe.

VI. FINDINGS

The Commissioner, based on the review of the medical documentation offered to support the claims of safety for Lavema compound solution and Lavema enema powder finds that Winthrop Laboratories, Division of Sterling Drug, Inc., has failed to present adequate evidence of safety for these products. Therefore, pursuant to 21 CFR 130.14(b), the request of Winthrop Laboratories for a hearing on the withdrawal of the new drug application for Lavema compound solution and Lavema enema powder is denied. No objection or documentation was presented by any other firms and, in accordance with the provisions of 21 CFR 130.15, this failure is construed as an election by any other firm not to avail itself of the opportunity for the hearing.

The Commissioner further finds that the approval of the new drug application heretofore approved for Lavema compound solution and Lavema enema powder (NDA's 12-587 and 11-370) should be withdrawn on the basis of a lack of substantial evidence of safety.

Therefore, pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (secs. 505, 701, 52 Stat. 1052-1053, 1055-1056, as amended, and 76 Stat. 781-785, as amended; 21 U.S.C. 355, 371), and under authority delegated to the Commissioner (21 CFR 2.120), notice is given that the approval of the new drug applications for Lavema compound solution and Lavema enema powder (NDA's 12-587 and 11-370) are withdrawn, effective immediately.

Dated: March 6, 1973.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc. 73-4543 Filed 3-8-73; 8:45 am]

National Institutes of Health AD HOC COMMITTEE ON SMOKING AND HEALTH

Notice of Meeting

Pursuant to Public Law 92-463, notice is hereby given of the meeting of the ad hoc committee on smoking and health, March 25, 1973, at 2 p.m., National Institutes of Health, Building 31, Conference Room 6. This meeting will be open to the public from 2 p.m. to 5 p.m. on March 25 to discuss the best method to control the levels of tar and nicotine in cigarettes and the organization of an expanded inter-disciplinary tobacco research program.

Mr. Frank Karel, Associate Director for Public Affairs, NCI, Building 31, Room 19A31, National Institutes of

Health, Bethesda, Md. 20014 (301-496-1912) will furnish summaries of the open meeting and roster of committee members.

Dr. Gio B. Gorn, Executive Secretary, Building 31, Room 11A03, National Institutes of Health, Bethesda, Md. 20014 (301-496-6616) will provide substantive program information.

Dated: March 2, 1973.

JOHN F. SHERMAN,
Deputy Director,
National Institutes of Health.

[FR Doc. 73-4558 Filed 3-3-73; 9:45 am]

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. D-73-220]

CERTAIN HUD EMPLOYEES IN REGION VIII (DENVER)

Redelegation of Authority To Administer Oaths

Each of the following incumbent employees and their successors in the Department of Housing and Urban Development, Region VIII (Denver, Colo.), is hereby authorized to administer oaths under section 311(a) of the Civil Rights Act of 1968, Public Law 90-284, 42 U.S.C. 3611(a), and to verify complaints filed under the Civil Rights Act of 1968:

1. Equal opportunity specialists.
2. Housing opportunity officer.
3. Contract compliance employment officer.
4. Title VI—Complaint compliance officer.
5. Secretary to Assistant Regional Administrator for Equal Opportunity.

(Redelegation of authority by Regional Administrator effective January 22, 1971; 36 FR 11821, June 19, 1971.)

Effective date. This redelegation of authority shall be effective as of January 22, 1973.

ROBERT J. BARELA,
Assistant Regional Administrator
for Equal Opportunity, Region VIII.

[FR Doc. 73-4617 Filed 3-3-73; 8:45 am]

DEPARTMENT OF TRANSPORTATION

Coast Guard

[CGD 73-39N]

SHELL OIL CO.

Notice of Qualification as Citizen of
United States

This is to give notice that pursuant to 46 CFR 67.23-7, issued under the provisions of section 27A of the Merchant Marine Act, 1920, as added by the Act of September 2, 1958 (46 U.S.C. 883-1), the Shell Oil Company of 1 Shell Plaza, Houston, TX 77001, incorporated under the laws of the State of Delaware, did on February 14, 1973, file with the Commandant, U.S. Coast Guard, in duplicate, an oath for qualification of a corporation as a citizen of the United States following the form of oath prescribed in Form CG-1260.

The oath shows that:

(a) A majority of the officers and directors of the corporation are citizens of

the United States (list of names, home addresses, and citizenship attached to the oath);

(b) Not less than 90 percent of the employees of the corporation are residents of the United States;

(c) The corporation is engaged primarily in a manufacturing or mineral industry in the United States, or in a territory, district, or possession thereof;

(d) The aggregate book value of the vessels owned by the corporation does not exceed 10 percent of the aggregate book value of the assets of the corporation; and

(e) The corporation purchases or produces in the United States, its territories, or possessions not less than 75 percent of the raw materials used or sold in its operations.

The Commandant, U.S. Coast Guard, having found this oath to be in compliance with the law and regulations, on February 19, 1973, issued to the Shell Oil Co. a certificate of compliance on Form CG-1262, as provided in 46 CFR 67.23-7. The certificate and any authorization granted thereunder will expire 3 years from the date thereof unless there first occurs a change in the corporate status requiring a report under 46 CFR 67.23-7.

Dated: March 2, 1973.

W. F. REA, III,
Rear Admiral, U.S. Coast Guard,
Chief, Office of Merchant
Marine Safety.

[FR Doc. 73-4556 Filed 3-3-73; 8:45 am]

Federal Aviation Administration APPLICATION OF AREA NAVIGATION IN NATIONAL AIRSPACE SYSTEM

Policy Regarding Implementation of Area
Navigation Concepts Recommended By
Joint FAA/Industry Task Force

Correction

In FR Doc. 73-4366, appearing at page 6093 for the issue for Tuesday, March 6, 1973, the fifth paragraph should read as follows:

Any interested person who wishes to express his views or comment with respect to this report may do so by submitting them in writing to the Federal Aviation Administration, Air Traffic Service, Chief, Automation Division, AAT-500, 300 Independence Avenue SW., Washington, DC 20591. Individual copies of the report may be obtained from the above address. All communications received prior to May 31, 1973, will be considered in the formulation of a final policy.

ADVISORY COUNCIL ON INTERGOV- ERNMENTAL PERSONNEL POLICY

RECOMMENDATIONS REGARDING
PERSONNEL POLICIES AND PROBLEMS

Notice of Closed Meeting

Pursuant to the provisions of section 10 of Public Law 92-463, effective Jan-