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August 20, 1976

No. 25

TO: All Members of PVC/VCM Mailing List

Letter Highlight

The National Institute of Occupational Safety and Health is re-investigating the health aspects of vinyl chloride to bring its criteria document up to date.

Ladies and Gentlemen:

We are taking advantage of the attached mailing to distribute to you a copy of the Notice that appeared in the July 29, 1976 edition of the Federal Register regarding the National Institute of Occupational Safety and Health's (NIOSH) request for additional information on vinyl chloride.

James - note - let them in

Although the Notice only requests the submission of new information regarding vinyl chloride so that the criteria document can be updated, we have just learned that NIOSH is actually going beyond the mere request for information and is sending investigators into plants as well. Ultimately, all the information it accumulates will be used to determine whether the Vinyl Chloride Standard should be revised.

Obviously, this is another area that we must follow closely.

Cordially yours,

Jerome H. Heckman

Enclosure

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employment. Section 22(c) of the Act authorizes the National Institute for Occupational Safety and Health (NIOSH) to develop recommended occupational safety and health standards (criteria documents) and to perform all functions of the Secretary of Health, Education, and Welfare, under sections 20 and 21 of the Act. Since 1972, NIOSH has developed and forwarded to the Assistant Secretary for Labor criteria documents on more than 30 subjects. Published and unpublished information relating to many of the criteria documents which were published during 1972-1974 has increased at such a rate that NIOSH must now consider an update of the following 13 criteria documents:

Criteria Documents:	GPO Number
Hot Environments.....	1733-00010
Carbon Monoxide.....	1733-00006
Noise.....	1733-00007
Ultraviolet Radiation.....	1733-00012
Inorganic Lead.....	1733-00013
Coke Ovens.....	1733-00015
Toluene.....	1733-00019
Inorganic Mercury.....	1733-00022
Vinyl Chloride.....	(Not available from GPO)
Sulfuric Acid.....	1733-00034
Ammonia.....	1733-00036
Cotton Dust.....	1733-00044
Silica.....	(Not available from GPO)

Each criteria document includes among other items an evaluation of available information relative to the areas listed below.

Any person having new information or data in any of the areas listed below, or in other areas considered relevant to the establishment of a safe and healthful occupational environment involving these agents is requested to submit such information, with accompanying documentation to the Director, Division of Criteria Documentation and Standards Development, (FEDERAL REGISTER Notice No. 6), NIOSH, 5600 Fishers Lane, Park Building, Room 3-18, Rockville, MD 20852, within 30 days.

1. Establishment of safe occupational environmental levels for such agents including levels for acute and chronic exposure to airborne concentrations of the chemical agents as well as safe practices concerning direct contact with such agents.

2. Establishment of biologic standards, i.e., the levels of such agents, metabolites, or other effects of exposure which may be present within man without his suffering ill effects taking into consideration (a) the correlation of airborne concentrations of, and extent of exposure to, such substances with effects on specific biologic systems of man such as the circulatory, respiratory, urinary, and nervous system, and (b) the analytical methods for determining the amount of the substance which may be present within man.

3. Engineering controls, including ventilation, environmental temperature, humidity, and housekeeping and sanitation procedures, with attention to the technological feasibility of such controls.

4. Specifications for the conditions under which personal protective devices should be required.

5. Methods, including instruments, for air sampling and sample analysis of the chemical agents and methods of measuring levels of exposure to the physical agents.

6. The need for medical examinations for workers exposed to such agents, the frequency of such examinations, and the specific diagnostic tests which should be used and the rationale of their selection.

7. Work practices or procedures which may be instituted for control of the workplace environment in normal operations and those which may be instituted when occupational environmental levels are temporarily exceeded or where peak concentrations of chemical agents in man are reached.

8. The types of records concerning occupational exposure to such agents that employers should be required to maintain.

9. Warning devices and labels which should be required for the prevention of occupational diseases and hazards caused by such agents.

All information received concerning these substances, except that information which is trade secret and protected by Section 15 of the Act, will be available for public inspection at the foregoing address.

Dated: July 20, 1976.

EDWARD J. BAIER,
Acting Director, National Institute
for Occupational Safety
and Health.

[FR Doc. 76-21906 Filed 7-29-76; 8:45 am.]

Food and Drug Administration

[Docket No. 76N-0249; DESI 9295]

BUCLIZINE HYDROCHLORIDE FOR ORAL ADMINISTRATION

Drugs for Human Use; Drug Efficacy Study Implementation; Followup Notice and Opportunity for Hearing

In a notice (DESI 9295; Docket No. FDC-D-302 (now Docket No. 76N-0249)) published in the FEDERAL REGISTER of March 9, 1971 (36 FR 4558), as amended by a notice published in the FEDERAL REGISTER of March 13, 1975 (40 FR 11794), the Food and Drug Administration announced its conclusions that the drug products described below are (1) effective for the management of nausea, vomiting, and dizziness associated with motion sickness; (2) lacking substantial evidence of effectiveness for the following claims: "Conditions in which emotional stress is a complicating or causative factor such as essential hypertension, sterility, hyperkinesia, palpitation, cramps, hyperhidrosis, tremor, headache, and insomnia"; "Additional antihistaminic, antiemetic, antinotion sickness, and hypotensive properties make it a unique compound in the field of non-phenothiazine tranquilizers"; and for the relief of bronchial asthma; and (3) possibly effective for its other labeled indications, including vertigo. The March 9, 1971 notice also offered an opportunity for a hearing concerning the indications concluded at that time to lack substantial

evidence of effectiveness. No person has submitted any data in support of the possibly effective indications, and these indications are now reclassified as lacking substantial evidence of effectiveness. This notice offers an opportunity for a hearing concerning those indications and sets forth the conditions for marketing of drug products for the indications for which they continue to be regarded as effective. Persons who wish to request a hearing may do so on or before August 30, 1976.

The notice that follows does not pertain to the indications stated in the March 9, 1971 notice to lack substantial evidence of effectiveness. No person requested a hearing concerning them, and they are no longer allowable in labeling. Any such product labeled for those indications is subject to regulatory action.

1. NDA 9-295; Vibazine Hydrochloride Tablets containing buclizine hydrochloride, previously marketed by Pfizer Laboratories, Division of Pfizer, Inc., 235 E 42d St., New York, NY 10017.

2. NDA 11-378; Softran Tablets containing buclizine hydrochloride, previously marketed by Stuart Pharmaceuticals, Division of I.C.I. Unit, State College, P.O. Box 751, 3411 Silverside Rd., Wilmington, DE 19897.

3. NDA 11-76; Softran Tablets containing buclizine hydrochloride, previously marketed by Stuart Pharmaceuticals.

In a notice published in the FEDERAL REGISTER of February 2, 1975 (38 FR 3208), the approval of NDA 11-378 for Softran Tablets was withdrawn on the ground of failure to submit required reports under section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 355(j)). At the time that notice was published, no final conclusions concerning the possibly effective indications had been reached. Those conclusions have now been reached, and the purpose of including Softran (buclicine hydrochloride) Tablets (NDA 11-378) in this notice is to inform all interested persons of such conclusions and offer from the opportunity to request a hearing concerning all issues relating to its legal status.

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

In addition to the holder(s) of the new drug application(s) specifically named above, this notice applies to all persons who manufacture or distribute a drug product, not the subject of an approved new drug application, that is identical, related, or similar to a drug product named above, as defined in 21 CFR 310.6. It is the responsibility of every drug manufacturer or distributor to review this notice to determine whether it covers any drug product he manufactures or distributes. Any person may request an opinion of the applicability of this notice to a specific drug product he manufactures or distributes that may be identical, related, or similar to a drug product named in this notice by writing to the Food and Drug Administration, Bureau of Drugs, Division of Drug Labeling Con-

MONDAY, AUGUST 23

- 8:45 a.m.----- Call to order and announcements. Approval of minutes. Progress report on CZM program.
- 9:15 a.m.----- Issues and concerns of the Alaska coastal program. A panel discussion. Economic dependence on the coast. Native interests and concerns.
- 9:45 a.m.----- Committee's discussion of above topics.
- 10:15 a.m.----- Brief recess.
- 10:30 a.m.----- Continuation of panel. Resource management/ fish and game.
- 10:45 a.m.----- Alaska CZM Program—A review of its progress to date and its response to issues and concerns raised above.
- 11 a.m.----- Committee's discussion of above topics.
- 11:45 a.m.----- Oral statements (if any) by interested persons.
- 12:15 p.m.----- Lunch.
- 1:30 p.m.----- OCS impacts on Alaska. A panel discussion. OCS policy development, community impacts study methods. Industrial problems and working arrangements with State.
- 2:15 p.m.----- Committee discussion of above topics.
- 2:45 p.m.----- Continuation of panel. Federal planning for lease sales, baseline studies. The impact of Yakutat.
- 3:15 p.m.----- Brief recess.
- 3:30 p.m.----- Committee's recommendations.
- 4:30 p.m.----- Adjourn.

TUESDAY, AUGUST 24

- 11:10 a.m.----- Leave Juneau via Alaska airlines flight 63.
- 10:50 a.m.----- Arrive Yakutat.
- 11:30 a.m.----- Onsite inspection of City of Yakutat. Meetings with local officials regarding OCS impacts.
- 5 p.m.----- Adjourn.
- 7:25 p.m.----- Return to Juneau via Alaska airlines 66.
- 9:05 p.m.----- Arrive Juneau. Please contact executive secretary to receive additional information on onsite visit. Dr. Richard Keating, 202/634-4245

WEDNESDAY, AUGUST 25

- 9 a.m.----- Call to order.
- 9:15 a.m.----- Legislative issues related to Alaska coastal management. A panel discussion. The Tanker Bill. State-local relationships. CZM legislative initiatives.
- 10 a.m.----- Committee discussion of above topics.
- 10:30 a.m.----- Brief recess.
- 10:45 a.m.----- Continuation of panel. Forest practices. Legislative needs from the administration's view.
- 11:15 a.m.----- Committee's discussion of above topics.
- 12 n.----- Lunch.
- 1:30 p.m.----- D-2 Lands: Implications for coastal management.

WEDNESDAY, AUGUST 25—continued

- 2 p.m.----- Committee's discussion of above topic.
- 2:30 p.m.----- Report on interstate coordination for OCS issues (Pacific).
- 3 p.m.----- Brief recess.
- 3:15 p.m.----- Committee's recommendations.
- 4:30 p.m.----- Adjourn.

THURSDAY, AUGUST 26

- 9 a.m.----- Call to order.
- 9:15 a.m.----- Committee's recommendations of substantive policies for evaluation of CZM.
- 10 a.m.----- Brief recess.
- 10:15 a.m.----- Continuation of above topic.
- 10:45 a.m.----- Discussion of GAO final report.
- 11:30 a.m.----- Lunch.
- 1 p.m.----- Review of national legislation amending the CZM Act. A panel discussion. OCS report on 586 implementation at the national level.
- 2:30 p.m.----- Brief recess.
- 3 p.m.----- Committee's recommendations.
- 3:15 p.m.----- Discussion of agenda, time and place of next meeting.
- 4 p.m.----- Adjourn.
- 4:30 p.m.----- Leave Juneau via Alaska airlines 67.
- 7:45 p.m.----- Arrive Anchorage.

FRIDAY, AUGUST 27

- 7:45 a.m.----- Leave Anchorage via Alaska aeronautical flight 109.
- 8:15 a.m.----- Arrive Kenai.
- A.M.----- Inspections. Meetings with local officials.
- P.M.----- Kachemak Bay—A case study of State decision making and public attitude — Frank Tupper, Kachemak Bay Defense Fund.
- Beaufort Sea Lease Sale—A case study No. 2 of State decision making—Pat Doherty, Department of Natural Resources.
- 6 p.m.----- Leave Kenai via Alaska aeronautical 134.
- 6:30 p.m.----- Arrive Anchorage.

Please contact Executive Secretary to receive additional information regarding onsite visit. Dr. Richard Keating, 202-634-4245.

Dated: July 22, 1976.

T. P. GLEITER,
Assistant Administrator for
Administration, National Oceanic and Atmospheric Administration.

[FR Doc.76-21973 Filed 7-28-76; 8:45 am]

DEPARTMENT OF HEALTH,
EDUCATION, AND WELFARE
Alcohol, Drug Abuse, and Mental Health
Administration
NATIONAL ADVISORY MENTAL HEALTH
COUNCIL
Meeting

In accordance with Section 10(a) (2) of the Federal Advisory Committee Act

(5 U.S.C. Appendix I), announcement is made of the following National Advisory body scheduled to assemble during the month of September 1976:

NATIONAL ADVISORY MENTAL HEALTH COUNCIL

September 8-10: 9 a.m. to 5 p.m.
Conference Room 14-105, Parklawn Building,
Rockville, Maryland
Open: September 8
Closed: Otherwise
Contact: Mrs. Zella Diggs, Room 11-101,
Parklawn Building, 5600 Fishers Lane,
Rockville, Maryland 20852, 301-443-4333

Purpose: The National Advisory Mental Health Council advises the Secretary, Department of Health, Education, and Welfare, the Administrator, Alcohol, Drug Abuse, and Mental Health Administration, and the Director, National Institute of Mental Health, regarding policies and programs of the Department in the field of mental health. The Council reviews applications for grants-in-aid relating to research, training, and service in the field of mental health and makes recommendations to the Secretary with respect to approval of applications for, and the amount of, these grants.

Agenda: On September 8, the meeting will be open for discussion of NIMH policy issues. These will include current administrative, legislative and program developments. Otherwise, the Council will conduct a final review of grant applications for Federal assistance and this session will not be open to the public, in accordance with the determination by the Administrator, Alcohol, Drug Abuse, and Mental Health Administration, pursuant to the provisions set forth in Section 552(b) (5) and 552(b) (6), Title 5, U.S. Code, and Section 10(d) of Public Law 92-463 (5 U.S.C. Appendix I).

Substantive information may be obtained from the contact person listed above.

The NIMH Information Officer who will furnish summaries of the meeting and rosters of the committee members is Mr. Edwin Long, Deputy Director, Division of Scientific and Public Information, NIMH, Room 15-105, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20852, 301-443-3300

Dated: July 23, 1976

CAROLYN T. EVANS,
Committee Management Officer,
Alcohol, Drug Abuse, and
Mental Health Administration.

[FR Doc.76-21967 Filed 7-28-76; 8:45 am]

Center for Disease Control

OCCUPATIONAL SAFETY AND HEALTH

Request for Information on Certain
Chemical/Physical Agents

Section 20(a) (3) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 669(a) (3)) provides that the Secretary of Health, Education, and Welfare, on the basis of information available to him, shall develop criteria dealing with toxic materials which will describe exposure levels that are safe for various periods of