



[4110-28-M]

National Archives and Records Service

ARCHIVES ADVISORY COUNCIL

Meeting

Notice is hereby given that the National Archives Advisory Council will meet at the time and place indicated below. Anyone interested in attending, or who wishes additional information, should contact the person shown below.

NATIONAL ARCHIVES ADVISORY COUNCIL

Meeting Dates: November 29-December 2, 1978; November 30: 7 p.m. to 10 p.m.; December 1: 9 a.m. to 3 p.m.; December 2: 9 a.m. to adjournment.

Place: Room 418, National Archives and Records Service, 8th and Pennsylvania Avenue NW., Washington, D.C. 20408.

Agenda: Implementation of Preservation Report, Accessioning and Processing Priorities, and the National Historical Publications and Records Commission.

For further information contact: Robert Brookhart, General Services Administration (NS), Washington, D.C. 20408. 202-523-3911.

Issued in Washington, D.C., on October 17, 1978.

JAMES E. O'NEILL,
Deputy Archivist
of the United States.

[FR Doc. 78-30364 Filed 10-26-78; 8:45 am]

[4110-86-M]

DEPARTMENT OF HEALTH,
EDUCATION, AND WELFARE

Center for Disease Control

TUBERCULOSIS THERAPY AND GONOCOCCAL
INFECTIONS

Open Meetings

The following meetings will be convened by the Center for Disease Control and will be open to the public for observation and participation, limited only by the space available:

Meeting on Tuberculosis Therapy

Dates: November 7-8, 1978.

Time: 9 a.m.

Place: Room 165, Building 6, Center for Disease Control, 1600 Clifton Road NE., Atlanta, Ga. 30333.

Purpose: To review tuberculosis short-course therapy study data and discuss the need for and nature of additional data to be gathered.

Additional information may be obtained from: Dr. Dixie E. Snider, Jr., Chief, Research and Development Branch, Tuberculosis Control Division, Bureau of State Services, Center for Disease Control, Room 222, Building 6, 1600 Clifton Road NE., Atlanta, Ga. 30333, telephones: FTS: 236-8956, commercial: 404-329-3956.

NOTICES

Meeting on Gonococcal Infections

Date: November 7-10, 1978.

Time: 8:10 a.m.

Place: Room 307, Building 1, Center for Disease Control, 1600 Clifton Road NE., Atlanta, Ga. 30333.

Purpose: To discuss Public Health Service recommended treatment regimens for gonococcal infections.

Additional information may be obtained from: Dr. Ronald K. St. John, Deputy Director, Venereal Disease Control Division, Bureau of State Services, Center for Disease Control, Room 3043, Building 1, 1600 Clifton Road NE., Atlanta, Ga. 30333, telephones: FTS: 236-3935, commercial: 404-329-3935.

Dated: October 20, 1978.

WILLIAM C. WATSON, JR.,

Acting Director,

Center for Disease Control.

[FR Doc. 78-30436 Filed 10-26-78; 8:45 am]

[4110-83-M]

Food and Drug Administration

[Docket No. 77N-00911]

BACTERIAL VACCINES AND BACTERIAL
ANTIGENS WITH NO U.S. STANDARD OF
POTENCY

Revocation of Licenses and Reclassification

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Commissioner of Food and Drugs is announcing revocations of licenses and a reclassification concerning bacterial vaccines and bacterial antigens with "No U.S. Standard of Potency" manufactured by six licensees. These actions result from manufacturers' response or failure to respond to an earlier notice of opportunity for a hearing.

EFFECTIVE DATE: October 27, 1978.

FOR FURTHER INFORMATION
CONTACT:

Joe Holloway, Bureau of Biologics (HFB-620), Food and Drug Administration, Department of Health, Education, and Welfare, 8800 Rockville Pike, Bethesda, Md. 20014, 301-443-1306.

SUPPLEMENTARY INFORMATION:

In a proposal published in the FEDERAL REGISTER of November 8, 1977 (42 FR 58266), the Commissioner announced his intention to revoke the license(s) for certain bacterial vaccines and bacterial antigens with "No U.S. Standard of Potency" classified as categories II and IIIB, under §§ 601.5(b) and 601.25(f) (21 CFR 601.5(b) and 601.25(f)), based on the recommendations of the panel on review of bacte-

rial vaccines and bacterial antigens with "No U.S. Standard of Potency." The Commissioner agreed with the panel's recommendations and adopted them as the grounds for revocation.

THE PRODUCTS

After publication of the panel's report, a notice of opportunity for a hearing was published in the FEDERAL REGISTER of December 9, 1977 (42 FR 82162) on a proposal by the Commissioner to revoke categories II and IIIB product licenses as follows:

(1) Category II. Biological products determined to be unsafe or ineffective or to be misbranded and which should not continue in interstate commerce. Bacterial Vaccine Diagnostics and Bacterial Vaccine T-50 made from *Streptococcus pyogenes* type L-8 or by prescription (Hollister-Stier, Division of Cutter Laboratories, License No. 8).

(2) Category IIIB. Biological products for which available data are insufficient to classify their safety and effectiveness and which should not continue in interstate commerce. Mixed Respiratory Bacteria (Center Laboratories, Inc., License No. 193); Staphage Lysate (SPL), type I, and types I and III combined, for Staphylococcal Disease (Dehmont Laboratories, Inc., License No. 299); Pooled Stock B.A.C. No. 1, Pooled Stock B.A.C. No. 2, Gram-Negative B.A.C. and Pooled Skin B.A.C. (Hoffmann Laboratories, Inc., License No. 283); Bacterial Vaccines for Treatment (Special Mixtures) (Hollister-Stier, Division of Cutter Laboratories, License No. 8); PIROMEN (Pseudomonas polysaccharide) (Travenol Laboratories, Inc., License No. 140); V-677 Streptococcus Vaccines (Intravenous) (Eli Lilly and Co., License No. 56).

ACTION

The manufacturers' responses to the notice of opportunity for a hearing concerning the above products and the Commissioner's action concerning their responses are as follows:

The following firms did not request a hearing concerning their products:

(1) Hollister-Stier, Division of Cutter Laboratories, Inc., for Bacterial Vaccine Diagnostics, Bacterial Vaccine T-50, and Bacterial Vaccines for Treatment (Special Mixtures);

(2) Center Laboratories, Inc., for Mixed Respiratory Bacteria.

(3) Travenol Laboratories, Inc., for PIROMEN (Pseudomonas polysaccharide); and

(4) Eli Lilly and Co., for V-677 Streptococcus Vaccines (Intravenous).

The Commissioner has received numerous letters from patients and doctors expressing concern over the recommendation to revoke the license for the manufacture of V-677, Streptococcus Vaccines (Intravenous). Most let-

ters provided testimonials in support of the effectiveness of the V-677 product for the treatment of arthritis. Some letters requested a formal hearing.

The Commissioner recognizes the concern and the sense of frustration some patients must feel regarding the proposed revocation. However, the law provides that the safety and effectiveness of biological drugs must be established by scientifically sound evidence. The expert panel evaluated all the bacterial vaccines, using the same criteria to establish safety and effectiveness. These standards are set forth in the regulation that established the biological review (see 21 CFR 601.25(d)). The data submitted by Eli Lilly and Co. did not satisfy the criteria, and the panel and the Commissioner concluded that V-677 should be removed from the market pending the results of scientific studies to establish its safety and effectiveness. In addition, the testimonials submitted by individuals do not satisfy the statutory standard and do not support approval of a biological drug (see *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609 (1973)).

Several persons who commented expressed a willingness to volunteer for testing of V-677. Persons who wish to participate in investigational new drug (IND) clinical trials of V-677 or who are otherwise interested in the availability of this product should contact manufacturers or other organizations concerning the possible submission of an IND for V-677 or similar products.

The Commissioner advises that a hearing may be requested only by a manufacturer whose license is the subject of the proposed revocation. If a hearing is requested by the manufacturer and granted, any person desiring to participate in the hearing may do so (see § 12.45 (21 CFR 12.45)). However, if a licensee is given the opportunity to request a hearing but fails to demonstrate an interest in continuing to market the product by not requesting a hearing or submitting data, there is no hearing in which to participate. The December notice provides that the failure of a licensee to request a hearing constitutes an election not to avail itself of the opportunity. Under the biologics law, section 351 of the Public Health Service Act (42 U.S.C. 262), no product can be lawfully marketed except by a person holding an unrevoked license. Although anyone can apply for licensure, patients and/or doctors cannot compel a licensee to continue to produce or to take any particular action to protect its license. For this reason, the Commissioner is obliged to deny requests for a hearing from patients.

Further response to comments concerning V-677 and other products re-

viewed by the panel on Review of Bacterial Vaccines and Bacterial Antigens with "No U.S. Standard of Potency" will be included in the final order soon to be published, respecting the November 8, 1977 proposal.

The following firms requested hearings:

(1) Hoffmann Laboratories requested a hearing and presented data concerning its Bacterial Antigen Complexes, License No. 283. However, Hoffmann Laboratories subsequently requested that its establishment license and product licenses to manufacture the six Bacterial Antigen Complexes reviewed by the panel and four other products not reviewed by the panel be revoked. The request for license revocation constitutes a withdrawal of the request for a hearing, and consideration of the data is unnecessary.

(2) Delmont Laboratories, Inc., requested a hearing and submitted data and information in support of its Staphage Lysate (SPL) type I and types I and III combined, License No. 299. The Commissioner concludes that these data would not only justify a hearing but are adequate to justify reclassification at this time. The Commissioner finds that the potential benefits outweigh the potential risk in use of the product. Therefore, Staphage Lysate (SPL) type I, and types I and III combined, for Staphylococcal Disease (bacterial antigen made from staphylococcus) are reclassified from category IIIB to category IIIA (biological products for which available data are insufficient to classify their safety and effectiveness but which may remain in interstate commerce pending completion of testing). Because no hearing is necessary for a category IIIA product, the December notice is withdrawn for the product.

Accordingly, under the Public Health Service Act (sec. 351, 58 Stat. 702 as amended (42 U.S.C. 262)); §§ 314.200, 601.5(b), and 601.25(f) and (g) (21 CFR 314.200, 601.5(b), and 601.25(f) and (g)); the Federal Food, Drug, and Cosmetic Act (secs. 201, 502, 505, 701, 52 Stat. 1040-1042 as amended, 1050-1053 as amended, 1055-1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321, 352, 355, 371)) and under the authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), the following product licenses are revoked:

(a) Hollister-Stier, Division of Cutter Laboratories, for the manufacture of Bacterial Vaccine Diagnostics (bacterial vaccines for diagnostic use containing (1) *Aerobacter aerogenes*, (2) *Corynebacterium pseudodiphtheriticum*, (3) *Diplococcus pneumoniae*, mixed, (4) *Escherichia coli*, (5) *Gaffkya tetragena*, (6) *Hemophilus influenzae*, (7) *Hemophilus pertussis*, (8) *Klebsiella pneumoniae*, (9) *Neisseria ca-*

tarrhalis, (10) *Proteus vulgaris*, (11) *Pseudomonas aeruginosa*, (12) *Salmonella enteritidis*, (13) *Salmonella paratyphi*, (14) *Salmonella schottmulleri*, (15) *Salmonella typhosa*, (16) *Shigella dysenteriae*, (17) *Shigella flexneri*, (18) *Streptococcus fecalis*, *pyogenes*, *viridans*, and *nonhemolyticus*, (19) *Staphylococcus albus*, and (20) *Staphylococcus aureus*). License No. 8; Bacterial Vaccines for Treatment (Special Mixtures containing one or more of the following organisms: (1) *Aerobacter aerogenes*, (2) *Corynebacterium pseudodiphtheriticum*, (3) *Corynebacterium (propionibacterium) acnes*, (4) *Corynebacterium xerosis*, (5) *Escherichia coli*, (6) *Gaffkya tetragena*, (7) *Hemophilus pertussis*, (8) *Proteus vulgaris*, (9) *Pseudomonas aeruginosa*, (10) *Salmonella enteritidis* (this organism was inadvertently omitted when the notice of opportunity for a hearing was published), (11) *Shigella paradyenteriae* (Type Y), (12) *Salmonella paratyphi*, (13) *Salmonella schottmulleri*, (14) *Salmonella typhosa*, (15) *Shigella dysenteriae*, (16) *Shigella flexneri*, and (17) *Streptococcus fecalis* (*Staphylococcus albus* and *aureus* were incorrectly listed for this product when the proposal and the notice of opportunity for a hearing were published)), License No. 8; Bacterial Vaccine T-50 (made from *Streptococcus pyogenes* type L-8 or by prescription), License No. 8;

(b) Center Laboratories, Inc., for the manufacture of Mixed Respiratory Bacteria (made from (1) *Staphylococcus aureus* and *albus*, (2) *Streptococcus mitis* and *salivarius*, (3) *Streptococcus pyogenes*, Group A, (4) *Diplococcus pneumoniae*, I, II, and III, (5) *Klebsiella pneumoniae*, two strains, (6) *Neisseria catarrhalis*) License No. 193;

(c) Eli Lilly and Co., for the manufacture of V-677 Streptococcus Vaccines (Intravenous), License No. 56;

(d) Travenol Laboratories, Inc., for the manufacture of PIROMEN (*Pseudomonas polysaccharide*), License No. 140; and

(e) Hoffmann Laboratories, Inc., for the manufacture of Pooled Stock B.A.C. No. 1 (bacterial antigens made from (1) *Diplococcus pneumoniae*, (2) *Streptococcus species*, (3) *Staphylococcus species*, (4) *Neisseria catarrhalis*, (5) *Escherichia coli*, (6) *Hemophilus influenzae*), Pooled Stock B.A.C. No. 2 (bacterial antigens made from (1) *Diplococcus pneumoniae*, (2) *Klebsiella pneumoniae*, (3) *Streptococcus species*, (4) *Pseudomonas aeruginosa*, (5) *Escherichia coli*, and (6) *Aerobacter aerogenes*) and Gram-negative B.A.C. (bacterial antigens made from (1) *Pseudomonas aeruginosa*, (2) *Escherichia coli*, (3) *Aerobacter aerogenes*), Pooled Skin B.A.C. (bacterial antigens made from (1) *Staphylococcus species* and (2) *Proteus vulgaris*), License No. 283;

Shipment in interstate commerce by manufacturer of a product after effective date of revocation constitutes a violation of the Public Health Service Act. The Commissioner advises that those products for which licenses are herein revoked do not constitute a danger to public health and those lots that have already been sold and delivered may be resold through their expiration dates.

All data and information not prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, that have been used by the Commissioner in reaching this decision, may be seen in the office of the Hearing Clerk between 9 a.m. and 4 p.m., Monday through Friday.

Effective date. These actions are effective October 27, 1978.

Dated: October 19, 1978.

DONALD KENNEDY,
Commissioner of Food and Drugs.
(FR Doc. 78-30350 Filed 10-26-78; 8:45 am)

[4110-03-M]

[Docket No. 78N-0378]

GRAS SAFETY REVIEW OF MANGANESE SALTS
Public Hearing

AGENCY: Food and Drug Administration

DN: Notice.

SUMMARY: In response to several requests, the Food and Drug Administration (FDA) announces a public hearing concerning the safety of manganese salts. The hearing will enable those parties who have so requested to present data, information, and views as part of the agency's review to determine whether the salts are generally recognized as safe (GRAS) or subject to a prior sanction.

DATE: The hearing will be held November 6, 1978.

ADDRESS: The hearing will be held in the Lee Building, Federation of American Societies for Experimental Biology, 9650 Rockville Pike, Bethesda, Md. 20014.

FOR FURTHER INFORMATION CONTACT:

Corbin I. Miles, Bureau of Foods (HFF-335), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C Street SW., Washington, D.C. 20204, 202-472-4750; or

George W. Irving, Jr., Life Sciences Research Office, Federation of American Societies for Experimental Biology, 9650 Rockville Pike, Bethesda, Md. 20014, 301-530-7033.

ADDITIONAL INFORMATION:
FEDERAL REGISTER of April 21,

1978 (43 FR 17055), the Commission of Food and Drugs issued a notice advising the public that an opportunity would be provided for the oral presentation of data, information, and views at public hearings to be conducted by the Select Committee on GRAS Substances of the Life Sciences Research Office, Federation of American Societies for Experimental Biology (hereafter referred to as the Select Committee), concerning the safety of manganese salts and silicates and the Select Committee's tentative determination of whether or not they are GRAS or subject to a prior sanction.

A written statement on silicates was submitted by the PQ Corp., P.O. Box 258, Lafayette Hill, Pa. 19444, in lieu of an oral presentation at a public hearing. No requests for a public hearing were received. Accordingly, no hearing will be held on silicates.

The Select Committee received requests for a public hearing on manganese salts from the American Feed Manufacturers Association, Inc., 1701 North Fort Myer Drive, Arlington, Va. 22209; Southeastern Minerals, Inc., Bainbridge, Ga. 31717; and Chemetals Corp., 711 Pittman Road, Baltimore, Md. 21226 (formerly a division of Diamond Shamrock Corp., 1110 Superior Avenue, Cleveland, Ohio 44114). No other requests were received for a hearing on manganese salts.

Under the procedures set forth in the April 21, 1978, notice, announcement is hereby made that a hearing on manganese salts will be held at 9 a.m., on November 6, 1978, in the Lee Building, Federation of American Societies for Experimental Biology, 9650 Rockville Pike, Bethesda, Md. 20014. Those who have requested to make oral presentations will be expected to complete their presentations within the period indicated and in accordance with the following schedule:

1. American Feed Manufacturers Association, Inc., and Southeastern Minerals, Inc.: Mr. L. H. Boyd and/or A. Poitevin will make a joint presentation for both corporations—30 minutes.

2. Chemetals Corp.: Dr. Dennis De-Craene—15 minutes.

The hearing will be chaired by a member of the Select Committee and will be transcribed by a reporting service. A transcript of the hearing will be placed on public display in the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

Dated: October 23, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner
for Regulatory Affairs.

(FR Doc. 78-30353 Filed 10-26-78; 8:45 am)

[4110-03-M]

[Docket No. 78M-0260]

LOMBART LENSES LTD.

Premarket Approval of Amsol Soft Contact Lens

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces approval of the application for premarket approval under the Medical Device Amendments of 1976 of the Amsol (deltafillicon A) Soft Contact Lens sponsored by Lombart Lenses Ltd. After reviewing the Ophthalmology Device Classification Panel's recommendation, FDA notified the sponsor that the application was approved because the device had been shown to be safe and effective for use as recommended in the submitted labeling.

DATE: Petitions for administrative review by November 27, 1978.

ADDRESS: Requests for copies of the summary of safety and effectiveness data and petitions for administrative review may be addressed to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT:

Keith Lusted, Bureau of Medical Devices (HFK-402), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Avenue, Silver Spring, Md. 20910, 301-427-7550.

SUPPLEMENTARY INFORMATION: The sponsor, Lombart Lenses Ltd., Norfolk, Va. 23501, submitted an application for premarket approval of the Amsol (deltafillicon A) Soft Contact Lens to FDA on April 6, 1977. The application was reviewed by the Ophthalmology Device Classification Panel, an FDA advisory committee, which recommended approval of the application. On June 30, 1978, FDA approved the application by a letter to the sponsor from the Director of the Bureau of Medical Devices.

Before enactment of the Medical Device Amendments of 1976 (the amendments), soft contact lenses were regulated as new drugs. Because the amendments broadened the definition of the term "device" in section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)), soft contact lenses are now regulated as class III devices (premarket approval). As FDA explained in a notice published in the FEDERAL REGISTER of December 16, 1977 (42 FR 63472), the amendments provide transitional provisions to assure continuation of premarket