

investigators selected children from this population who exhibited behavior disturbances or symptoms on the Connors' Teacher Rating Scale (a minimum of five disturbances or symptoms, or three at the "very much" level). In addition, the investigators selected only those children who were diagnosed as suffering hyperkinesis of 6 months' duration as confirmed by their parents. The investigators' criteria for excluding children from this study were: (1) Signs (or history) of definite organic brain damage, (2) I.Q. below 80 (as measured by WISC), (3) psychosis, (4) physical contraindications, or (5) under the treatment of other physicians.

The children were randomly separated into two groups, one receiving Deaneer, and the other placebo. Deaneer was administered at 300 mg per day the first week, 400 mg per day the second week, and 500 mg per day for the remaining 10 weeks of the study. Drug effect was measured by the following tests given at baseline and at the end of the study: (1) WISC; (2) Wide Range Achievement Test (WRAT); (3) Porteus Maze Test; (4) Connors' Teacher Rating Scale; (5) Connors' Parent Rating Scale; and (6) global evaluations by the teacher, parents, and psychiatrist.

The Bureau of Drugs reviewed this study in the notice of January 8, 1975. The Bureau criticized the study because the investigators had selected a method of analyzing the data after the study was completed without an adequate explanation of steps taken to minimize analyst bias. Riker's hearing submission reanalyzed the study using Connors' Rating Scales, an acceptable method.

This study, as now analyzed, fails to establish the effectiveness of Deaneer. The investigators found no significant differences between Deaneer and placebo groups under the parent and teacher questionnaire using Connors' Rating Scales. Nor did they find any significant differences under any of the achievement tests. The fact that there were no significant differences under these critical parameters diminishes the value of the psychiatrist's global evaluation, the only parameter which significantly favored Deaneer. Accordingly, this study fails to substantiate a claim of effectiveness for Deaneer.

Nevertheless, even if the results of this study had favored Deaneer more significantly, it is not an adequate and well-controlled clinical investigation within the meaning of 21 CFR 314.111(a)(5)(ii).

Contrary to the investigators' assertion, there is no assurance

provided by a method of selection that the test and control groups were comparable in pertinent variables as required by 21 CFR 314.111(a)(5)(ii) (a)(2)(iii). Similar to the investigators in the Lewis study discussed above, the investigators in this study did not ensure that the conditions of the patients admitted to the study were of similar etiology.

Another deficiency of this study is the investigators' failure to explain the methods of observation and recording of results in making the psychiatrist's global evaluation (21 CFR 314.111(a)(5)(ii) (a)(3)). This is particularly critical to an evaluation of this study because only this parameter revealed a significant result favorable to Deaneer. The investigators' failure to explain how the children were assessed in the global evaluations obscures the meaning of this parameter. Contrary to Riker's assertion, this omission was not resolved by the investigators' final report of this study.

E. Other medical data. Riker's hearing request submission also included data on neurological involuntary movements, such as Dopa-induced dyskinesias, tardive dyskinesias, and Huntington's chorea. Riker admits that these data are inconclusive as to whether Deaneer is effective treatment for these conditions. Moreover, because these data concern indications not in Deaneer's labeling, they are irrelevant to this proceeding.

Riker also submitted an article on the influence of 2-dimethylaminoethanol on the level of acetylcholine in the brains of mice, and two articles on the suppressant effects of two stimulants (neither of which was Deaneer) on the growth of hyperactive children. These articles clearly are not related to the effectiveness of Deaneer.

Finally, Riker submitted a study entitled "Deanol vs. Placebo in Hyperactive Children," Riker Number 546-058, by James A. Lewis (unpublished). Riker retracted this study after notification from the Bureau that it was not filed in conformance with 21 CFR 314.200(c)(2). It is worth noting, however, that the investigator found no significant differences between Deaneer and placebo.

IV. Riker's Response to the Proposed Final Order

On July 23, 1982, the Director of the National Center for Drugs and Biologics served upon Riker a proposed order denying a hearing and withdrawing approval of the new drug application for Deaneer Tablets for the reasons noted

above (21 CFR 314.200(g)(3)). Riker's response to the proposed final order was a single-page letter and a final report on study 546-058, "Deanol vs. Placebo in Hyperactive Children," by James A. Lewis and Barbara S. Lewis.

Riker does not dispute any of the specific criticisms found in the proposed order, but maintains without explanation that the data were not afforded an adequate and fair medical review. This bare assertion does not raise a genuine and substantial issue of fact which justifies a hearing.

Nor does Riker's untimely resubmission of study 546-058 raise a genuine and substantial issue of fact which would justify a hearing in this matter. The study, as noted in the proposed order, found no significant differences between Deaneer and placebo. This finding is not disputed in the study's final report which has not been submitted by Riker. (See page 25.) Consequently, even if the Commissioner were to consider this study as appropriately filed, it fails to reveal any drug effect.

V. Findings

On the basis of the foregoing review of all the evidence submitted, and after providing an opportunity to comment on this order, the Commissioner finds that (1) there is a lack of substantial evidence that Deaneer has the effects it purports or is represented to have under the conditions of use, prescribed, recommended, or suggested in its labeling, and (2) Riker has failed to set forth specific facts showing that there is a genuine and substantial issue of fact requiring a hearing.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 505(e), 52 Stat. 1052-1053 as amended (21 U.S.C. 355(e)) and under authority delegated to the Commissioner (21 CFR 5.10) the request for a hearing is denied, and the approval of NDA 11-417 for Deaneer Tablets, including all amendments and supplements thereto, is hereby withdrawn. Distribution of this drug product in interstate commerce without an approved new drug application is illegal and subject to regulatory action. This order is effective June 23, 1983.

Dated: May 12, 1983.

Mark Novitch,

Deputy Commissioner of Food and Drugs.

[FR Doc. 83-13710 Filed 5-23-83; 8:45 am]

BILLING CODE 4160-01-M

[Docket Nos. 81N-0391 and 82N-0095; DESI 6514 AND 11935]

Drugs for Human Use; Drug Efficacy Study Implementation; Oral Prescription Drugs Offered for Relief of Symptoms of Cough, Cold, or Allergy; Withdrawal of Approval

AGENCY: Food and Drug Administration.
ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of the new drug application for Omni-Tuss Suspension and those parts of another application that pertain to Pyribenzamine and Ephedrine Tablets. The basis of the withdrawal is that there is a lack of substantial evidence that the fixed-combination drugs are effective in the relief of symptoms that the fixed-combination drugs are effective in the level of symptoms of cough, cold, or allergy.

EFFECTIVE DATE: June 23, 1983.

ADDRESS: Requests for an opinion of the applicability of this notice to a specific product should be identified with the appropriate docket number and directed to the Division of Drug Labeling Compliance (HFN-310), National Center for Drugs and Biologics, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: David T. Read, National Center for Drugs and Biologics (HFN-8), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3650.

SUPPLEMENTARY INFORMATION: In notices published in the Federal Register of May 25, 1982 (47 FR 22606 and 22604), the Director of the then Bureau of Drugs revoked the temporary exemption for the two drug products described below which permitted these products to remain on the market beyond the time limit scheduled for the implementation of the Drug Efficacy Study. Those notices also proposed to issue orders withdrawing approval of the new drug applications, or parts thereof, that provide for these drug products. The proposal was based on the lack of substantial evidence of effectiveness that each ingredient in the combination products contributes to the claimed effects or is present in an amount considered to be effective, as required by section 305(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) and 21 CFR 314.111(a)(5) and 300.50. The two products are:

1. NDA 12-668: Omni-Tuss Suspension, containing codeine sulfate, phenyltoloxamine dihydrogen sulfate, chlorpheniramine maleate, ephedrine sulfate [all as cation exchange resin

complexes of sulfonated polystyrene), and guaiacol carbonate; Pennwalt Corp., Pharmaceutical Division, 755 Jefferson Rd., Rochester, NY 14623 (DESI 6514; Docket No. 81N-0391).

2. NDA 5-914: As it pertains to Pyribenzamine and Ephedrine Tablets containing tripeleannamine hydrochloride and ephedrine sulfate; Ciba Pharmaceuticals Co., 556 Morris Ave., Summit, NJ 07901 (DESI 11935; Docket No. 82N-0095).

Neither Pennwalt Corp. nor Ciba Pharmaceuticals requested a hearing on the two products listed above. Failure to file an appearance and request a hearing constitutes a waiver of the opportunity for a hearing.

The three other products listed in the two May 25, 1982, notices—Ambenyl Expectorant (47 FR 22604; see also 47 FR 50344), and Tussionex Tablets and Suspension (47 FR 22606)—and a product related to Omni-Tuss Suspension called Ru-Tuss Expectorant, manufactured by Boots Pharmaceuticals, Inc., are not affected by this notice. The manufacturers of these products have requested hearings; the products will be the subject of future Federal Register notices.

Any drug product that is identical, related, or similar to Omni-Tuss Suspension and Pyribenzamine and Ephedrine Tablets and is not the subject of a pending hearing request or an approved new drug application is covered by the new drug applications reviewed and is subject to this notice (21 CFR 310.6). Any person who wishes to determine whether a specific product is covered by this notice should write to the Division of Drug Labeling Compliance (address given above).

The Director of the National Center for Drug and Biologics, under the Federal Food, Drug, and Cosmetic Act (sec. 505, 52 Stat. 1052-1053 as amended (21 U.S.C. 355)) and under the authority delegated to him (see 21 CFR 5.82 and 47 CFR 26913 published in the Federal Register of June 22, 1982) finds that, on the basis of new information before him with respect to the products, evaluated together with the evidence available to him when the applications were approved, there is lack of substantial evidence that the two drug products will have the effects they purport or are represented to have under the conditions of use prescribed, recommended, or suggested in their labeling.

Therefore, pursuant to the foregoing finding, approval of those parts of NDA 5-914 that provide for Pyribenzamine and Ephedrine Tablets, and approval of NDA 12-668, and all amendments and

supplements thereto, are withdrawn effective June 23, 1983.

Shipment in interstate commerce of the above products, or any identical, related, or similar product that is not the subject of a pending hearing request or an approved new drug application, will then be unlawful.

Dated: May 18, 1983.

Harry M. Meyer, Jr.,
Director, National Center for Drugs and Biologics.

[FR Doc. 83-13857 Filed 5-23-83; 8:45 am]

BILLING CODE 4180-01-M

Health Resources and Services Administration

Home Health Services; Section 339 of the Public Health Service Act; Delegation of Authority

Notice is hereby given that the following delegations have been made regarding home health services under section 339 of the Public Health Service Act (42 U.S.C. 255), as amended.

1. Delegation from the Administrator, Health Resources and Services Administration, to the Regional Health Administrators, Regions I-X, with authority to redelegate, of the following authorities under Section 339 of the Public Health Service Act (42 U.S.C. 255) within their respective regions (for projects that are not multiregional or national in scope):

(a) Under section 339(a), to make grants to public and nonprofit private entities and loans to proprietary entities to meet the initial costs of establishing and operating home health programs;

(b) Under section 339(b), to make grants to public and private entities to assist them in developing appropriate training programs for paraprofessionals (including homemaker home health aides) to provide home health services.

2. Delegation from the Administrator, Health Resources and Services Administration, to the Director, Bureau of Health Care Delivery and Assistance, with authority to redelegate, of all the authorities under section 339 of the Public Health Service Act except those authorities specifically delegated to the Regional Health Administrators, excluding the authorities to submit reports to Congress or a Congressional committee and to issue regulations.

Previous delegations and redelegations made to officials within the Public Health Service of authorities under Title III of the Public Health Service Act may continue in effect provided they are consistent with this delegation.

The above delegation was effective on May 12, 1983.

Dated: May 12, 1983.

Robert Graham,
Administrator, Health Resources and
Services Administration.

[FR Doc. 83-13865 Filed 5-23-83; 8:45 am]

BILLING CODE 4160-16-M

Public Health Service

National Center For Health Services Research; Assessment of Medical Technology

The Public Health Service (PHS), through the Office of Health Technology Assessment (OHTA), announces that it is coordinating an assessment of what is known of the safety and clinical effectiveness and use (indications) of ambulatory electroencephalographic (EEG) monitoring in the diagnosis of seizure disorders. Specifically, we are interested in: (1) The technical issues concerning the reliability and usefulness of the data gained from 24-hour monitoring while the patient follows usual daily activities and sleep; (2) general indications for use of the procedure; and (3) its diagnostic implications.

For the purposes of this announcement, ambulatory electroencephalographic (EEG) monitoring is defined as long-term (24-hour), continuous brain activity monitoring. The ambulatory EEG monitor uses a portable cassette recorder capable of recording brain rhythms during a patient's routine daily activities and sleep. The recorder stores signals derived from on-head differential preamplifiers. Ambulatory EEGs using cassette tape recorders usually have only four channels available for detecting epileptiform events, except in instances where the fourth channel is used for cardiac monitoring.

The PHS assessment consists of a synthesis of information obtained from appropriate organizations in the private sectors and from PHS agencies and others in the Federal Government. PHS assessments are based on the most current knowledge concerning the safety and clinical effectiveness of a technology. Based on this assessment, a PHS recommendation will be formulated to assist the Health Care Financing Administration (HCFA) in establishing Medicare coverage policy. Any person or group wishing to provide OHTA with information relevant to this assessment should do so in writing no later than September 15, 1983, or within 90 days from the date of publication of this notice.

The information being sought is a review and assessment of past, current, and planned research related to this technology, a bibliography of published controlled clinical trials and other well-designed clinical studies since 1978 and other information related to the characterization of the patient population most likely to benefit, the clinical acceptability, and the effectiveness of this technology. Proprietary information is not being sought, but published commercial information may be submitted.

Written material should be submitted to: Martin N. Erlichman, National Center for Health Services Research, Office of Health Technology Assessment, Park Building, Room 3-10, Stop #2, 5600 Fishers Lane, Rockville, Maryland 20852.

For further information contact Martin Erlichman, Health Science Analyst, at the above address or by telephone (301) 443-4990.

Dated: May 16, 1983.

Harold Margulies,

Director, Office of Health Technology
Assessment, National Center for Health
Services Research.

[FR Doc. 83-13856 Filed 5-23-83; 8:45 am]

BILLING CODE 4160-17-M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

Idaho; Modification of District Boundaries, Resource Areas and a Resource Area Headquarters Office

May 16, 1983.

Pursuant to the authority vested in the Secretary of the Interior by the Taylor Grazing Act of June 28, 1934 (48 Stat. 1269) as amended and delegated to the Director, Bureau of Land Management by 235 DM 1.1, the boundaries of the Burley and Idaho Falls Districts are changed.

In conjunction with the boundary change one Resource Area is modified, an office is moved and its name is changed, three Resource Areas are abolished and two Resource Areas are established.

SUMMARY: This notice sets forth a series of administrative boundary and name changes between Bureau of Land Management administrative units in Idaho. Part of the lands involved are managed under Section 3 and part under Section 15 of the Taylor Grazing Act. The jurisdiction transfer will not affect the status or use of the public lands in any way. The changes are confined to the Burley and Idaho Falls Districts.

DATE: The changes in boundaries and unit names become effective on July 1, 1983.

ADDRESSES: Bureau of Land Management District Offices involved are:

Burley District Office, Route 3, Box 1,
200 South Oakley Highway, Burley,
Idaho 83318.

Idaho Falls District Office, 940 Lincoln
Road, Idaho Falls, Idaho 83401

FOR FURTHER INFORMATION CONTACT:
Fred Cook, Public Affairs Office, Idaho
State Office, 3380 Americana Terrace,
Boise, Idaho 83706, (208) 334-1170, FTS
554-1770.

SUPPLEMENTARY INFORMATION: As a part of the merger of the Bureau of Land Management and the Minerals Management Service activities in Idaho, the relocation of personnel in the southern and southeastern part of Idaho to better serve the public and improve the management of resources on public lands was approved by the National Director on February 17, 1983. A summary of these changes is as follows:

1. The boundary between the Idaho Falls and Burley Districts is changed. All of the Public Lands administered by the Burley District in Bannock County and a portion of Caribou County are transferred to the Idaho Falls District. A map of the Idaho Falls District is available at the Idaho Falls District Office, located in Idaho Falls, Idaho.

2. In the Idaho Falls District, the Soda Springs Resource Area is abolished. Established in its place is the Pocatello Resource Area which includes the lands transferred to this district along with the lands that were encompassed by the Soda Springs Resource Area. A map of the new Resource Area is available at the Idaho Falls District Office, located in Idaho Falls.

3. The Bureau of Land Management Resource Area Headquarters Office at Soda Springs, Idaho is to be closed and a new Resource Area Headquarters Office established at Pocatello, Idaho known as the Pocatello Resource Area, Idaho Falls District.

4. The three Resource Areas in the Burley District; Magic RA, Raft River, RA, and Bannock-Oneida RA are abolished. In their place, two Resource Areas are established in the Burley District. They are the Snake River RA and Deep Creek RA. The Snake River RA encompasses the public lands generally found in Twin Falls and Cassia Counties. The Deep Creek RA encompasses the public lands generally found in Oneida County and that portion of Power County lying south of the Snake River. A map of the specific